Joint CNRA/CRPPH/RWMC Workshop

REGULATING THE LONG-TERM SAFETY OF RADIOACTIVE WASTE DISPOSAL

Proceedings of an NEA International Workshop jointly organised by:

The Committee on Nuclear Regulatory Activities (CNRA)
The Committee on Radiation Protection and Public Health (CRPPH)
The Radioactive Waste Management Committee (RWMC)

and hosted by:

the Spanish Nuclear Safety Council (CSN)
and the Spanish Radioactive Waste Agency (ENRESA)

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ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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

- to achieve the highest sustainable economic growth and employment and a rising standard of living in Member countries, while maintaining financial stability, and thus to contribute to the development of the world economy;
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NUCLEAR ENERGY AGENCY

The OECD Nuclear Energy Agency (NEA) was established on 1st February 1958 under the name of the OEEC European Nuclear Energy Agency. It received its present designation on 20th April 1972, when Japan became its first non-European full Member. NEA membership today consists of all OECD Member countries, except New Zealand and Poland. The Commission of the European Communities takes part in the work of the Agency.

The primary objective of NEA is to promote co-operation among the governments of its participating countries in furthering the development of nuclear power as a safe, environmentally acceptable and economic energy source.

This is achieved by:

- encouraging harmonization of national regulatory policies and practices, with particular references to the safety of nuclear installations, protection of man against ionising radiation and preservation of the environment, radioactive waste management, and nuclear third party liability and insurance:
- assessing the contribution of nuclear power to the overall energy supply by keeping under review the technical and economic aspects of nuclear power growth and forecasting demand and supply for the different phases of the nuclear fuel cycle;
- developing exchanges of scientific and technical information particularly through participation in common services;
- setting up international research and development programmes and joint undertakings.

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

Foreword

Radioactive waste management activities enjoy a high priority within the programme of the OECD Nuclear Energy Agency (NEA), notably the discussion of geological disposal concepts for long-lived radioactive wastes and the associated safety aspects. Significant progress has been made since the beginning of the 80s in this field, and plans are now being established at national level for the careful implementation of deep geological repositories.

As for other nuclear facilities, safety studies are essential elements of the licensing of waste repositories. Specific national regulations exist in many countries in order to define the basic safety criteria for disposal and the regulatory process to be followed. Their purpose is to ensure that suitable safety objectives can be met in practice and that the siting, construction, operation and the closure of the repository could be licensed following a stepwise procedure. Within NEA, several standing Committees, namely the Committee on Nuclear Regulatory Activities (CNRA), the Committee on Radiation Protection and Public Health (CRPPH) and the Radiation Waste Management Committee (RWMC) cover the issues involved at the scientific, technical and regulatory level. As a first step in the direction of closer co-operation among them, they decided to sponsor a joint workshop, on "Regulating the Safety of Radioactive Waste Disposal", with emphasis on long-term safety issues and the dialogue between regulators and implementers of disposal systems about the resolution of these issues.

The Workshop was organized by a programme committee composed of representatives of the three sponsoring NEA Committees, under the Chairmanship of Mr. Lars Högberg, Director General of the Swedish Nuclear Power Inspectorate and Chairman of CNRA. The workshop took place in Cordoba, Spain in January 1997, at the invitation of the Spanish Authorities, which hosted it and published the proceedings.

These proceedings contain the papers presented at the Workshop, which were all invited, an account of the main discussions and conclusions , and a compilation of summaries of existing national regulations. The opinions presented are those of the speakers and do not necessarily express the official views of countries or international organisations concerned.

Table of contents

PROCEEDINGS: Regulating the Long-Term Safety of Radioactive Waste Disposal

SESSION II: MAKING A SAFETY CASE

COMPILATION: Summaries of National Regulations on the Disposal of Long-Lived Radioactive Waste

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WELCOME ADDRESSES

Welcome Address by Mr. Aníbal Martín, Vice-Chairman of the Nuclear Safety Council (Spain)

Good morning dear Colleagues and welcome to Córdoba.

After NEA's invitation to the member states to host the joint CNRA/CRPPH/RWMC Workshop on "Regulating the Long-Term Safety of Radioactive Waste", the Spanish Nuclear Safety Council did not hesitate to accept such an invitation, offering its support and assistance to organize this event in Spain together with ENRESA, our Nuclear Waste Agency. This initiative was proposed by our Regulatory Body shortly after last year's reorganization. One of the objectives thereof being to increase regulatory activities concerning high level radioactive waste management.

We think that a meeting like this may offer an excellent opportunity to know, first hand, other countries' experience regarding high level waste safety assessment, as well as sharing such experience and opinions.

Taking into account that all papers have been explicitly invited and the reputation of the speakers, we are sure that the technical level of this workshop will constitute an excellent and remarkable reference, with which next years' activities can be faced.

The Programme Committee has oriented the Workshop towards open discussion and communication among implementers and regulators. In this way, a very balanced view of what should be the regulatory dialogue can be obtained. This equilibrium is paramount to the subject, one with important uncertainties, and whose solution will require an especially sensible approach from regulators and implementers.

The great interest shown in this Workshop, demonstrated by the level and number of speakers, is a matter of satisfaction for the Nuclear Safety Council. We would like this Workshop, the first example of the JOINT CNRA/CRPPH/RWMC CO-OPERATION ON THE REGULATORY ASPECTS OF RADIOACTIVE WASTE MANAGEMENT, to be the starting point for further activities useful in the implementation of a forum for discussion of regulatory knowledge and experience in the field of long term waste management.

Finally, I would like to point out that the selection of the city of Córdoba as host city was made after several different considerations were taken into account. Firstly, it is the capital of the province where the Spanish Intermediate and Low Level Waste Repository is located. Secondly, we believe that Córdoba is well known historically for its commitment over the last two thousand years to Sciences and Fine Arts and thirdly, it provides a wonderful warm environment to host our seminar.

So, welcome to Spain and a special welcome to Córdoba for a fruitful Seminar.

Córdoba, January 20, 1997

Welcome Address by Mr. Antonio Colino
President of ENRESA (Spain)

Good morning Ladies and Gentlemen,

First of all I would like to welcome all the participants and, at the same time, I wish to take this opportunity to thank the NEA for their initiative in organizing this workshop.

Although I was appointed chairman of ENRESA only a few weeks ago, I am fully aware of the important effort in bringing together so many distinguished speakers, representing both regulators and implementers, to discuss the regulatory issues associated with the long-term safety of a deep geological disposal system.

In my view, the long term safety of high level radioactive waste management is the main challenge facing our sector, from the point of view both of the research programmes to be carried out and of the guarantees that the public authorities must provide in relation to the decision-making. Society demands of its governments a rigorous process of information and participation, but the governments in turn require that both the decisions taken by the regulatory authorities and actions undertaken by the agencies involved, be the result of a constructive and iterative process of study and discussion.

Furthermore, regulation of the long-term safety of radioactive wastes cannot be accomplished in isolation. International cooperation is required in order to make it possible to progress towards the common objective of safely managing radioactive wastes.

It is for us an honour and a great pleasure to have the opportunity to cooperate with the NEA once again and, in particular, to host this workshop in collaboration with our Nuclear Safety Council (CSN).

I wish you a pleasant and fruitful meeting and, at the same time, I hope you will enjoy the flavour and atmosphere of this lovely town of Córdoba, which to us is particularly dear, because as you know it is the capital city of the Province hosting our El Cabril repository for low and intermediate level waste.

Thank you.

Welcome Address by Mr. Lars Högberg, Chairman of CNRA

Ladies and Gentlemen,

It is indeed a honour and a pleasure to welcome you all to this workshop on behalf of the three OECD/NEA committees involved: The Committee on Nuclear Regulatory Activities, CNRA, of which I am the chairman, the Radioactive Waste Management Committee, RWMC, and the Committee of Radiation Protection and Public Health, CRPPH. As a chairman of the programme committee for the workshop, I want at this moment to extend my warm and sincere thanks to the Spanish Nuclear Safety Council, CSN, and to the Spanish Radioactive Waste Agency , ENRESA, for the excellent way in which they have taken on the hosting of this workshop, and in doing so, adding social and cultural events to the technical programme. Given the very long-term national commitment to safety that is required for management and final disposal of high-level, long-lived waste, I think it was very appropriate to have the workshop in Córdoba, a city with a very long history of human achievement.

Ladies and Gentlemen,

For many years, NEA has provided a forum for cooperation among member countries on a wide variety of waste management issues, first through the work of the Committee of Radiation Protection and Public Health and then through the Radioactive Waste Management Committee. Lately, regulatory issues have received increasing interest, as the regulatory bodies in several member countries are facing the first steps in the process of licensing repositories for high-level long-lived waste. Therefore, the NEA Committee on Nuclear Regulatory Activities made the original proposal for this workshop to address what most NEA member countries regard as one of the main regulatory challenges over the next decades, namely the licensing of final repositories for spent fuel and highly active waste from reprocessing as well as some other types of waste containing significant amounts of long-lived nuclides. Indeed, there are three types of challenges involved:

First, there is the *scientific* challenge to map and model the features, events and processes that influence the safety performance of the waste repository to provide reasonable scientific assurance of this safety performance over many thousand years, may be up to a hundred thousand years and more.

Secondly, there is the *technical* challenge to ensure that the technical and geological properties of a repository as built are indeed consistent with the models and data used in the performance assessment.

Thirdly, there is the *democratic* challenge to gain public acceptance of the level of safety and radiation protection used as a basis for licensing, including acceptance of the type of assurance to be provided that such a level will be achieved.

Dealing with these challenges will require a continuous and constructive communication process between all parties involved - the implementers, the regulators, and the general public. Transparency of the regulatory process, and good communication with the general public is especially important to regulators, as the regulators are in the end accountable to the general public, whose health and safety they have been given the task to protect.

Addressing all these challenges at the same time would require a large conference, rather than a workshop. Therefore it was decided that this workshop should mainly focus on the scientific and technical challenges involved in providing reasonable assurance of safety and the associated interaction between regulators and implementers.

Without achieving a reasonable international convergence of opinions between regulators on how to address these scientific and technical challenges, it will however be very difficult to meet the third challenge: to gain public acceptance of regulatory decisions in any of our countries. Recognizing the need for such convergence, and recalling the NEA Steering Committee's call for coordination of the work of the main committees of the NEA, it was thus quite natural that the CNRA, the RWMC and the CRPPH found it timely to arrange this joint workshop on Regulating the Safety of Radioactive Waste Disposal.

As I am one of those facing the task to summarize the conclusions of this workshop on Wednesday, I hope that I then shall be able to find such convergence of opinions emerging in many areas as well as common opinions on where further work in international cooperation is needed. I think we all are looking forward to such results of this workshop.

With these words, I think it is high time to declare this Workshop on Regulating the Safety of Radioactive Waste Disposal as duly opened, and to give the floor to the chairman of the first session, the vice-chairman of the Spanish Nuclear Safety Council, Mr. Martin.

Thank you, Ladies and Gentlemen.

SESSION I-A: SETTING THE SCENE

Background and scope of the workshop

Jean-Pierre Olivier
NEA

My task at the beginning of this workshop is to recall a number of considerations which led NEA to organise it, in co-operation with our Spanish Colleagues, as well as the recommendations from the Programme Committee with regard to its scope and objectives. In addition, I intend to comment briefly on the structure of the workshop and the compilation of the summaries of national disposal regulations, which was prepared and distributed prior to the workshop as a reference document.

Background and scope of the workshop

Considerable progress has been made in radioactive waste management during the last two decades in many countries, particularly concerning the disposal of certain types of radioactive waste. In particular, the disposal of low-level, short-lived waste, is currently practised at the industrial scale in at least eight NEA Member Countries, and it can be regarded as being technically solved, even if there are obvious difficulties still at the political level, for example when sites have to be selected. There is in this area a great deal of licencing experience available, but the Programme Committee felt that, although the reporting of such experience could be useful in some respect, there was a greater interest in looking specifically into the high-level, long-lived waste and spent-fuel disposal situation, which is going to be a major challenge at the regulatory level soon, a challenge that will continue well into the next century.

At the initiative of representatives from regulatory authorities and as a first step in the direction of an increased co-operation among the three competent NEA Committees in the field, it was decided to hold a joint workshop, with the purpose to identify and discuss the main regulatory issues related to the management of radioactive waste, the focus being on the incremental licensing process associated with deep geological disposal systems and their long-term safety. As was indicated in the initial information note, the workshop has been designed to allow an in-depth discussion of:

- the regulatory assessment framework, objectives and criteria applicable to the long-term safety of geological disposal systems;
- the preparation of a safety case;
- the measures to judge the safety case and demonstrate compliance with regulatory requirements;
- the experience available; and
- the main regulatory issues to be faced and resolved in the next ten years.

A major aim of the workshop is to discuss the requirements which regulators may set and compare these with the scope and the depth of safety analyses which are currently feasible for implementers.

In other words, we have tried to create the conditions for a useful dialogue between, on the one side, those who will have to provide evidence that their proposed disposal systems are going to perform safely and in accordance with regulatory criteria; and, on the other side, those who have the responsibility to decide technically and professionally, as the competent national authorities, whether and under which conditions the proposed systems are acceptable. At this stage of the discussions, we hope that non-technical aspects, such as public acceptance and politics, can essentially be left aside, and that we can concentrate on what could be considered objectively a matter of technical safety, therefore avoiding too much formalisation. Of course, the impact of non-technical aspects cannot be ignored or neglected, but the Programme Committee felt that it does not strictly belong to the scope of the workshop. This is why we have decided to exclude fuel cycle strategies and identification and selection of potential geological disposal sites from the scope of the workshop.

Structure of the Workshop

As can be noted from the programme, after this morning devoted to introducing the subject, we are going to have two sessions of about 4 hours each on how to make the safety case, and how to judge it respectively. Given the amount of information available and supposedly known on long-term performance assessments and existing regulations, we do not expect detailed presentations of what has been done in each country, but rather an account of the experience obtained through such activities including at NEA, and an indication of what are the key problem areas. We are going to make to some extent an exception for the two examples of Konrad and WIPP, which are the only cases so far of long-lived waste geological repositories under licensing. I say to some extent, because the two cases have not been finally decided and because we cannot reasonably expect that a full debate on these two cases is going to take place publicly in front of all of us. Nevertheless, we do hope that most regulatory bodies will have some preliminary views and experience to report during session III and that we will have a good picture of the situation everywhere, in order to promote a truly fruitful dialogue on the last day.

We count therefore on the sessions' chairmen and the speakers to ensure that the presentations and discussions of to-day and to-morrow do concentrate on the right issues and provide a firm basis for our concluding session on Friday.

The Compilation of disposal regulations

This compilation was designed to provide summaries of national situations, as a reference and aid to the workshop discussions. It would take too much time to make a synthesis but as the countries' answers include the main elements of what should constitute a good radioactive waste disposal regulatory "bible", I have attempted to list these elements here:

1. Start from a clear national policy/strategy for the management (and disposal) of long-lived waste based on sound principles: sustainable development, precautionary approach, radiation and environmental protection, cost-benefit distribution, etc.; which exists already in many countries.
2. Make sure that the national institutional framework defines clear and separate responsibilities for regulators and implementers and allows them to have formal and informal contacts throughout the regulatory process.
3. Clarify the meaning of the geological disposal concept designed as a final management step with inherent safety features, but no intention in principle to retrieve waste, at least after an

initial time period (such as until the time of repository sealing and closure or shortly after); and limit accordingly the credit given to institutional control measures (this is still in discussion in some countries).

4. If geological disposal is the way forward (which has still to be confirmed in a few countries), proceed according to a careful step by step process, based on R&D progress, interim decisions and gradual implementation of deep repositories.
5. With regard to disposal regulations, consider the pros and cons of prescriptive versus non-prescriptive approaches, and the interest of relying on broad objectives and criteria aiming at a generally acceptable safety level, rather than on detailed requirements on how to reach this level in practice.
6. In particular, consider long-term radiation protection criteria, whether they are expressed in dose or risk targets, or natural radionuclide concentrations, as safety indicators and not as strict limits (i.e. no basic difference between 0.1 and 0.3 mSv/y); in the same vein, interpret timescales defined for regulatory purpose (about 10.000 y for quantitative performance assessments, with a transition later to qualitative assessments) with flexibility.
7. Admit that performance assessment will never be a perfect illustration of long-term safety, but that, in spite of its inherent limitations and unavoidable uncertainties, it constitutes an essential tool, among other less sophisticated techniques, to understand the fundamental processes affecting the potential long-term behaviour of repository systems and their safety.
8. Therefore, in the absence of exact yardsticks to measure acceptability and to demonstrate compliance, admit that regulatory decisions will have ultimately to be made on the basis of expert judgements and reasonable assurance considerations, which are essentially the job of technically competent regulatory authorities, even if non-technical issues do also have a role to play in the process and need to be debated.
9. Make the whole regulatory process as open and transparent as possible, with clear documentation of the basis for regulations and decisions, and with appropriate procedures for periodic and independent reviews, consultations with local authorities and the general public, etc.
10. In short, continue to promote an ambitious and rigorous regulatory system in terms of long-term safety objectives and depth of the review process (and make this known); but at the same time give due considerations to inherent limitations regarding the far future and be prepared to rely, as appropriate, on expert judgements and a reasonable assurance approach when taking decisions (and make this also known).

This is, of course, my personal interpretation of the main points which have been made implicitly or explicitly in the compiled summaries of national regulatory situations, sometimes more in the form of questions than statements, and it may be worthwhile to keep them in mind at the start of the workshop. Thank you for your attention.

The Regulator's perspective

Sören Norrby
SKI, Sweden

1. Objectives

Nuclear power production and other practices give rise to considerable amounts of radioactive waste. The safe management and disposal of the waste, be it low-, intermediate- or high-level radioactive waste, is a national responsibility, hopefully soon codified in an international convention. Regulation of the safe management and disposal of the radioactive waste is one of the necessary means to fulfill this national responsibility.

Recommendations on general safety objectives and good practices related to radioactive waste management are given by international organisations such as the OECD/NEA and the IAEA. Moreover, international conventions and other supranational legal instruments, such as EU directives, lay down requirements on the safe management of radioactive waste.

There is a development towards a broader scope of regulations, covering not only nuclear safety and radiation protection issues but also more general environmental, societal and ethical issues. This is reflected in international documents, e.g. the *OECD/NEA Collective Opinion: The Environmental and Ethical Basis of Geological Disposal (1995)* and in national legislation on Environmental Impact Statements (EIS). Also in other aspects focus should be broad to include not only a specific facility but the total system (waste treatment, transportation and disposal). One very important aspect in EIS is the discussion on alternatives to what is proposed. The alternatives could include different types of disposal options and maybe also methods that may be developed in the future, such as transmutation of high level waste, and should include also the zero alternative (e.g. the proposed action is not carried through). For high-level radioactive waste, final disposal in deep geological repositories appears to be the preferred option in many countries. The repository will normally be a multi-barrier system consisting of different types of engineered barriers and the geological barrier.

These different alternatives may have different impact on human health and on the environment. One principle that is generally accepted is that we should offer the same level of protection to future generations as we require today. The effects in different time frames must then be evaluated, and should in principle cover time periods during which the waste remains hazardous. Also the burdens on future generations may be very different depending on what alternative is chosen. A decision not to dispose of spent fuel or radioactive waste will require active measures for safeguarding in the future, but will also keep different alternatives open.

2. The role of the regulator and the implementer

The implementer of the system for waste management and disposal and the regulator* will have different roles. International recommendations; e. g. the IAEA Safety Series 111-F, The Principles of Radioactive Waste Management (1995) and the IAEA Safety Series 111-S-1, Establishing a National System for Radioactive Waste Management (1995); emphasize the importance of keeping apart the roles and responsibilities of the implementer and the regulator. This is particularly important if the implementer is a governmental organisation.

The responsibility for the management and disposal of radioactive waste is with the implementer, who, in one way or another, has taken over that responsibility from the generator of the waste. National legislation could vary on how the responsibility of the implementer is defined but will in principle include planning, development of waste management systems and facilities as well as construction and operation of facilities. One very important part of the implementer's responsibility is to demonstrate the safety of a proposed activity or facility. National legislation also normally defines the system for financing of present future costs for waste management and disposal, and the respective roles and responsibilities of the generator of waste, the implementer and the regulator with regard to that system.

The regulator's responsibility is to define safety and radiation protection requirements, to issue guidance on safety assessment methodology and documentation, to review the implementer's safety assessments as a basis for licensing of waste management and disposal activities and facilities and to inspect and review construction and operation of nuclear facilities to ensure compliance with licensing conditions. Depending on national legislation the regulator may also be responsible for review and supervision of R&D programmes, site selection processes and of funding systems etc.

The regulator and the implementer have different responsibilities and this affects requirements on competence. The implementer must have competence in design, construction and operation of facilities. The regulator must have insight and understanding in these matters but will not be responsible for the activities as such but for regulatory supervision of the activities. As regards the assessment of safety both the implementer and the regulator need to have high competence.

3. Different approaches in regulation

Even if the principles for separation of implementory and regulatory functions are given (i.e. the above mentioned IAEA documents) national legislation may vary in different aspects. There may be differences in national legislation on how necessary R&D is carried through and reported, in licensing procedures and in level of detail of regulation. However, the implementer is normally responsible for all actions needed for R&D work, planning, design, construction and operation of facilities and also for demonstrating safety.

Regulations may vary considerably as regards the level of detail. In some countries the level of detail may be very high, e.g. setting subsystem criteria and giving rather detailed requirements on

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* In some countries, there is not a single regulatory authority and the regulatory functions discussed in this paper may be distributed among several governmental authorities. In such cases the implementor has the right to expect a coordinated regulatory approach from the government side.

demonstration of compliance with regulatory criteria. In other countries requirements on subsystems and demonstration of compliance with regulations is of a much more general nature. Both approaches have advantages and disadvantages.

One disadvantage in detailed regulations is that it may restrict the possibility to incorporate new methods and techniques in design and safety assessment. An advantage with detailed regulations is on the other hand that the requirements on demonstration of compliance become more clear and not subject to interpretation in the way it may be in a less detailed regulatory system. A detailed regulatory system may in practice transfer some responsibility for chosen technical solutions to the regulator, as it may restrict the implementer's freedom to make his own choice. Less detailed regulations may have the opposite advantages and disadvantages.

One aspect that will be of importance is the type of licensing procedure chosen. A licensing procedure may aim at one single decision on a waste management facility. This may seem attractive, as there is only one battle to be fought, with very clear-cut roles for the implementer and the regulator. In practice, it may be difficult to succeed in one-step licensing of a disposal solution typically involving a large amount of scientific and technical development with associated uncertainties. The licensing procedure may also be a stepwise procedure in which it is possible to learn from earlier phases and to adjust technical solutions and to improve in safety assessment methodology in later phases. A phased licensing procedure obviously has its advantages. On the other hand it may seem to be too undefined, thus creating an impression that there are too many loose ends that have to be tied up later on. Still a stepwise licensing procedure seems to be preferable, as it provides more opportunity for a constructive dialogue between implementer and regulators. This dialogue should also be transparent to, and in appropriate forms involve independent experts and the general public, so as not to create suspicions that important discussions on controversial issues are hidden from the public, which would have a negative impact on public acceptance.

Whichever licensing approach is chosen, it is the task of the regulator to specify an appropriate set of safety and radiation protection objectives, including risk tolerance criteria, and quality requirements for performance assessments to demonstrate compliance with the objectives and criteria. Moreover, it is the task of the regulator to ensure public acceptance of these objectives, criteria, and requirements for demonstration of compliance, as regulators are ultimately accountable to the general public, whose health and safety they are given the responsibility to protect. If a phased licensing approach is chosen, it is important that the regulator, or the government, early on defines the 'rules of the game' for the step-wise decisionmaking involved.

4. Performance Assessment. Demonstration of compliance with regulatory criteria

To demonstrate compliance with given safety and radiation protection objectives and criteria the safe performance of the disposal concept must be assessed. To that end systematic assessment methods have been developed. The methods must basically build on a genuine understanding of the repository system and it's development over time periods typically being in the order of 10^3,10^4, 10^5 and 10^6 years depending on what type of waste is of concern. For spent fuel the radioactive inventory in a repository will represent a hazard in comparison to naturally occurring uranium deposits for time periods of 10^5 to 10^6 years.

Performance assessment methods include techniques for defining the scenarios that should be evaluated, methods for modelling of the repository system, procedures for verification/validation of these models, deterministic/probabilistic assessment methodology, quantitative/qualitative evaluation etc. It is obvious that the assessment of a repository system for very long time periods will be an extremely demanding task. A variety of available tools should be used in the assessment. Multiple lines of reasoning will be valuable. Deterministic and probabilistic methods should be regarded as complementary. Even if it is to be preferred to have a quantitative evaluation of the effects of the repository system it should be recognized that these two methods are not in contradiction. Both are needed. We should bear in mind that also a quantitative assessment to a great extent builds on qualitative presumptions and expert judgement. However, a quantitative evaluation has advantages over a qualitative evaluation in that uncertainty and sensitivity analysis can easier be done and this will help in understanding the possible development of the performance of the repository system over time.

Also in selecting the disposal concept, in defining design parameters for the engineered barriers, in defining the site selection process (even if also many other factors are relevant) and in the choice of parameters for characterization of a site, performance assessment methods are of importance as tools for reaching a safe repository system in the end.

How well we ever succeed in assessing the safety of a repository there will always be uncertainties in the assessments. This must be recognized. The biosphere will not be stable over time periods of several ten thousands of years or longer. Therefore it will not be possible to predict doses to man in these time perspectives. The geosphere on the other hand will be much more stable than the biosphere over the time periods of concern. Therefore it is meaningful to quantitatively assess the repository system (geosphere and engineered barriers) for very long time periods. It may then be useful to calculate doses also for these time periods, related to some type of model biosphere, but to regard such doses only as indicators of safety. Also other safety indicators may be useful e.g. the release (source term) from the repository of long-lived radionuclides to the biosphere. Comparison with releases to the biosphere of naturally occurring radionuclides may be useful.

Human intrusions in the repository represent a special type of scenarios where the frequency for a possible intrusion is extremely difficult to evaluate and it may be reasonable that the regulator defines the scenarios that have to be evaluated and how this evaluation should be made.

It is obvious that the demonstration of compliance with given criteria is a very difficult task. A broad approach including multiple lines of reasoning utilizing deterministic and probabilistic methods, as well as quantitative and qualitative methods and also using different safety indicators is useful. However, no matter how detailed and careful we are, we will never have a clear-cut case where the answer to compliance is "yes" or "no". The concept of "reasonable assurance" will be useful. What is reasonable is not always evident. Multiple lines of reasoning and open procedures may help in reaching agreement on that.

The handling of risk profiles and uncertainties in the licensing of the Swedish SFR final disposal facility for low and intermediate level radioactive waste provides an interesting example. A key issue in the licensing process was the risks associated with the about 10 TBq of long-lived nuclides, that SFR may contain. In the analysis made by SKI and the Swedish Radiation Protection Institute, SSI, it was found that, in a realistic case, the resulting radiation dose would likely be considerably lower than that man receives from natural sources. However, some combinations of circumstances were identified where a few persons drinking water from a well downstream the repository might receive individual doses in the range 1-10 mSv/year. In the SFR assessment, the appearance of such doses was estimated to be improbable, as this presumes that a combination of mutually independent, pessimistic assumptions are simultaneously fulfilled, such as an uncontrolled well in the vicinity of the repository as an exposure path, and a detrimental formation of complex ions from cellulose residues. However, quantitative probability estimates were not considered meaningful as a basis for decisions. In summary, and considering the pessimistic assumptions, SKI and SSI concluded that the SFR facility presented a risk profile with respect to probability of exposure of limited groups that did not deviate significantly from what the Swedish society accepts today with respect to exposure from naturally occurring radioactive substances, e.g. radon in houses or wells, without requiring special measures to be taken by the society. Based on these findings and conclusions the SFR operating license was granted.

Under all circumstances good documentation of all steps in the assessment including the reasons for screening out or keeping certain elements in the performance assessment is of utmost importance. This is part of quality assurance in performance assessment.

5. Communication of performance assessment results

The scientific and technical background for final disposal of radioactive waste may be very complex, especially for high-level waste and spent fuel, for which the time perspectives may be in the order of hundred thousands of years. Also the performance assessment methods will be complex. There are good reasons to have a strategy and methods for communication of performance assessment results to politicians, other decision makers and to the general public. First of all this is a matter of democracy. A decision, and the basis for this decision, that is of concern to many must be explained. The regulatory procedures often require the participation of different groups and this is normally the case in Environmental Impact Assessments. Thus, performance assessment methodology and performance assessment results must be explained. This however does not mean that performance assessment methodology should be simplified in such a way that the quality of performance assessment is compromised. Who would accept a simplified assessment of aeroplane safety if this would imply a less reliable safety assessment? Instead efforts must be made to explain and to encourage open discussions on performance assessment methodology and results.

The answer to how performance assessment methodology and results can be communicated is not only simple brochures. These may be needed, but this is not enough. There is not one simple answer to what should be done. Openness and good communication procedures between those parties concerned (regulators, implementers, local politicians etc.) is necessary and will be a good basis for understanding.

Performance assessment will in some respect always be subjective. Even if the implementer as well as the regulator scrutinize the assessments very carefully it may be valuable to have a "peer review" of the assessment. An international peer review may give support to the assessment and may indicate where improvements could be made. In this way the credibility of the assessment may be increased.

6. Conclusions

Most important is the recognition that regulation of long-term safety of radioactive waste is difficult. Because of the very long time periods it will also be very difficult to demonstrate strict compliance with quantitative criteria. Therefore it is crucial that regulatory criteria and requirements are formulated in such a way that demonstration of compliance is facilitated. The criteria should be formulated so that important issues such as completeness of assessment, QA, traceability etc. are emphasized. Also, it is important to ensure consistency between the properties of engineered and geological barriers assumed in the performance assessment and the parameters to be controlled and achieved in the design and manufacturing of engineered barriers and in site characterisation and selection. Moreover, it should be recognized that a decision on long-term safety of radioactive waste disposal always will be a decision under uncertainty. Also, transparency of the regulatory procedures in general is important for the understanding and acceptance of waste disposal. Openness, stepwise procedures, peer review etc. may help in achieving acceptance. But most of all we should emphasize the importance of thorough understanding of what we do, be it construction and operation of a repository or, most important, the assessment of safety. All this should also be communicated to political decisionmakers and the general public. This could lead to credibility in safety assessment methodology and in the end to the public acceptance of waste disposal. A prerequisite for that is the competence not only of the implementer but also of an independent regulator.

Requirements for repository licensing: The implementer's perspective

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Nuclear waste disposal - a challenging task requiring a broad consensus

There have been repeated, extravagant claims made that nuclear waste disposal is the greatest technical challenge facing our society and is an unsolved problem. As a (potential) implementer of geological repositories, I do not subscribe to such exaggerated views. I do, however, believe that achieving the necessary technical, political and social consensus for siting, licensing, constructing and operating a repository for high-level wastes is a major challenge. One important reason for this is that a range of different players are involved, each with a different viewpoint and a different rôle.

The principal groups involved include politicians, regulators, implementers, independent scientists, environmentalists and (last – but in this case certainly not least) the general public. In many countries all of these groups have engaged themselves to some extent in the issue of waste disposal regulations.

It is perhaps worthwhile to digress here and illustrate this point with an extreme example from within the very open system in the USA, where various approaches have been tried– with limited success to date. The US Nuclear Regulatory Council (NRC) early on back-calculated from the overall safety requirements of the Environmental Protection Agency (EPA) specific detailed criteria which were impracticable and non-transparent; they did, however, based on their long experience with reactor safety regulation, make very sensible statements on the issue of compliance through "reasonable assurance" and they also made provision for compliance based on fulfilling global safety goals. The US Department of Energy (DOE) ignored the global criterion and also the pragmatic statements by NRC on reasonable assurance and focused too strongly on the individual criteria. Politicians in the US Congress mixed in at a very detailed level concerning waste management systems, facility siting and even particular dose limits; the independent scientific committee created by the National Academy of Sciences (NAS) to satisfy the legislation of the Congress to advise on the safety standards for Yucca Mountain created some clarity and also some more confusion.

In the midst of this confusion of different players, all presenting their own perspectives on the issues involved, one very clear, common objective must be that an intensive dialogue is established and maintained at all levels. Different views on the best procedures for siting licensing and constructing repositories may always exist; if they do, however, they should be based on different judgement of the facts available to all participants and not on ignorance of the arguments and the perspectives of other participants in the process. Dialogue is necessary between all the players mentioned above. In this Workshop, the spotlight is directed upon the particular dialogue between regulator and implementer. This is, indeed, one of the most important exchanges since the debate between these two players sends important signals to others. Open exchange between regulators and implementers in waste management has long been a positive feature of the work of various international groups such as those of the NEA

(RWMC, PAAG, SEDE) and of the IAEA (the original INWAC, the Sub-Group on Principles and Criteria). My perception is that dialogue at a national level has in some cases been less intensive or, at least, more formalised and polarised – partly due to concerns over demonstrating regulatory independence. I am pleased that this Workshop continues and strengthens the international tradition of dialogue.

To encourage appropriate debate, I will try to present an overview of the implementer perspective. What do we see as the key overall requirements for finally licensing a deep geologic facility? What do we expect of the regulatory authority and of the body of regulations which they will develop? What are the main remaining concerns of implementers facing the challenge of providing safe, accepted, cost-effective disposal facilities?

Requirements for repository licensing

Lest the most obvious be forgotten, it is important to repeat here the obvious fact that no repository should ever be licensed unless the disposal concept is sound, the technical and engineering work is of high quality, and the characteristics of the chosen site are appropriate for providing long-term protection of man and the environment. A robust repository system offering a high level of safety based on a conservatively-chosen, simple, well-understood and passive set of safety barriers must be the aim of every implementer.

To demonstrate convincingly to himself, to the regulator and to the public that the proposed repository will, indeed, provide adequate safety, the implementer further requires a set of assessment models and of corresponding data. Here again, the term robust is appropriate. The models must adequately represent all processes which could lead to releases from the repository and the data must be sufficiently representative of present and future conditions or, at least of pessimistic scenarios of present and future. Models or data which knowingly overestimated potential negative consequences of the repository are perfectly acceptable for regulatory purposes; optimising repository concepts may require more realistic modelling. The status of the models and data available today has been reviewed at regular intervals over the past years and will be addressed in this Workshop by Ken Dormuth.

The next requirement in the licensing process is a proper regulatory framework. This topic will be addressed by Mel Knapp and Allan Duncan. From the implementer's point of view, an important feature of the framework is that it should yield regulations which are strict but fair, transparent to all concerned and practicable. These issues form the core of the implementer/regulator dialogue and will be addressed in more detail later in this paper.

Using his models and data within the given regulatory framework, the implementer must now produce a safety case. This case will be based strongly upon quantitative analyses of potential system behaviour but will include also qualitative arguments and indirect evidence of his understanding of long-term system behaviour. An extremely challenging task is to present the safety case in an open and transparent manner to a range of audiences. Most important of these is the regulatory body. In principle, however, the dialogue here should be the most straightforward since the regulator will speak the same language, i.e. he can be expected to accept also the more complex analyses and arguments. For less specialised audiences, however, the implementer also has to present an understandable safety case. The challenge is to simplify – but not falsify or trivialise – complex technical analyses.

Given the above range of pre-requisites for licensing a repository, it is clear that important requirements must also be fulfilled by the implementing body itself. First and foremost, the implementer must build a competent and committed team which is dedicated to fulfilling the goals set. Scientific integrity, technical competence, organisational flair, commercial understanding and ability to communicate at all levels – these are the qualities which every implementing body should strive to encourage in its ranks. Within these ranks, there should be present not only technical expertise from a range of disciplines, there should also be generalists with experience at co-ordinating interdisciplinary work and with the ability to focus specific project work onto the most relevant safety areas.

What does the implementer expect of the regulator?

Already at a personal level, the implementer has a wish list of qualities he would like to see in all regulators. The chances of progressing towards safe disposal are much higher when the regulatory body staff also possesses all of the desirable implementer qualities listed in the previous paragraph. Dialogue between equal partners is most fruitful.

Further important regulator attributes are independence, objectivity and fairness. In order that they speak the same "language", it helps if regulator and implementer are both convinced that safe geologic disposal is in principle, at least, achievable. The joint objective should be to ensure that specific proposed repository systems and sites will be realised only if they provide sufficient safety. A final specific demand on regulators is that they be competent and mature enough to actually take decisions in the face of remaining uncertainties. It can be all too tempting to postpone or prolong a decision process in order to marginally extend a database which, by definition will never be complete.

The next items on the implementer's wish list concern the regulatory framework itself. A prime concern here is that the regulatory body provides "a level playing field" for the process of repository licensing. This means that a framework consistent with risk assessment in other comparable technological areas should be established. In many countries there is an obvious tendency to impose stronger requirements in the nuclear area in general and in radioactive waste disposal, in particular. This observation applies less to the levels of dose or risk set than to the complexity of the regulatory procedures and to the high demands on compliance demonstration. An equal concern of the implementer is that the regulations are as clearly interpretable as possible – whilst still making clear explicitly that interpretation and judgement will always play an essential rôle in judging compliance. The regulator himself must be a reasonable person (and not, for example, a radiation protection "fundamentalist" convinced that strict ALARA rules must be applied to long-term disposal). He must also work to convince others (e.g. politicians) that "reasonable assurance" is a sound concept which is applied also in other areas of decision-making. Finally, the regulatory framework should emphasise the stepwise approach towards repository implementation which today is broadly supported. In particular, because iterative safety assessments of a repository are a feature of stepwise procedures, the requirements on scenario completeness, model performance and data quality must be more relaxed at earlier iterations in the process than for a final safety analysis.

The schematic curves in Figure 1 (derived from an earlier idea of Frank Parker) illustrate the characteristic growth of confidence in results of safety analyses for a well chosen site as a function of the growth in understanding of the geological and engineered barriers in the repository. Also indicated are some of the formal regulatory review steps foreseen in the Swiss licensing system. It is obvious that more convincing safety demonstrations become possible with progress in the project work. It is also obvious that differences in judgement can lead to differing conclusions from optimists and pessimists.

Moreover, it is (too) often the case that implementers belong to the former category and regulators to the latter!

Most of the characteristics of regulators or regulations which have been mentioned above would be easily agreed by both parties to be desirable. There is perhaps more scope for polarisation of views concerning the sensitive issue of interactions of both regulators and implementers with further bodies – and in particular with the public. Regulators have an understandably strong commitment to demonstration of their independence and technical competence. This can lead to public formulation of views or judgements in a manner judged by the implementer to be unnecessarily provocative. Honest disagreement between technical experts is on occasion to be expected and should not be disguised; unnecessary provocativeness, serving only to overemphasise differing judgements, can lead to public misunderstanding and, thus, to technical input to societal decision making becoming even more discredited.

To risk specific examples of polarising statements here, we could point to particular interactions within the Canadian and the Swiss deep disposal programmes. As a first official response to the major Concept Assessment Project completed by AECL and Ontario Hydro, the Canadian regulatory body, AECB, produced a staff response which was "primarily a statement of deficiencies and focused on the negative aspects". The fact that this report continued with a disclaimer, briefly mentioning that the project also had positive aspects, does not justify opening the public regulator/implementer exchange in an undertaking of national importance in such a negative fashion. A less public recent example of insensitive formulation occurred in the Swiss programme. A written review by geological experts of the regulators expressed directly their "astonishment at how little" the implementer had taken into account the scientific results which he had himself had produced; the actual situation was rather that the weighting of the same, uncontested results by implementer and regulator was different. After some months and many intensive discussions, both parties eventually agreed upon which few differences in opinion were of real importance; thereafter it was possible to reach a documented consensus on the directions of future work.

Concern at the effects of such over-hasty formulations does not, to my mind, reflect over-sensitivity of the implementer; it arises rather from a desire to serve the public better by separating true technical disagreement from academic scientific debate. As a self-protective measure, it would be imprudent and also unfair to conclude this section without noting that at least as many unnecessary squabbles of a pseudo-technical nature have resulted from over-statements, over-simplifications and deliberate omissions in public statements from the implementer side of the waste disposal field.

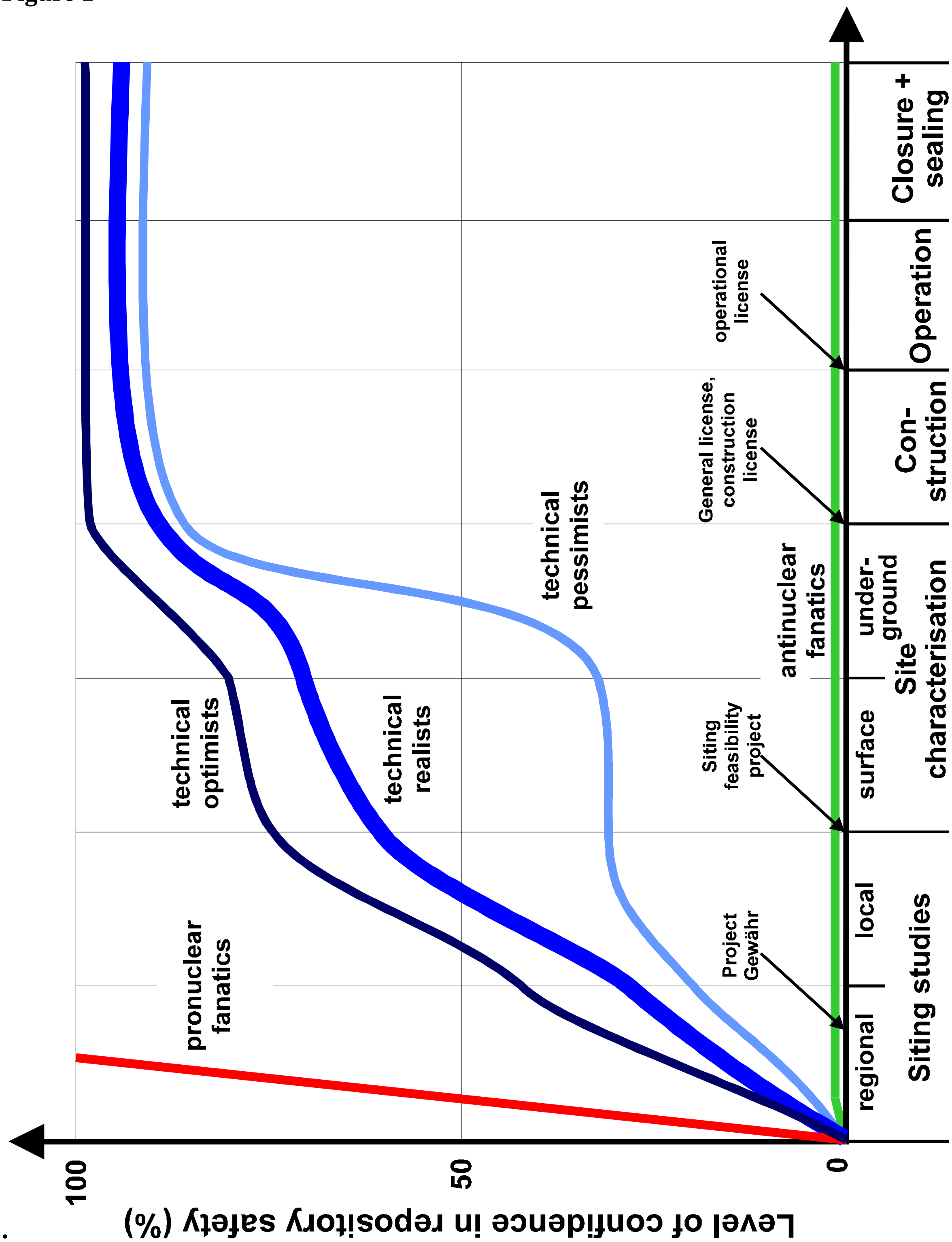
Concerning communication between implementer and regulator, a goal for both sides should be to reach – if necessary in hard technical discussions – a consensus on repository safety. If this is judged adequate, both sides should be prepared to present the appropriate case to politicians and public. There is occasionally a tendency of regulators to hope that repository projects can be publicly accepted before a formal licensing decision is taken. The implementer view is that approval of his project by competent, independent regulators is an essential pre-requisite to achieving the necessary political and public support.

Key areas of implementer concern

This paper has been devoted to general issues, on the assumption that specific more technical topics will be covered in subsequent overviews and particular difficulties in preparing and judging safety cases will be covered in the individual project presentations. None the less, the opportunity is taken here of presenting from an implementer perspective a concluding list of key areas where more debate and some decisions are needed.

Firstly, implementers are not convinced that the "level playing field" referred to above has yet been provided. A different yardstick is applied by many countries when setting regulations in the nuclear area – especially with respect to compliance requirements. A more technical area of implementer concern involves the current state of performance assessment modelling. Some models (e.g. for coupled processes) need improvement; many datasets (e.g. for characterising fractured rock, for defining probability distributions) need extension. Regulators and implementers must strive to reach a consensus on the quality required of models and data which may be used in safety assessments for licensing. Consensus must also be finalised on appropriate safety indicators and for dose or risk measures agreement on justifiable reference biospheres is needed. The approach to be used in judging the importance of human intrusion should be settled. Most important of all, however, is that regulators promulgate requirements for repository safety which are practicable; in particular, compliance requirements must be based on the concept of reasonable assurance and not on expectations of rigorous, predictive proofs of future system behaviour.

Figure 1


Level of confidence in repository safety (%)
100
50
0
pronuclear fanatics
technical optimists
technical realists
technical pessimists
antinuclear fanatics
Project Gewähr
Siting feasibility project
General license, construction license
operational license
regional
local
Siting studies
surface
under-ground
Site characterisation
Con-struction
Operation
Closure + sealing

SESSION I-B: THE CURRENT SITUATION

The Radiation Protection Context

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1 - Introduction

Radioactive waste should be disposed of in a manner that protects both man and the environment from the harmful effects of radiation. Radiation protection considerations are not the only ones which come into play in the final choice of a solution: social, economic and political aspects must be taken into account, along with public opinion.

Radiation protection is, however, an essential part of the licence application file which has to be submitted to the authorities. In this sense, the title given to this paper may be misleading and imply that the radiation protection system is merely a framework for the decision maker.

As everyone knows, the ICRP is the reference for all radiation protection matters. It should be recognised, however, that as regards waste, its role has been very limited, despite a specific publication on the subject over a decade ago (ICRP 46 "Radiation Protection Principles for the Disposal of Solid Radioactive Waste"). Many experts and decision makers have never read this publication, even though it is quoted in most national regulations and international safety standard texts.

It would therefore appear that current debate on a subject which directly involves radiation protection is being held outside the realm of the ICRP.

Our intention is not to claim a monopoly but to recognise that in the case of such a complex subject involving varied skills such as waste management, safety and radiation protection, it is vital that each of these "scientific communities" be allowed to contribute to the debate.

In an attempt to better address this problem, the ICRP has decided to set up two Task groups, one centered around solid waste, which will clarify ICRP 46 for decision makers and another, more general one, which covers all kind of waste including discharges of effluents into the environment and whose aim will be to reiterate radiation protection principles as applied to waste. I have been appointed president of the first Task Group and the second one is headed by John Dunster. Moreover a working party has been set up under the leadership of Jack Valentin to clarify ICRP’s statement on protection of the environment.

We should also mention the Task Group on chronic exposure headed by Abel Gonzalez which is of interest for residues produced by PAs events.

I don’t intend to speak on the ICRP's behalf about documents which are being elaborated and which will no doubt give rise to difficult debate within Committee 4 and the Main Commission. My aim is simply to indicate some lines of thought to you.

2 - Recent Developments in the Radiation Protection Policy

The primary aim of ICRP policy is « to provide an appropriate standard of protection for man without unduly limiting the beneficial practices giving rise to radiation exposure ».

Two kind of effects have to be taken into account : deterministic effects which can be avoided by restricting the doses to individuals below well known thresholds and stochastic effects which cannot be completely avoided because no threshold has been demonstrated for them.

ICRP considers that some residual risk is acceptable as long as it has been limited by all reasonable means. The conceptual framework developed by ICRP is based on three principles namely : justification of a practice on the grounds that it produces sufficient benefit to offset the radiation detriment that it may cause ; optimisation of the protection, in relation to any particular source within a practice, economic and social factors being taken into account ; and finally limitation of the exposures that an individual may incur from the combination of all the relevant practices.

The strength and coherence of the system lies in its ability to be applied to different types of situations. However, over the last decade, it has become necessary to develop the system by highlighting the way it is applied to these different kind of situations (fig. 1).

ICRP extended the system of dose limitation to encompass probabilistic situations by introducing the concept of potential exposures. Furthermore, it divided exposure situations into « practices » and « interventions ». Practices are defined as those human activities that « increase overall exposure to radiation [by] introducing new blocks of sources, pathways and individuals, or by modifying the network of pathways from existing sources to man. ICRP defines intervention situations as those where « the sources, pathways and exposed individuals are already in place when decisions, about control measures are being considered » (ICRP paragraph 100). Thus it is clear that process of disposing of solid waste falls into the category of a practice.

The three principles (justification, optimisation and limitation) apply to practices while in the case of intervention only two of them are to be used (justification and optimisation) : « the use of these dose limits, or of any other pre-determined dose limits, as the basis for deciding on intervention might involve measures that would be out of all proportion to the benefit obtained and would then conflict with the principle of justification » (ICRP 60, paragraph 131).

The principle of optimisation considered to be the key to the radiation protection system, is strengthened in the case of practices by the introduction of a new concept : the constraint-a source related restriction on the amount of exposure an individual could receive from the planned operation of that source. Thus the use of a constraint is prospective. It is not a form of dose limit to be used retrospectively.

In concrete terms, the logic of the ICRP policy applied to practices is as follows : control the sources by establishing and maintaining effective defences against radiological hazards in such a way that radiological objectives are satisfied which means the implementation of the three basic principles above mentioned. Should this not be the case (accident) the situation may then call for intervention.

The main ICRP publications to be considered to understand the above mentioned developments are the following :

- ICRP 26 proposed a system of dose limitation that today would be regarded as being applicable to « normal » situations, i.e., circumstances where the doses are reasonably certain to be incurred with a magnitude that can be estimated albeit with some error.

- ICRP 46 acknowledged that the system of dose limitation required modification in order to cover future exposures from disposal of long-lived radioactive wastes. In such circumstances there is no certainty that a particular exposure situation will occur but probabilities may be assigned to exposure situation. ICRP 46 proposed that dose limits are applied to the most likely exposure situation (the normal evolution scenario) and that a risk limit is applied to probabilistic situations.

- ICRP 60 extended the system of dose limitation to encompass probabilistic situations by introducing the concept of potential exposures. Furthermore, it divided exposure situations into « practices » and « interventions ».

- ICRP 64 developed an overall framework for potential exposures and the report is intended to provide a basis for the preparation of more detailed guidance related to specific practices, including radioactive waste disposal.

3 - Difficulty of Application to Long-lived Radioactive Waste

The management of long-lived waste represents a real challenge for the radiation protection system as it has just been described (fig. 2).

Firstly because it poses ethical problems which are not solved by the ICRP risk management policy. Applying justification, optimisation and limitation principles tacitly implies that the advantages and disadvantages being compared involve the same generation of individuals, whereas when it comes to waste, the detriment is passed on to future generations who will have gained no direct benefit from the advantages of these practices.

Secondly because the long lifetimes of the radionuclides contained in the waste and the corresponding risks make realistic assessment of exposure levels difficult. Moreover, verification of compliance with objectives is impossible, except in the short term. Finally, should an unexpected event occur (i.e. something that would be termed an accident if it happened now), there is no certainty that it would be possible to intervene if future generations had forgotten the whereabouts of the repository.

Is it necessary to establish a risk management policy peculiar to waste? We do not think so, firstly because, as mentioned in the preceding section, the strength and coherence of the radiation protection policy lies in its ability to be applied to all situations. Secondly because exceptions are misunderstood by the public and decision makers, even if there is a good reason for them; see for instance the ICRP recommendation not to use limits for accidental situations.

The path to be taken therefore consists in clarifying the application of radiation protection principles and concepts within the context of long-lived waste disposal, taking into account both recent proposals by the ICRP and proposals made within other international organisations.

Our thoughts on the matter can go in several directions:

- *Ethical considerations.* Transfer of risks from today's generation to future generations due to waste disposal should be examined when making a choice between dilution/dispersion and concentration/containment options. Thus geological disposal would make it possible to reduce individual and collective doses to the public now and for generations to come, but risks from intrusion will have to be taken into account.

- *The radiation protection policy must be implemented at the design stage.* The disposal options correspond to passive protection systems which do not need monitoring and which are sufficiently robust, i.e. whose performance levels are only slightly susceptible to uncertainties and/or whose design, *a priori*, takes possible contingencies into account.

Hence the importance for decision makers of not reducing the safety assessment to a simple check of compliance with dose or risk criteria. The robustness of a project can be appreciated by examining whether or not the safety functions can be affected by features, events and processes likely to considerably affect the performance levels of a disposal system.

It is not a case of predicting the future but of testing the system to obtain a reasonable level of confidence in its ability to fulfill the safety functions attributed to it.

- Even more than in other fields, *optimisation should be the guiding principle* in the choice of protection. Since waste is considered to represent not an independent practice but the final stage of a practice, it is not appropriate to apply the justification principle, and the limitation principle is of limited use for the following reasons :

  - the limit for the public is far less restrictive than the constraint associated with the repository ; the constraint is therefore the most favoured management tool,

  - implementation of the limitation principle implies the possibility of checking, *a posteriori*, that the limits have been respected, which is not possible in the case for long-lived waste,

  - the choice of limits correspond to a risk level considered as tolerable is linked to the state of development of society.

It remains to be seen how the optimisation principle can be applied.

4 - Issues and Proposals

A. Disaggregation of probabilities from consequences

Issues

Two types of long-lived waste repository evolution scenarios are generally considered. One is a reference scenario considered as the most probable, corresponding to gradual degradation of barriers with time. The other are probabilistic scenarios which call into play natural phenomena (earthquakes and climatic phenomena) or phenomena of man-made origin (intrusion, greenhouse effect etc.).

The first question is whether exposures corresponding to the reference scenario should be treated as normal exposures expressed in terms of dose and the others as potential exposures expressed in terms of risk or should both kind of scenarios be considered as giving rise to potential exposures ?

The second question is to the expression of the risk associated with potential exposures, either in an aggregated or a disaggregated way, highlighting the two terms of it (the probability of an event leading to exposure and the consequences of this exposure).

ICRP 46 presents a very straightforward approach to risk in aggregating probability and consequences. However, in Publication 64, ICRP suggests that in some circumstances separation of the probability of an exposure situation arising from the consequences in terms of health effects may be useful. This may well be the case in solid waste management, particularly when considering human intrusion as it may be very difficult, or impossible, to assign a meaningful value to the probability of intrusion.

One example of where disaggregation is useful is when deterministic effects may arise. Deterministic effects may be viewed differently to stochastic effects by society. Broadly, in this context, human intrusion scenarios are the only situations where deterministic effects can be experienced, albeit only following disposal of HLW and possibly ILW. Furthermore, the only steps that can be realistically taken to reduce risks from direct human intrusion into a repository is to reduce the probability of occurrence by appropriate siting of the repository or, possibly, by relying on some form of warning markers.

Proposals

Generally, it may be useful for decision making to know the level of dose that may arise in particular situations.

More specifically, risks from direct human intrusion into a repository should not be included in an assessment undertaken for comparison with criteria derived from consideration of "normal" situations (e.g. the ICRP 46 criteria). This is developed further in Section 4.

B. Optimisation

Issues

Difficulty in performing conventional optimisation techniques as future collective dose cannot be estimated reliably. In order to estimate collective doses, assumptions have to be made about the size and habits of the exposed population, and for time periods beyond a few hundred years into the future, such assumptions amount to little more than speculation.

The uncertainties can mask the differences between the various options under consideration.

The delay between cost outlay and benefits expected from protection options. In most cost-benefit analyses, these delays are relatively short and the two terms in the equation can be estimated on a similar basis.

Finally, decision makers tend to maximise rather than optimise protection, and this is in response to the uncertainties, the sensitivity of public opinion and the difficulty in finding sites.

Proposals

Optimisation should be approached as an exercise in common sense and this is consistent with the approach to optimisation in the ICRP 60 recommendations.

Reference could be made to sound engineering practice: can reductions in radiation dose and risk be achieved through engineering measures that can be implemented in a cost-effective manner?

The relevance of collective dose estimates should be addressed.

Consideration of the fact that the decision maker needs to know the evolution of the mean individual dose rate of the critical group, even if only to apply adequate risk factors and that the collective dose leads to the association of two uncertainties namely individual exposure and the number of persons exposed.

C. Time periods

Disposal of long-lived radioactive waste may give rise to exposures many hundreds of thousands of years into the future. For radiation protection purposes, it is convenient to divide the future into two broad time frames: the period of institutional control and the subsequent time period.

Issues

After the period of institutional control, uncertainties include lack of knowledge of future site evolution and of human habits.

Proposals

ICRP 46 criteria are framed in terms of doses and risks but in order to calculate these quantities, one needs to make assumptions about human behaviour. ICRP acknowledged this in § 46 of ICRP 46 where the concept of hypothetical critical groups is introduced. It is important for ICRP to provide more guidance on this topic or prompt international groups or organisations who can. Furthermore, one cannot define critical groups independently of the biosphere. It is proposed that the idea of a reference biosphere be developed (this is probably an issue for BIOspheric Model Validation Study (BIOMOVS) to address). International agreement on criteria for future biospheres and critical groups would avoid a situation where there is pointless speculation about possible future biospheres and thus enable effort to be directed at areas amenable to investigations, e.g. waste degradation and migration through the geosphere.

There are other possible safety indicators including the flux of radionuclides from the geosphere, radiotoxicity of the waste and how this changes with time, and radionuclide concentrations in the biosphere. These were discussed in a recent International Waste Advisory Committee (INWAC) sub-group report. There are problems in what to compare these indicators to but, nevertheless, ICRP could develop ideas on their role and utility, particularly with respect to assessing safety in the very long term.

Conclusions

In the light of the above, it might be convenient to divide the period after institutional control into a number of time frames, with the basis for assessing the safety of the repository changing between each time frame in a way that takes the increasing uncertainty into account.

D. Implementation of the principles

Issues

The licensing issue of most concern is probably not what the formal radiation protection criteria should be, but rather how to demonstrate compliance with a set of criteria or indicators. For example, what kind of specific requirements should be set by the regulators?

One of the essential aspects, not sufficiently considered in ICRP 46, in applying the radiation protection system to solid long-lived waste is the importance of the design phase, and the way in which all the various items of information should be integrated into an overall safety case.

It is essential to allow the authorities to make decisions based on precise regulatory requirements. As complex models with numerous parameters can be implemented so as to reach a desired conclusion, these requirements should not be expressed in terms of probability or exposure levels which are likely to occur in the very long term. Rather, the regulatory requirement should be a technical one chosen in such a way that it is easily checked. The Task Group should evaluate the feasibility of this concept.

Generally, ICRP 60 and 64 acknowledge the necessity of introducing some technical and managerial conditions (quality assurance, sound technology, assessments).

Proposals

ICRP could point out that an evaluation of the radiological acceptability of a waste disposal facility will involve consideration of many factors including compliance with numerical criteria and other safety indicators, as mentioned above. The overall radiological safety assessment should be developed in a structured, iterative manner within a quality management system. The ultimate objective should be to provide a reasonable assurance of safety rather than having the unachievable objective of providing absolute assurance.

5 - Conclusion

The preliminary ideas we have just presented need to be developed and discussed by radiation protection specialists and those responsible for waste management and safety, if they are to have an impact on the decision makers who will be using them.

Our aim is not to present an exhaustive point of view on the safety assessment of long-lived waste storage but to deal with radiation protection aspects by querying the contribution of the ICPR system when it is applied to this particular case and the possible interpretations of it, without destroying the logic of the system.

See figure 1

See figure 2

REGULATING THE LONG-TERM SAFETY OF RADIOACTIVE WASTE DISPOSAL IN THE UNITED STATES

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A INTRODUCTION

Thank you for this opportunity to present the U.S. Nuclear Regulatory Commission (NRC) staff's views on regulating the disposal of spent nuclear fuel (SNF) and other high-level radioactive waste (HLW) in the United States. Most of this paper will focus on NRC's geologic disposal regulation set forth in Title 10, Part 60 of the *U.S. Code of Federal Regulations* (U.S. Nuclear Regulatory Commission, 1983), hereafter called Part 60. However, as a matter of background, it is important to point out that NRC is one of three Federal agencies with a role in the disposal of SNF and HLW. The U.S. Department of Energy (DOE) has the responsibility for the actual disposal of SNF and HLW. This responsibility includes determining the suitability of the proposed site as well as developing and operating the geologic repository. The U.S. Environmental Protection Agency (EPA) has been charged with developing the necessary environmental standards that will be used to evaluate the safety of the geologic repository developed by DOE. NRC is the regulatory agency that will determine whether DOE's proposed repository system complies with EPA's standards and with NRC's implementing regulations.

Currently, EPA is developing environmental standards specific to the proposed site at Yucca Mountain, Nevada, in accordance with the provisions of the Comprehensive Energy Policy Act of 1992 (EnPA). EnPA directed the United States' National Academy of Sciences (NAS) to make findings and recommendations to EPA on issues related to the environmental standards that will apply specifically to the potential repository at Yucca Mountain. The NAS completed its deliberations and issued findings and recommendations, *Technical Bases for Yucca Mountain Standards,* in August of 1995 (National Research Council, 1995). EPA now must issue environmental standards for Yucca Mountain that reflect these findings and recommendations. After EPA issues its standards, NRC must revise Part 60 to be consistent with them.

NRC anticipates that the EPA standards under development for the Yucca Mountain site will require a quantitative performance assessment as the means to estimate post-closure performance of the repository system, as did the generic standards published by EPA in 1985 at 40 CFR Part 191.[1] However, because new

[1] Part 191 was vacated by the U.S. Court of Appeals for the First Circuit and remanded to EPA for further consideration. These standards were subsequently revised and reinstated for disposal of HLW and transuranic wastes at sites other than Yucca Mountain.

EPA standards developed pursuant to EnPA are not available at this time, in this paper the staff will continue to refer to the 1985 EPA standards, for illustrative purposes.

That being said, it is important to recognize that, in addition to the absence of currently applicable environmental standards, the entire regulatory framework for the management of HLW in the United States is in a state of flux because the U.S. Congress is considering providing additional direction and focus to the program. Any Congressional re-direction can be expected to profoundly affect both EPA's new environmental standards for Yucca Mountain ¾ tentatively designated 40 CFR Part 197 ¾ as well as NRC's implementing regulations in Part 60.

B NRC'S GEOLOGIC DISPOSAL REGULATIONS

B.1 The Basic Safety Goal

NRC's regulatory role causes it to have a strong interest in both the form and the content of EPA's applicable environmental standards. NRC's first interest is to protect public health and safety. It therefore looks to EPA's standards to define an adequate level of safety. A basic premise here is that the standards should ensure that future generations are afforded the same level of protection we are afforded today.

Any environmental standard should have as its underlying basis a safety goal for the allowable health risk to an individual or population. EPA's 1985 standards, however, are considered technology-based" in so far as they expressed in terms of release limits derived from EPA's analyses of the expected performance of hypothetical geologic repositories. Using a "world-average" biosphere, EPA estimated the health effects that might be caused by those repositories, compared that level of health effects with the estimated impacts of unmined uranium ore, natural background radiation, and similar reference points, and then required that any *real* repository perform as well as EPA's hypothetical repositories (see Federline, 1993).

In contrast to EPA's technology-based safety goal, the International Commission on Radiation Protection (ICRP) recommended a "health-based" safety goal (ICRP, 1985). The ICRP examined other risks accepted by society and, on that basis, developed recommended dose and risk limits for individuals who might be exposed to future repository releases. The ICRP's recommendations can be characterized as health-based because they represent the ICRP's judgment as to the highest *level* of health risk that any person or population should ever be subjected to, regardless of the costs
or technical difficulties of achieving compliance.

In its 1995 report, the NAS recommended that EPA adopt health-based standards for Yucca Mountain that limit individual *risk* to the average member of the exposed critical group, and that compliance should be evaluated at the time and place where greatest risk occurs, following repository closure. The NAS also recommended that suitable exposure scenarios and associated reference biosphere assumptions, appropriate for site-specific conditions at Yucca Mountain, should be defined by rule to preclude speculation on future human lifestyle and behavior.

B.2 Part 60

Part 60 currently requires that DOE demonstrate significant contributions from multiple barriers to overall system performance, that DOE consider alternatives to major design features of the geologic repository, and conduct long-term tests. All these measures, taken together, were intended to provide the Commission with sufficient confidence that the overall performance objective (i.e., compliance with EPA's 1985 standards) would be achieved.

Promulgated in the early 1980's, the existing Part 60 regulations comprise five subparts, with the principal technical criteria appearing in Subpart E. Other subparts address the contents of a potential license application, quality assurance (QA) requirements, and the respective consultation roles of States, Indian Tribes, and affected units of local government, in any potential geologic repository licensing proceeding.

To receive authorization to construct a geologic repository, DOE must demonstrate compliance with the performance objectives of Subpart E and NRC must find, with "reasonable assurance," that such demonstration has been made. Part 60 sets out a number of general siting and design criteria to facilitate the demonstration of compliance, but stops short of mandating specific site suitability ¾ or exclusionary ¾ criteria. If potentially adverse conditions are identified (i.e., evidence of Quaternary-age igneous or seismic activity, perched water bodies), they must be thoroughly analyzed and sufficient demonstration must be made of the existence of compensating favorable conditions (i.e., depth of water table, low vertical or horizontal permeability). Although the multiple barrier concept allows for the use of certain engineering measures to contain and isolate waste, the technical criteria in Subpart E are structured to favor the selection of a candidate site with certain favorable (natural) waste isolation capabilities. Thus, because of site- and design-specific considerations, the language in Part 60 is intentionally non-prescriptive; that is, it leaves to DOE the opportunity and responsibility to determine how to design a geologic repository for a particular geologic setting.

NRC's Part 60 regulations identify compliance with EPA's environmental standards as the overall performance requirement for a geologic repository. In their
1985 form, the EPA standards established containment requirements that limit cumulative releases of radioactive material to the accessible environment, weighted by a factor approximately proportional to radiotoxicity, and integrated over 10,000 years following permanent closure. The 1985 EPA standards also included limits on dose to individuals and ground-water protection requirements applicable for the first 1000 years.

Because the 1985 EPA standards were stated in probabilistic terms, demonstration of compliance must also be probability-based. Accordingly, the measure of total system performance for a geologic repository under the 1985 EPA standards would be expressed by the complementary cumulative distribution function (CCDF) for cumulative normalized radioactive releases to the accessible environment over 10,000 years. The representation of repository performance by a CCDF thus incorporates:

- Consideration of the various parameters affecting the performance of the geologic repository; and

- Consideration of a range of anticipated and unanticipated processes, conditions, and events that could affect future geologic repository performance.

In addition to incorporating EPA's standards as the overall system performance objective, Subpart E of NRC's implementing regulations also set forth in Section 60.113 quantitative limits for the performance of certain repository subsystems. These subsystem criteria were developed, consistent with the Commission's multiple-barrier, "defense-in-depth" regulatory philosophy, to enhance confidence that the overall system performance objective could be met. Regulations appearing at Section 60.113 establish specific performance objectives for the engineered barrier system (EBS) and the geologic setting. The Commission recognized the need for flexibility in implementing these performance objectives at specific sites and provided for

Commission approval of other subsystem performance objectives, as justified, on a case-by-case basis. The current subsystem performance objectives require the following:

- Substantially complete containment of waste in the waste packages for a minimum period of 300 to 1000 years after closure.
- Controlled rate of radionuclide release from the EBS (e.g., one part in 100,000 per year of the inventory of radioactive waste that remains in the repository 1000 years after closure).
- Pre-waste-emplacement ground-water travel time of at least 1000 years.

DOE must apply to NRC for authorization to construct a geologic repository and, in the application, must demonstrate that waste can be disposed of without unreasonable risk to the public, demonstration of which must include meeting the above performance objectives. After completing construction of the repository, DOE then may apply to NRC for a license to receive and possess SNF and HLW. Once waste emplacement has been completed, DOE must apply for a license amendment in order to permanently close the repository.

C UNCERTAINTIES

C.1 Background

In the preamble to Part 60 and in a subsequent effort to conform these regulations to the 1985 EPA standards (since withdrawn, as noted earlier in this paper, pending completion of new EPA standards), the Commission discussed what it believed DOE would have to do to demonstrate compliance with NRC's disposal regulations. In particular, the Commission discussed the reasonable assurance concept and related the concept generally to the performance objectives and supporting siting and design criteria. The reasonable assurance concept in Part 60 parallels language that has been commonly used and accepted in other NRC nuclear regulatory licensing practices. In the context of Part 60, the Commission has discussed how this concept may be applied to any potential HLW licensing proceeding.

In reaching a potential construction authorization decision, the Commission is concerned that "... its final judgments [regarding compliance with the performance objectives] be made with a high degree of confidence...." To reach a reasonable assurance finding, the Commission believes that it will need to do two things. First, it will need to confirm that its numerical performance standards have been met. This will be done independently, for example, using NRC's own performance assessment capability to corroborate DOE's conclusions and supporting calculations. Second, the Commission believes that it will need to satisfy itself that DOE's analyses of the site and design are sufficiently conservative, that the limitations of its analyses are well-understood, and that appropriate allowances have been made for the time period, hazards, and uncertainties involved. To do this, the staff will selectively probe DOE's assessment for potential weaknesses, based on a familiarity with the methods, site data, and prevailing assumptions used in Yucca Mountain performance assessments.

One of the greatest challenges to NRC's making these determinations will be to understand and evaluate DOE's treatment of uncertainties in its analyses. Various methods may be used (e.g., probability distributions and/or conservative "bounding" analyses). Previous licensing experience suggests that the Commission ultimately will have to seriously consider both quantitative and non-quantitative arguments, to ascertain whether DOE's handling of uncertainty is adequate.

C.2 Treatment of Uncertainties

The NRC staff has identified three types of uncertainties (see Fehringer, 1991). These uncertainties have been defined as "regulatory," "technical," and "residual"; each is discussed below.

C.2.1 Regulatory Uncertainties

"Regulatory uncertainties" involve questions about *what* must be proven to demonstrate compliance with a regulatory requirement, rather than *how* the demonstration of compliance will be made. Regulations may contain ambiguities or unclear language that may lead to more than one interpretation, or situations where what must be proven to demonstrate compliance with a requirement is not completely defined in the requirement, itself.

The two principal sources of potential regulatory uncertainty in the HLW program are, of course, the EPA standards themselves, and NRC's implementing regulations. A key part of the staff's strategy for implementing EPA's HLW standards is the identification of potential regulatory uncertainties in these standards, and the development of regulatory language to reduce or eliminate those uncertainties. As regulatory uncertainties are identified, the staff will work with EPA to clarify EPA's standards and guidance, and to amend NRC's implementing regulations, or to develop additional staff guidance.

As noted in the beginning of this paper, Congress mandated a new and different process for developing the HLW disposal regulations for the proposed repository at Yucca Mountain. In summary, EnPA directed the NAS to evaluate the scientific basis for Yucca Mountain-specific standards and directed EPA to promulgate new environmental standards based on and consistent with the findings and recommendations of the NAS.

Important differences exist between the NAS findings and recommendations (see National Research Council, 1995) and prior EPA standards for SNF and HLW, as well as between the existing geologic disposal regulations at Part 60. The staff is currently cooperating with the EPA staff to help ensure the development of implementable HLW standards that consider the NAS recommendations. Once EPA issues its final standards, NRC must conform its regulations within 1 year. NRC anticipates that EPA will propose new standards specific to Yucca Mountain sometime in 1997. The staff expects that demonstration of compliance with these new standards will still require some type of probabilistic analyses because of the uncertainties inherent in assessment of geologic repository performance over the large spacial scales and long time frames involved.

For its part, NRC is considering developing simplified implementing regulations specific to a Yucca Mountain repository. The staff has performed a preliminary review of Part 60 to identify areas where changes may be needed to be consistent with a new dose-based standard and to be sensitive to the NAS findings and recommendations. Moreover, the staff plans to recommend options to the Commission for implementing EPA's new 40 CFR Part 197 within NRC's regulations, soon. The staff expects that these efforts, once completed, will be the principal means through which regulatory uncertainties in the NRC-EPA regulatory framework will be addressed and resolved.

Finally, it should also be noted that in the late 1980s, the staff and its technical assistance contractor, the Center for Nuclear Waste Regulatory Analyses (CNWRA),[2] applied classic systems engineering techniques to Part 60, using a methodology called *Systematic Regulatory Analysis* (SRA ¾ see Holonich and Johnson,

[2] The CNWRA is a Federally Funded Research and Development Center located in San Antonio, Texas.

1994; and Mackin *et al.,* 1995). In this context, SRA consisted of first determining what the operational and post-closure functions of a repository were, then identifying the safety hazards associated with those functions, and then identifying the regulations that would most effectively and efficiently control those safety hazards. As a result, a number of perceived regulatory uncertainties were identified (CNWRA, 1990). As the staff considers possible revisions to Part 60 in the future, it will also take into consideration the recommendations resulting from the SRA.

C.2.2 Technical Uncertainties

Technical uncertainties concern how compliance with a requirement will be demonstrated. Technical uncertainties can be generally categorized as: (1) "data uncertainty," defined as uncertainty in our knowledge of the state of a system;
(2) "future states uncertainty," reflecting our imperfect ability to predict the future states of the environment in which the repository will exist; and (3) "model uncertainty," which concerns our inability to clearly forecast the performance of the repository in its environment. NRC may be able to address some technical uncertainties, before the receipt of a license application, through rulemakings or the development of additional regulatory guidance. However, the responsibility for dealing with technical uncertainties is primarily that of DOE. DOE can be expected to rely on site characterization as well as its own total-system performance assessment efforts, to identify, characterize, and reduce technical uncertainties. The NRC staff will rely on its independent technical capability to evaluate the significance of this type of uncertainty.

Early in 1995, the staff recognized the need to refocus its pre-licensing repository program on resolving issues most significant to repository performance. Since then, the scope of the NRC pre-licensing program has been adjusted to focus on only those topics most critical to repository performance (see Sagar, 1997). These *Key Technical Issues* or KTIs include: (1) igneous activity; (2) structural deformation and seismicity; (3) evolution of the near-field environment; (4) container life and source term; (5) thermal effects on flow; (6) repository design and thermal-mechanical effects; (7) total-system performance assessment and integration; (8) activities related to development of environmental standards and implementing regulations for Yucca Mountain; (9) unsaturated and saturated flow under isothermal conditions; and (10) radionuclide transport. These issues were identified from a review of DOE's site characterization program and the staff's independent work, and it is recognized that additional topics may emerge as important contributors to repository performance in the future. The staff is working with DOE to evaluate the significance of each of the KTIs and to develop paths to their resolution, at the staff level.

As it carries out its pre-licensing responsibilities, the staff will continue to engage in specific activities that will support progress toward resolution of these KTIs. These activities include: (1) evaluation of alternative conceptual models, including underlying data and assumptions; (2) independent modeling for use in sensitivity and importance analyses; (3) limited technical investigations, including laboratory tests, to enhance NRC's independent understanding of relevant processes; (4) review of DOE data and independent literature; and (5) establishment of acceptance criteria to guide reviews and issue resolution. While conducting these activities, the staff will periodically reevaluate the significance of the KTIs based on new information and experience. Throughout its pre-licensing interactions, the staff will continue to encourage DOE to develop the methods necessary to evaluate the significance of technical uncertainties and to reduce them, to the extent practicable, before it submits a license application to NRC.

C.2.3 Residual Uncertainties

Despite EPA, NRC, and DOE efforts to reduce regulatory and technical uncertainties, some sources of uncertainty are expected to persist in the HLW program. These so-called "residual uncertainties" can result from one or more of the following: inadequacy of field or experimental data; inappropriately-used or invalid conceptual models; and the possibility that important processes or future system states have not been identified. Both DOE and NRC need to consider the significance of residual uncertainty in deciding whether there is reasonable assurance that the regulatory requirements will be met.

In general, residual uncertainties will be addressed by using judgment. The staff distinguishes between two types of judgment: technical expert judgment, and decision-maker judgment. The first type of judgment ¾ "technical expert judgment" or simply "expert judgment" ¾ is used to identify residual uncertainties and quantify them to the extent practicable, and to estimate the effect of these uncertainties on repository performance. The second type of judgment ¾ "decision-maker judgment" ¾ addresses the regulatory significance of any latent uncertainty. The decision makers ¾ e.g., a Licensing Board or the Commission ¾ must evaluate and determine whether the residual uncertainties are sufficiently unimportant such that there is reasonable assurance that the requirements will be met, despite these uncertainties.

Nearly every aspect of site characterization and performance assessment will involve significant uncertainties. As noted above, the primary method to evaluate, and perhaps reduce, these uncertainties should be collection of sufficient data and information during site characterization. However, factors such as temporal and spatial variations in the data, the possibility for multiple interpretations of the same data, and the absence of validated theories for predicting the performance of a repository for thousands of years, will result in some residual uncertainty. Therefore, it will be necessary to complement and supplement the data obtained during site characterization with the interpretations and subjective judgments of technical experts (i.e., expert judgments) as well as to conduct confirmatory testing and analyses after construction is authorized.

NRC has traditionally accepted, for review, expert judgment, to evaluate and interpret the factual bases of license applications and thus is expected to appropriately consider the judgments of DOE's experts regarding the performance of the geologic repository. Such consideration, however, envisions DOE using expert judgments to complement and supplement other sources of scientific and technical information, such as data collection, analyses, and experimentation. The staff believes that formal elicitation procedures, used prudently and appropriately, can help ensure that expert judgments are well-documented and that the technical reasoning used to reach those judgments is openly displayed for review. If conducted optimally, formal elicitation can reveal a wide range of scientific and technical interpretations, thereby exposing (and possibly quantifying) the uncertainties in estimates concerning repository siting, design, and performance, attributable to limitations in the state of technical knowledge. Formal procedures may also help groups of experts resolve differences in their estimates by providing a common scale of measurement and a common vocabulary for expressing their judgments.

Recognizing that DOE will use expert judgment in its geologic repository program,
the staff has recently developed formal guidance that: (1) provides general guidelines on those circumstances that may warrant the use of a formal process for obtaining the judgments of more than one expert (i.e., expert elicitation); and
(2) describes acceptable procedures for conducting expert elicitation when formally elicited judgments are used to support a demonstration of compliance with NRC's geologic repository disposal regulation (see Kotra *et al.*, 1996).

After all reasonable efforts to reduce uncertainty have been made, some residual uncertainty will remain. This uncertainty may result from conflicting expert opinion or uncertainty about whether unidentified processes or future system states will have an effect on repository performance. Decision-maker judgment will need to address whether these residual uncertainties are sufficiently well-bounded to find, with reasonable assurance, that the regulations have been met. There are proven decision-science techniques that can be used to reconcile these differences for decision makers, such as weighted averaging. In the case of the consideration of unidentified processes or future system states, the demonstration of a model validation strategy may prove to be an acceptable way to demonstrate the adequacy of the modeling assumptions and performance predictions.

D INCREMENTAL DECISION PROCESS

Under DOE's current program approach, the development of the Yucca Mountain site involves several sequential activities. At present, DOE is investigating the site, with the intent of completing a "Viability Assessment" in 1998. This Viability Assessment will be the basis for DOE's management decision on whether to continue with the development of Yucca Mountain as a HLW repository. This decision, which entails the development of realistic cost estimates and schedules for licensing, will be made by DOE independently, although NRC plans to comment on it. Should DOE decide to proceed, the current schedule calls for a decision on site suitability in 1999 and a recommendation to the President of the United States in 2001. Next would come the development and submission of a license application, in 2002, to NRC, for authorization to construct the repository. If NRC authorizes construction, DOE would apply to NRC for a license to receive and possess SNF and HLW subsequent to completion of repository construction. The conditions under which the Commission would grant such licenses are currently specified in Part 60.

At this time, and until it submits a license application, DOE is not an NRC licensee, and there is no formal burden of proof on DOE. For example, in the context of its Viability Assessment, which is entirely a DOE decision, DOE can be expected to address uncertainties only to the extent necessary to support its management decision, and subject to whatever level of proof it deems appropriate. The staff expects, but of course cannot require, that the technical bases for this, and other DOE decisions concerning the repository, will be robust and accompanied by sufficient information such that a technically competent independent reviewer could repeat DOE's analyses and arrive at the same technical conclusions.

The technical bases supporting the safety case advanced to NRC in a formal license application, on the other hand, will be subject to a more exacting standard. DOE officials submitting an application must affirm that the information supporting it is accurate. The staff will review DOE's license application and prepare a *Safety Evaluation Report* documenting its findings with regard to DOE's compliance demonstrations. After the staff's review, affected parties will have an opportunity for a hearing before an independent Licensing Board; the staff considers such a hearing extremely likely. A hearing is very much like a civil trial in the United States, with similar rules of evidence, expert witnesses who are sworn, and opportunity for cross-examination. It is likely that skeptical experts will examine DOE's (and the NRC staff's) conclusions with great care and challenge the quality of DOE's data, technical analyses, and conclusions based on expert judgment. Thus, not only must there be sufficient information so that an independent reviewer can repeat DOE's analyses, but the information must be developed using a rigorous QA process. For example, DOE must be able to demonstrate that its computer codes do perform as it says they perform, and that it used those exact codes and not similar versions, which might have performed differently.

As discussed above, since DOE is not now a formal applicant, it may address uncertainties and develop a level of proof as it wishes. However, once a license application is submitted, by law, NRC will have only 3 years to perform its review and conduct a hearing to reach a licensing decision. Therefore, to comply with the mandated timeframe, NRC is now reviewing DOE's site characterization activities and investigations to enable early identification and resolution of potential licensing issues. NRC's current comments address both the technical merit of DOE's activities and the sufficiency of DOE's QA program to provide information whose rigor will withstand the licensing process. In its comments on DOE's Viability Assessment, NRC expects to address the technical quality of DOE's work, the extent to which issues, particularly the KTIs appear to have been resolved, and what the staff thinks remains to be done for DOE to submit a successful application for construction authorization. The staff also intends to comment on the reasonableness of DOE's projected costs and schedules for licensing.

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The UK System for Regulating the Long-Term Safety of Radioactive Waste Disposal

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Abstract

This paper describes the general system for regulation of disposal of solid, long-lived radioactive wastes. It outlines the relevant Government policy, the framework of legislation and arrangements for implementation, the associated guidance produced by regulatory bodies and the approach to assessment by regulators of a safety case for radioactive waste disposal. Also, for the purposes of discussion in the Workshop, it describes some of the practical issues which are still in development in the UK in regard to regulatory methodology.

RADIOACTIVE WASTE MANAGEMENT POLICY

Government policy on radioactive waste management is set out in a White Paper of July 1995 "Review of radioactive waste management policy - final conclusions" [1]. The policy is based on the same basic principles as apply more generally to environment policy, and in particular on that of sustainable development. The White Paper gives a widely quoted definition of this concept as "development that meets the needs of the present without compromising the ability of future generations to meet their own needs".

A 1994 White Paper [2] on sustainable development sets out the following supporting principles:

- decisions should be based on the best possible scientific information and analysis of risks;
- where there is uncertainty and potentially serious risks exist, precautionary action may be necessary;
- ecological impacts must be considered, particularly where resources are non-renewable or effects may be irreversible; and
- cost implications should be brought home directly to the people responsible - the polluter pays principle.

More specifically, and consistent with the above, Government policy is that radioactive wastes should be managed and disposed of in ways which protect the public, workforce and the environment. The radiation protection principles and criteria adopted in the UK and applied by the regulatory bodies are designed to ensure that there is no unacceptable risk associated with radioactive waste management. In defining these principles and criteria and in their application by the regulators, it is recognised that a point is reached where additional costs of further reductions in risk exceed the benefits arising from the improvements in safety achieved, and that the level of safety and the resources required to achieve it should not be inconsistent with those accepted in other spheres of human activity.

THE REGULATORY FRAMEWORK

Radioactive Substances Act 1993 (RSA 93)

Under RSA 93, no person may dispose of radioactive waste except in accordance with an authorisation under the Act, or except where the waste is excluded by the Act or by an Exemption Order. The developer of a disposal facility for radioactive wastes will be required to apply to the relevant Agency for authorisation of disposals on or from the site of the facility.

Control under the Act is exercised in England and Wales by the Environment Agency and in Scotland by the Scottish Environmental Protection Agency. Where an application is made for disposal of radioactive waste on or from a site licensed under the Nuclear Installations Act 1965, the Agency is required to consult the "relevant Minister" and the Health and Safety Executive before deciding whether to grant an authorisation and, if so, subject to what terms and conditions. In this context, the "relevant Minister" is in England the Minister of Agriculture, Fisheries and Food and in Scotland and Wales, the Secretary of State. A Memorandum of Understanding between the Environment Agency, MAFF and the Welsh Office sets out working arrangements so that each can discharge their responsibilities and exercise their functions under or in consequence of the Act. This Memorandum sets out arrangements for consultation and exchange of information in respect of applications for authorisations, environmental monitoring and radiological assessments.

Health and Safety at Work etc Act 1974 and Nuclear Installations Act 1965

The safety of operational nuclear facilities in the UK is regulated by the Health and Safety Executive (HSE) using the 1965 Nuclear Installations Act - as amended (NI Act) under the general requirements of the Health and Safety at Work, etc Act. The NI Act requires organisations to obtain a nuclear site licence from the HSE before using a site for licensable activities. It also enables HSE to attach conditions to any licence granted. Such conditions include the requirement for licensees to justify the safety of operations, i.e. provide a safety case.

It is intended that the safety of long lived waste repositories during their operational phase will be regulated under the NI Act. The licensee(s) of such facilities would thus need to provide a safety case for the operational phase. HSE's Nuclear Installations Inspectorate would independently assess such cases and regulate the associated operations.

Radiological protection standards

The National Radiological Protection Board, (NRPB), has a statutory responsibility to advise government departments and statutory bodies on the acceptability and applicability for the UK of the recommendations of ICRP. In 1993, NRPB issued a statement on the 1990 recommendations of ICRP [3]. A statement on radiological protection objectives for the land-based disposal of solid radioactive wastes [4] was issued in 1992. The advice contained in the NRPB statements has been taken into account by the environment agencies in preparation of Guidance on Requirements for Authorisation of Disposal Facilities on Land for Low and Intermediate level Radioactive Wastes [5].

Euratom requirements

A Directive issued under the Euratom Treaty lays down basic safety standards for the health protection of the general public and workers against the dangers of ionising radiation [6].

Article 37 of the Euratom Treaty of the European Community requires that "each Member State shall provide the Commission with such general data relating to any plan for the disposal of radioactive waste in whatever form as will make it possible to determine whether the implementation of such a plan is liable to result in the radioactive contamination of the water, soil or airspace of another Member State". Not more than six months after receiving the data, the Commission will publish its Opinion in the Official Journal after consulting a Group of Experts. The relevant consents to bring the facility into operation cannot be issued until the Opinion of the Commission has been published.

Town and Country Planning Act, 1990

Any proposed specialised land disposal facility is likely to be a development under the Town and Country Planning Act 1990 and as such to require planning permission in addition to being subject to other regulatory requirements. Planning applications are made to the local planning authority, but the relevant Secretary of State may call in planning applications which he considers might raise issues of national or regional importance. Before determining any called-in planning application, the Secretary of State will normally hold a public inquiry.

Any such disposal facility will also be subject to EC Directive No 85/337, on the assessment of the effects of certain public and private projects on the environment. This was implemented for projects that require planning permission in England and Wales by the Town and Country Planning (Assessment of Environmental Effects) Regulations 1988 and, in Scotland, by the Environmental Assessment (Scotland) Regulations 1988. "Installations designed solely for the permanent storage or final disposal of radioactive waste" require environmental assessment in every case. Where environmental assessment is required, the developer must prepare an environmental statement that includes a description of the likely significant effects on the environment and the measures envisaged to avoid, reduce or remedy any significant adverse effects.

Involvement of environment agencies under Town and County Planning Act

In determining a planning application, the planning authority or the inspector at any planning inquiry may consult the relevant Agency on possible environmental impacts of the development. Where requested to do so, the Agency will also comment, in the light of the information available at the time, on whether or not there appears to be any impediment to issue of an authorisation for disposal of waste of the categories and quantities intended. Similarly, HSE/NII would be consulted on whether there appears to be any impediment to granting a site licence.

Not withstanding any provisional views given by the Agency at the planning stage, the authorisations under RSA 93 and licensing by HSE/NII under the NI Act 1965 will remain legally separate from decisions under the town and country planning legislation.

In commenting on the development proposal to the planning authority or the inspector at any planning inquiry, the Agency will consider whether:

- the proposal is consistent with government policy for radioactive waste management as set out in the 1995 White Paper [1]

- the disposal system chosen is appropriate for the relevant wastes;

- the site, including the geological and hydrogeological environment, is suitable for the purpose;

- the facility design, proposals for development and the engineered structure appear suitable for the categories and quantities of waste proposed; and

- the proposals appear likely to secure protection of human beings and the environment on a continuing basis both in relation to the normal evolution of the system and to disruptive events.

PRINCIPLES AND REQUIREMENTS FOR DISPOSAL:

For the purpose of implementing Government policy on radioactive waste management, and after extensive consultation, the environment agencies have prepared Guidance on Requirements for Authorisation of Disposal Facilities on Land for Low and Intermediate level Radioactive Wastes [5]. Amongst other things this Guidance sets out principles and requirements for disposal of low and intermediate level wastes in the first instance but it has regard to the presence of long-lived radionuclides in the wastes and so, in due course, will be broadly applicable also to the disposal of high level wastes.

The essential principles are as follows:-

Principle No. 1 - Independence of safety from controls

Following the disposal of radioactive waste, the closure of the disposal facility and the withdrawal of controls, the continued isolation of the waste from the accessible environment shall not depend on actions by future generations to maintain the integrity of the disposal system.

Principle No. 2 - Effects in the future

Radioactive wastes 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.

Principle No. 3 - Optimisation (as low as reasonably achievable)

The radiological detriment to members of the public that may result from the disposal of radioactive waste shall be as low as reasonably achievable, economic and social factors being taken into account.

Principle No. 4 - Radiological protection standards

The assessed radiological impact of the disposal facility before withdrawal of control over the facility shall be consistent with the source-related and site-related dose constraints and, after withdrawal of control, with the risk target.

The associated radiological requirements are,

Requirement R1 - Period before control is withdrawn (dose constraint)

In the period before control is withdrawn, the effective dose to a representative member of the critical group from a facility shall not exceed a source-related dose constraint. Also during this period, the effective dose to a representative member of the critical group resulting from current discharges from the facility aggregated with the effective dose resulting from current discharges from any other sources at the same location with contiguous boundaries shall not exceed an overall site-related dose constraint of 0.5 mSv/y.

Requirement R2 - Period after control is withdrawn (risk target)

After control is withdrawn, the assessed radiological risk from the facility to a representative member of the potentially exposed group at greatest risk should be consistent with a risk target of 10^{-6} per year (i.e. 1 in a million per year).

Requirement R3 - Use of best practicable means

The best practicable means shall be employed to ensure that any radioactivity coming from a facility will be such that doses to members of the public and risks to future populations are as low as reasonably achievable.

Requirement R4 - Environmental radioactivity

It shall be shown to be unlikely that radionuclides released from the disposal facility would lead at any time to significant increases in the levels of radioactivity in the accessible environment.

And the related technical requirements are:

Requirement R5 - Multiple-factor safety case

The overall safety case for a specialised land disposal facility shall not depend unduly on any single component of the case.

Requirement R6 - Site investigations

The developer shall carry out a programme of investigations to provide information necessary for the safety case and to demonstrate the suitability of the site.

Requirement R7 - Facility design and construction

The facility shall be designed, constructed, operated and be capable of closure so as to avoid adverse effects on the performance of the containment system.

Requirement R8 - Waste form and characterisation

The developer shall derive waste acceptance criteria consistent with assumptions made in assessments of the performance of the system and with the requirements for handling and transport.

Requirement R9 - Monitoring

In support of the safety case, the developer shall carry out a programme to monitor for changes caused by construction of the facility and emplacement of the waste.

Requirement R10 - System of records

The developer shall set up and maintain a comprehensive system of records for the recording of detailed information on all aspects of the project affecting the safety case.

Requirement R11 - Quality Assurance

The developer shall establish a comprehensive quality assurance programme for all activities affecting the safety case. This shall include supporting activities such as research and assessment.

In addition to these principles and requirements, of course, due consideration will be given to the basic principles for radioactive waste management set out in the IAEA Safety Fundamentals [7], published under the RADWASS programme, and to the Standards and Guides which flow from them.

REGULATORY ASSESSMENT

Background:

In the UK, the applicant for an authorisation to dispose of radioactive waste is solely responsible for preparing and presenting the regulator with a satisfactory safety case. The regulator is responsible for examining the quality of the scientific basis of this case, the way in which it has been applied, the quality and traceability of data used, the way in which uncertainties have been treated, and, eventually, the conclusions offered by the applicant in regard to the safety of the proposed disposal arrangements. There is no intention for the regulator to conduct a full, separate safety analysis but it is necessary for the regulator to have the capability , or access to the capability, for independent analysis of key elements of the applicant's case. In the UK, the antecedents of the Environment Agency have played a full part, internationally and domestically, both in the scientific development of this capability and in the creation of a substantial base for such work in the private sector independent of the nuclear industry. It is expected that this will avoid the practical and presentational difficulties associated with having the analytical capability concentrated only in bodies which have a business interest in the disposal proposal and will help to build public confidence in the regulatory decision-making process.

Post-closure safety assessment

For assessments covering the period after withdrawal of control over the disposal facility, the primary safety target is expressed in terms of annual radiological risk. Risk in the quantitative sense corresponds to a mathematical representation of the probability of a serious health effect in an individual over a specified period. However, the environment agencies take the view that sufficient assurance of safety is likely to be achieved only through considerations rather broader than evaluation of numerical values of risk, although this remains an important component of achieving such assurance. Examples of other safety indicators are given in the report of an IAEA working group [8] and include radiation dose, radionuclide flux, migration time, environmental concentration and radiotoxicity.

Therefore, in presenting a safety case for the period after withdrawal of control, the applicant should provide a wide range of information including, for example:

- assessments of radionuclide release from the waste and from the various barriers constituting the disposal system;

- overall results from probabilistic risk assessments of the disposal system which explore the relevant uncertainties;

- suitable breakdowns of such risk assessments to show, for example, the probability distribution of doses and the contribution of important radionuclides;

- results of dose and risk assessments for cases or situations of particular interest, including high consequence cases (e.g. human intrusion);

- a comprehensive record of the judgements and assumptions on which the risk assessments are based;

- indicators of collective radiological impact (to answer the question as to how widespread any significant elevation of risk may be as a result of radioactivity from the disposal facility);

- results from scoping calculations for extreme events and for processes not otherwise considered;

- a demonstration that the possibility of a local accumulation of fissile material such as to produce a neutron chain reaction is not a significant concern; and

- overview statements which seek to place the different items of information contributing to overall assurance of safety into a total context.

The above information will be necessary for understanding the performance characteristics of a disposal facility and the robustness of the safety case. In particular, the applicant will be expected to demonstrate that all reasonable steps have been taken to reduce uncertainties and to clarify the nature of the uncertainties remaining.

Assessment timescales

In general, assessments of the radiological impact of a facility should cover the timescale over which the models and data by which they are generated are valid. In the very long term, irreducible uncertainties about the geological, climatic and resulting geomorphological changes that may occur at a site provide a natural limit to the timescale over which it is sensible to attempt to make detailed calculations of disposal system performance. The timescale over which the environment agencies will expect to see detailed calculations of risk will therefore depend on the site and the facility and is a matter for the applicant to justify. Simpler calculations and qualitative information may be required to indicate the continuing safety of the facility at longer times.

Future human actions

A range of future human actions having the potential to breach the natural or engineered barriers or significantly impair the performance of the system can be envisaged. These may be deliberate, i.e. taken with knowledge of the location and hazardous nature of the facility , or inadvertent because the location or purpose is unknown. The environment agencies consider that it is not necessary to undertake quantitative risk assessments of deliberate human actions, since it is assumed that no such action would be taken without due regard to the safety implications and the economic and environmental values of the time.

The applicant may advance arguments to justify a very low probability of inadvertent actions affecting the disposal system for a period following closure by reference to the proposed post-closure management plans. However, in the longer term, institutional controls cannot be relied upon and the applicant will be expected to assess the likelihood and consequences of possible future human actions. Useful guidance and a general framework for consideration of the effects of future human actions on deep disposal facilities is contained in a report of a Nuclear Energy Agency Working Group on the assessment of future human actions at radioactive waste disposal sites [9].

Treatment of uncertainty

The treatment of uncertainty is central to the establishment of the post-closure safety case for a radioactive waste disposal system. Uncertainties are not of themselves obstacles to establishing the safety case, but rather matters requiring consideration in a variety of ways and assimilation into the structure of the case as appropriate. They arise *inter alia* from natural variability, the practical limitations on sampling relevant processes and data, alternative interpretations of data, and natural events and human activities that may affect radionuclide release, transport and exposure pathways.

Some uncertainties, for example those associated with dosimetric data and the dose-risk factor, are common to all radiological assessments and are normally left implicit in the setting of standards for protection; there is no special reason to include them explicitly in assessments supporting the safety case for a disposal system. Other uncertainties may be eliminated from further consideration by making simple deterministic assumptions based on reasoned arguments. For example, to deal with future human behaviour the developer should present assessments in terms of the impact on potentially exposed groups based on observed past and present human behaviour, justifying the particular groups chosen. Some uncertainties may be quantified and incorporated into numerical assessments of probability or risk. Quantification of other uncertainties may be inappropriate. Where such uncertainties are important to the case, they may be treated by making deterministic assumptions and exploring the effects of varying these.

The applicant will need to demonstrate that the safety case takes adequate account of all relevant uncertainties. This will entail:

- definition of the scope of the assessment;
- systematic identification of all relevant sources of uncertainty;
- quantification of significant uncertainties, where practicable;
- implementation of measures to reduce overall uncertainty; and
- maintenance of a detailed audit trail.

Role of risk assessment

In its review of radioactive waste management policy [1] the Government concluded that it is inappropriate to rely on a specified risk limit or risk constraint as the criterion for determining the acceptability of a disposal facility. A risk target, however, should be used as an objective in the design process (see Requirement R2). The Government also took the view that reliance cannot be placed exclusively on estimates of risk to determine whether a disposal facility is safe. While such calculations can *inform* a judgement about the safety of a facility, other technical factors, including ones of a more qualitative nature, will also need to be considered in arriving at the decision.

Notwithstanding this, a risk assessment provided by the applicant is likely to be an important part of the post-closure safety case, although the relative importance of quantitative and qualitative arguments will change as uncertainties increase with the evolution of the disposal system over time. One particular value of a risk assessment conducted in a thorough manner lies in the disciplined and systematic approach it imposes. But the totality of an assessment will be complex; the expression of the outcome as a single value of risk does not convey the implications of the assumptions and logic which underpin it. The contribution which a risk assessment makes to the safety case for a disposal facility needs to be judged at least as much by its assumptions and logical structure as by the results it delivers.

In a risk assessment, all the features of the disposal system which can be shown to contribute significantly to post-closure safety, or which may be adverse to safety, will need to be disaggregated, analysed in depth and mathematically modelled in a manner which achieves overall consistency of approach. In this process many assumptions will be made, each of which needs to be recorded. Only if each assumption is separately identified can it be adequately tested and the effect of making a different assumption explored.

PRACTICAL REGULATORY ISSUES FOR DISCUSSION

So far as the regulatory methodology is concerned some practical issues remain to be resolved. In the UK there is already a substantial body of experience in dealing with disposal of low level waste by shallow burial but, as in most other countries, little direct experience in dealing with geological disposal of long-lived intermediate and high level wastes. The issues fall into two categories; those of a technical nature and associated with the long timescales involved and those of an administrative or legal nature.

Technical Issues

Most of these issues are well recognised and have been the subject of discussion for some time. The difference now is that decisions are imminent and will have to be made on a basis that is transparent, capable of clear explanation to all interested parties and that secures the confidence of society at large.

They include,

Model Validation

Do we understand the relevant physical and chemical processes well enough? Are our models good enough representations of the natural processes? Will they be good enough for the relevant timescales? What is enough? What to do if regulators or, more importantly, society at large cannot be convinced on these points?

Handling of Uncertainties

How to identify and handle those uncertainties in elements which may have an important and perhaps irreversible influence on long-term outcomes?

Critical Groups or Potentially Exposed Groups

How to define for the purpose of assessing consequences against a target for risk or potential exposure given the two-dimensional nature of this parameter (i.e. probability and consequence)?

Spatial Equity

How to ensure that legitimate interests of those who have derived no benefit from the source of waste are adequately protected? The history of sea-dumping may be informative here. (This is distinct from temporal equity which is fully recognised by reference to protection of future generations)

Protection of the environment, as such

How to identify those sectors of the environment (flora and fauna) which may be affected? How to measure the effects? What standards of protection to apply? How to enforce?

Decision logic

To what extent should decisions be based on pass/fail by reference to some fixed standard or upon a multi-attribute analysis which allows, in some transparent fashion, for discretion and qualitative judgement? If the latter, how is transparency and public confidence achieved.

Administrative/legal issues

Geological disposal of long-lived radioactive waste is a relatively novel and emotionally charged subject in most societies. There seems to be a general appreciation of the need for operators, regulators and the public to be in close communication in step-wise progress through the actual process of investigating, designing, constructing and operating a new, deep disposal facility. In the UK at least, and in regard to specific proposals under development, the formal regulatory process starts only when an application is made to the relevant Agency under the Radioactive Substances Act. Also, it is only at this point that associated arrangements for making information available to the public and for recovering regulatory costs from the operator come into force.

Thus, the formal administrative or legal position is not wholly conducive to close communications in the very early stages when an operator is unable to submit a full application. In order to overcome this difficulty in the UK, provision is made for staged or step-wise application and, for the situation where an operator is not even at this point in development of a disposal proposal, consideration is being given to having an agreement by which the operator may submit information to the regulator for views as to its value in support of any eventual application for waste disposal authorisation and by which information may be made available to the public.

Potential advantages of such an agreement may be:

- for the operator, confirmation that he is pursuing a path which ought ultimately to lead to regulatory acceptance, even though the regulatory body would not be committing itself in any formal regulatory sense under the agreement;

- for the regulatory body, to maintain and develop its assessment expertise, and to keep abreast of work being undertaken by the operator so as to prepare itself for receipt of a formal application and for providing evidence to the planning inquiry for the repository:

- for Government, in that such an agreement would help to ensure that its policy was being implemented smoothly: and

- for members of the public and interest groups in that, if information provided under the agreement were made open and transparent, they would have an early opportunity to comment on the operators' proposals:

Potential disadvantages may be:

- prejudice to the subsequent regulatory process:

- prejudice to a future planning inquiry into a repository:

- lack of provision for public consultation on important decisions until after irreversible steps had been taken:

- allowing the operator to keep documents private by making claims of commercial confidentiality which the regulator might judge to be inappropriate in the proper regulatory context.

  Because of the importance attached to transparency and maintenance of public confidence in the regulatory system this proposal will be subject to a consultation process.

In order to be able to comment, effectively, on any proposal for deep disposal of long-lived waste consideration is also being given to the terms and conditions of an authorisation and to what would be required to satisfy them. This raises issues which may merit discussion. They include the following,

Definition of "Disposal": When is waste emplaced in a repository actually disposed of, for legal purposes?

Boundaries of Applicability: Should the same authorisation apply to the operational phase and to the closure and post-closure requirements?

Types of Radioactivity limit: Should activity limits relate to volume, mass, emplacement rate, total for repository (or structural element of it) or to a combination of these.

Discharges during operational phase: Is there likely to be any unusual requirement in respect of any liquid and gaseous discharges during this phase.

Restrictions: How best to express limits for heat generation, for criticality or for incompatible materials. (e.g. cellulosics in the presence of actinides).

Non-Standard Waste forms: How to deal with out-of-specification waste or waste not covered by safety case.

Waste Retrieval: How to address provision for this if necessary?

Quality Assurance/Checking: How, and when, best to address the need for checking of packaged waste before emplacement?

Records: What provision needs to be made for marking of packages and for keeping of records, and for how long?

Closure and Post-Closure Requirements: What needs to be included in the authorisation, as such? (As opposed to being defined in the safety case)

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Long-term Performance Assessment

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Abstract

Many countries have adopted quantitative criteria for the performance of a high level radioactive waste repository. These criteria require the estimation of the risk or dose to organisms on the surface over many thousands of years or longer. The models are constructed taking account of competing requirements for simplicity, realism, and conservatism. Exposure scenarios are developed and analyzed that encompass the features, events, and processes that could lead to exposure. The validity of the models employed cannot be demonstrated directly through comparison of model results with observed system behaviour. Instead, indirect methods are used to establish model reliability. In some cases, some of the uncertainty in the results is quantified through the use of probabilistic methods. However, the uncertainty cannot be completely quantified, and judgment is an important element in developing the models and in determining their reliability. There is a broad international consensus among practitioners of long-term performance assessment that performance assessment models can provide sufficiently reliable information regarding long-term repository performance for use in licensing.

INTRODUCTION

Many countries have adopted quantitative criteria for the performance of a high level waste repository. The time over which repository performance must meet the criteria is many thousands of years at least. To provide evidence that a given repository system will perform satisfactorily over such a long time, proponents use mathematical models to estimate effects that can be compared with the applicable criteria. It is the use of such models to assess the future performance of a repository in terms of established criteria that we refer to here as "long-term performance assessment." The following is a discussion of some important aspects of long-term performance assessment as it is practiced internationally.

Although the individual components of the repository systems being considered differ, the systems are similar in concept. The waste, in the form of spent fuel or a solidified high level waste from reprocessing, is placed in a container made of metal, such as copper, steel, or titanium alloy. The containers are designed to last at least many hundreds of years in the underground environment, and in some cases are designed to last millions of years. The waste containers are placed in excavated openings a few hundred meters to perhaps a thousand meters below the earth's surface. In most repository concepts, each container is surrounded by a "buffer," based, for example, on bentonite clay. The underground excavations are eventually sealed in a manner that depends on the properties of the rock in which the repository is constructed. In most cases, the sealing involves the filling of the excavations with mixtures of clay, crushed rock, and sand. The host rocks under consideration include crystalline rock, salt, clay, or tuff. The repository may be located well below the water table in water-saturated rock, or may be above the water table.

The criteria for performance of the repository system take various forms, but all have as a basis a limitation on the rate at which contaminants from the underground waste are expected to reach living organisms on the surface. Typically this is expressed as a limit on either estimated radiological risk or estimated radiological dose to humans. Risk criteria specified fall in the range of 10^{-6} to 10^{-5} serious health effects per year. Dose criteria generally fall in the range of 0.01 to 0.1 millisieverts per year. To produce results for comparison with the criteria, the models estimate releases and transport of radionuclides from the underground waste to persons on the surface. The most common approach is to estimate the exposure of an individual on the surface belonging to a relatively homogeneous, hypothetical group of persons that is expected to receive the greatest exposure because of its location, lifestyle, and diet (the critical group).

Models that play a role in the long-term performance assessment include models of particular components of the repository system or a subset of important processes, and integrated models of the entire repository system, intended to include the effects of all significant features, events, and processes. Examples of the first type of model include detailed electrochemical models of corrosion and three dimensional models of groundwater flow through fractured rock. The second type of model, the system model, although generally employing simplified treatments of some of the individual components and processes, is more comprehensive, because it treats the integrated system, including waste form, container, repository seals, geosphere, and biosphere. It is the second type of model that we refer to here as a "performance assessment model."

It is not possible within the scope of this paper to discuss all of the various criteria and modeling approaches employed by different countries and organizations. Instead, general trends and specific examples will be discussed. For more detailed discussions of assessment methods employed in some countries, the reader is referred to recent reports on the subject [1] [2].

CHARACTERISTICS OF PERFORMANCE ASSESSMENT MODELS

Long-term performance assessment may be used to contribute information for

- a safety case in support of licensing,
- a comparison of alternative repository sites and designs,
- optimization of repository designs, and
- the setting of action levels for comparison with monitoring results.

What is required of the models in terms of processes modeled, accuracy, precision, and results produced varies greatly with the application. In general, emphasis has been placed on the development and application of system performance assessment models for use in safety cases, and it is this application that will be discussed here. Their use for the other applications has not been given great attention as yet. It is important to note, however, that models developed for a safety case may not be sufficiently realistic or accurate for the other applications.

The use of simplifying assumptions has been found to be necessary in developing models of the entire repository system. The need for simplifying assumptions when carrying out an assessment of the entire system arises for several reasons:

- processes are modeled on vastly different spatial scales, from a few millimeters near the waste and the containers to many kilometers in the geosphere;
- the effects of all the significant processes, such as the various chemical and physical processes affecting the release of contaminants and their transport through sealing materials, the rock, and the biosphere, must be treated in the system model; and
- the data needed for more detailed modeling of the entire system may not be available.

There is a further reason to accept simplicity in the models. It is generally acknowledged that the application of the models to support a safety case must be an iterative process, with a loop that incorporates input from regulatory staff and other reviewers in order that the modeling provide the information necessary for the decision-makers. This places a great deal of importance on transparency of the models, as they must be followed and accepted by the reviewers. This transparency is more readily achieved if the models employ simple rather than complex concepts, small amounts of data with clearly documented origins, and simple, well-documented mathematics [3].

In any case, simplifications (relative to the more thorough treatments of the individual processes in detailed models) are always made in creating the system model. For example, although it is well within current technology to model groundwater flow through the subsurface in three dimensions, and even to model flow through individual fractures, total systems assessments typically employ one-dimensional stream tubes, with constant properties over the tube length, when analyzing contaminant transport through the geosphere within the system model [1].

The safety case typically includes evidence that a realistic estimate of risk or dose would fall below the criterion. This evidence can be provided by models that incorporate very conservative assumptions, i.e., assumptions that would cause the models to over-predict the risk or dose. The logic is that if an obviously high estimate is below the criterion, a realistic estimate would be even farther below. In fact, it should be satisfactory for a safety case to use only very conservative models, even if they are completely unrealistic, provided that the estimates from these models fall below the criteria. For example, one could assume that the critical group uses water from waste containers, with no hold-up or dilution. If that resulted in the estimated dose to an individual of the critical group falling below the criterion, it would represent strong support for the safety case. However, if, as is more likely, the result of such an assumption were to greatly exceed the criterion, it would provide little useful information; calculations founded on more realistic, less conservative assumptions would be needed. All assessments need to strike a balance between realism and conservatism in the models. It can generally be expected that the more realistic the models become, the more detailed and precise they become. However, more detailed and precise modeling is not necessarily more accurate.

Scientific review and criticism can lead to increased complexity in the models as scientists strive for more comprehensive treatment of known processes, even if those processes are not expected to greatly influence the end result.

In view of the foregoing considerations, some characteristics of an ideal model for total system performance assessment can be identified. An ideal model would be

- sufficiently simple to allow reviewers to understand and judge its reliability,
- sufficiently realistic to convince scientific reviewers of its validity, and to show compliance with regulatory criteria if the system is indeed safe, and
- sufficiently conservative to provide unequivocal support for the safety case.

These characteristics are not entirely compatible and the models employed will be characterized by a balance of simplicity, realism, and conservatism.

SCENARIOS

A scenario, as the term is used here, is a cause-effect chain that could lead to exposure of an individual of the critical group (or, more generally, any target organism). To be complete, a performance assessment must account for all significant scenarios. Scenario analysis typically involves a procedure to identify the set of features, events, and processes that could affect the estimated risk or dose, and a scenario can be viewed as a subset of this set. It cannot be certain that all significant scenarios have been included; however, a large amount of cooperative international work has been done on scenario analysis, which justifies some confidence that major features, events, or processes are not being overlooked [4].

A risk-based criterion requires that the probability of occurrence of each scenario be estimated as well as the probability that a health effect would be incurred by the individual of concern if the scenario occurs. However, there is often a large uncertainty in the estimated dose for a given scenario, much of it associated with uncertainty in the values to be assigned to the model parameters. A probabilistic analysis is often employed to determine a distribution of doses associated with the scenario, the expected dose, and ultimately the probability that the individual will incur a health effect.

There is some disagreement among practitioners internationally regarding whether the probabilities of occurrence of the scenarios should be quantified and whether probability distributions of dose for each scenario should be calculated. The debate will not be elaborated on here. However, it should be noted that there are scenarios that have some possibility of occurring and for which the estimated doses would greatly exceed criteria. Thus it would seem that a safety case can only be made by taking probability into account, either quantitatively or qualitatively.

Some scenarios involve major disruptions to the vault caused by natural events, such as earthquakes, volcanoes, or meteorites. These could lead to large exposures due to the repository, but it is expected that proper siting and design would reduce the probability of repository disruption sufficiently to satisfy the risk criteria.

More troublesome are scenarios involving disruption by humans. There seems to be general agreement among practitioners that intentional intrusion by a future society, i.e., intrusion explicitly for the purpose of gaining access to the waste, should be disregarded on the basis that the society entering the vault has taken responsibility for the future safe handling and disposition of the materials. However, there is significant disagreement as to the treatment of scenarios in which humans accidentally intrude upon the vault and receive exposures. One method treats these scenarios in the same way as the others, by means of an analysis that estimates risk on the basis of probability and consequence of the scenarios [5]. At least one school of thought rejects such an approach on the grounds that human activities are fundamentally unpredictable [6].

RELIABILITY

In 1991, the OECD/NEA, IAEA, and CEC published an international collective opinion, developed by radioactive waste management committees of those organizations, stating that, “safety assessment methods are available today to evaluate adequately the potential long-term radiological impacts of a carefully designed radioactive waste repository system on humans and the environment” [7].

The OECD/NEA Working Group on Integrated Performance Assessments of Deep Repositories has reviewed the progress in the development and application of performance assessment methods since the collective opinion and have concluded that no new insurmountable problems have been encountered and that the collective opinion remains valid. They also note areas in which significant improvements have been made in the methods and their application [1].

Nevertheless, the reliability of individual assessments will continue to be questioned by reviewers. They cannot be convinced of the reliability of the models through a direct comparison of model results with system performance, because of the long time scales involved. Instead, the reliability of the models must be established indirectly. This is accomplished by

- subjecting the underlying model assumptions to experimental testing,
- confirming underlying assumptions on the basis of widely accepted scientific knowledge,
- investigating the consistency of assumptions and model results with analogs in which relevant processes have operated for very long times,
- performing sensitivity analyses to identify important features, events, and processes, and to focus attention on areas where gaps in knowledge are significant,
- comparing the predictions of detailed component or process models to observation,
- comparing the outputs of component or integrated system models with those of other models on standard cases,
- applying qualitative reasoning and alternative modeling approaches to the analysis of parts of the system or the system as a whole, and
- subjecting the models and the results to thorough peer review.

In the end, the review rests on the judgment of the reviewers as to the reliability of the models, rather than any categorical proof of model validity. Judgment will always be a component of developing and applying the models, and of establishing the reliability of the models and the overall assessments to which they contribute.

Uncertainty in the reliability of the models and in the completeness of the scenarios being considered are examples of uncertainty that is in large degree not quantifiable. Other uncertainty, such as that arising from lack of complete information about the physical and chemical characteristics, can be quantified, at least in principle, by reflecting it in the distribution of values assigned to model parameters and calculating the corresponding distribution in the model results. Such probabilistic analysis provides additional information that can be helpful in decision-making, and would seem to be particularly appropriate when applying risk-based performance criteria.

CONCLUSION

There is a broad international consensus, at least among practitioners of long-term performance assessment, that performance assessment models can provide sufficiently reliable information regarding long-term repository performance for use in licensing [7]. In fact, this opinion extends beyond persons directly involved in conducting performance assessment. For example, the Committee Studying the Technical Bases for Yucca Mountain Standards, organized under the auspices of the United States National Research Council, has stated, with reference to an assessment of Yucca Mountain as a potential repository site, "So long as the geologic regime remains relatively stable, it should be possible to assess the maximum risks with reasonable assurance. … Established procedures of risk analysis should enable the combination of the results of all repository system simulations into a single estimated risk to be compared with the standard. (Human intrusion is excluded from such a combination …)" [6].

Some disagreements exist regarding appropriate methodology. The most notable such disagreements regard the way in which human intrusion scenarios are to be incorporated in standards and analyses (note the above parenthetical comment), and whether probabilistic analysis should be employed. These would not, however, appear to present insurmountable difficulties.

The models cannot provide absolute proof of safety. Their reliability for any particular assessment is a matter of judgment, and will be a major topic of any review of a safety case in which they are employed. Various procedures can be used to build confidence in the results of the models, but some uncertainty will always remain and judgment by experts and by decision-makers will continue to be an important element. Qualitative reasoning, based on experimental and theoretical knowledge of components of the repository system, natural analogs, and important features, events, and processes must supplement the information provided by the models to develop confidence in the long-term safety of the repository system.

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SESSION II: MAKING A SAFETY CASE

Review of Existing Integrated Performance Assessments and Preliminary Lessons Learnt from NEA Activities

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1. Introduction

Within NEA, discussions have taken place for many years on performance assessment for radioactive-waste repositories and on related activities such as site characterisation. NEA's Radioactive Waste Management Committee (RWMC) has been very active in this area and has implemented two subgroups - the Performance Assessment Advisory Group (PAAG) and the Co-ordinating Group on Site Evaluation and Design of Experiments for Radioactive Waste Disposal (SEDE) - in which many detailed technical discussions take place.

A wealth of information has been accumulated from many interesting discussions within PAAG and SEDE over the last few years; this paper aims to summarise the current status of performance assessment (PA) based on the findings of these discussions. Besides the discussions during its yearly meetings, PAAG has set up several working groups to cover some areas in more depth and to produce documentation, as well as other products such as databases. The experiences from some of these working groups will also be drawn upon in this paper. The working groups referred to in this paper include

- the Probabilistic Safety Assessment Group (PSAG)
- the Working Group on Integrated Performance Assessments (IPAG)
- the Working Group on Scenario Development/FEP-list
- the Working Group on Validation and Confidence Building (which also includes members of RWMC and SEDE)

The SEDE Group has to work in a way that accommodates the differences between repository concepts and geological settings represented by the participating programmes and regulatory bodies. This is achieved by keeping the treatment of the geosphere in performance assessments as a focus for the work of the Group. The work is less amenable to being progressed through working groups than through topical workshops, although a highly successful working group has operated on Measurement and Physical Understanding of Groundwater Flow through Argillaceous Media ("The Clay Club"). Workshops of direct relevance to the use of site characterisation data in performance assessments have included:

- Heterogeneity of Groundwater Flow and Site Evaluation (1990)

– Characterisation of Long-Term Geological Changes for Disposal Sites (1994)

Increasingly it is recognised as valuable to deal with site characterisation issues of direct relevance to performance assessment through a jointly agreed action between SEDE and PAAG. A highly successful example of such collaboration on a complex issue was the workshop held in 1993: "The Role of Conceptual Models in Demonstrating Repository Post-Closure Safety".

It is important to point out that the summary presented in this paper can only represent a small fraction of the areas covered by PAAG and SEDE. It is subjective by its nature and represents only the views of the authors and not necessarily those of PAAG and SEDE.

For the areas that are considered to be most important for our workshop, the following information is available:

– The state-of-the-art of Integrated Performance Assessments: An International Collective Opinion (Title: "Can Long-Term Safety be Evaluated?") recording the consensus at that time on performance assessment methodology was issued in 1991 [1]. The first phase of IPAG, which came to an end in 1996, investigated the current status of Integrated Performance Assessments by means of a detailed analysis of 10 recent Integrated PA studies [2]. Furthermore, over the past several years, one or two contemporary PA studies have been presented and discussed during each of PAAG's yearly meetings.

– Development of understanding and assessment of modelling capabilities: For many years, NEA (PAAG and SEDE) has been involved in international studies evaluating models for geosphere groundwater flow and radionuclide transport (e.g. INTRACOIN, HYDROCOIN, INTRAVAL, ARAPP, GEOTRAP) and the results of these studies have been discussed at NEA-co-sponsored symposia (e.g. [3]).

  Periodically, the modelling capabilities for other important phenomena relevant to repository systems have also been revisited (e.g. near-field processes, biosphere transport, gas effects).

– Improvement of PA-related methodologies: Many methodological aspects have been discussed either by PAAG or by its working groups. Areas that have been covered include, for example, the treatment of uncertainty and variability, probabilistic methods, scenario development, future human actions and validation and confidence building.

In this paper, it is considered to be most useful to concentrate on Integrated Performance Assessments. A good starting point for the discussion of the current status of Integrated Performance Assessment is the NEA/IAEA/CEC-Collective Opinion "Can Long-Term Safety be Evaluated?". The key messages of this Collective Opinion are summarised in the next section. The results of the first phase of IPAG are then used to indicate progress that has been made since 1991. The discussions of recent PA studies and of other related investigations by PAAG and SEDE and some insights from the discussions underway within the Working Group on Validation and Confidence Building will be used to complement this brief progress evaluation.

2. Key Messages of the NEA/IAEA/CEC-Collective Opinion (1991)

Following a systematic review of the state-of-the-art in the development of methods for safety assessment "the NEA Radioactive Waste Management Committee and the IAEA International Radioactive Waste Management Advisory Committee

- **Recognise** that a correct and sufficient understanding of proposed disposal systems is a basic prerequisite for conducting meaningful safety assessments,
- **Note** that the collection and evaluation of data from proposed disposal sites are the major tasks on which further progress is needed,
- **Acknowledge** that significant progress in the ability to conduct safety assessment has been made,
- **Acknowledge** that quantitative safety assessments will always be complemented by qualitative evidence, and
- **Note** that safety assessment methods can and will be further developed as a result of ongoing research work.

Keeping these considerations in mind the two Committees

- **Confirm** that safety assessment methods are available today to evaluate adequately the potential long-term radiological impacts of a carefully designed radioactive waste disposal system on humans and the environment, and
- **Consider** that appropriate use of safety assessment methods, coupled with sufficient information from proposed disposal sites, can provide the technical basis to decide whether specific disposal systems would offer to society a satisfactory level of safety for both current and future generations."

This Collective Opinion was endorsed by the CEC Experts for the Community Plan of Action in the Field of Radioactive Waste Management.

According to Annex 1 of the Collective Opinion document,

"The general approach to safety assessment consists of a number of interrelated elements:

- Broad identification of possible future evolution of the selected disposal system (scenario development);
- Development and application of appropriate models;
- Evaluation of potential radiological consequences in an integrated assessment
- Uncertainty and sensitivity analyses;
- Validation and review of all components of the assessment;
- Comparison of results with criteria;
- Documentation of the assessment"

Feedback between these elements and their continuing refinement as repeated assessments are performed, are important aspects of safety assessment.

This list of elements is, today, still considered to be an appropriate representation of the key activities undertaken when conducting an integrated performance assessment. It is also important to note that most of these elements are, to a large extent, independent of regulatory criteria and guidelines.

3. Progress in Performance Assessment during the last few years

Since issuing the Collective Opinion in 1991, PA methods have been further developed and experience has been gained in the application of these methods. Following its evaluation of ten recent PA studies, the Working Group on Integrated Performance Assessments (IPAG) came to the conclusion that

"– dealing with data from actual sites, as has been increasingly practised in PA since 1991, presents some challenges and requires more resources than expended in earlier PAs, but

– no new insurmountable problems have been encountered in the application of PA, and thus the findings of the NEA/IAEA/CEC Collective Opinion document remain valid."

The work of IPAG and information from some other studies indicate that the general approach to PA, as described in Annex 1 to the Collective Opinion, is still valid in its broad sense, including the elements listed there. Progress has, however, been made in most of these elements, including the following important topics:

- Scenario development. In recent assessments, more emphasis has been placed on the "comprehensive identification of relevant features, events and processes (FEPs), and tracking decisions on treatment and/or incorporation of FEPs into assessment models" [2]. For this purpose, a PAAG Working Group is currently finalising an "International FEP-Database" that will help to address the question of completeness.

  The long-term performance of the geosphere is of particular importance in this respect. Key aspects are geochemical, rock-mechanical and hydrological conditions and their evolution with time. The stability of such conditions in relation to the long-term performance of the engineered system and to quantification of the overall system performance underpins the robustness of the deep geological disposal concept for radioactive wastes.

- Development and application of appropriate models. [2] mentions that significant advances have been made, (i), in the handling of large site-specific data sets, (ii), in the modelling of three-dimensional groundwater flow and transport, (iii), in our understanding of transport of contaminants, (iv), in the quantification of geochemical phenomena and (v), in the modelling of particular processes, such as colloid-mediated transport and gas-mediated release. It should also be mentioned that some of the recent assessments made use of more sophisticated probabilistic codes and that, in many assessments, more rigorous quality assurance procedures are applied.

  Furthermore, international projects have considered in much detail how to model geosphere transport and extensive model testing has been performed (e.g. INTRAVAL, see [4]). Specific experiments, both in the laboratory and in the field, have been performed to assist the model developments. Much progress has been made in modeling complex geological situations and model testing is much more advanced, Today, a more realistic picture exists on "what is possible and what is simply unachievable" in model testing [4].

  As a result of interactions between PAAG and SEDE, the GEOTRAP Project has been set up to assist in the development of robust treatments of radionuclide transport in heterogeneous geological media. This objective is seen as achievable because there is now a sufficient information base on programmes of integrated modelling and testing. In particular, meaningful experiments have been and will be conducted on tracer transport that build confidence in processes of radionuclide retention and retardation such as sorption and rock matrix diffusion.

It is now widely accepted that for some phenomena, especially those related to the nature of the surface environment and human behaviour in the far future, there is inherent and irreducible uncertainty. In these cases, it may be necessary to use stylised representations, e.g. as being considered in respect of the biosphere [5]. As far as possible, such representations should take account of site specific factors that are quantifiable with some confidence (robust) in the long term, e.g. related to the natural dilution potential and credible future use of resources at a site.

– Uncertainty and sensitivity analysis. These aspects were considered to be important in all recent PA studies, and much emphasis is placed on them. With respect to uncertainties, it is widely accepted that three major sources need to be considered: scenario uncertainty ("have all relevant phenomena been considered?"); conceptual model uncertainty ("are the relevant phenomena correctly represented?") and parameter variability and uncertainty. It is also generally accepted that treatment of parameter uncertainty is straightforward, whereas analysis of both scenario uncertainty and conceptual model uncertainty is not a simple undertaking. IPAG came to the conclusion that no single approach of treating uncertainties can be recommended and that either a deterministic or a probabilistic approach, or parallel use of both, may be appropriate.

  It is generally accepted that spatial variability of geological media is important and geostatistical approaches have been developed and used to good effect in the hydrocarbon, mineral exploitation and water resources industries for many years. This gives confidence in their applicability in performance assessments.

  Sensitivity analysis is considered to be important to identify critical uncertainties; critical uncertainties are those that can impact decision making and which therefore require special attention with respect to validation (see below).

– Validation and review of all components of the assessment. It is nowadays widely accepted that a whole variety of activities contributes to validation, or to use the increasingly popular, more general term, confidence building. It has become obvious that the term validation, as used in waste management, can create misunderstanding and difficulties when not properly defined, because validation in a strict philosophical sense can never be achieved in an open system (see e.g. [6]); validation is therefore, in many studies, now replaced by other terms, such as confidence building. If a rather broad view is taken and confidence not only in the PA study but in the whole decision making process is considered, then the following elements can be identified that can contribute to enhanced confidence:

  . sound qualitative principles for repository design and siting (e.g. multibarrier concept, siting in a stable geological environment etc.)
  . quantitative assessment of system performance with an indication of the available level of confidence in the results produced.
  . involvement of the scientific community and the public (e.g. through peer review by independent scientists, easily available information etc.)
  . clearly defined roles and responsibilities for technical bodies (implementer, regulator)

Although only the second point is, in a strict sense, directly applicable to PA, the other points can be very important to achieve confidence by the public. Only the second point will, however, be further discussed in the remainder of this section.

In order to achieve an appropriate level of confidence, an iterative approach is required. By choosing an adequate design, by performing experiments, by model development and model testing (with experiments both in the field and the laboratory), and with the help of a logical chain of arguments (e.g. simplification through conservative assumptions etc.), confidence is built in the performance of individual components of the system and in our ability to assess their performance. This is complemented by qualitative and/or semi-quantitative evidence, e.g. from analogue studies, by the use of isotope hydrology etc. The evaluation of confidence in the behaviour of the whole system is achieved through sensitivity analysis ("to which components and phenomena is the overall performance most sensitive?") and uncertainty analysis ("for these critical components and phenomena, can the spectrum of possibilities lead to an unacceptable performance of the system?") and is complemented, for example, by peer review. This evaluation then leads to a statement of the available level of confidence in the results given. Often, such a statement will be for a bounding type of result ("there is reasonable assurance that the consequences of a system will not exceed the regulatory guidelines"), because, in many cases, uncertainty in some phenomena will be compensated by pessimistic assumptions.

It is important to recognise that the approach chosen to achieve an appropriate level of confidence will change as the project progresses and more data on specific repository components become available. This allows a reduction in the uncertainty in the assessment of the performance of these components; these components can then play a more important role in the safety case. One example of this type of observation is the role of the geosphere transport barrier for fractured host rocks: in the earlier phases of the repository project, when only limited data are available and, for example, the existence of “fast channels” cannot be excluded, the performance of the geosphere transport barrier will be negligible for the extreme end of the spectrum of possibilities in uncertainty analysis. As the project progresses, and as more data become available, the uncertainty can (hopefully) be reduced, a better performance can be relied upon and the geosphere transport barrier will play a more important role in the safety case.

The interaction between site characterisation and performance assessment should lead to the identification of the geosphere functions that are important to establishing a safety case for the repository system, and why other functions are accorded low importance or discarded. This is helpful when comparisons are effected between performance assessments for different repository concepts and sites and reliance is seen to be placed on different functions.

– Documentation of the assessment is considered to be of key importance. Nevertheless, many organisations recognise that this is an area for further improvements. This was also indicated by the discussions within IPAG. One of the key dilemmas is to be comprehensive, while, at the same time, keeping the report readable (e.g., with respect to the number of pages). It may, therefore, be necessary to prepare different documentation for differing audiences. In (IPAG, 1996) a proposal is made on what should be included in a PA report for the technical audience. Further, it is necessary to mention that poorly defined terminology can lead to confusion.

For all the elements mentioned, the discussion shows that no dramatic changes have taken place since 1991. Nevertheless, progress has been made in many areas and it is expected that further improvements will also be made in future. The collection and evaluation of data from proposed disposal sites will continue to be a major task on which further progress is needed. An intense interaction between site characterisation and PA will be a pre-requisite for a successful project. This interaction should be a continuous process rather than an iterative one so that the validity of the use of site data and observations can be established.

4. Summary and Conclusions

– PA is considered to be an integral part of repository development and the capability to conduct PAs is well developed in most programmes.

– There exists a general consensus that PA methodology is sufficiently advanced to be used in decision making for developing a repository. In many programmes, however, it is still necessary to extend the information base to be used in PA. This is especially true for information characterising proposed disposal sites. A close interaction between site characterisation and performance assessment will be necessary for a successful project, as indicated by Röthemeyer's adaptation of Kant: "Performance assessment without nature observation is empty, nature observation without performance assessment is blind." [7].

– Independent of the resources spent, PA will never be able to predict the future accurately. There will always be irreducible uncertainties. Despite those uncertainties, the consequences can be bounded when replacing uncertainty with pessimism. Calculated consequences, therefore, often err on the side of pessimism.

– In many programmes, PA is used in an iterative manner; several iterations will be performed before a final license application is made. Numerous programmes have already performed several iterations. These iterations correspond to the phased approach adopted in many projects. For such an approach, it is important to recognise that even significant residual uncertainty may be acceptable in earlier iterations and the question to be answered is: "how good is good enough for the next step?"

– PA includes activities in the following areas

  . development of sufficient understanding to allow the conceptualisation of the repository system and the identification the relevant cases (scenarios) to be studied

  . quantification of repository behaviour for the cases identified

  . interpretation of the results produced. The interpretation includes an evaluation of the compliance with regulations and an assessment of the available level of confidence in the results

  . production of appropriate documentation is essential

  In all these areas, further developments are expected. These developments will allow a reduction of uncertainty and an enhanced confidence in and acceptance of evaluated repository projects.

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Regulating Long-Term Safety
The Konrad Safety Case

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Abstract

The German Federal Government plans to open the Konrad mine as a repository for low- and intermediate-level radioactive waste. In 1982, an application was made for the initiation of the licensing procedure. In 1990, a revised version of the compliance report was declared sufficient for public participation, by the licensing authority of the federal Land Lower Saxony. The public inquiry began in September of 1992, and was concluded in March of 1993. Through this inquiry, a 10 year debate on the long-term safety of the Konrad site was brought to an end. The discussions involving the licensing authority, objectors and external experts, mainly focused on the completeness of the data base, the conservativeness and robustness of the safety assessment, and the diversity of the models used.

The Konrad safety case is based on deterministic calculations of groundwater flow within the environment of the repository. Groundwater transport times exceeding 300 000 years have been calculated. Relevant radiation exposures have been calculated for I-129 and U-238 alone. With regard to the completeness of the data base, the experience gained in the Konrad mine in which mining activities are being continued, the well layered and relatively uniformly stratified geology are strong points in the safety case's favour. With respect to the conservatism of the safety assessment, the failure to take into account groundwater salinity, the established great age of the groundwater, the overestimation of rock permeabilities and underestimation of dilution are important arguments. The robustness and diversity of the safety assessment were demonstrated by the use of various conceptual and hydrogeological models, a variety of codes, and a large number of parameter sets.

Status of the licensing procedure

The federal government of Germany plans to open the Konrad mine as a repository for low and intermediate-level radioactive waste. Konrad is a former iron ore mine situated close to Braunschweig, in Lower Saxony. Under atomic law, the BfS (Federal Office for Radiation Protection) is responsible for planning, building and operating repositories in Germany. In 1982, an application was made for the initiation of the licensing procedure. The compliance report for the Konrad project was submitted in 1986. In 1990, a revised version of the compliance report was declared sufficient for public participation by the licensing authority of the Land of Lower Saxony. In 1991, this licensing authority was advised by the supervising BMU (Federal Ministry for the Environment, Nature Conservation and Nuclear Safety) to make public the compliance report. The public inquiry began on September 25th, 1992, and was concluded on March 6th, 1993. No new issues were raised by the objectors during the public inquiry. Since 1993, the licensing authority has been working out the details of the licence for the Konrad repository.

The Konrad Safety Case

The Konrad site is located in Lower Saxony between the cities of Braunschweig and Salzgitter. The repository will be embedded in a low, permeable, so-called Oxfordian formation, at a depth of 800 - 1300 m below ground. The host formation belongs to the Upper Jurassic, and is largely covered by a layer of clay of the Lower Cretaceous, which is a few hundred meters in thickness. The repository area extends over a distance of 1.8 km from east to west, and 3 km from north to south. The hydrogeological model area is defined by natural boundaries. It extends over about 15 km from east to west, and 45 km from north to south, and has a depth of 2.5 km. An outcrop of the Oxfordian host rock , extends a further 30 km to the north of the site. The average horizontal hydraulic head gradient is less than 0.5%, and the groundwater salinity increases with depth, to about 220 g/l. On the basis of two hydrogeological models, 3-dimensional groundwater calculations were performed for a wide range of parameter sets, without taking into account the salinity of the groundwater [1]. In addition to this, 2-dimensional groundwater calculations were performed, taking into account density effects [2], [4]. Within the scope of the various groundwater models, transport times of between a few hundred thousand to more than 10 million years were calculated. The groundwater calculations were supported by analysis of environmental isotopes and noble gases in brines from the Konrad mine [3]. They prove that these brines contain a large fraction of concentrated salt solutions from evaporite formation with halite deposition, dating from 150 million years ago or earlier. This indicates a very low exchange rate between deep groundwater and meteoric water, and confirms the conservativeness of the calculated minimum groundwater transport time of about 300 000 years. On the basis of this transport time, radiation exposures were calculated for periods of up to 10 million years.

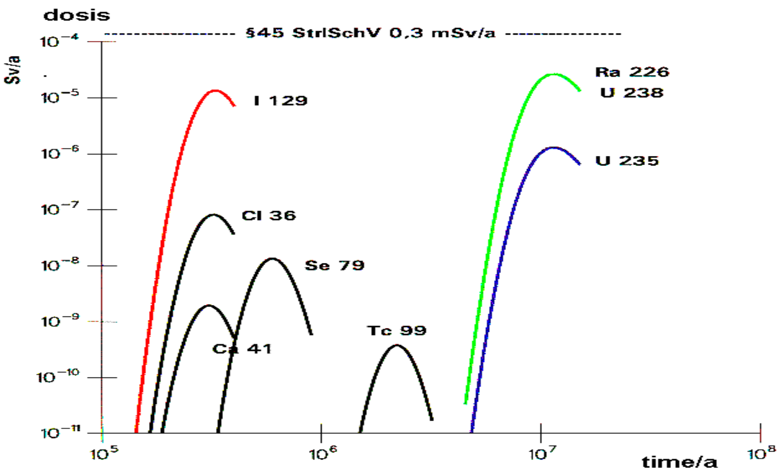

Figure 1.: Radiation exposures in the post-operational phase

Main points of effort in the licensing procedure

An essential prerequisite for the performance of long-term safety assessments, is the provision of a realistic and complete data base. The results of the safety assessments directly depend on the type and amount of radioactive waste which is, according to the plans, to be disposed of in the repository. For the Konrad repository, the emplacement of up to 650,000 m^3 in waste package volume with a total activity in the order of 10^{18} Bq and an alpha emitter activity of about 10^{17} Bq is planned. In terms of long-term safety, the inventory of long-lived radionuclides represented the main point of interest within the discussions with the licensing authority. According to the requirements of the BfS, the waste producers provide for an extensive data base about waste origin, type, packaging, radionuclide inventories and annual numbers of waste packages to be dealt with. In spite of the high quality of the data base, it is difficult to arrive at a detailed estimate of the expected radionuclide inventories which extends beyond an operational phase of more than 40 years. Changes in waste processing and production influence the amount and type of waste. Even the operation of the existing Morsleben repository for low and intermediate-level radioactive waste shows that detailed information about the radionuclide inventories only becomes available, after facility-specific waste quality assurance has been carried out.

Intensive discussion focused on the completeness of the geological data base. Thanks to the existing Konrad mine, an extensive data base exists for the host rock and the surrounding area. In addition to this, two investigative drifts were driven from shaft 2, to enable investigation of the overlying clay formations and the Excavation Damage Zone (EDZ). The relatively well stratified and uniform geology of the overlying clay layers and the host rock, already provided strong arguments for the feasibility of applying measured data from the surrounding area to the more distant area (Fig. 2.). Weak points in the confidence building process were that only one deep borehole test along with hydraulic tests was carried out for the whole site, and that no hydraulic data were available for fault or tectonically disturbed zones. This lack of data was compensated for by means of various theoretical methods, and a large amount of data from the drilling of industrial boreholes.

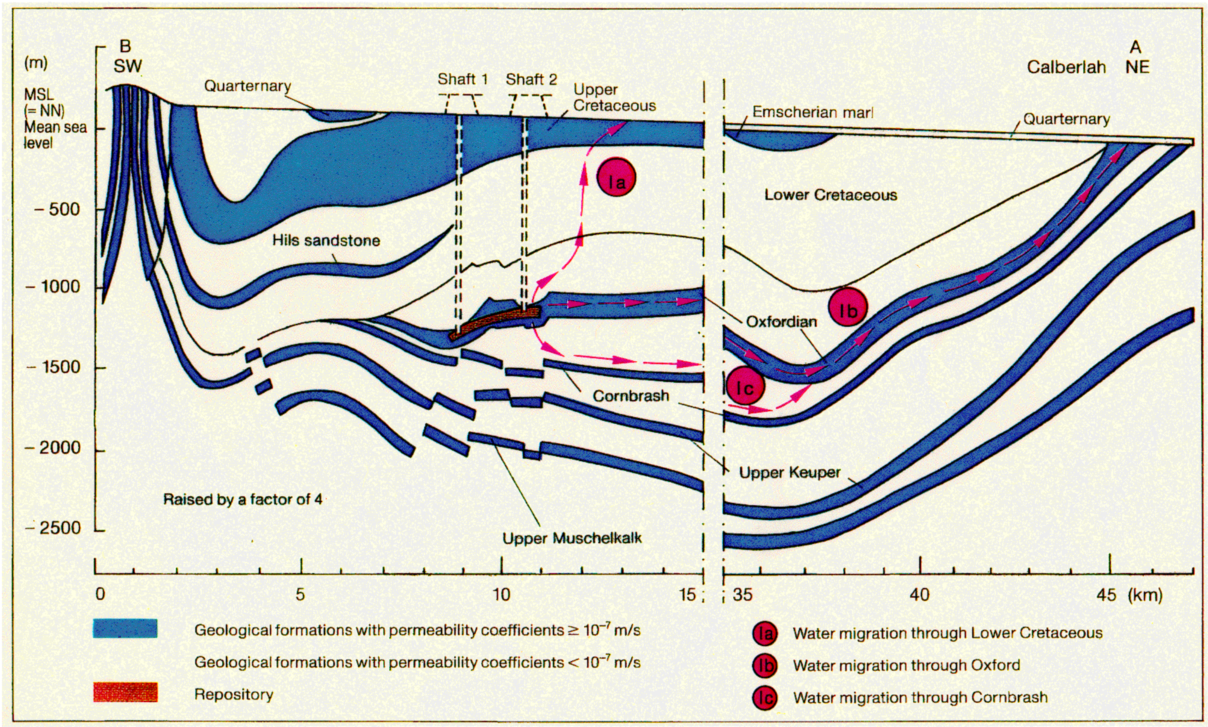

Figure 2.: Vertical cross section of the hydrogeological model area

The most important focus of the Konrad long-term performance assessment is the calculation of groundwater flow and transport times within the environment of the repository. Two hydrogeological models were developed. The first one is concerned with fracture zones and overall increase in permeability within the geological formation. The second deals with fracture zones according to locally increased levels of permeability. Three-dimensional freshwater calculations, and two-dimensional salt water calculations were carried out in accordance with the different hydrogeological models. The model calculations give rise to transport times of between 300 000 years and more than 10 million years (Table 1.). In addition, geochemical analyses were carried out as confidence-building measures in support of the groundwater movement calculations. The environmental isotope and noble gas content of brines from the Konrad mine was measured. The results can only be explained in terms of a very low rate of exchange between brines left over from evaporite formations deposed 150 million years ago, and waters from more recent sources. In this regard, the age of the groundwater content of brines from the Konrad mine, was assessed to be in the order of 10 million years, which corresponds with the calculated groundwater movement, taking into consideration the salt water content. The use of diverse models confirms the robustness of the most relevant conclusion of the safety assessment, which concerns the isolation potential of the site. Only very few safety assessments were performed taking human actions into consideration. The drilling of boreholes into the repository, and mining of the residual iron ore were, to some extent, taken into account. It was, however, difficult to bring possible human actions within the framework of an existing iron ore mine into the assessment, with criteria for this kind of scenario not included in the regulations.

characte-ristics	Layered-Mod.	Layered-Mod.	Fault-Mod.	Fault-Mod.	Shaft-Mod.
dimension	3	2	3	2	1
flow	freshwater	saltwater	freshwater	saltwater	freshwater
conductivity of upper clay in m/s	10^{-10} - 10^{-12}	10^{-11}	10^{-11} increased by fac. 10-60	10^{-8}	3. 10^{-9}
width of path	> 1000 m	> 1000 m	> 100 m	300 m	3 m
travel time	> 3. 10^{5} years	> 10^{6} years	> 10^{6} years	> 10^{6} years	> 10^{5} years

Table 1: Comparison of different groundwater flow model concepts

The licensing authority also focused on very detailed discussion of the conservativeness of the safety case. The failure to take into account salt water barrier effects within the safety case and the great age of the groundwater content of Konrad brines, were the most powerful arguments for demonstrating the conservativeness of the safety case. The conservative character of the safety case was also supported by the fact that levels of permeability for the relevant barriers were overestimated, and that geochemical retardation and dilution were underestimated. In spite of the large number of conservative assumptions, an extensive discussion of conservativeness involving opposing points of view, proved to be necessary. One reason for this were the licensing authority's requirements for quantifying the conservativeness of the safety case. This conservatism is the result of a conceptual model which is already clearly conservative, and fails to take into account barriers and processes which act as barriers. As a result of this failure to take barriers and barrier processes into account, there is no way of quantifying them within the framework of the safety case. The licensing authority wished, contrary to this, that the conservativeness of the data set used in the safety case be subject to demonstration. With reference to this, the lack of an analysis of stochastic uncertainty within the safety case, represented a weak point in the BfS safety assessment. This was, however, to some extent compensated for, by deterministic parameter variations within the safety assessment.

Outcome of the licensing procedure

The long-term safety of the Konrad repository could be demonstrated for very long periods of time. The BfS was forced to limit the inventories for the Konrad repository, despite the established conservativeness of the conceptual model and the data set which forms the basis of the safety case, and calculated radiation exposures after a period of 300 000 to 10 million years, following the sealing of the mine. The I-129 inventory will most likely be limited to 110 kg, and the U-238 inventory to 150 Mg. The licensing authority justifies these limitations through the calculated organ doses, which exceed the dose limitations by approximately 50%. The acceptable inventory will be low compared with the radioactive natural background in the host rock, especially with regard to the latter.

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The Legal, Regulatory and Safety Basis for Opening WIPP

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Abstract

Current laws in the United States of America (USA) direct the U.S. Department of Energy (DOE) to site, design, operate, and decommission a deep geological repository for safe disposal of transuranic radioactive waste[a] (TRUW) at the Waste Isolation Pilot Plant (WIPP) site. In 1992, the U.S. Congress withdrew land from public use and set it aside for the WIPP site and appointed the U.S. Environmental Protection Agency (EPA) as the regulator for safe disposal of TRUW. In 1993, the DOE established the Carlsbad Area Office (CAO) to integrate the nation's management of TRUW and to open the WIPP site for safe disposal of TRUW in compliance with applicable laws and regulations. In September 1996, the U.S. Congress passed the Land Withdrawal Amendments Act 18 which among other things, exempted WIPP from the Land Disposal Restrictions of the Resource Conservation and Recovery Act of 1977 and reduced the 180 day waiting period subsequent to the EPA's certification of compliance to 30 days so that WIPP may now open as early as November 1997.

The CAO submitted the final Compliance Certification Application (CCA) to EPA on October 29, 1996, and is on schedule to open WIPP in November 1997, about three years earlier than scheduled before the establishment of the CAO. The performance assessment (PA) embodied in the CCA demonstrates that WIPP meets the EPA's regulatory requirements for radioactive releases for the 10,000 year regulatory period in both the undisturbed and disturbed (human intrusion) scenarios. Thus, it confirms the judgment of the National Academy of Sciences WIPP committee as expressed in the October 1996 National Research Council Report, WIPP: A Potential Solution for the Disposal of Transuranic Waste, that "radionuclide releases at WIPP will be within the limits allowed by EPA, for both the undisturbed and disturbed cases, even with the severe criteria defined in 40 CFR 194". Accordingly, the resultant safety basis for WIPP has been evaluated and has been shown to result in human exposures lower than those allowed by appropriate U.S. and international standards.

Detailed planning, compliance-based research and development (R&D), teamwork among project participants and early and open iterative interactions with the regulators, oversight groups and other interested parties in the certification/permitting process are key components of this progress. Albeit unique domestic components are involved in the WIPP process, and challenges to the timely opening remain (e.g., evolving regulations and potential lawsuits), the lessons learned at the WIPP to date contribute to solving the remaining current global societal challenge of the nuclear energy cycle, i.e., the safe disposal of long-lived radioactive waste.

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[a] Waste containing more than 100 nanocuries (3,700 becquerels [Bq] of alpha-emitting transuranic isotopes (radionuclides with atomic weights greater than uranium) per gram of waste, with half-lives greater than 20 years. Maximum surface dose rate for TRUW is 1,000 rems (10 sieverts [Sv] per hour and the maximum activity level averaged over the volume of the canister is 23 curies ($851 x 10^9$ Bq) per liter.

I. BACKGROUND

Fifty years of residue from civilian and military applications of nuclear energy continue to amass in temporary stockpiles around the world pending the opening of the world's first disposal system for long-lived radioactive waste. A long-standing international scientific consensus is that long-lived radioactive waste may be safely disposed of in well-sited and carefully designed deep geological disposal systems (repositories). However, schedules for the development and opening of repositories for radioactive waste typically experience delays around the world. Often, these delays are attributable to opposition by interest groups that feed on the general public's inattention to and lack of information about the intricate state-of-the-art science and engineering, and the 10,000-year period governing the safe performance of a repository for long-lived radioactive waste. It is, thus, a global imperative and challenge to inform and convince the public that a given repository is safe for the waste type considered and the time period of concern. Since the risks to the public from TRU waste (which are largely alpha emitters) result from the ingestion and/or inhalation of these radionuclides (Figure 1), the best approach to their safe disposition is to bury them in deep, stable geological formation thus removing them from the biosphere.

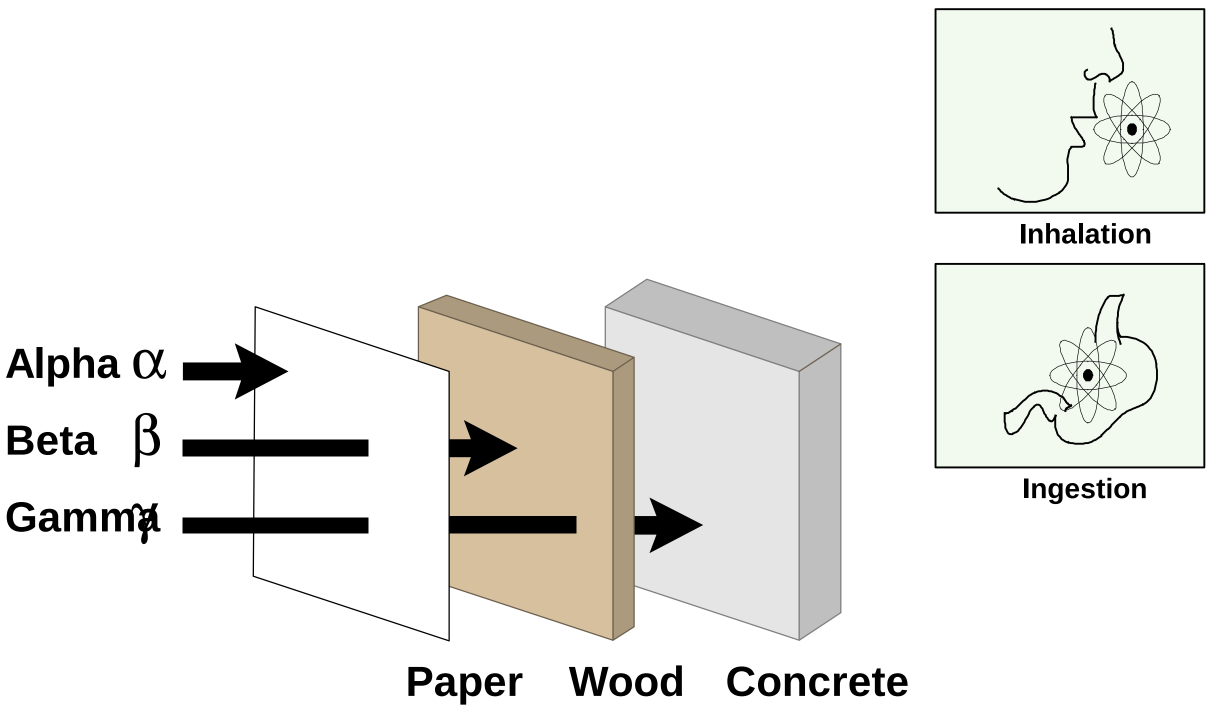


Figure 1. Risks to the Public From Transuranic Waste

In recognition of this approach, the USA DOE has commenced the licensing process to open a deep geological repository for safe disposal of TRUW, a long-lived radioactive waste that also contains hazardous constituents, at the WIPP site (Figure 2) in November 1997. The surface and subsurface facilities required for safe receipt and disposal of TRUW at the WIPP site were completed in 1988. However, the opening of the WIPP repository has been delayed for several years, mainly to facilitate voluntary and statutory DOE compliance with evolving regulations. If opened as scheduled, the WIPP will be the world's first repository for long-lived radioactive waste. Thus, the continued success of the WIPP is of global importance for the safe disposal of long-lived radioactive wastes and, possibly, for the future of nuclear power.

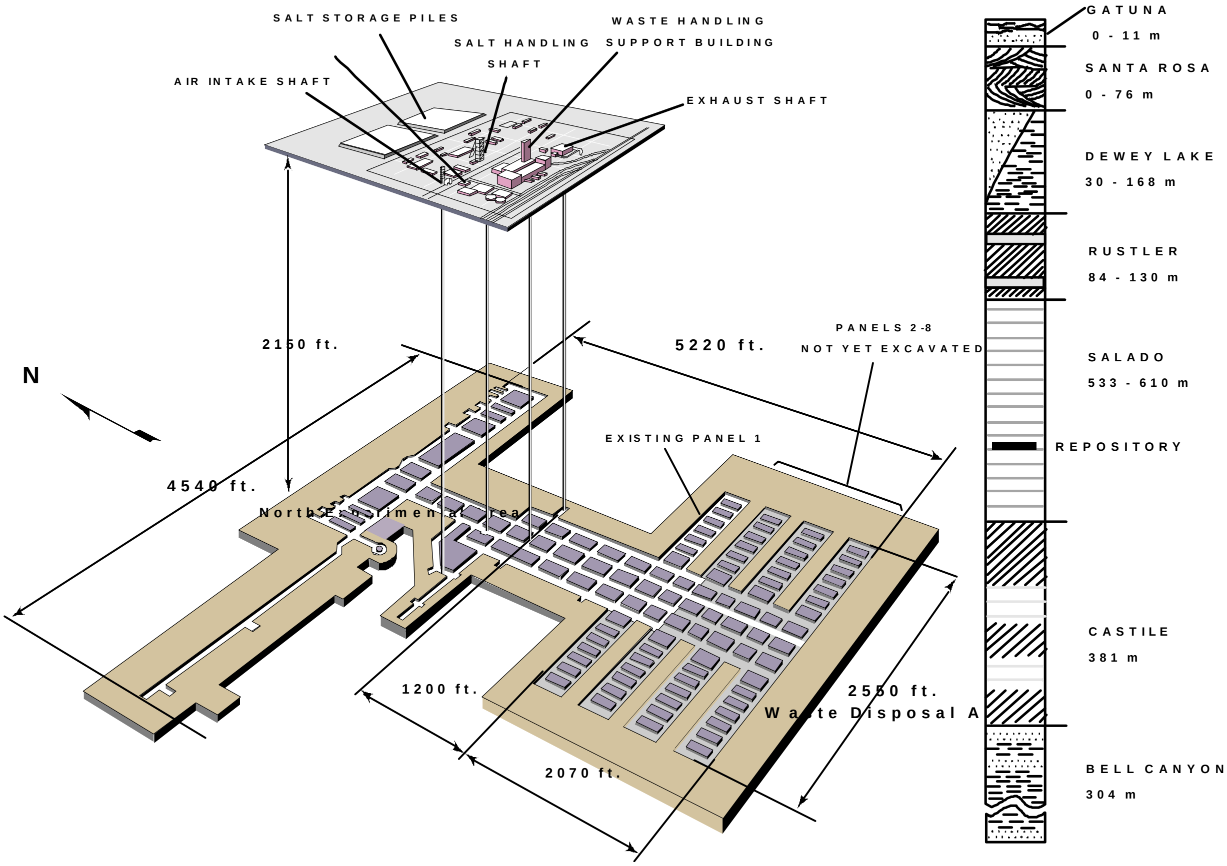


Figure 2. WIPP Facility and Stratigraphic Sequence

A. Waste Types/Volumes

There are two main types of TRUW, contact handled (CH) and remote handled (RH). CH-TRUW ranges in radioactivity from more than 100 nanocuries (3,700 Bq) per gram of waste up to waste/waste packages with a surface dose rate not greater than 200 millirem (2 milliSv) per hour. RH-TRUW ranges in surface dose rate from more than 200 millirem to 1000 rems (10 Sv) per hour. By law [4], only five percent of the total RH-TRUW volume may exceed a surface dose rate of 100 rem (1 Sv) per hour.

In 1994, the CAO assembled a task force to establish the existing TRUW inventory and to estimate the future TRUW inventory and to estimate the future TRUW inventory through the year 2033. To date, the nation's TRUW inventory has been estimated and reported by the CAO in three Baseline Inventory Reports (BIRs). The BIR data serve as input both for the establishment of the WIPP WAC and PA calculations.

The most recent BIR [16] estimates that about 58,000 cubic meters (m^3) CH-TRUW and about 4,000 m^3 RH-TRUW are currently stored at 30 storage/generator sites. 96 percent of this waste is stored at five sites. Additional TRUW generated at these sites through the year 2022 was estimated at about 54,000 m^3 CH-TRUW and 23,000 m^3 RH-TRUW [16], for a total of 112,000 m^3 CH-TRUW and 27,000 m^3 RH-TRUW. The maximum disposal capacity of the WIPP repository is 175,584 m^3 for all types of TRUW, i.e., both CH and RH. The RH is additionally limited to five percent of the RH-TRUW volume between 100 and 1,000 rems (1 Sv) per hour.

Thus, the current WIPP repository baseline design accommodates expected CH-TRUW volumes through the year 2022 (the year currently projected for termination of TRUW disposal at the WIPP site is 2033). However, the currently projected RH-TRUW volume through the year 2022 exceeds the current statutory limit [4] for the WIPP repository.

The ongoing environmental cleanup of nuclear weapons complex sites and the dismantling of the nuclear weapons arsenal will generate additional TRUW. The DOE is responsible for 137 sites in 33 states nationwide, representing a total surface area of approximately 8,500 square kilometers. Many of these sites contain areas with radioactively contaminated structures, soil, and groundwater. Recent estimates indicate that the "nuclear-weapons-complex", which has created a 300-billion dollar cleanup legacy, is the single largest environmental program in history[17] The dismantling of nuclear weapons will also result in radioactive waste that might meet the WIPP WAC. Like the waste in the environmental cleanup program, the amount of TRU resulting from the dismantling of nuclear weapons remains to be established. Potentially, the nation has to dispose of more TRUW than that currently authorized for the WIPP pursuant to the LWA[4].

It should be noted that about 60 percent of the existing TRUW is mixed with chemical constituents classified by the EPA as "hazardous"[11]. Thus, before the WIPP site can be opened, it must also comply with applicable laws and regulations pertaining to hazardous waste[11-14].

B. The Waste Isolation Pilot Plant

As shown in Figure 3, the WIPP site is situated in southeastern New Mexico. It was selected in 1974 as the potential site for a TRUW repository and subjected to exploratory drilling the same year. Based on promising site characterization data, an underground test facility and, subsequently, a portion of the TRUW emplacement/disposal facility, were constructed in the candidate host formation between 1980 and 1988. By late 1988 all surface facilities required to safely receive and handle TRUW were also in place.

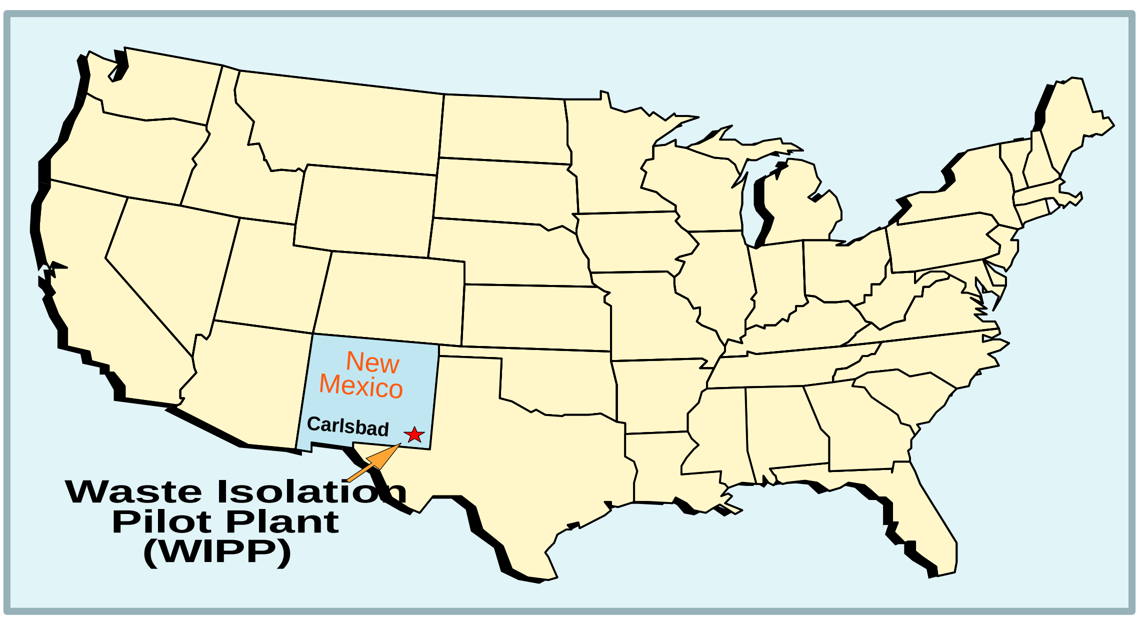


Figure 3.

Although the DOE was essentially self-regulating at the WIPP site in 1988, it had entered into a voluntary agreement with the state of New Mexico in 1981 that subsequently was amended to include compliance with 40 CFR 191. However, three aspects of 40 CFR 191 were remanded by the court in 1987, so the DOE did not have a formal yardstick for measuring the safe long-term performance of the WIPP repository until the repromulgation of 40 CFR 191 in December 1993.

As illustrated on Figure 2, the proposed WIPP repository is located about 650 meters below the ground surface in the Salado Formation. The Salado Formation is a 225-250-million-year-old, 600-meter-thick, regionally extensive, essentially impermeable, tectonically and seismically undisturbed/quiescent and stable sedimentary rock sequence dominated by rock salt (mainly halite). The WIPP site is, however, located in a natural resources area; commercial oil and gas exploration and extraction and potash mining occur within ten miles of its boundary,

The current WIPP baseline repository design comprises eight TRUW disposal panels, one panel of which has been completely excavated. Each panel is subdivided into seven rooms. Each room is 10 meters wide, 4 meters high, and 912 meters long. Other dimensions of the proposed WIPP repository and the adjoining underground test/experimental facility are shown in Figure 2.

C. Legal, Regulatory and Safety Bases

Current laws in the USA [1-4] direct the DOE to safely manage TRUW resulting from past, current, and future defense-related nuclear activities, and to open and operate a deep geologic repository for safe disposal of TRUW at the WIPP site in compliance with applicable laws and regulations. One of these laws, the WIPP Land Withdrawal Act of 1992 (LWA)[4], directed the EPA to develop and promulgate final disposal regulations for the WIPP repository.

The EPA promulgated the final disposal regulations in December 1993, hereinafter referred to as 40 CFR 191. It should be recognized that 40 CFR 191 contains internationally unique requirements for the long-term performance of the WIPP repository, both in terms of concepts and stringency [e.g., 6,7]. For example, post-closure mandatory human intrusion scenarios have to be considered in safety/performance assessment (PA) calculations supporting the CCA. Also, the internationally agreed upon radioactive waste disposal risk is in the range of 10^{-4} to 10^{6}. The 40 CFR 191 risk factor is 10^{-3}.

In February 1996, the EPA promulgated 40 CFR 194[8], which contains criteria for compliance with 40 CFR 191. These criteria introduce new or revised requirements, including new quality assurance (QA) requirements, more disruptive human intrusion scenarios, definitions of the data range and related minimum probability, and definition of the minimum confidence level required in the PA results projecting the long-term performance of the WIPP repository through the 10,000-year regulatory period. For example, "reasonable expectation" in 40 CFR 191 was defined in terms of minimum probability and confidence levels in 40 CFR 194 as follows:

- "The number of CCDFs [complementary cumulative distribution functions] generated shall be large enough such that, at cumulative releases of 1 to 10, the maximum CCDF generated exceeds the 99th percentile of the population of CCDFs with at least a 0.95 probability" (40 CFR 194.34[d]); and
- "Any compliance application shall provide information which demonstrates that there is at least a 95 percent level of statistical confidence that the mean of the population of CCDFs meets the containment requirements of §191.13 of this chapter" (40 CFR 194.34[f]).

These two new definitions/requirements effectively reallocates the substantial reliance on long-term radionuclide containment from the natural system to the engineered barriers system. Interestingly, when 40 CFR 191 was first promulgated in 1985, the regulatory emphasis was on ensuring that engineered barriers could not be used by the applicant to compensate for flaws in a site's ability to contain radionuclides. Indeed, the 10,000-year regulatory period "was chosen for the containment requirements because EPA believed it was long enough to encourage use of disposal sites with natural characteristics that enhance long-term isolation,…"[8].

The regulatory evolution continued. The preamble of 40 CFR 194[8] states: "The Agency intends to publish the final version of the Compliance Application Guidance (CAG) at a later date to provide detailed guidance on the submission of a complete compliance application." The CAG was released on March 30, 1996. It "summarizes and explains the final rule to assist the Department of Energy in the preparation and compilation of the WIPP Compliance Certification Application (CCA) and to assist in EPA's review of the CCA for completeness". The CAG describes an enormous amount of detailed information that needs to be included in the CCA package to meet the EPA's "completeness" criterion. However, the EPA also states that "The CAG is solely intended as guidance."

TRUW also contains non-radioactive constituents which are classified by the EPA[11] as "hazardous". Therefore, the WIPP repository must also comply with applicable hazardous waste laws and regulations, primarily the Resource Conservation and Recovery Act (RCRA) 12, as amended, and 40 CFR 264 13, and 40 CFR 268 14, respectively. Although the EPA initially promulgated both of these regulations, it has since transferred the related authority to approve hazardous waste disposal at the WIPP site in compliance with 40 CFR 264 to the New Mexico Environment Department (NMED). As a result, the opening of the WIPP must be approved by two independent regulators, i.e., the EPA and NMED.

The CAO commenced the regulatory process for opening the WIPP in 1995. The draft CCA (DCCA) for "undisturbed" disposal of TRUW and the draft No Migration Variance Petition for disposal of hazardous constituents were submitted to the EPA in March and May of 1995, respectively. The CAO also submitted the RCRA Part B Permit application to receive and handle hazardous constituents at the WIPP site to NNED in May 1995. The DCCA submittal was amended in July 1995 with "disturbed" (human intrusion) performance scenarios. The purpose of the DCCA submittals was to initiate and maintain a compliance certification dialogue with the EPA to facilitate the EPA's one-year review of the CCA.

This approach has proven beneficial as the meaningful, technical dialogues among the CAO and EPA staffs have been numerous and productive. A number of issues have been identified, addressed and resolved as the licensing process was anticipated. Accordingly in October 29, 1996, the CAO submitted the final Compliance Certification Application (CCA) to the EPA. It is a massively detailed and complex document comprised of nine chapters and over fifty appendices amounting to about 24,000 pages. In addition, their are over 700 references, amounting to another 80,000 pages, cited within the CCA chapters and/or appendices. In a presentation to the National Academy of Science WIPP Committee on the review process, an EPA official stated that the agency was conducting its completeness and technical review concomitantly. An announcement of open public comments was published in the Federal Register on November 15, 1996, giving the public 120 days to comment on the CCA.

It is anticipated that EPA will hold a public hearing in February 1997 and that a draft proposed rule will be issued in March 1997 on the CCA. A subsequent 120 day open comment period and additional public hearings will follow publication of the proposed rule. It appears that EPA is working toward meeting the one year CCA review period stipulated in the Land Withdrawal Amendments Act of September 1996.

The EPA and CAO technical staffs have continued their discourse on administrative and technical issues and a great number of technical exchange meeting have been held and more scheduled early in 1997. EPA has requested substantial additional materials and data, often above and beyond that required by the regulating or criteria documents. Nonetheless, the CAO and its contractors have complied in as forthright and timely a manner as possible. The underlying, fundamental principle at work here is that "in a licensing process one must give the regulator what they want/need to facilitate their decision-making" not surprising many of the requests have focused on quality assurance records, conceptual models, experimental data, and peer review processes and results. We remain confident that we can meet the EPA needs and facilitate their compliance decision.

The performance assessment embodied in the CCA demonstrates definitively that the WIPP meets the regulatory standards for the required 10,000 year period in both the undisturbed (Figure 4) and the disturbed (Figure 5) scenarios. Figure 5 depicts the conceptual model for the disturbed case, resulting from multiple human intrusion drill holes through the repository. In no case do significant quantities of radionuclides reach the accessible environment other than through direct borehole releases, nor do they migrate through the Culebra to the accessible environment. The most significant quantified release in the 10,000-year regulatory period results from drill hole cuttings which amounts to 0.6 m^3 of uncompacted waste. The resultant safety basis of the WIPP for such releases is calculated to result in a mean dose to humans of 3 mrem to a typical driller who inadvertently drills through the waste panels for the disturbed (human intrusion) scenario. For the undisturbed scenario a conservative bounding calculation resulted in a dose of less than 1 mrem for an unrealistic drinking pathway using radionuclide concentrations in brine from the repository horizon at the accessible environment boundary.

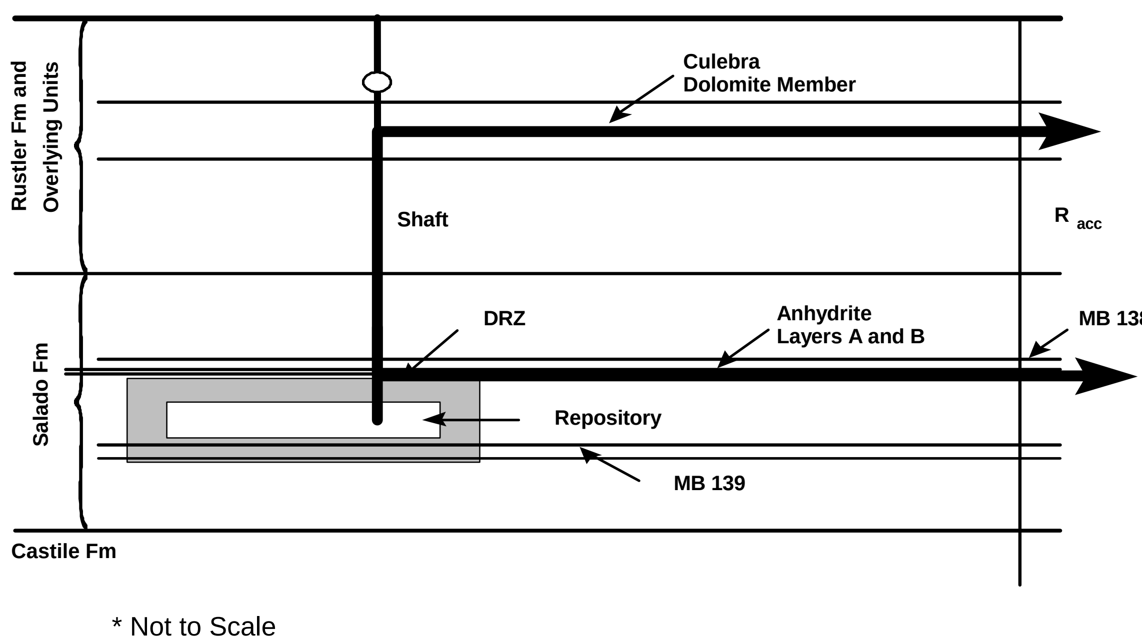
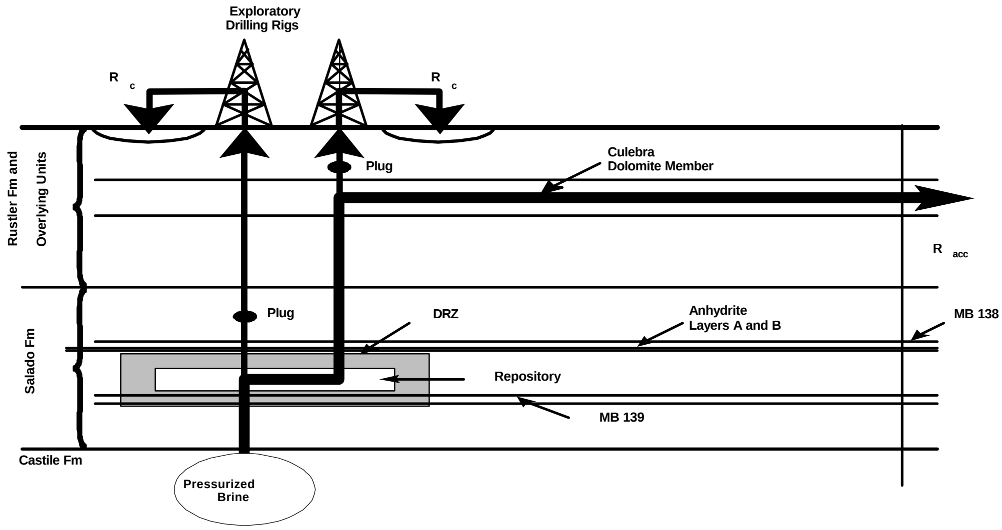


Figure 4. Undisturbed Case



* Not to Scale

Figure 5. Disturbed Case

IV. REMAINING CHALLENGES

The most apparent and imminent challenges to the opening of the WIPP in November 1997 are embodied in the new or modified requirements promulgated by the EPA in 40 CFR 194 and the related CAG. Five specifically significant regulatory challenges are:

- new QA requirements;
- new requirements for peer review;
- new human intrusion requirements;
- increased calculation requirements; and
- increased documentation requirements.

However, the extremely low probability but high consequences resulting from mandatory figments of human imagination, i.e., inadvertent human intrusions, remain the main regulatory challenge to the scheduled opening of the WIPP. The challenges imposed by the extremely unlikely human intrusion scenarios are heightened by the associated high confidence level required in PA calculations by 40 CFR 194. A 95 percent confidence level in the performance of a natural system over 10,000 years may only be attainable by numerical manipulations.

Constrained by a fixed budget, the only way the CAO can promptly address these broad-ranging administrative, scientific, technical, and financial challenges is to reallocate staff and financial resources. Thus, the CAO has rescheduled previously planned activities and has reallocated staff and financial resources to promptly address the new challenges introduced by 40 CFR 194 and the CAG. For example, about 3 million dollars have been reallocated and some 20 independent experts and two independent contractors have been retained to conduct the peer reviews required under 40 CFR 194.27.

However, major threats to the expeditious opening, and possibly the future, of the WIPP repository may not be those imposed on the CAO but rather actions taken by or against the EPA.

Certain interest groups have already demonstrated a hitherto unsuccessful affinity to sue the EPA over 40 CFR 194. Thus, continued attempts to interfere legally with the certification of the WIPP based on procedural issues are conceivable and anticipated.

Notwithstanding, the CAO is confident that it will continue to be successful in addressing existing challenges to the opening of the WIPP in a timely and scientifically credible manner. Indeed, the CAO must address these and other challenges to the opening and operation of a safe TRUW repository at the WIPP site to the satisfaction of the regulators in order to be able to provide the nation an environmentally safe solution to the disposal of long-lived radioactive waste.

V. CONCLUSIONS

The WIPP repository is on schedule to open in November 1997 and to become a first-of-a-kind facility for safe disposal of TRUW, a long-lived radioactive waste. The CAO's successful strategy to date for the cost-effective and prompt opening of the WIPP repository is based on:

- compliance with all applicable laws and regulations;
- a thorough evaluation of total repository and system performance; and
- maintenance of a productive dialogue with regulators, oversight groups, and stakeholders that enhances CAO decisions.

Remaining challenges to the prompt opening of the WIPP, albeit comprising many unique components, are of global importance. The opening and operation of the WIPP repository will reduce radiation risks to and increase the protection of human health and the environment both now and in the future. Three main reasons for this conclusion are:

1. The certification of the WIPP repository is governed by comprehensive and very strict laws and regulations. Many scientists[6,7] consider the current set of disposal regulations the most stringent set of regulations in the world.

2. Approximately 30 permanent residents live within a ten-mile radius of the WIPP site, where the TRUW will be disposed of about 625 meters below the surface in an essentially impermeable, tectonically and seismically quiescent and stable, 225-250-million-year-old rock salt formation. In contrast, approximately 60 million people reside within 50 miles of the 28 sites where TRUW (and other long-lived radioactive wastes) currently are stored in metal drums, and wooden and metal boxes at surface and near surface facilities such as earth-covered mounds, concrete culverts, trenches, and tents. Over 70 percent of the drums are more than 10 years old and are deteriorating. For example, 20-30 percent of the drums stored in mounds contain pinholes. Moreover, the estimated average cost to the taxpayers to continue to safely store current TRUW over the next 25 years is about 400 million dollars per year.

3. Without a facility for safe disposal of long-lived radioactive wastes, the environmental cleanup of radioactively contaminated sites will be constrained and/or impeded as might the dismantling of nuclear weapons.

In summation, the TRUW disposal problem is an acute societal imperative that must and can be safely resolved at the WIPP site. Thus, opposition to opening the WIPP is neither environmentally responsible nor in the best interest of the welfare of current and future generations.

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Canadian Used Fuel Disposal Concept Review

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Abstract

A federal government environmental assessment review of the disposal concept developed under the Canadian Nuclear Fuel Waste Management Program is currently underway. The Canadian concept is, simply stated, the placement of used fuel(or fuel waste) in long-lived containers at a depth between 500m and 1000m in plutonic rock of the Canadian Shield. Atomic Energy of Canada Limited submitted an Environmental Impact Statement in 1994 and the public hearing aspect of the concept review is in its final phase. A unique aspect of the Canadian situation is that government has stipulated that site selection can not commence until the concept has been approved. Hence, the safety and acceptability of the concept is being reviewed in the context of a generic site. Some comments and lessons learned to date related to the review process are discussed in this paper.

1. PURPOSE

The purpose of this paper is to pass on some comments and lessons learned from the concept approval phase of the Canadian Nuclear Fuel Waste Management Program. Some aspects of the ongoing federal government environmental assessment review of the Canadian concept for used fuel disposal are unique and should be of interest to the broad international community.

2. BACKGROUND

In 1978, the governments of Canada and the province of Ontario established the Nuclear Fuel Waste Management Program to assure the safe and permanent disposal of nuclear fuel waste. Responsibility for research and development on disposal in a deep underground repository in intrusive igneous rock was allocated to Atomic Energy of Canada Limited(AECL). Responsibility for studies on interim storage and transportation of used fuel was allocated to Ontario Hydro. The Ontario government also directed Ontario Hydro to provide technical assistance in its areas of expertise to assist AECL in the research and development on disposal. Pre-closure safety assessment was an important area of assistance.

In 1981, the governments of Canada and Ontario announced that "No disposal site selection will be undertaken until after the concept has been accepted".

The process by which the acceptability of the concept was to be determined was through a federal environmental assessment review, including public hearing. The review panel, consisting of eight members, was established in 1989. Through a public consultative process they established a set of guidelines which the proponent was to meet in preparing the 'safety case', or in Canadian terminology, the Environmental Impact Statement(EIS).

The EIS was submitted by AECL to the government in October 1994 and was subject to extensive review by various government agencies, professional societies, non government agencies and the public over a nine-month period.

The public hearing aspect of the federal review commenced in March 1996 and is composed of three phases. Phase I considered broad societal issues, including, for example, ethical questions related to disposal. Phase II concentrated on technical issues associated with the proposed disposal concept. Phase III, which started on January 13, 1997, involves the Panel traveling to sixteen communities in five provinces to seek public input. Phase III is scheduled to be completed at the end of March 1997. The Panel's recommendations to the government are expected in the summer of 1997 with a subsequent government decision in late 1997 or early 1998.

The management and organization of the Canadian Nuclear Fuel Waste Management Program is currently in transition. In the concept approval process currently underway, AECL continues to be the proponent. Ontario Hydro, which owns 90% of the used nuclear fuel in Canada has, in line with a recently-issued federal government policy, taken over the direction and full funding of the Program, and plans to take the lead in siting if the government decides that disposal should proceed.

3. COMMENTS AND LESSONS LEARNED

A number of comments and lessons learned related to the environmental assessment review process are given below.

- **A comprehensive review of a proposed concept early in a project life-cycle has several benefits.**

The advantages of such a review are that it provides an opportunity for external review and assessment of the safety and acceptability of the proposed concept prior to the commitment of significant expenditures associated with siting; it provides an opportunity for all major stakeholders (including other review agencies and the public) to identify their expectations and concerns in a public forum; and provides a thorough and independent review which is important for the development of sound public policy.

- **The composition of the review panel is an important aspect of the review.**

While many of the issues raised in this review pertain to the methodology associated with the post-closure safety assessment, an equivalent number of issues have been raised pertaining to the social acceptability of deep geological disposal - e.g. social disruption from potential transportation incidents, community conflict that may be raised during a siting process, etc. In this review the eight Panel members represent constituencies from a wide range of Canadian life - including geoscience, biology, sociology, theology, engineering, aboriginal affairs and public policy.. This is an important aspect of the Canadian review process, and critical to the determination of social acceptability.

- **It is difficult to prepare and defend a safety case where there is not a defined site.**

Most environmental impact statements and associated reviews are concerned about site-specific projects or undertakings. In this situation the government has mandated that siting can not occur until the concept has been approved. This has necessitated that several aspects of the assessment be based on generic site characteristics, for example, transportation safety studies and socio-economic impact studies. In the case of geological characteristics, site information consistent with AECL’s Whiteshell Research Area were assumed. Review agencies and the public want specifics and are often not satisfied with generic responses. Even though this is only a concept review the expectation for level of proof is high. In some cases agencies reviewed the safety case as it were the final safety case, with associated expectations. Also, public expectations of what should be included in a conceptual review are more demanding than that which can be offered at a conceptual stage. Lastly, without a defined site, all communities within the Canadian Shield are potential hosts for the repository, hence concern is more widespread than necessary and is not mitigated by a constructive relationship between proponent and community such as might exist with a ’real’ project.

- **It is difficult to maintain a clear understanding amongst reviewers and the public of a broadly-defined concept.**

The Canadian concept is, simply stated, the placement of used fuel(or fuel waste) in long-lived containers at a depth between 500m and 1000m in plutonic rock of the Canadian Shield. Examples have been given of specific designs that could be used to implement the concept, with the safety of these ‘case studies’ assessed. Often in the course of the concept review these design details have been incorrectly assumed to be attributes of the concept itself. This has led to confusion, and opportunities to create confusion, as to what is the subject of the review and what is subject to approval.

- **The review process must encourage public participation.**

In this review the Panel has implemented a number of mechanisms to encourage and solicit public views on the disposal concept. This has included the provision of participant funding (for attendance at hearing, to review and assess the EIS and for the creation of their own submissions); advertising in national, regional and local papers to notify the public about dates, times and locations of the hearings; community sessions in a less formal atmosphere (i.e. where registration and written submissions are not required) and specifically designated sessions in First Nation or aboriginal communities (to be run according to local custom).

4. CONCLUSION

The Canadian program for used fuel management is nearing an important milestone, that of concept approval(or rejection). The process itself of concept review and approval without a proposed site is new to the Canadian regulatory scene and has been a learning process for all concerned. Some comments and lessons learned have been discussed in this paper. The Panel's report, expected this summer, will hopefully provide their perspective on the process followed and will, because of unique aspects of the process, be of broad interest.

Additional Remarks

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Although, the concept of geological disposal and the use of multiple barriers to isolate the waste from the surface environment may be simple making the case for safety of geological disposal is not simple. It is, in fact, inherently complex. This complexity comes about for a number of reasons. The use of multiple barriers introduces a degree of complexity resulting from the need to understand the performance of the different barriers under conditions expected in vault, from the need to understand and model the interactions among the barriers and from the need to communicate and defend this understanding. There are many features, events and processes (FEPs) that are potentially significant. Understanding, characterizing, and modeling the barriers can introduce a substantial degree of complexity, particularly in the case of the geosphere barrier, and requires expertise in large number of disparate scientific and engineering disciplines. The large number of contaminants, radionuclides and chemically toxic contaminants, that are potentially of concern, and differences in interactions between the different contaminants and the barriers introduces a further degree of complexity. The long time frames over which analyses need to be carried out also contributes a degree of complexity and difficulty in making the case for safety. Finally there are many potential questions that reviewers and intervenors can pose and dealing with all these question can add complexity simply because of the shear amount of information that must be considered. Thus developing and presenting safety cases to demonstrate compliance with quantitative dose or risk constraints is inherently complex.

The use of general principles and generalized arguments and descriptions of the performance of a geological disposal facility system can be helpful and indeed such arguments are important and form a necessary part of communicating the safety case - to both technical and non technical audiences. But such generalized arguments have a limited value when considering the specifics of a particular safety case.

Specific safety cases, that seek to show compliance with dose or risk or concentration limits, require, for a given design of disposal facility and for a given set of geological conditions, detailed argumentation and modeling that are specific to the case in hand and to the specific issues that arise from the given situation. Indeed it can be argued that compliance with quantitative limits cannot be demonstrated without defining the specifics of the disposal system - the container material and design, the vault design, the geochemistry, specifics of the geosphere etc. Thus quantitative safety analyses are site specific and design specific.

Further, uncertainty is inherent to estimating the long term performance of geological disposal systems. Coping with this uncertainty and estimating its importance, in a given set of circumstances also adds complexity.

Because of:

- the number of questions that can be posed, the number of contaminants of potential concern,
- the number of FEPs of interest,
- the need to demonstrate an acceptable degree of understanding of the behaviour of each of the individual barriers of the multi-barrier system, their interactions, and of the evolution of the system with time, and,
- the need to deal with uncertainty, to define uncertainties and to determine the importance of uncertainty

the documentation associated with a safety case is extensive.

Thus preparing the safety case, on the one hand, and reading and understanding the documentation, on the other hand, represents a real challenge to proponents and to regulators and other reviewers. If this challenge is to be met successfully, dialogue among all interested parties but particularly between the proponent of the safety case and the regulator is critical.

Thus regulatory expectations need to be defined as precisely as possible but given the issue involved and the fact that no country has yet licensed a geological disposal facility for long-lived radioactive wastes, it must be recognized that presenting, reviewing and refining a safety case will necessarily involve iteration. Such iteration will be required to clarify regulatory expectations in the light of information presented to regulators, and to clarify explanations and argumentation presented by proponents to respond to regulatory comments and concerns. In this process proponents need to be prepared to adapt their safety cases to deal with new issues that arise from regulatory review and regulators need to be able to adjust their expectations in the light of what can be achieved in practice. Again dialogue is critical.

Finally, it is important for regulators and decision makers to take account of the incremental process that is expected to be followed in developing disposal technology, characterizing prospective sites, first using surface based techniques and then on the basis of exploratory excavations, designing and constructing a disposal facility , commissioning and then operating a given facility and eventually decommissioning and then closing the facility (see figure 1). At specific points in this process regulatory decisions will be required, e.g. to undertake an exploratory excavation, to begin construction of a facility, to initiate operations, to begin decommissioning and eventually to close the facility and place it is a passively safe state. The nature of the safety case that will form the basis for regulatory decision making can be expected to evolve throughout this process as additional information becomes available as the project proceeds. At this point in time when many countries are near the beginning of this process or are moving to siting, considerable benefit can be obtained from carrying out preliminary licensing discussions, possibly including mock licensing exercises.

Figure 1

The Stages in Implementing Geological Disposal of Nuclear Fuel Waste

- Concept and Technology Development
- Site Screening/Characterization
- Exploratory Excavation
- Construction
- Initial Operation
- Continued Operation
- on-going monitoring, review and assessment
- End of Operation
- Decommissioning
- Closure

Key Points for Safety Assessment of a Deep Disposal Facility in France: Operator Standpoint

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1. INTRODUCTION

The act of December 30th 1991 gives to ANDRA the responsibility to conduct research in at least two underground laboratories located at selected sites in order to qualify the geological disposal option for high level and long lived nuclear wastes.

The final objective of this program is to produce in 2006 a report including a safety case and the description of draft disposal concepts for the different investigated sites.

The mediation action performed in 1993 resulted in the choice of three sites.
Two of these sites are located in sedimentary argillaceous formations :

- In the Eastern part of the Parisian Basin (Meuse-Haute Marne)
- In the South-East French sedimentary basin (Gard)

The third one concerns a granitic formation under sedimentary cover in the South-West region of "Seuil du Poitou" (Vienne).

This paper presents important issues for safety assessments identified from preliminary assessments performed on each of the three sites. These assessments are included in the applications for implementing and operating the underground laboratories to be built from 1998 (DAIE).

2. REGULATORY FRAMEWORK

The act of 1991 voted by the French Parliament and the Basic Safety Rule RFS III.2.f issued by the Ministry of Industry in June 1991 set the general regulatory framework for studies relative to geological disposal.

The act of 1991 specifies that the retrievability of the waste packages should be studied.
It stresses that the decision on the deep disposal option will only be taken in 2006 and should be voted by the parliament.

The RFS III.2.f gives the general guidelines for deep disposal licensing :

- Safety standards,
- Methodology for safety assessment including,
  scenario development, treatment of uncertainties and consideration on biosphere and future human actions,
- Conceptual basis associated to safety.

These different elements will be discussed in this paper.

3. SAFETY STANDARDS

The approach currently developed in France for assessing the safety of nuclear waste disposals is deterministic.

It relies on the definition of a Normal Evolution Scenario (NES) which takes into account every events and processes which are almost certain to occur.
Altered Event Scenarios (AES) are considered as well. They are linked to the occurrence of random events or low probability events.
Associated to the NES the criteria is a dose limit which should not exceed one fourth of a mSv/year.

This value corresponds to a fraction of the limit of exposure of the public in a normal situation, in accordance with the possibility of exposure from several sources.
A risk limit may be considered for low probability scenarios.

Main issues relative to this topic concern:

3.1 SCENARIO PROBABILITIES

Some probabilities are difficult to assess since they consider human activities in the long term.
It is thus advisable, for each type of scenario, to distinguish between dose criteria and probability criteria without calculating a global risk.
A difficult issue associated to the evaluation of probabilities of events interfering with a deep disposal is related to the time scale involved.
Perpetuation of consequences of a particular event in the very long term implies that the probability per year concept shown in the ICRP 46 criterion curve is not always adequate and should be replaced for some events by cumulative probabilities over time.

3.2 TIME CUT-OFF TO CONSIDER FOR THE ASSESSMENTS

Since uncertainties increase with time, it may be difficult, on the long term (after 10000 years), to make convincing evaluation of doses.

The US National Academy of Science suggests, for instance, to restrict the compliance period for Yucca Mountain to 1 million years based on the period of geological stability of the site.

Qualitative or quantitative arguments based on an analysis of different safety indicators such as activity release rates, radionuclide concentrations in waters or residual activity in the waste as compared to natural background activities may be envisaged.
After 1 million years the IAEA states that little credibility can be attached to quantitative or even qualitative assessments |1].

The French position is to consider no time cut-off in the assessments since maximum release rates for some long lived radionuclides may be well beyond 1 million years. However evolution of some parts of the system such as the geosphere will be somehow stylized in these long time frames.

3.3 INDIVIDUAL DOSES TO THE CRITICAL GROUP VERSUS COLLECTIVE DOSES

The ICRP recommends to consider individual dose limits to the critical group for postclosure safety assessments of deep disposals. For workers, during the operational phase of the repository, collective doses may be applied for optimization. The benefits to deal with collective doses for the postclosure phase may be however questionable considering the time periods and the difficulty to make predictions on the size and distribution of populations in the future. Nevertheless some disposal options may be compared on the basis of collective doses using conventional assumptions.

3.4 WHAT IS THE MEANING OF PROTECTING THE ENVIRONMENT ?

If quantitative answers should be given to develop this point it may be necessary to set criteria. Another solution would be to develop arguments justifying, for instance, that protection of human health protects at the same time the environment.

3.5 ARE CRITERIA FOR SUBSYSTEMS USEFUL ?

These criteria are developed in the US regulation.
They concern different critical parts of the repository such as: periods for total containment by the artificial barriers, minimum water transit times and maximum activity release to the accessible environment on a given period.

They are very constraining and prevent optimization; they, however, facilitate demonstration and could help public acceptance. The RFS III.2.f states that objectives for barrier performances should be the results of an iterative process. Nevertheless waste package specification should be elaborated early in the program.

4. SCENARIOS

The procedure now implemented in most countries to approach exhaustivity and traceability of decisions in scenario construction goes through the screening of FEPs lists established at the international level.
It should be noticed that selecting FEPs is a small part of the activity behind defining scenarios where choice of conceptual models, determination of the transfer pathways and identification of the dominant mechanisms represent most of the work and the major sources of uncertainties.

Moreover, in some countries, the scenarios to consider are specified by the safety authority which is helpful for the applicant and simplify licensing.

In France, these scenarios listed in the RFS III.2.f. will be complemented by specific scenarios for the sites ensuing from the mediation (i.e. Messinian scenario) or resulting from the new regulatory context (abandoned repository).

4.1 EXTREME SCENARIOS IN THE VERY FAR FUTURES

Stable geosphere conditions in the future is a prerequisite for site selection.
However, quantitative evaluation of consequences of low probability extreme scenarios in the far future (after 1 million years) corresponding for instance to uncovering of the repository could be helpful to appreciate the risk and determine if these situations are acceptable or not, for populations at that time. An example of such conditions is considered at Gorleben in the framework of the subrosion scenario.

These kinds of situations could be stylized and a common approach between countries envisaged. Conclusions on this type of analysis may have some implications on the repository concept and waste package specifications.

5. UNCERTAINTIES

The quantification of uncertainties in deterministic assessments is a difficult task since combining pessimistic values for parameters may lead to unrealistic consequences.
This could indicate that even without considering full probabilistic assessments, stochastic treatment of uncertainties may provide useful information if the result is expressed in terms of confidence bounds.
In more general terms, and pointing out that not all sources of uncertainties may lead to quantification, it should be useful to know if acceptability criteria may be defined in this matter.

6. BIOSPHERE

The compatibility between conventional aspects in the description of future biospheres and consideration of biosphere evolution associated with climatic variations should be examined.

Important issues in defining scenarios correspond to the assumptions related to the choice of the main water supplies for the needs of the critical group.

Several questions are pending due to the rapid evolution in the present utilization of aquifers on real sites:

If an aquifer is currently exploited for water resources, how to consider the evolution of this exploitation in the very far future? Should this exploitation be considered as a permanent occupation on the site or temporary occupation? How should be chosen the locations of wells for assessments: present locations or pessimistic locations ?
What is the logic behind the elimination of potential sources of release depending on the available quantity of water for the critical group?

These choices which may lead to orders magnitude differences in consequences and were not really considered in projects like BIOMOVS should be discussed at the international level.

7. FUTURE HUMAN ACTIONS

The RFS recommends to consider the corresponding intrusion scenarios only after loss of memory of the repository which is supposed to occur after 500 years. Some key points may be underlined.

One important aspect in this matter is the assumption on the technological level of future populations.
If this level is the same as today, detection and knowledge of the effects of radioactivity may be accounted for. This would eliminate most human intrusion scenarios.

It is usually considered that only inadvertent human intrusions should be considered and that voluntary human actions should be discarded.
In that case should archaeology be considered ?
Selection of particular types of scenarios like sabotage or assumptions on variation of economic situations have large implications on the level of robustness for the concept during the operational period, taking into account the waste retrievability option.

Specific human intrusion scenarios common to all deep disposals sites as, for example, the examination of cuttings after exploratory drilling, should be eliminated on the basis of their probabilities or treated in a stylized way ? Arguments given at the international level may be useful.

8. CONCEPT DESIGN

Concept optimization as recommended by the ICRP should be based on the application of the ALARA principle. Interpretations vary between countries, however the identification of some common backgrounds at the international level may be beneficial.

In this respect, what should be the relative weight to give to short term or long term consequences?
This point concerns long lived radionuclides.
If short term consequences are to be put forward, this implies that waste concentration in limited volumes and confinement should be maintained as long as possible even when uncertainties about the geosphere increase.
If long term consequences are the main concern, this puts the emphasis on dilution and dispersion in the geosphere and may lead to favour controlled release in the medium term.

Optimization of repository concepts (concentrate or dilute), but also waste package specifications and future of research on separation of long lived radionuclides may depend on decisions in that matter.

Optimization means thus delays or evolution of specifications for the artificial barriers and in particular, for the waste packages. Is this acceptable when they are already being produced?

The multibarrier concept is recommended at the international level, however the role of barriers and levels of redundancy depend very much on the site or type of host rock formation.
It may be useful to give more precise recommendations about this concept and common approaches put forward?

9. RETRIEVABILITY AND SAFETY

The AIEA recommends not to leave undue burdens to future generations associated to waste management.
This has some implications on the retrievability period which should remain limited. Safety authorities should provide indications on this particular point.

The situation of the repository during a retrievability period of a long duration has some impacts on safety that should be dealt with, considering specific scenarios. One of them could be the abandonment of the repository without closing.

10. CONCLUSION

Different countries have different experiences about safety assessment which are discussed at the international level in forums like OECD/NEA/PAAG. This allows to identify some important aspects and constitutes first returns of experience from application of international recommendations and national regulations. On this basis some indications on directions to follow for complementing present regulations can be identified.

11. REFERENCE

[1] Safety indicators in different time frames for the safety assessment of underground radioactive waste repositories. IAEA-TECDOC-767. October 1994

Lessons Learnt From Spanish Experience In High Level Waste Disposal

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ABSTRACT

This paper summarises the main lessons learnt from the ENRESA's existing experience in the disposal of high level waste and describes the progress made over the last 10 years towards the development of a deep geological repository.

The spanish high level waste management policy is presented as well as major past achievements and future objectives in the high level waste programme.

Past interactions with regulatory authorities is briefly described and key issues encountered in interpreting the regulations and preparing the safety case are discussed.

The most relevant conclusion is the need for a gradual and systematic process of interaction between the regulators and the implementers in order to build a common understanding of repository performance, interpret the regulatory criteria and achieve the necessary convergence at the early stages of the licensing process. International cooperation is also proposed to analyse and discuss regulatory issues, as well as increasing the understanding of regulatory criteria and compliance requierements.

A. BACKGROUND

HIGH LEVEL WASTE MANAGEMENT POLICY

The Spanish policy for management of spent fuel and high level waste (HLW), stated in the General Radioactive Waste Plan, foresees direct disposal in deep geological formations after an adequate period of interim storage firstly at the NPP site and later in centralized interim storage facility. A siting programme has been underway since 1987. The siting programme includes studies in rock salt, granite and clay, formations which are considered most promising as host rocks for a final repository.

The general strategy for HLW management in Spain is under review by the Ministry of Industry and Energy, taking into account the difficulties encountered in the site selection process, the socio-political and public acceptance aspects and the evolution and trends in other countries.

As a result of this review, a delay of about the years is envisaged in the high-level waste program, being the year 2010 the expected date for the designation of candidate sites and the year 2035 the expected date when the deep geological repository will become operational.

HIGH LEVEL WASTE PROGRAM

- Interim storage of spent fuel:

The spent fuel storage capacity of the pools at the nuclear power plants is being increased by reracking.

A storage and transport license was obtained in the US (NRC) for a metallic spent fuel cask to be used at the nuclear power plants or at a centralized storage facility. Licensing of this cask before the Spanish regulatory authorities was completed in 1996.

A centralized interim storage facility is envisaged for the year 2013, considering a 40 year service lifetime of the nuclear power plants.

- Final disposal of spent fuel:

Regarding final disposal of spent fuel, a deep geological repository is considered the most suitable option. The basic strategy comprises three major areas of activity:

◊ **Identification of suitable sites.**

Major past achievements include the compilation of a great amount of geological data and the confirmation of the existence of a great number of favourable areas for geological disposal.

Work continues on the study of favourable zones, with the objetive of identifying 15 to 20 suitable zones for the year 2000.

The Government plants to set-up a law to regulate the siting process and establish the participation of local/regional institutions and the public as well as defining the compensations for nearby municipalities.

The designation of candidates sites is now foreseen for the year 2010.

◊ **Deep Geological Repository.**

Conceptual designs have been developed for the three host rock options (granite, clay and salt) currently being considered. A preliminary integrated performance assessment of a repository in granite was completed at the end of 1996.

Future activities will be devoted to the development of the methodologies and tools required for the long-term safety assessment of repositories in granite, clay and salt. These activities will play an important role in the HLW program, integrating site, repository design and R+D data and providing guidelines for future R+D plans. Safety assessments for repositories in granite and clay are scheduled for the year 2000.

◊ **R&D Plan.**

The R&D data provides the necessary scientific and technical support to the siting and the deep repository activities.

Work on the 3rd R&D Plan (1995-1999) continues with the following objectives:

- Verification of the instrumental and numerical methodologies developed for the characterization of sites and geological barriers.

- Verification of the feasibility and performance of the engineered barriers at full scale and under real conditions of temperature and depth.

- Acquisition of basic data of the most relevant processes of the different repository subsystems.

Major on-going R&D projects are the following:

- Full-scale heating test of engineered barriers in granite (FEBEX), being developed in collaboration with NAGRA, ANDRA, GRS and other Spanish and French organizations. On-site installation started in July 1996 and was successfully completed by the end of 1996. The actual heating phase is scheduled to start at the beginning of 1997.

- A large scale in-situ demonstrationg test for repository sealing in argillaceous host rock (RESEAL), developd in collaboration with ANDRA and SCK/CEN and started in early 1996.

- Source Term for Performance Assessment of Spent Fuel as a Waste Form, developed in collaboration with FZK, FUB, CEA, SCK/CEN, STUDVISK, VTT and JRC, and started in early 1996.

- Corrosion Evaluation of Metallic Materials for Disposal Canisters, developed in collaboration with FZK, FUBE and SCK/CEN and started at the beginning of 1996.

- A Natural Analogues Program, covering aspects related to the near field and far field, started in mid 1996 and will continue until 1999.

- Characterization of argillaceous formations (Mt. Terri Project).

INTERACTION WITH REGULATORY AUTHORITIES

The interaction between the implementing agency and the regulators has been very extensive in areas such as:

- Low Level Waste Disposal: Cabril Facility.

- Decommissioning of facilities: Andújar milling plant, Vandellos NPP.

- Interim storage of HLW: Dual purpose container (DPT).

For the final disposal of HLW, this interaction has been limited to the development of common R+D projects, information exchange and common participation in CEC exercices such as those related to building a safety case for hypothetical underground repositories in clay and cristalline rock. However, the Nuclear Safety Council and ENRESA have initiated a number of contacts and meetings in order to establish a closer dialogue and interaction process regarding R+D plans and HLW disposal.

B. INTERPRETING THE REGULATIONS.

In Spain, there is no specific legislation for the development of radioactive waste disposal facilities. At present, the licensing process of such facilities is conducted on the basis of the legal framework existing in the field of nuclear and radioactive installations.

Regarding the HLW management, two specific regulations have been set up by the Nuclear Safety Council.

- The general siting criteria for the geological disposal of radioactive waste (1985), which provides qualitative criteria for the site selection of a deep repository.

- The radiological acceptance criteria for radioactive waste disposal facilities (1987), which provides a quantitative criteria for long-term radiaction protection. The risk limit is established as 10^{-6} per year or the risk associated to an equivalent yearly dose of 0,1 mSv to the most exposed individual in the critical group.

The regulation of the long-term safety of HLW disposal is a major challenge which presents new or unusual features of repository safety analyses which lead to significant discussion. These features are:

- The long time scales which must be taken into consideration in the analyses.

- The prominent role of the geological medium and the large spatial scale involved in the evaluation of the performance.

- The uncertanties associated to the time scale and the spatial scale.

As a result of these specific aspects, the key problems encountered in interpreting and applying the regulations are:

- The specification of cut-off times for the safety assessments, taking into account that the level of confidence for some predictions might decrease with time.

- The type of assessment and the role of safety indicators in the different time frames of the analysis. Cut-off times may rather be viewed as transition points for the method and detail of the assessment, with a gradual shift from quantitative to qualitative evaluations.

- The definition of credible scenarios which scope the range of potential future behaviours of the repository system, and the evaluation of the probabilities associated to their ocurrence.

- The treatment of uncertainties in scenarios, conceptual models and parameters and the approaches to achieve a reasonable level of confidence in the performance predictions and the compliance with the regulations. The understanding of the effects of uncertainties in our current models and data should contribute to provide a reasonable assurance that these current approaches will not underpredict potential releases from the repository.

C. PREPARING THE SAFETY CASE

The preparation of a safety case for a deep geological repository is a major undertaking presenting three specific features:

- The diversity of the technical and scientific disciplines which are involved

- The complexity of their integration in the safety assessment

- The need for a continuous and iterative process of evaluation and research and development to achieve a reasonable level of confidence in the predictions.

In the spanish experience, iterative safety assessments are performed to provide quantitative indications of the actual evolution of the repository system as well as to provide input for site selection, to guide R&D work and to optimise and compare conceptual facility designs.

Major problems encountered in the preparation of the safety case were the following:

- The development of a systematic and comprehensive approach for the treatment of FEP's and the definition of scenarios, which ensure completeness and transparency for subsequent expert review and updating.
- The treatment of human intrusion scenarios and the approach for incorporating these scenarios into a compliance assessment.
- The modelling of the interfaces and interactions between engineered and geological barriers, incorporating aspects such as gas generation and migration, corrosion products, near-field chemistry, excavation disturbed zone.
- The long-term stability and durability of the engineered barriers and the consequences on the future evolution of the system.
- The treatment of the spatial variability in the geosphere to allow sufficiently realistic predictive modelling over the timescales considered.
- The evaluation of the long-term stability of the geological barriers and its implications on the future performance of the repository.
- The treatment of uncertainties in site characterization and flow and transport modelling, either by probabilistic modelling, bounding estimates or alternative conceptual models, in order to increase the confidence in the assessment calculations.
- The coordination and consistency between the site characterization strategy and the geosphere performance modelling, making allowances for the uncertainties associated to the proposed site reconaissance scheme.
- The definition of critical groups in the biosphere, possibly using a reference approach or stylised presentations, to avoid speculation about future human behaviour.
- The modelling of the geosphere-biosphere interface and its implications on dilution factors and doses to man.
- The definition of future biosphere features and transport properties, possibly using a standarised approach.

D. CONCLUSIONS

Based on the preceding discussions, the following conclusions can be drawn:

- Major challenges are present in both regulating and demonstrating compliance with regulations in the disposal of high level waste. These challenges are strongly related to the safety assessment methodology and the measures for building confidence in the predictions.

- A gradual and systematic process of interaction between the regulatory authorities and implementing agencies must be established in order to:

  a) Promote dialogue and technical exchange to build a common understanding of the repository performance.

  b) Interpret the regulatory criteria and apply them to the safety case

  c) Gain experience in making decisions under the presence of uncertainties

  d) Achieve the necessary convergence at earlier stages to facilitate the future licensing process

- International cooperation should be promoted to analyse and discuss regulatory issues, including understanding of regulatory criteria and demonstration of compliance.

Making a Case for the Long-Term Safety of Radioactive Waste Disposal

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Abstract

The paper presents the lessons learned and problems identified in making a case for the long-term safety of the deep geological disposal of the United Kingdom's inventory of intermediate-level and certain low-level radioactive wastes.

1. Introduction

United Kingdom Nirex Limited (Nirex) is responsible for researching, developing and operating a deep geological disposal facility for the United Kingdom's inventory of intermediate-level and certain low-level radioactive wastes. This responsibility is discharged on behalf of the waste producers - in accordance with "the polluter pays" principle - and in compliance with Government policy. Much of the inventory of intermediate-level waste is produced as a consequence of the reprocessing of spent nuclear fuel and therefore contains significant quantities of long-lived radionuclides. Following a site selection exercise, Nirex carried out preliminary investigations at sites near Dounreay in the north of Scotland and Sellafield in the north-west of England between 1989 and 1991. In 1991, Sellafield was chosen as the focus of further investigations. Whilst both sites appeared geologically suitable, the transport of radioactive wastes would be much reduced for a repository at Sellafield with approximately 60% of the wastes being produced at the nearby Sellafield Works operated by British Nuclear Fuels plc. With the Sellafield site continuing to show good promise, it was decided that a more-detailed, in situ investigation of the geology and hydrogeology was required to inform a decision whether to apply to develop a repository. A public inquiry was held between September 1995 and February 1996 into the proposal by Nirex to develop the Rock Characterisation Facility (underground laboratory) to obtain the required information. A decision on the outcome is awaited.

The lessons learned and problems identified in making a case for the long-term safety of the deep geological disposal of the wastes during this process are summarised briefly.

2. Risk

As noted in the paper presented at this Workshop by Allan Duncan (Environment Agency) [1] UK Government policy [2]is that a risk target should be used as an objective in the design process. Risk is defined as the product of the probability that a radiological dose will be received and the probability that that dose will cause fatal cancer or a serious hereditary defect. In line with the IAEA-INWAC Sub-Group [3] Nirex believes that this is a highly appropriate quantitative indicator of long-term safety that allows many of the relevant uncertainties to be taken into account. Unfortunately, the concept of risk is not well understood, as revealed by reporting in the media of a whole range of socio-economic issues, and, in the absence of authoritative information, risk has not been applied in an obvious way to other areas of pollution control. So even though Government policy makes it clear that other technical factors, including ones of a more qualitative nature, will also need to be considered in arriving at the decision (whether the disposal facility is safe), there is a difficulty in presenting risk assessments as a means of quantifying uncertainty. The criticisms can be summarised as a failure to distinguish between a traditional "treatment of errors", which can and should be addressed in the quantification of risk, and the concept of conditional risk, where a clear statement of assumptions must be made in support of its quantification.

3. Critical Groups or Potentially Exposed Groups

The risk target addressed in the section above is expressed in terms of the annual risk to an average member of "the critical group". The calculated risk is quite sensitive to the definition of the critical group. The presentation of a range of results corresponding to a range of defining assumptions might overcome that difficulty. However, experience at the RCF Public Inquiry indicates that the focus of many interested parties would be upon the maximum risk that could be calculated. Whereas it is superficially attractive to respond by placing probabilities on the conditions defining the critical group, this would imply an artificial precision in predictions of future human behaviour, thereby undermining the credibility of the safety case. The guidance available [4] is that the developer should justify the choice of "critical group". Given the above considerations, this demands the use of reasoned arguments and the establishment of a soundly-based relationship with the regulatory body such that these arguments can be explored.

4. Timescale for Assessments

An effective multi-barrier containment system will delay any return of significant quantities of radionuclides from the repository to the human environment to long times after closure of the repository. The uncertainty in the evolution of the repository system inevitably increases at longer times in the future such that, perversely, the better the containment system the more uncertain the developer becomes concerning the quantification of risks. UK Government policy includes statements by the National Radiological Protection Board [5] that a one million year time-frame is considered to be highly questionable and assessments beyond times of, at most, a few million years should concentrate on qualitative discussions.

In the longest timescales, the undecayed inventory of radionuclides in the repository would be dominated by uranium-238, with a half life of 4.5×10^9 years. Since it is unreasonable to propose any engineered containment system that will operate over such timescales it is inevitable that much of the inventory will be released eventually and that calculated risks will be found to increase as the time-frame for the assessment is extended up to and beyond one million years. It is then presentationally difficult to cut off quantitative calculations because the impression is given that the maximum risk from the repository has been excluded from the assessment. More generally, the presentation of results in different time frames, corresponding to different levels of uncertainty, requires more consideration that it currently receives. Other performance indicators are available that may be more appropriate for considering the risks from long-lived radionuclides, such as comparison with concentrations of naturally-occurring radionuclides at the site of interest. Efforts are being made in the Nirex programme to explore the use of such indicators without the need to resort to the same level of sophistication in calculations as in quantification of risk, implying an unrealistic level of certainty.

5. Use of PSA

As noted in the paper presented by Allan Duncan [1] there is an expectation that probabilistic safety assessments will be conducted. Nirex believes that this is entirely appropriate given the need to address uncertainty in an explicit manner in the calculation of risk, against the design target set by Government policy. However, the development of robust probability density functions - often using formal data elicitation procedures - that ensure the realisation of the full range of uncertainties is not well-understood. Far from building confidence that uncertainty is being addressed in an appropriate manner, the assignment of a range of values to a parameter such as sorption of a radionuclide on a rock is seen as reflecting incompetence or worse. This view is especially true of experimental scientists, who would prefer a single value to be given to each parameter - possibly with an "error band" to reflect experimental error. Such conflict is particularly important if one accepts that statistical (stochastic) modelling is essential to represent the heterogeneous geological media of relevance to most potential repository sites.

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BUILDING THE SAFETY CASE FOR A HYPOTHETICAL UNDERGROUND REPOSITORY IN CLAY

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1. INTRODUCTION

In order to obtain experience on the process of preparing the license application for an underground repository and its evaluation at the European level, the European Commission has launched the project *"Building the safety case for a hypothetical underground repository in clay"*.

The study contract (ETNU-CT93-0102) was signed on 31 December 1993 by the European Commission and by ONDRAF/NIRAS who acted as main contractor. Four other radioactive waste management agencies from EU countries were associated to the contract: DBE (Germany), ANDRA (France), COVRA (Netherlands) and ENRESA (Spain). The safety authorities of four of the countries involved (Belgium, Germany, Netherlands and Spain) also had the status of associated contractors(1).

This study was intended as a desk simulation of the process of preparing a license application for a deep geological disposal of high-level waste and spent fuel in clay. It included also discussions with the safety authorities of the countries involved in the study, aiming at a final safety report that is acceptable for the agencies/applicants and the safety authorities.

Given the limited time and resources available, the safety file could be drafted only at a conceptual level, on the basis of a table of contents that was agreed upon by the agencies and the safety authorities, and addressing all items that are relevant for safety and licensing. It was also not possible to completely revise the draft safety file, to incorporate all the comments made by the safety authorities. The safety file has been drafted taking due account of available information from existing studies, in particular from the operation of the underground laboratory in Mol (HADES project).

A discussion of the impact of retrievability was added as an annex to the safety file, keeping in mind that a retrievable option must not have a negative impact on the safety of the repository.

During the course of the study, several issues were identified that are of major relevance for licensing. They are dealt with in section 3.

(1) A similar project has been launched for a repository in crystalline rock, involving the same radioactive waste management agencies and safety authorities, DBE acting as main contractor. [2]

2. TABLE OF CONTENTS OF THE SAFETY FILE

The radioactive waste management agencies and the competent authorities involved have reached agreement on the following table of contents of the safety file:

1. General Information
2. Waste Description
3. Site Characteristics
4. Disposal Facility Design
5. Repository Construction
6. Repository Operation
7. Quality Assurance
8. Operational Safety
9. Repository Closure and Post-closure Monitoring
10. Organization and Financial Aspects

The detailed table of contents is appended to this paper.

It must be kept in mind that, given the limited time and resources available, the safety file could be drafted only at a conceptual level, although addressing all items that are relevant for safety and licensing.

It was also not possible to completely revise the draft safety file, to incorporate all the comments made by the safety authorities.

The parties involved also agreed to add a discussion on the impact of retrievability as an annex to the safety file. The contents of this annex is also appended to this paper.

3. FUNDAMENTAL ISSUES

This section summarises the results of the final discussions between the radioactive waste management agencies and the safety authorities with respect to the fundamental issues that were recognized.

The definition of **dose constraints** was such an issue whose application has been recommended by the IAEA as an important concept to improve radiological protection during the operational as well as the post-operational period. This concept has been accepted as a very useful concept by all parties involved in the desk study. It must be remembered that dose constraints are source related and are a fraction of the dose limits. The setting of dose constraints is within the competence of the national authorities.

Long-term dose and risk limits/constraints are closely related to each other in the ICRP recommendations. In Germany, no risk limits have been defined by the safety authorities, but on the other hand, risk has been considered in probabilistic investigations, e.g. for the plan document of the proposed Konrad repository. In France also, no risk limit/constraint is defined. In Belgium and in Spain, the risk criterion is an important aspect of the safety assessment.

Another important issue is the definition of **cut-off times** for quantitative long-term safety assessments. All participants agreed that the uncertainties of calculations for long-term safety assessments continuously increase with the period considered and therefore reliability decreases. But some doubts arise whether it is useful to specify a cut-off time as a fixed limit.

In France, a cut-off time of 10,000 years has been defined for quantitative safety calculations. The same cut-off time has been recommended by the IAEA and was also encouraged by the German Reactor Safety Commission but has not yet a legal status. For the Konrad site, safety calculations have been performed for a longer period to include the maximum release of radionuclides at 300,000 years. For some Belgian studies, calculations have been extended even to longer periods (1,000,000 years).

The consideration of a cut-off time of 10,000 years can be justified by a significant decrease of radioactivity up to this date. But this decrease is no abrupt event and therefore the participants discussed other convenient criteria to define cut-off times. The discussion indicated that it is not useful to specify a global cut-off time, but it would be more convincing to define a range of cut-off times which can be applied referring to characteristics of the site, the emplacement strategy and waste properties. Furthermore, criteria should be adapted to the different post-closure periods of the repository and consider the different uncertainties for the different periods.

From the Dutch side, a proposal has been made to use the hazards of natural uranium deposits as a criterion for the definition of some kind of cut-off time. But apart from the advantage of natural analogues to give the chance to study the long-term development of uranium deposits as well as the consequences in the surrounding areas, a weak point arises from the fact that natural analogues do never totally reflect the conditions in a final underground repository for radioactive waste. So the physico-chemical properties of natural uranium minerals as well as their radionuclide inventory are significantly different from those of spent fuel or high level waste. Further distinctions result from the different site specific former and actual geological conditions. Therefore natural analogues can only be used as indicators for long-term safety together with others. A general problem for all long-term predictions is the fact that the future development of the biosphere and of the human living conditions can be hardly foreseen.

In conclusion, all participants agreed that in the field of long-term safety assessments and cut-off times, there is still a lack in the definition and verification of long-term safety indicators and criteria which should be closed by further R&D work.

Human intrusion scenarios are special issues of the long-term safety assessment which have been discussed and analyzed within the framework of a NEA workshop in 1989(2). A fundamental point for the evaluation of the probability of human intrusion scenarios is the estimation of hypothetical intentions and objectives of such actions. For granite host rocks, the absence of any resources which may be of economic value is proposed as an important criterion for site selection and a measure to minimize the possibility of future human intrusion scenarios. In the regulatory framework of most European countries, no special requirements have been defined to avoid human intrusion, but e.g. in France, human intrusion is considered to be very unlikely during a period of 500 years after repository closure, which implies that the minimum date to be retained for a human intrusion scenario is 500 years after closure. The licensee should verify that the likelihood of such scenario has been minimized. For the proposed Konrad repository in Germany, the safety authorities also requested to prove that human intrusion at the site was very unlikely.

Site selection is a basic issue for repository safety but up to now binding legal requirements for site selection have been implemented only in France. For most other countries the authorities have issued only

(2) "Risks associated with human intrusion at radioactive waste disposal site", Proceedings of an NEA Workshop, Paris, 1989 (NEA, 1990). See also "Future human actions at disposal sites" (NEA, 1995).

recommendations and therefore site selection is an issue of the agencies which are responsible for the final disposal of radioactive waste. Nevertheless, there will be a continuous dialogue and discussion between the agencies and the safety authorities during the site selection procedure to identify a suitable site that complies with the safety requirements and would be acceptable for both parties.

Fundamental issues for repository operation are the **waste acceptance criteria and procedures**. In Germany, requirements for waste acceptance have been defined for the operating Morsleben repository as well as for the proposed Konrad repository, but all these waste acceptance criteria are provisional. For the Spanish El Cabril repository for low level waste, acceptance criteria were defined before the start of the operation and they have been revised in order to incorporate the experience gained during the operational period.

An important aspect with respect to waste acceptance is the clear definition of the responsibilities of the waste producer and the operator of the repository. These responsibilities enclose the assurance by the producer of the compliance with the waste acceptance criteria. For the case that received waste packages do not comply with the waste acceptance criteria, procedures must be defined by the safety authorities. Depending on the failures found, it should be decided whether reconditioning of the package is necessary. It might be necessary -if no such installation is available at the repository - to ship the package to an external reconditioning facility. For this shipment a new license would be necessary. All participants, including the safety authorities, agree in principle that such shipments should be avoided by appropriate quality assurance provisions at the producers/conditioners site and by some flexibility of the waste acceptance criteria, as long as this is compatible with the long-term safety assessment. The possibility to perform (basic) reconditioning at the repository site might be foreseen. It also seems useful to adapt the waste acceptance criteria continuously to the actual state of conditioning techniques during the lifetime of the repository.

Discussion of repository operation has shown that **radiological constraints** must be defined for normal and faulty conditions such as it has already been done in Germany and Spain(3). Such constraints are very similar or even identical with those defined for nuclear power plants. The compliance of the repository with the safety requirements for the operational period as well as for the post-closure period will be confirmed by an overall monitoring programme which supervises all safety relevant radiological and non-radiological aspects.

The scope and duration of this **monitoring programme** was also an issue for discussion. The safety authorities mainly see it as a measure to verify and justify assumptions made for the long-term safety assessment and therefore as an important element in confidence building. The agencies principally agreed to this point of view, but they indicated some limitations which must be kept to avoid any injury of repository operation and of safety relevant items. So any perforation of the engineered and natural barriers by monitoring installations should be avoided in order not to create pathways for radionuclide migration. Therefore monitoring of the emplacement areas must be non-destructive. Furthermore, there were some reservations of the agencies with respect to the possible goal of some kind of monitoring, since many safety relevant parameters can not be measured due to their slow development. But it is obvious that if any deviations of measured data from the assumptions defined for the safety calculations are observed, the safety assessment shall be repeated.

All participants agreed that further development of international guidance is necessary with respect to the objectives, scope and duration of post-closure monitoring.

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(3) Only for the liquid and gaseous releases of the El Cabril facility.

There was consensus on the fact that testing of any components should be clearly separated from the emplacement areas (prior to repository construction in the underground laboratory, or in selected areas of the repository). Such testing is part of the site characterisation programme.

The **quality assurance** programme which has been outlined in the safety file is based on the ISO 9000 standards. It was rather generally formulated. In a real safety file a repository-specific quality assurance programme is to be included.

All participants agree that further development of international quality assurance standards for a repository is necessary.

The standards of operational safety as described in the safety file were generally accepted. There has been some discussion on the monitoring of barren rock which has been requested by the German safety authorities and which is meant as monitoring of the **natural radioactivity** of the granite. Experience has shown that the radioactivity and the radon exhalation in some kind of granite may come close to the regulatory limits. In other countries no special requirements for monitoring of barren rock have been defined, but monitoring would be implemented if there is any specific suspicion for higher natural radioactivity. In principle, the evaluation of the natural radioactivity of the host rock and its compatibility with regulatory limits for environmental protection is a matter which will be discussed already at the site characterisation stage.

All participants agreed that further development is necessary to complete the international standards for decommissioning (**clearance levels** for different kinds of material) as well as a fundamental investigation of the objectives, scope and duration of post-closure monitoring.

Some discussion was launched on the question whether it makes sense to include a chapter on **financial aspects** in a safety file. In the debate it has been stated that financial aspects are so far relevant to licensing and safety, because an underground repository is very expensive and therefore the safety authorities may wish to see whether the financial resources of a licensee could satisfy the financial requirements for the construction, operation and closure of the repository. In the European countries the waste producers are obliged to establish a fund and to pay an annual amount to it depending on the waste arisings. In Spain, the application for construction has to be accompanied by a safety report and some other documents, one of them dealing with financial aspects. A verification of the financial potential of a licensee has been requested by the European Commission.

A basic problem for the discussion on **retrievability** is the fact that actually no international consensus exists on the objective of retrievability. Therefore the goal of the document that was prepared by COVRA, was to summarize the present status of discussion and in particular to explain the Dutch position.

The basic position of COVRA on this issue is that retrievability should contribute to safety and must not affect it. Long-term safety must have priority over retrievability. There were some doubts of the participants whether this basic objective could be ever reached because retrievability seems to be in contradiction to the basic goals of a repository: the long-term isolation of the radioactive waste from the biosphere, which is best achieved by the immediate and proper backfilling of all underground excavations after waste emplacement. In contrast, retrievability would require to keep the repository open for a limited time after the completion of the operations. The safety assurance for this period would rely on active actions, which is also in contrast to the basic principles. The principle "to minimize burden on future generations" will be also ignored. But COVRA explained that from its point of view, retrievability is a compromise and of minor annoyance in comparison to long-term interim storage in surface facilities which was, at least at present, the alternative in the Dutch discussion for the final disposal of radioactive waste. In fact, no real advantage of retrievability could be identified at the discussion and COVRA agreed that retrievability is more a political requirement based on public opinion than a technical demand.

In the Netherlands, a basic study on retrievability will be launched to define the issue, the objectives, the feasibility, the consequences and necessary compromises on other issues. It was expected that the results of this study will be the starting point of a new discussion and re-evaluation of the retrievability option in the Netherlands.

4. CONCLUSIONS

This study was intended as a desk simulation of the process of preparing a license application for a deep geological disposal of high level waste and spent fuel in clay. It included also discussions with the safety authorities of the countries involved in the study, aiming at a final safety report that is acceptable for the agencies/applicants and the safety authorities. Given the limited time and resources available, the safety file could be drafted only at a conceptual level, nevertheless addressing all items that are relevant for safety and for licensing. It was also not possible to completely revise the draft safety file, to incorporate all the comments made by the safety authorities.

During the course of the study, several issues were identified that are of major relevance for licensing:

- different licensing procedures in different countries;
- operational dose limits and dose constraints;
- long-term dose and risk limits and constraints;
- methodology to ensure compliance with the long-term safety objectives;
- definition and meaning of a cut-off time for quantitative long-term safety assessments;
- role of other safety indicators in different time frames;
- human intrusion scenarios;
- site selection criteria and procedures;
- importance of natural radioactivity in the host rock;
- adaptation of the repository design to geological findings;
- waste acceptance criteria and procedures;
- objective, scope and duration of the monitoring programmes during the different stages of the lifetime of the repository;
- establishment and implementation of a repository-specific quality assurance programme;
- classification of accident scenarios;
- establishment of clearance levels;
- objectives of the retrievability option.

It was recognised that some of the issues need further study:

- objectives, scope and duration of post-closure monitoring programmes;
- objectives of retrievability;
- establishment of unconditional and conditional clearance levels for different types of materials;
- the use of other safety indicators in relation to the definition of a cut-off time for quantitative safety assessments.

It was also felt that more international guidance should be developed, e.g. with respect to repository-specific quality assurance programmes.

It must be borne in mind that the results of this study must not be considered as binding for real applications in the future, neither by the agencies nor by the safety authorities.

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APPENDIX - TABLE OF CONTENTS OF THE SAFETY FILE

4.12. Safeguards
- 4.12.1. Basic design concepts on international safeguards
- 4.12.2. Proposal for the Application of safeguards to the reloading and buffering facilities
- 4.12.3. Proposal for application of safeguards to the underground facilities
- 4.12.4. Proposal for application of long-term safeguards

5. REPOSITORY CONSTRUCTION

5.1. Construction strategy
- 5.1.1. Separation of construction activities from waste disposal
- 5.1.2. Hazards in construction areas and consequences on operational areas
- 5.1.3. Procedure for commissioning new disposal areas in operation

5.2. General description of construction activities

5.3. Surface Facilities
- 5.3.1. Site infrastructure
- 5.3.2. Conventional repository facilities
- 5.3.3. Nuclear repository facilities

5.4. Equipment and techniques used in shaft sinking

5.5. Underground facilities
- 5.5.1. Equipment and techniques used for underground excavations
- 5.5.2. Underground transport
- 5.5.3. Ventilation
- 5.5.4. Influences of geological conditions found in situ on the design and the construction of the repository
- 5.5.5. Initial extent of the underground facilities
- 5.5.6. Shaft landing station
- 5.5.7. Underground infrastructure
- 5.5.8. Main galleries
- 5.5.9. Disposal area
  - 5.5.9.1. Spent fuel disposal galleries
  - 5.5.9.2. Vitrified HLW disposal galleries
  - 5.5.9.3. Long lived LLW and Long lived ILW disposal area

5.6. Construction related safety standards
- 5.6.1. Safety standards and principles
- 5.6.2. Control procedures and measures

5.7. Test programme for the repository commissioning

5.8. Construction schedule

6. REPOSITORY OPERATION

6.1. Principles and applicable standards

6.2. Operational program and sequence

6.3. Operational organization
- 6.3.1. Organizational structure
- 6.3.2. Operational Instructions

6.4. Conventional mining operations
- 6.4.1. Personnel and materials hoisting via the shafts

9.5.4. Shafts

9.5.4.1. Dismantling and recover of reusable installations after radiological clearance

9.5.4.2. Backfilling and sealing

9.5.5. Boreholes

9.6. Safeguards, Post-closure surveillance and monitoring program

9.7. Sequence / operational schedule for decommissioning

10. ORGANIZATION AND FINANCIAL ASPECTS

10.1. Organization during the construction period

10.2. Organization during the operational period

10.2.1. Organization of operational activities and personnel requirements

10.2.2. Organization during the decommissioning period

10.3. Organization during the post closure period

10.3.1. Institutional control

10.3.2. Record keeping

10.4. Cost estimation and financial provisions

10.4.1. Design and initial construction

10.4.2. Operation

10.4.3. Sealing

10.4.4. Institutional control

11. LONG-TERM SAFETY ASSESSMENT

11.1 Post-Closure Safety Principles and Applicable Standards

11.2 Radiological Impact Assessment Methodology

11.3 Basic Information and Data

11.3.1 Disposal Concept and Design

11.3.2 Radionuclide Inventory and Residual Heat

11.3.3 Canister Life

11.3.4 Near field environment

11.3.4.1 Chemistry

11.3.4.2 Radiation field

11.3.4.3 Gas Generation

11.3.5 Performance of Buffer and Backfill Materials

11.3.6 Disturbance of the Host Rock by the Repository

11.3.7 Thermomechanical Assessment of the Geological Formation

11.3.8 Hydrogeological Modelling of the Site

11.3.9 Biosphere

11.4 Criticality Assessment

11.5 Radiological Impact Assessment

11.5.1 Scenario Development

11.5.1.1 Identifying and Screening FEPs

11.5.1.2 Scenarios Construction

11.5.1.3 Screening of Scenarios

11.5.1.4 Description of the Selected Scenarios

11.5.1.5 Probability Evaluation of Scenarios

Towards decisions!

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The base case of the TVO-92 safety analysis was that, most likely, significant amounts of radioactive substances will never come out of the repository and no individual will ever be exposed to significant levels of radiation caused by final disposal of spent fuel deep in the Finnish bedrock [1]. The recent safety analysis update TILA-96 reconfirms this [2]. The cornerstone of the Finnish plans for final disposal of high-level radioactive waste has been and continues to be a canister with sufficiently long expected life-time to allow the radioactivity of the wastes to decay to non-harmful levels. So far nothing has come out that would place such expectations under serious doubt.

On the other hand, the safety criteria for final disposal of high-level waste usually require that the system shall not rely on one release barrier only. Therefore, most of the contents of the TVO-92 and TILA-96 are devoted to discussion of what happens if the perfect isolation by the canister is somehow lost. The analysis is centred around the “reference scenario”, which simply assumes that at some time point in the future the integrity of the canister is completely lost. As an alternative, the case of a leaking canister is considered.

The calculations are made for the contents of one single canister. The result for the reference scenario is that the individual doses will always remain several orders of magnitude below the proposed individual dose limit of 0.1 mSv/a. Moreover, a simple multiplication yields that even if all the canisters of the planned repository failed, the proposed dose and release criteria would not be violated.

Nevertheless, a scenario, though unlikely but still conceivable, can always be defined which leads to doses or activity releases above the proposed limits. For such cases the current criteria proposal rules that the risk be considered. In TVO-92 the estimated maximum individual dose from the post-glacial displacement scenario was slightly above 1 mSv/a. What can we say about the risk? The criteria proposal requires that it should be less than the risk corresponding to the risk arising to an individual from a radiation dose of 0.1 mSv/a.

My argument is that assessment of risks like this simply falls outside the domain of science, and any estimate of the risk for a future individual from such a scenario can be challenged. Of course, even the consequence assessment is associated with uncertainties, but at least a part of them can, in principle, be addressed by scientific means. The basic requirement for a scientifically meaningful statement is that one can devise a method for testing it. For testing the risk estimates for scenarios such method hardly exists. It may be hard enough to produce any estimate for the probability of a future post-glacial rock displacement, but it is plainly impossible to show that the estimate is correct.

This is not to say that discussion of scenario probabilities would lack any meaning. The probabilities can be used as an instrument of communication and argumentation but the rules and restrictions of such discussion should be accepted and understood by all parties involved. One might, for example, argument that the probability of a future post-glacial displacement scenario like that of the TVO-92 safety analysis must be less than 1 % for the next million years or so – which would be more than sufficient for the proposed criterion – because otherwise there should be plenty of evidence from such displacements in the past. Someone might even want to estimate how improbable it is not to find such displacements from a given area. Considerations like these may be useful discussion points. On the other hand, who says that the future would be simply a repetition of the past? Even if one took that for granted, it is still not science: the argument cannot be tested. Therefore, the 1 % upper bound is not a scientific estimate.

The key question is whether safety analysis can produce the kind of quantitative risk estimates which alone would solve the lisensing dilemma. My answer is negative. Licensing needs judgements and, finally, a decision based on these judgements. Probabilities are a natural ingredient of human concepts of future and are an obvious part of the decision-making for future, but the search for objective risk estimates for scenarios is doomed to fail. For the search for total risk estimates of final disposal the failure is, of course, even more obvious. Quoting from Chapman et al. [3], "it is not possible to analyse the mathematically possible combinations of future possibilities for all components of the disposal system and the natural environment and it is thus not possible to calculate scenario probabilities ... we see scenarios as simply a means of illustrating possible behaviour of the system and exploring how such behaviour might arise. This information then assists in making decisions on the acceptability of a disposal option... "

Another thing is what role the probabilities can play in consequence analysis. Some performance analysts accept the limitations of assessing scenario probabilities but emphasise the importance of probabilistic treatment of some specific classes of uncertainties, in particular those arising from variability. Indeed, stochastic modelling of, for example, groundwater flow may give a useful picture of different possibilities for what the flow situation may look like in reality. However, claiming that stochastic modelling is a natural way of treating natural variability lacks ground at least as long as there is no known natural law that would underlie the variability and make the estimation of the probabilities possible on a sampling basis. At least for typical crystalline rock any sample by means of, say, borehole measurements, is representative only for that place and that time point and there is no way of showing that sampling would lead to convergence towards the distribution for the key parameters of interest in the rock volume of interest and the time period of interest in performance analysis. Stochastic modelling of spatial variability is therefore subject to the same epistemological problems as the assessment of scenario probabilities.

Licensing of a final repository will require more than simply comparing calculation results from safety analysis with numerical regulatory limits. Like Chapman et al. [3] point out, someone, in the end, has to make the decision whether the repository is acceptable. My advise is that, for grounding such decisions, one should mainly focus on

- technical evaluation of the plans and
- producing conservative estimates of consequences of the proposed actions for a few bounding scenarios.

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Making a Safety Case

Summary of a discussion of unsettled issues in safety assessments
from the perspective of SKB Sweden,
by

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Abstract

A compilation is made of areas or issues where a need is seen

- for clarification of concepts,
- for greater international consistency in understanding, or
- for more discussions around the practical limitations that surround an assessment of long term safety.

None of the compiled issues are in fact new, the list should be seen as highlighting areas where further efforts are merited to create a better understanding of the Safety Case, especially with regard to public understanding.

Protection of nature

In contrast to the situation with man and radiation, the units of harm and the goals of protection are not easy to define. The global nature of this issue would require a set of internationally accepted working definitions. Especially for protection of populations, and protection of natural diversity.

A determined effort in this area might bring about a better understanding of what are the critical factors in the protection of nature, what methods do we have or need to develop for the purpose and what limits etc. can be set to make the compliance issue quantitative.

Safety Case and time

Another issue of global nature that needs more discussion is the time dependence of the assessment procedures and the Safety Case.

There is a common understanding that the assessment methods and requirements on the Safety Case must reflect uncertainties in the assessment, and thus be time dependent. This understanding can however be interpreted in very differently and the guidance given in the various countries are different.

A broad international comparison should be made of how the time aspect is handled for radioactive waste in different countries, and the arguments for it. There should also be made a generic comparison of how different kinds of toxic wastes are handled and regulated with regard to the time aspect.

Stylised or reference examples

Uncertainties are not only coupled to time. There is also factors influencing the safety case that are very difficult to predict in a systematic way, but can have such a great effect on risk evaluations that they must be discussed. Examples are the long term changes in the ecosystems of primary biosphere recipient of deep ground waters, human actions that might influence the repository, mans utilisation of nature and the concept of critical groups .

How to establish a set of reference descriptions to illustrate such factors, has long been discussed among safety assessors and recently in BIOMOVS. The main value of internationally agreed upon reference descriptions is that they permit easy comparison between alternative repositories or over time and bring about a better understanding of sensitivities in the rest of the system. The role and utility of such stylised, reference descriptions in different areas should be clarified.

Retrievability

Of many issues with a strong coupling between technique and acceptance, like multiple barriers, post closure monitoring, information preservation etc., only one will be high-lighted - retrievability.

As the practical development of the repositories comes closer the more often retrievability is discussed. There seems to be a wide agreement that retrievability should not be a compensation for lacking safety as understood today, and that retrievability should not be allowed to compromise required passive safety features. However, there is great variation in the time spans discussed, techniques that could be used, criteria for initiating retrieval etc.

The understanding of retrievability as a concept and its role in the Safety Case could be enhanced and differences in approach could be better understood if an international overview could be produced.

Completeness

Although the processes and features important for safety, the equipment to collect data, and the tools to model are continuously improving, we - the safety assessors - believe that we have a fairly good understanding and capacity in these areas. There is now a tendency to focus more and more on the question of completeness. Have we really identified everything important? and How can we show it?

National and international work has been done on the completeness issue for FEPs, conceptualisation, scenarios, recipients, etc. This work has largely improved the systematics and the documentation. However there is a danger with this, the work is focused more and more on marginal phenomena and extreme events.

There should be made an international effort, with a strong participation from the regulators, to discuss questions like: What are the reasonable limits for completeness? How complete is complete enough?

The Safety Case for licensing or stepwise development

Obviously the licensing of a geologic repository is not a simple process, nor can it be accomplished in one step. There is a need to show the basis for many more actions and decisions than just the filing of a licence application. In a structured development of a repository the design, the site, the data base, the performance evaluations etc. are all developing in parallel.

To be of practical use the assessment of performance or safety and the presentation of the conclusions in safety reports is required to have the qualities needed for both stepwise development and for licensing. Most of the problems that are encountered stem from the fact that a detailed understanding and quantification is only generated by the ongoing development or siting work. And you are often only allowed to do that work if you show you have that understanding.

The main difference is that in the development phase there will be a focus on showing that your imperfect understanding or your unknown data set is predictable, that your sensitivity to variations is low or that you have ample margins to accommodate unexpected results.

I would be good for the understanding of the role of safety reporting, especially for the interested public or local political groups, to have more discussion of the qualities that should be strived for in these intermediate stage safety reports.

Regulatory Compliance for a Yucca Mountain Repository: A Performance Assessment Perspective

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Abstract

The U.S. Department of Energy's Yucca Mountain Site Characterization Project is scheduled to submit a License Application in the year 2002. The License Application is to show compliance with the regulations promulgated by the U.S. Nuclear Regulatory Commission which implement standards promulgated by the U.S. Environmental Protection Agency. These standards are being revised, and it is not certain what their exact nature will be in terms of either the performance measure(s) or the time frames that are to be addressed.

This paper provides some insights pertaining to this regulatory history, an update on Yucca Mountain performance assessments, and a Yucca Mountain Site Characterization Project perspective on proper standards based on Project experience in performance assessment for its proposed Yucca Mountain Repository system.

The Project's performance assessment based perspective on a proper standard applicable to Yucca Mountain may be summarized as follows: a proper standard should be straightforward and understandable; should be consistent with other standards and regulations; and should require a degree of proof that is scientifically supportable in a licensing setting. A proper standard should have several attributes: (1) propose a reasonable risk level as its basis, whatever the quantitative performance measure is chosen to be, (2) state a definite regulatory time frame for showing compliance with quantitative requirements, (3) explicitly recognize that the compliance calculations are not predictions of actual future risks, (4) define the biosphere to which risk needs to be calculated in such a way as to constrain potentially endless speculation about future societies and future human actions, and (5) have as its only quantitative requirement the risk limit (or surrogate performance measure keyed to risk) for the total system.

Introduction

The U.S. Department of Energy's (DOE's) Yucca Mountain Site Characterization Project (YMP) is scheduled to submit a License Application in the year 2002. The License Application is to contain a Safety Analysis Report that demonstrates compliance with the regulations promulgated by the U.S. Nuclear Regulatory Commission (NRC). The NRC regulations, in turn, implement standards promulgated by the U.S. Environmental Protection Agency (EPA). These standards are being revised, and it is not certain, at this point, what their exact nature is to be in terms of either the performance measure(s) or the time frames that are to be addressed.

At the request of the U.S. Congress, the National Academy of Sciences (NAS) made recommendations to the EPA to aid their effort at writing standards applicable specifically to a Yucca Mountain repository. This NAS report was issued in August 1995. [1] The DOE has expressed its views on this report by the NAS in written comments and recommendations to both the NAS and the EPA(1). The EPA effort at creating a draft standard for a Yucca Mountain repository is in progress. A summary of the DOE/YMP perspective on the NAS recommendations to the EPA has been presented elsewhere [2] in terms of issues important to the regulatory framework for Yucca Mountain, namely (a) regulatory time frame, (b) risk/dose limit, (c) definition of the reference biosphere, (d) human intrusion, and (e) natural processes and events.

This paper provides some insights pertaining to this regulatory history, an update on Yucca Mountain performance assessment activities, and a DOE/YMP perspective on proper standards. The DOE/YMP perspective presented here is based on the project's experience in implementing and evaluating performance assessments for its proposed Yucca Mountain Repository system.

Need for a New Site-Specific Standard for the Yucca Mountain Site

The DOE/YMP performance assessment perspective on the need for a standard for the Yucca Mountain Site is simply that there was a conceptual mismatch between the processes determining performance at the unsaturated Yucca Mountain site, located in a closed basin, and the 1985 EPA standard. [3] This conceptual contrast was masked by the fact that early calculations of system performance by both the EPA and the DOE showed negligible risks for the specified regulatory time frame. The basis for this mismatch lies at the heart of the approach of the EPA in setting the 10,000 year cumulative release limits of their 1985 standard. The EPA approach was to assume a generic conceptual model and then to use it to determine allowable releases from a repository system by calculating backwards from allowable health effects for a global population:

- a decision was made that 1,000 health effects per 100,000 metric tons of heavy metal over 10,000 years for a 10 billion person global population was an allowable population risk (a comparison was made with the same calculation for natural background radiation that suggested 6,000 premature cancer deaths per year, in the U.S., illustrating the conservative nature of this standard: it represents a cancer risk allowance of about 10^{-8} times the global background)

- the 10 billion-person population was divided by a health-effects to dose conversion factor for radionuclides in the spent-fuel inventory (no low-dose threshold)

(1) Letter from S.J. Brocoum (DOE), to R. Clark (EPA), 29 March 1996, re: Additional recommendations to the Environmental Protection Agency Standard for Yucca Mountain.

- a maximum allowable population dose for each radionuclide, per 1,000 metric tons of heavy metal, was thus obtained

- a table of radionuclide-specific release limits was created, with a formula to assure cumulative releases will not exceed a total dose resulting in the allowable excess deaths in the global population.

The EPA's rationale for the selection of this low allowable risk factor and approach was in part that "it provides a level of protection that appears reasonably achievable by the various options being considered within the national program for commercial wastes." Because of expected uncertainties, however, individual and groundwater protection requirements also were made part of this standard.

Except for its degree of conservatism, there was nothing wrong with the EPA approach for sites that resemble the conceptual model on which the standard was based. For Yucca Mountain, however, there is a great conceptual mismatch: there is no radionuclide transport mechanism leading to a global dose.

It was the degree of conservatism and the conceptual misfit between Yucca Mountain and the EPA's 1985 standard that led to questions of the general applicability of this standard to Yucca Mountain. These questions eventually resulted in the Congress directing the EPA to write a site-specific standard for Yucca Mountain. A slightly revised version of the 1985 EPA standard still applies to U.S. disposal facilities for high-level waste, spent nuclear fuel, and transuranic wastes other than Yucca Mountain, however.

Recent Developments in Yucca Mountain Performance Assessment

Since the Total System Performance Assessment of 1995 (TSPA 1995)[4], several improvements have been made to the models used to evaluate system performance. First, an order of magnitude improvement of system performance has been realized through improved thermal-hydrology calculations together with more sophisticated assumptions about the likelihood that water may directly flow over the waste form. Even if there is dripping water falling on waste packages, drips are not likely to directly contact the waste form since "failure" openings are very small and are expected to be filled with corrosion products. These assumptions are thought to be more realistic, but require verification through confirmatory testing.

Second, a compensating decrease in system performance is the likely result of a new understanding of water flux in the unsaturated zone. The revised mean-value estimate of percolation flux is up to 4.5 mm/year for the area modeled, with about 7 mm/year over the repository block underlying the higher topography, with higher fluxes during pluvial periods. This larger flux may be compared with the TSPA-1995's average ambient flux for its high range of 1.25 mm/year. Pluvial periods were estimated to have flux increases from 0 to 4 times ambient, with an average increase of 3 times ambient (some recent estimates of precipitation increases accompanying the start of a pluvial within 10,000 years are about 2.5 times the current annual precipitation).

To evaluate the new flux distribution estimates, preliminary system calculations were performed using the version of TSPA 1995 also updated for the thermal hydrology and engineered barrier performance improvements described above. No climate-change flux-multiplier has yet been included, but a simplified pluvial case was evaluated.

For 100,000 years, drinking-water-only peak annual doses to a person obtaining 2-liters water per day in the contaminant plume 20 km from the repository, given current, non-pluvial conditions, were about 10 mrem/year, from I and Tc. Peak annual doses (drinking-water only at 20 km) were about 14 mrem/year, for the hypothetical pluvial case which assumed pluvial fluxes for all of the 100,000 year period [Figure 1].

If a new standard requires the calculation of total dose rather than just drinking water dose, the multiplier on the drinking water dose may be roughly 10, depending on the radionuclide of interest, its pathways in the environment and into the individual, and the behavior of the individual (mainly the extent of consumption of homegrown agricultural products). Perhaps the new regulatory requirements will stipulate that the likely location of the potentially affected individual is to be where water is reasonably accessible to an individual agricultural household. This may be 30 km from the repository, since this is presently where most area residents are located who are practicing agriculture to some degree [Figure 2]. This could lower doses approximately 25-fold (more than an order of magnitude) [Figure 3].

Recent scoping calculations have suggested that taking credit for cathodic protection (waste package failure rate reduction), cladding life (waste form degradation rate reduction), and perhaps an insulating backfill (waste package failure rate reduction) can each contribute an order of magnitude reduction in doses over the long term (convolution may reduce that to two orders of magnitude, perhaps). Thus, new, more optimistic calculations may yield 100,000 year peak annual doses of about 0.0001 mrem/year for the agricultural individual scenario at 30 km, and a 10,000-year peak annual dose of 0.0 mrem/year for that same individual. [Figure 4]

Reasonable bounds on maximum infiltration and accompanying water-table elevation changes still need to be determined. However, it is not clear what the effect would be because increased dilution may at least partly balance the effects of greater releases and shorter travel times.

Performance Assessment Perspectives on Regulatory Standards

Standards Need to Acknowledge Irreducible Uncertainties

The U.S. Nuclear Regulatory Commission (NRC), in its 1983 regulation [5] governing the disposal of high-level radioactive waste and spent nuclear fuel stated: "Analyses and models ... shall be supported using an appropriate combination of such methods as field tests, in situ tests, laboratory tests which are representative of field conditions, monitoring data, and natural analog studies." These activities are part of what is necessary to provide “reasonable assurance” in the "demonstration of compliance."

An NRC elaboration on "Reasonable Assurance," (10 CFR Part 60 Statements of Consideration, 48 FR 28222 6/21/1983), suggested there will be irreducible uncertainties in long-term predictions: ... "there will be no opportunity to carry out test programs that simulate the full range of relevant conditions over the periods for which waste isolation must be maintained."

The U.S. Environmental Protection Agency (EPA) in its 1985 regulation on the disposal of spent nuclear fuel, high-level waste and transuranic waste, [3] stated: "Performance assessments need not provide complete assurance that the requirements ... will be met. ... what is required is a reasonable expectation, on the basis of the record before the implementing agency, that compliance ... will be achieved." In its introductory statements the EPA stated that “unequivocal numerical proof of compliance is neither necessary nor likely to be obtained.“ Thus, both the EPA and the NRC have recognized that there will be irreducible uncertainties in projections of system behavior over very long times.

The U.S. National Academy of Sciences' (NAS) National Research Council pointed out in a position statement that "there are certain irreducible uncertainties about future risk." [6] The Council acknowledged that "the EPA standards and the USNRC regulations recognize and accept a certain level of uncertainty," but "the discussion to date of the application of these standards and regulations does not warrant confidence in the acceptance of uncertainty in the licensing process." This statement appears to say that in the opinion of the National Research Council, regulators may have expectations of a degree of proof in licensing that exceeds "reasonable assurance" in the face of irreducible uncertainty. These high expectations on the part of regulators may, in part, reflect experience in the adjudicatory licensing process which tends to push an applicant toward greater than necessary conservatism.

FIGURES 1 AND 2 NOT AVAILABLE IN ELECTRONIC FORMAT

FIGURES 3 AND 4 NOT AVAILABLE IN ELECTRONIC FORMAT

The Adjudicatory Licensing Process

An adjudicatory licensing process is comparable with a hearing in a court of law. In discussing "The Scientist and Engineer in Court," Bradley [7] observed that legal decisions "are generally made on the 'weight of evidence'." When modeling is involved, the evidence consists of 1) the "scientific studies and research" aspect [i.e.: the model development phase], and 2) the "field justification" aspect [i.e.: the field calibration and subsequent application phases].

The application phase requires field data for calibration and separate sets of field data for establishing credibility, and affords room for challenge. Vulnerability may be minimized by 1) assuring that the model user is familiar with the development of the model and the conditions for which it was designed to be used, 2) assuring the modeler is very familiar with the data used, its nature, limitations, etc., and 3) assuring results are carefully and competently interpreted, and that limitations are recognized but not exaggerated.

The typical legal challenge to a modeling exercise includes detailed questioning of the supporting field sampling program and its data. Thus, modeling confidence can not be divorced from its basis in adequate site characterization, system design, and component testing programs. The way scientific modeling is likely to be treated in the licensing process is a challenge to the regulator writing a standard for permanent radioactive waste disposal. The standard must adequately protect public health and safety, and yet not make licensing impractical.

Protecting Public Health and Safety Through Regulations

One implication of the way that modeling is likely to be challenged in the adjudicatory process is that the value of the quantitative performance measure being addressed should not be unnecessarily conservative or based on what simplified generic models indicate to be achievable. A regulatory performance measure needs to reflect a societal judgement of a permissible risk level, and therefore is a governmental policy decision.

If a regulation or standard is unrealistically conservative, a site may be disqualified even though it is adequate in terms of protecting public health and safety. The National Research Council's opinion on this matter calls for a process that may be needed "to determine whether DOE's inability to meet a particular requirement is due to a disqualifying deficiency in the site or to an unreasonable regulatory demand, one that is unlikely to be met at any site and is unnecessary to meet public health." [6]

The portion of the Council's statement that says "one that is unlikely to be met at any site" seems to still partake of the assumption that all acceptable sites are roughly comparable in terms of operative processes. It may be, however, that some performance measure that can be met by hypothetical repositories in one class of geologic settings may simply not apply in other geological settings because different processes control performance. It does not follow that there is necessarily an adverse effect on public health and safety if there is a disconnect between the conceptual understanding that underlies a standard and the conceptual model that describes a specific site. However, it is not in a society's best interest to preclude a site offering acceptable performance because a standard requires that a threshold not be exceeded, if that threshold is not meaningful in terms of public health and safety.

For example, in the YMP's earliest evaluations of an idealized system placed into a simplified Yucca Mountain, releases were vanishingly small for the first ten-thousand years because the flux of water through the mountain was postulated to be extremely low, based on simplified interpretations of the available evidence. [8] Similar analyses were done by the EPA in support of their 1985 standard. [9] Both the YMP and EPA analyses were accompanied by caveats and sensitivity studies showing that if fluxes are higher than expected, releases and thus risks would be higher.

As has been noted above, site characterization results are supporting estimates of fluxes through the unsaturated zone significantly higher than estimated for the earlier, idealized calculations. Using these higher flux values in the former, simplified calculations suggests that the Yucca Mountain system could result in substantial releases and risks. However, a better understanding of the site coupled with a more complete engineered system design have allowed more sophisticated evaluations that show system performance has a high likelihood of being non-threatening to public health and safety even if there are higher fluxes through the unsaturated zone than previously anticipated.

These new results also illustrate that selecting an important process such as groundwater flux for added regulatory attention by creating a subsystem requirement for its rate, based on a very simple preliminary system model, reflects on the adequacy of that simplistic system model more than it reflects on the adequacy of a system designed for an actual location. This again underscores the need for a standard to be based on a societal judgement of acceptable risk and not on what is achievable by an idealized hypothetical system evaluated through simplistic modeling.

Conclusions: Attributes of Reasonable Standards and Regulations to Govern Disposal of High-Level Radioactive Waste and Spent Nuclear Fuel at a Yucca Mountain Repository

Standards, and their implementing regulations, should have as their overriding purpose the protection of public health and safety. These standards and regulations should be implementable, meaning that demonstrating compliance with such standards and regulations should be possible even in the confrontational settings that may be expected as part of an adjudicatory licensing process. To be implementable, a regulation or standard should be straightforward and understandable, should be consistent with other standards and regulations, and should require a degree of proof that is scientifically supportable in a licensing setting.

Several attributes would suggest an implementable standard. The first attribute of an implementable standard would be having a reasonable risk level as a basis, whatever the quantitative performance measure is chosen to be. The risk-level basis should reflect an acceptable level of health-risk to a defined population or to defined representative individuals. This requires a societal decision as to the level of an acceptable risk. It may be tempting to base a standard upon idealized calculations of what a conceptual repository is capable of meeting. This is not an appropriate approach because it is necessarily dependent on a limited conceptual understanding of a site and a preliminary idea of the engineered system to be emplaced in that site. The understanding of a site after characterization, coupled with more complete designs, may lead to an estimate of repository performance in that site that may fail to meet the idealized system standard, leading to the rejection of what may in fact be an effective and safe solution for society.

The second attribute would be a definite regulatory time frame for showing compliance with quantitative requirements. An undefined time frame, as would result from a requirement to meet quantitative limits at the time of peak dose, may not be implementable in an adjudicatory licensing process. As a qualitative goal, however, these types of speculative calculations may help the licensing authority make a more informed decision on the quantitative compliance argument.

A third attribute that would aid implementation is for the standard to explicitly recognize that the compliance calculations are not predictions of actual future risks. Instead, they are stylized, to an extent prescribed, sequences of methodology applications that provide the means for making societal-risk decisions. Results of compliance calculations are meant to provide reasonable assurance to a regulatory authority, recognizing that there are limitations to the analyses. The analyses incorporate assumptions that can not be verified, but that can be shown to reflect reasonable expectations or to reasonably bound those expectations.

A fourth attribute positively affecting implementation is for a standard to define the biosphere to which risk needs to be calculated in such a way as to constrain potentially endless speculation about future societies and future human actions. Prescribing stylized calculations for human intrusion scenarios is one approach, prescribing limits on human intrusion frequency is another. Prescribing the size, location, and characteristics of a nearby population, based on a cautious interpretation of the present, is also desirable. As a general principle, it is desirable to focus on the protection of nearby populations rather than the global population.

A final attribute is simplicity. The only quantitative requirement should be the risk limit (or dose or other surrogate performance measure keyed to risk) for the total system. Subsystem performance requirements that seem to add assurance have the drawback of being based on specific conceptual models of system performance that incorporate assumptions that allocate system performance to subsystems and components. This could limit the applicability of a standard to sites that fit the preconceived engineered system design and site conceptual model, and thus either drive site selection to overlook suitable alternatives, or require the creation of a site specific standard.

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Development of a Scientific and Technical Basis for Regulating Geological Disposal through Generic Assessment

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Abstract

PNC is currently developing a scientific and technical basis for regulating geological disposal in Japan through generic assessment, taking into account a wide range of geological environments. This paper discusses the information required for the regulatory process from the point of view of siting, repository design and setting the safety assessment framework. Key issues to be discussed in the regulatory process are identified in accordance with the aims of this workshop.

1. INTRODUCTION

In Japan, the program for geological disposal of high-level radioactive waste (HLW) is currently in the R&D phase. Generic assessments of the disposal concept are carried out without specifying host geological formations or sites. No regulations have yet been formulated for the safety goals for HLW disposal. The Power Reactor and Nuclear Fuel Development Corporation (PNC) is conducting R&D activities based on the lessons learned from the first progress report, referred to as H3, which summarized the results of R&D activities up to March 1992 [1]. The second progress report is scheduled to be submitted by March 2000 as the next major milestone in the HLW program. An important objective of the 2nd progress report is to provide a scientific and technical basis for the future regulatory process and siting decisions. An implementing organization will be established around the year 2000 to initiate the siting process. The repository is expected to be operational by 2030~mid-2040s.

A safety concept for HLW disposal in Japan is being developed for a wide range of geological environments; the concept is based on a multiple safety barrier system in a stable geological environment. The geological environment can be regarded as stable if, given the expected changes in geological conditions with time, the engineered barrier system (EBS) can be expected to function as designed.

The Japanese Archipelago is situated in a fairly active tectonic setting, which results in diverse and complicated geology. In order to support the safety case, disruptive events (natural and human-induced) should be avoided by appropriate site selection. The approach to demonstrating safety places the emphasis on the barrier performance of the near-field consisting of the EBS and the immediately surrounding host rock.

Generic assessment provides a more comprehensive scientific and technical basis for formulating regulatory criteria. Lessons already learned from experience in making the safety case indicate that certain key issues do not belong in the strictly scientific/technical framework but should be discussed within the regulatory process.

The objective of this paper is to discuss key issues in the regulatory process based on the information required for making the safety case.

2. CRITERIA FOR ASSESSING THE SAFETY CASE

Criteria to be considered within the context of HLW disposal can be classified into the following categories from the point of view of making the safety case;

- siting
- repository design and
- safety assessment framework.

In the Japanese disposal concept, siting criteria relate to

- avoiding disruptive events and
- identifying favorable geological environments in which the EBS can function as designed.

Repository design criteria relate to

- eliminating deficiencies in the repository system at the outset and
- providing a repository environment in which the EBS can function as designed.

Regarding the framework for safety assessment, performance criteria should be formulated based on demonstration of the overall safety of disposal system and not focused on specific barriers or features of the repository host rock.

It is not necessary to explicitly define all these criteria in the regulations. Nor is it necessary to define all the criteria at the same time, because siting, design and safety assessment will be carried out in a stepwise procedure.

The H3 generic assessment identified the following questions as being essential in a discussion of criteria for siting, repository design and the safety assessment framework.

- Siting
  - What disruptive events are relevant?
  - How can disruptive events be avoided?
  - What kind of geological environments are required to preserve the EBS?

- Repository design
  - How can initial deficiencies be avoided?
  - How should the repository be designed to meet the required criteria?

- Safety assessment framework
  - How long is the timescale for safety assessment? (time frame)
  - What are the key safety indicators?
  - How are scenarios for safety assessment identified? (completeness of scenarios)
  - How are scenarios evaluated?
  - How are models and parameter values validated?

3. INFORMATION REQUIRED FOR MAKING THE SAFETY CASE

3.1 SITING

Disruptive events to be avoided by appropriate site selection are volcanic activity, active fault displacement, high uplift and erosion rates and human intrusion. Earthquakes cannot be ruled out because the Japanese Archipelago is situated in a seismically active area. However extensive observations have indicated that the effects of earthquakes on deep underground structures are much less than on surface facilities. A repository can be designed in such a way as to reduce the effects of seismic activity sufficiently to be acceptable for the safety assessment. Changes in surface environments will not have any significant adverse effect on the repository isolation capability because the effects will be limited in relevant subsurface zones.

Information from geological records and evidence of regularity and continuity of occurrence are essential in planning to avoid natural disruptive events. It is possible to develop a chronological history of such natural events based on information available over the last several hundreds of thousands of years. The risk of human intrusion can be reduced by determining the location of exploitable natural resources.

At the sites where the risk of disruptive events can be minimized, the geological conditions required to ensure that the EBS will function as designed are favorable groundwater chemistry, low groundwater flux and physical stability (including isolation from surface perturbations). The geosphere is also expected to play a role in retardation of radionuclide transport.

3.2 REPOSITORY DESIGN

Deficiencies in repository design should be minimized by careful application of quality assurance/quality control (QA/QC) procedures to construction and installation of all disposal system components, as well as to sealing procedures. Monitoring may be necessary to ensure compliance with the implementation plan during the pre-closure and, if required, post-closure phases. Discussion of these technical aspects will provide a reliable basis for repository design criteria.

Certain disposal conditions can be controlled by repository design. For example, the near-field temperature is designed to be less than 100°C to minimize chemical alteration of the bentonite. Another example is that all overpacks are designed to retain their integrity for at least 1,000 years in order to rule out significant effects of radiogenic heat and radiolysis in the analysis of radionuclide dissolution and migration through the EBS. Criteria are also considered for emplacing bentonite in such a way as to avoid colloid-facilitated transport of radionuclides.

3.3 SAFETY ASSESSMENT FRAMEWORK

The uncertainties associated with the results of safety assessment increase with time. Time frames for safety assessment should be discussed not only in terms of a cut-off but also in the context of application of different types of safety indicators to be provided by the quantitative or qualitative assessment. Time frames have generally been discussed from the following viewpoints[2];

– long-term stability of the geological environment
– potential hazard of HLW and

– uncertainties due to changes in future biosphere conditions and human behavior.

The long-term stability of the geological environment can be discussed on the basis of scientific records. A toxicity index for HLW can be defined which represents the decrease in hazard of this waste with time, even though such a crude measure does not relate to risk arising from waste in a repository. A discussion of the level of acceptance of HLW compared to other potential hazards could, however, contribute to defining time frames. This type of discussion is not purely scientific and its subjective nature should be highlighted in the regulatory process. The fact that it is difficult to predict uncertainties due to changes in future human activities should be taken into account when discussing time frames, not only in terms of scientific aspects but also in the regulatory process.

In order to reinforce the results of dose or risk calculations, alternative safety indicators which may be less sensitive to uncertainties arising in the future should be used for example direct fluxes of radionuclides to the biosphere. Their specification should be discussed in the regulatory process with a view to applying such indicators in safety assessment.

In making the safety case, the safety assessment addresses uncertainties which still remain after siting and repository design. These remaining uncertainties are incorporated in scenarios, models and parameter values.

Scenarios for safety assessment are developed via a procedure based on system understanding and expert judgment. A systematic and transparent approach is essential for scenario development in order to ensure completeness. Independent peer review should also form part of the procedure. Well-documented, traceable information on scenario development can provide a sound scientific and technical basis for the discussion of safety assessment criteria.

Selected scenarios are evaluated either quantitatively or qualitatively. However, considering the difficulties involved in predicting future human activities, it has been suggested that inadvertent future human intrusion should be analyzed only in a stylized manner [3]. Discussions within the regulatory process are necessary in order to define such stylized intrusion scenarios.

Validation of models and parameter values is carried out by comparing model predictions with experimental results and/or evidence from natural analogues. It is, however, difficult to quantitatively define the validation criteria for particular models and parameter values to judge whether or not they can be accepted for performance assessment purposes. Indications of acceptance levels should be provided by the regulatory process.

PNC carried out deterministic calculations in order to evaluate individual doses in the H3 safety assessment. Deterministic calculations are more efficient than probabilistic calculations as a scientific basis for providing more transparent demonstrations of system performance. However, if low probability/high consequence events have to be analyzed, the use of probabilistic calculations and the combination of dose and risk should be considered.

4. CONCLUSIONS

- The information required to define relevant criteria for siting, repository design and safety assessment can be identified by analyzing the safety case via generic assessment.

- Independent discussions within the regulatory process are needed to define time frames, safety indicators, stylized scenarios for human intrusion and criteria for the validation of models and parameter values.

- The guidelines for assessing the safety case should be structured on the basis of information provided through scientific discussion and supplemented by independent discussions within the regulatory process.

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SESSION III: JUDGING THE SAFETY CASE

COMPLIANCE REQUIREMENTS

Review the long-term safety of the Konrad nuclear waste repository

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1. INTRODUCTION

1.1 Regulations and criteria for nuclear waste disposal in Germany

The disposal of radioactive waste in an underground repository is, in particular, governed by the following regulations:

- Atomic Energy Act (Atomgesetz - AtG) /1/
- Radiological Protection Ordinance (Strahlenschutzverordnung - StrlSchV) /2/
- Safety Criteria for the Disposal of Radioactive Waste in a Mine (Sicherheitskriterien für die Endlagerung radioaktiver Abfälle in einem Bergwerk) /3/
- Federal Mining Act (Bundesberggesetz) /4/

The general safety objectives for construction and operation of a repository for radioactive waste are laid down in the Atomic Energy Act and the Radiological Protection Ordinance. The basic aspects that must be taken into account to achieve these objectives are compiled in the German "Safety Criteria for the Disposal of Radioactive Waste in a Mine" as recommended by the German Reactor Safety Commission. The Federal Mining Act regulates all aspects concerning mining operation.

The fundamental objective of radioactive waste disposal in repositories is to ensure that waste is disposed of in such a way that human health and the environment are protected now and in future without imposing undue burdens to future generations. That means that radioactive waste shall be managed in such a way that the predicted impact on future generations will not be greater than the relevant levels of impact that are acceptable today.

The philosophy for long-term exclusion of unacceptable radionuclide concentrations in the biosphere is to transform the radioactive waste in a sufficiently corrosion- and leach-resistant form and to dispose it of in deep geologic formations with high isolation capacity. After termination of the operational phase the whole repository must be closed off safely from the biosphere.

The following issues of the long-term safety criteria are considered to be the most important ones:

- The required safety of a repository constructed in a geological formation must be demonstrated by a site-specific safety assessment which includes the respective geological situation, the technical concept of the repository with its scheduled mode of operation, and the waste packages intended to be disposed of.

- In the post-closure phase, the radionuclides which might reach the biosphere via the groundwater as a result of transport processes must not lead to individual annual doses which exceed the limiting values specified in paragraph 45 of the Radiological Protection Ordinance (0.3 mSv/y).

The required site-specific safety assessment for the operational, the decommissioning and the post-closure phase of a deep geologic repository has also to take into account the upper limit of acceptable inventory of radioactive waste. Within the scope of this safety assessment, the following issues have to be addressed:

The radiation exposure of individuals of the population due to radionuclides released from the repository into the biosphere during the post-operational phase has to be evaluated. For the assessment of long-term safety the safety criteria have to be met taking into account all relevant long-term safety indicators.

According to the Atomic Energy Act a license is required for the construction and operation of a repository. The plan approval procedure concentrates the investigation, evaluation, review and licensing of all relevant radiological and environmental aspects into one single licensing procedure. Specific licensing requirements are elaborated e.g. by means of ordinances, safety criteria, general administrative regulations, guidelines and technical standards. As part of the licensing procedure public involvement is required. Furthermore an environmental impact assessment for the site has to be made which covers all other environmental aspects.

1.2 Competent authorities in the Konrad licensing procedure

The Atomic Act (AtG) gives the responsibilities for disposal of radioactive waste to the Federal Government currently represented by the Federal Ministry for Environment, Nature Protection and Reactor Safety (BMU). The Federal Office for Radiation Protection (BfS) is the competent organization for construction and operation of the federal installations for the disposal of radioactive waste, e.g. the Konrad repository, acting as applicant.

The Government of the Federal State which hosts the repository acts as the competent licensing authority for this facility. For the Konrad site the Federal State Government of Lower Saxony represented by the Ministry of Environment (NMU) is the licensing authority.

1.3 Steps in the plan approval procedure

The demonstration of the long-term safety of the Konrad repository from the applicant’s point of view has been laid down in application documents containing safety assessments, additional analyses and documents which were presented to the licensing authority. These documents were worked out by the applicant in discussions with the licensing authority and deal with the following subjects of the Konrad site a former iron ore mine: interpretation of the geology and the hydrogeological situation, the development of geological and hydrogeological models, development of conceptual models, safety assessments and, demonstration of compliance with the regulations /5/ .

Preparing the license decision by the licensing authority expert institutions have been contracted by the NMU to support the authority in approving the plan by reviewing the safety case. The licensing authority and their experts reviewed the documents in order to scrutinize the applicant's safety statement and to obtain expert opinions according to the state of the art to special subjects.

For the long-term safety of the Konrad repository e.g. the following expert institutions were involved: the Geological Survey of Lower Saxony (NLfB) to evaluate the geological and hydrogeological situation of the site, the Technical Inspection Agency (TÜV) to assess the long-term safety, as well as other technical experts for special questions. By order of the TÜV the Company for Reactor Safety (GRS) prepared the expert opinions for groundwater modeling and radionuclide transport for the safety assessments.

2. PREPARING AN EXPERT OPINION FOR THE SAFETY ASSESSMENTS

2.1 Examination of the applicants documents

The principal results of the applicant's safety assessments were the demonstration of a limited release of radionuclides into the biosphere, very long travel times for released radionuclides from the repository to the biosphere of more than 300.000 years, and the demonstration of compliance with the given objectives. In scenario analyses the applicant developed the normal evolution scenario, migration of radionuclides with flowing groundwater, as the representative scenario applied in the safety assessments. From the applicant's point of view these safety assessments were carried out in a conservative way.

To judge the safety case the following steps have been carried out by GRS based on the models and assumptions contained in the licensing documents:

- review of the applicants documents
- review of the scenario analysis
- scrutiny of the models
- recalculations of the applicant's safety assessments
  - with the applicant's codes (e.g. SWIFT /6/)
  - with the experts diverse codes (e.g. NAMMU /7/)
- calculations with variation of parameters and boundary conditions

Based on the assumptions, laid down in the application documents, the experts were in accordance with the applicant's assessments.

2.2 Safety assessments of the experts

2.2.1 Groundwater transport analyses

Assessing the geological and hydrogeological situation of the Konrad site the geological expert institution NLfB came to a partly different interpretation of the hydrogeological modeling of the site than the applicant. NLfB developed a hydrogeological model as the basis for further safety assessments of the experts. The model distinguished more different hydrogeological layers than the applicant's model and took regions into consideration that consisted of disturbed zones and shear zones characterized by higher hydraulic conductivities. Assessing the data of the applicant's safety assessments NLfB developed modified data sets for the groundwater modeling and determined expectation values, bandwidths and distributions of hydraulic conductivities and porosities for each hydrogeological unit.

On the basis of the NLfB's interpretation of the Konrad site as a hydrogeological model and the corresponding data, GRS constructed a conceptual model and a suitable 3D numerical model (Fig. 1) for the finite element code NAMMU in order to perform the assessments. The so called expert model was built up as a discrete model on the basis of 30 east-west cross sections of the hydrogeology, taking into consideration the different hydraulic layers and their spatial extensions as well as the disturbed zones. The dimensions of the model were approximately 15 km EW, 50 km SN and 2 km in depth. In a first step 3D groundwater transport calculations were carried out taking into account the expectation values of hydraulic conductivities and porosities. Groundwater travel paths and travel times were identified with particle tracking methods. Comparison of the results with the licensing documents showed also long travel times of the fastest tracers from the repository to the biosphere of more than 300,000 years.

To demonstrate the influence of the parameter bandwidth on the results uncertainty analyses have been carried out using the GRS software system SUSA. Quantifying the level of knowledge about the parameters by the probability distributions and, if necessary, quantifying dependencies among them, parameter samples were generated as input data sets and 3D groundwater runs as well as particle tracking calculations were carried out. The evaluation of the travel paths showed some general pathways for tracers (Fig. 2). Furthermore the runs were evaluated concerning the shortest groundwater travel times from the recharge region to the repository as well as from the repository to the biosphere. The comparison of the distribution of shortest travel times with the shortest travel time of the deterministic calculation reflected the conservative character of the deterministic results against the mean value of the uncertain analysis.

2.2.2 Radionuclide transport analyses

Aim of the radionuclide transport analyses was to evaluate the radionuclide concentrations in the groundwater of the quaternary layer which might potentially be used for drinking and watering. To do this in a conservative way the analyses were carried out as a 1D modeling with the code SWIFT. Therefore a 1D transport model was generated from the deterministic groundwater approach. On the basis of the calculated groundwater velocities in the layers of the 3D model a pathline for the shortest groundwater traveltime was generated with the aid of the particle tracking analyses. A straightforward pathline from the repository to the biosphere was developed taking only into consideration the direct connection of materials with a higher conductivity and therefore higher groundwater velocities (Fig. 3) and skipping over the parts of paths through materials with lower conductivity. To generate source terms of radionuclides for the transport calculations the repository was homogenized and modeled with the GRS code MARNIE taking into account the groundwater flow through the repository, sorption of radionuclides, and solubility limits. The darcy flow of the 1D modeling corresponded with the groundwater flow through the repository. Radionuclide transport calculations were carried out for a nuclide vector of 48 radionuclides. Retardation effects were taken into account with nuclide and material specific distribution coefficients. Results of the calculations were the concentrations of radionuclides in the groundwater of the quaternary layer as a function of time.

The potential radiological exposure caused by the released radionuclides were analyzed by the TÜV. Radiation exposures in the vicinity of nuclear installations were calculated from the radionuclide concentration in the groundwater by means of a general administration regulation which has been developed to calculate radiation doses as consequences of releases from nuclear facilities /8/. It considered a self-sustaining farming community under current-day conditions. To be applicable to long-term safety assessments this model had been modified to account for the very long time periods considered. In this context, e.g. the increasing concentrations of daughter-nuclides within decay chains are important. Climatic changes will affect the agricultural development as well as the distribution coefficients of the nuclides in the soil and the transfer factors for the uptake of the nuclides by the roots. For the proposed waste inventory compliance with the dosis criteria was demonstrated.

2.2.3 Further analyses

In the past *exploration boreholes* were drilled in the region of the Konrad site. Most of them were sealed but all of them backfilled with sludges or debris falling into the borehole. To investigate the influence of the boreholes on the groundwater regime and the transport of radionuclides a submodel of the repository and the nearest boreholes were developed from the 3D groundwater model. The analyses showed that the boreholes had no influence on the groundwater characteristics and on the radionuclide transport.

The same investigations were made for the *sealed shafts*. Because of the very low hydraulic conductivity of the seals as well as the damage zones around the shafts, the analyses showed that the sealed shafts were of no influence on the radionuclide transport.

To demonstrate the consequences of *human intrusion* two scenarios were investigated. One scenario described the borehole drilling into an emplacement field of containers with the highest amount of activity. The other scenario dealt with constructing a new iron ore mine downstream from the repository. For both scenarios consequence analyses showed compliance with the given objectives.

Furthermore the long-term safety assessment involved consequence analyses concerning the influence of gas generation, microbial effects, temperature gradients, rock convergence, recriticality and chemotoxicity on long-term safety.

2.3 Assessment criteria

2.3.1 Dose limits and time span

As mentioned above the only given criteria for the long-term safety assessment were the limits for the individual doses, e.g. 0.3 mSv/y effective dose. The reactor safety commission (RSK), an advisory body of the BMU, recommended to restrict the use of deterministic dose limits to a time span of 10,000 years. However during the Konrad licensing procedure the authority required the dose limits to be used as assessment criteria over the whole calculated time span until reaching the concentration maximum of the radionuclides, e.g. millions of years.

2.3.2 Safety indicators

In addition to dose limits other safety indicators were also used for judging the safety case. First of all the groundwater velocity had to be drawn out as a safety indicator for this safety case. Safety assessments for the Konrad site were carried out using a freshwater model. Because the measured salinity of the groundwater increased with depth the experts concluded that the calculated groundwater velocities were much higher than the expected real velocities by at least one order of magnitude. Therefore the experts judged the transport to be governed by diffusion. As a result the expected shortest travel times for radionuclides were much longer than the calculated ones, e.g. more than 1 million years.

Furthermore the measured age of the groundwater in the mine was used as a safety indicator. At special locations in the mine it was estimated at more than some hundred thousand years. Comparison of the calculated groundwater age in the modeled repository (travel time from the recharge area to the repository) with the measured age showed also the overestimation of the groundwater velocity.

3. CONCLUSIONS

Subject of this report was to give an overview of the licensing authority's and experts activities and a short demonstration of our work in the licensing procedure for the German Konrad site concerning the safety assessments for judging the long-term safety case. Scrutinizing the applicant's application documents the experts were in accordance with the applicant's assessments and safety statements.
Because of a partly different hydrogeological interpretation of the site by NLfB we carried out our own safety assessments based on a hydrogeological model and different data sets developed by NLfB. Because of the given deterministic dosis criteria a deterministic safety assessment was carried out. To confirm the chosen best estimate data set for the deterministic safety assessments uncertainty analyses were performed. Judging the long-term safety, assessment criteria were applied: the given doses criteria and additional chosen safety indicators, e.g. the salinity of the groundwater in conjunction with groundwater travel time, the groundwater age and the time of potential radiation exposure. The time span for judging the safety case with the doses criteria was not limited so that especially the potentially disposable activity inventory into the repository was influenced by the dose limits. Taking the safety indicators into account the conservative approach of the freshwater modeling was evident. For the proposed waste inventory the long-term safety of the Konrad repository was demonstrated showing the compliance with the objectives.

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21.02.19990
Bundesanzeiger 64a 31.03.19990

Figures:

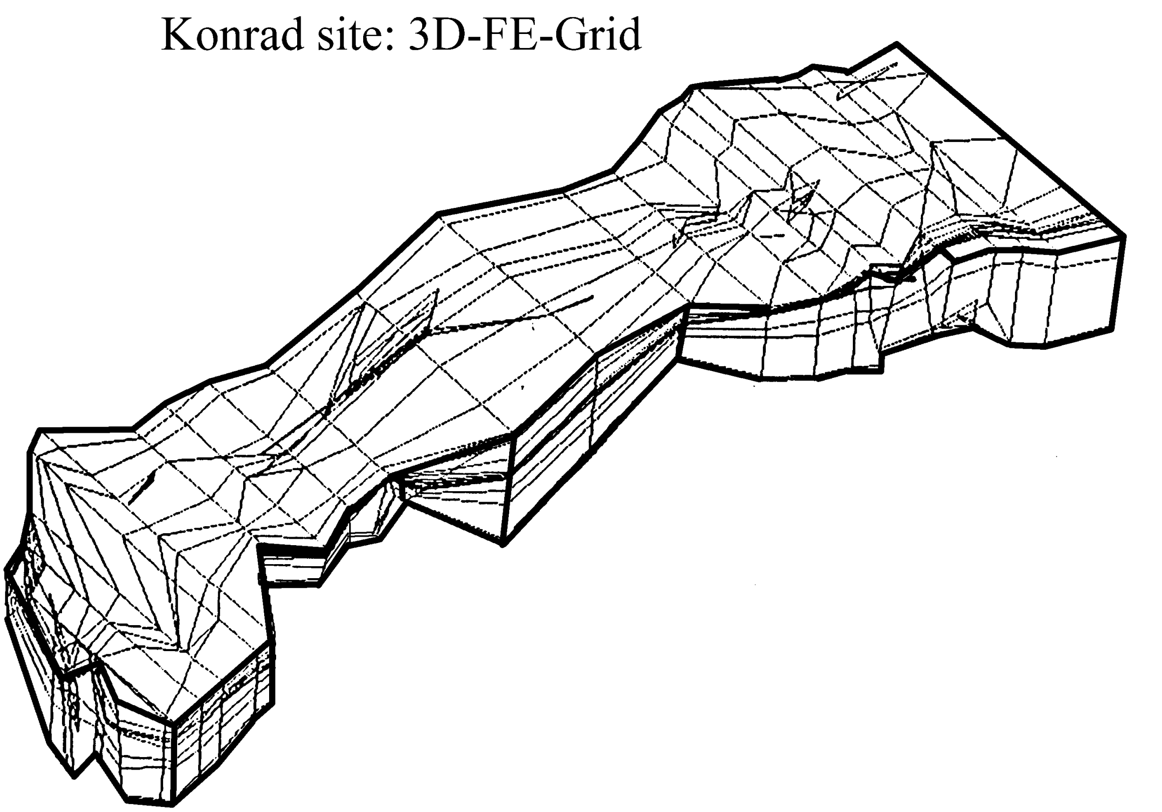

Fig. 1. Finite element model of the Konrad site

Repository Konrad

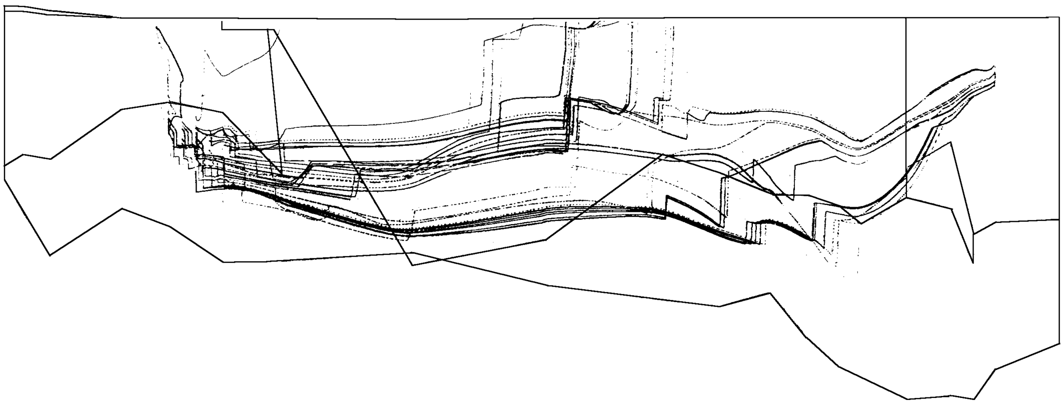

Fig. 2. Pathlines through the model

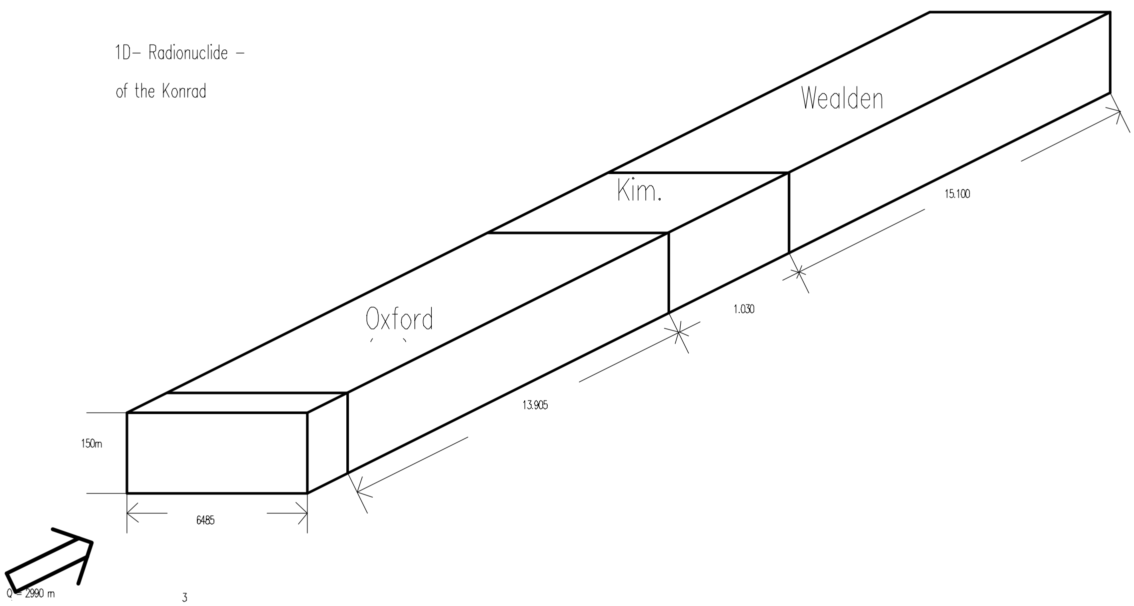

Fig. 3. 1D transport model

Selected Regulatory Issues Encountered in the Konrad Licensing Procedure

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Abstract

Regulations governing the long-term safety of radioactive waste disposal in Germany allow for considerable administrative discretion. This latitude was used by the licensing authority and the proponent in different ways. The experience gathered during the procedure is illustrated by means of two examples: the competition between the deterministic and the probabilistic approach and the time frame for long-term safety analyses.

Concluding from the gained experiences it appears decisive that the character of decreasing reliability of calculated results is reflected in the regulatory decision. Therefore some exceedence of a given limit might be tolerable in the farther future, not because of a less rigid protection of future generations but because of the more and more fictitious nature of calculated results. A qualitative rather than a quantitative implementation of such a procedure appears more adequate to the regulation of long-term safety than a fixed regulatory time frame or a deterministic criterion which is strictly applied to eternity. Methodologically a sensible combination of probabilistic and deterministic calculations is recommended which might compensate for their respective deficiencies and contribute to build confidence in a sufficient understanding of possible evolutions of the disposal system.

1. INTRODUCTION

Regulations governing the long-term safety of radioactive waste disposal in Germany allow for considerable administrative discretion. The Atomic Energy Act requires damage provision according to the state of science and technology. The Nuclear Licensing Procedures Ordinance specifies that the proponent has to submit a safety report containing the relevant evidence. The Radiation Protection Ordinance does not contain specific regulations for the judgement of the long-term safety of a repository in deep geological formations.

The safety criteria for the final disposal of radioactive wastes in a mine include a more specific protection goal for the post-operational period: after a repository has been decommissioned radionuclides which - as a consequence of transport processes that cannot be completely excluded - might escape from the sealed repository into the biosphere must not lead to individual doses which exceed the figures in § 45 of the Radiation Protection Ordinance. There, inter alia, an effective dose limit of 0.3 mSv/a is laid down. The safety criteria further require that demonstration of compliance with this protection goal must include a site-specific safety analysis using scientific methods. For that subsystems and sequences of events within the overall system are to be modelled on the basis of sufficiently conservative assumptions.

It is explicitly stated in the safety criteria that their concretization takes place in the frame of a licensing procedure according to the state of science and technology with due regard to the individual case. In particular, it is not specified in the safety criteria with which methods and for which period of time the long-term safety has to be demonstrated.

In the Konrad licensing procedure this room for administrative discretion had to be filled in a sensible and justifiable way. All the well known areas of debate including human intrusion scenarios, completeness of scenario analysis, long-term site evolution, climatic changes, reliability of expert judgements etc. had to be resolved for the specific case. The experience gathered during this procedure will be illustrated by means of two examples: the competition between the deterministic and the probabilistic approach and the time frame for long-term safety analyses.

2. PROBABILISTIC VERSUS DETERMINISTIC APPROACH

2.1 Course of events in the Konrad licensing procedure

During the eighties, the proponent submitted several deterministic safety analyses to the licensing authority. They were based on different conceptual models, used different numerical procedures and different computer codes, and included an analysis of the effect of data uncertainties by local sensitivity studies (paramter variations).

In 1991 the licensing authority required that the proponent should supplement his deterministic by probabilistic calculations even though the authority acknowledged that the proponent's deterministic approach on the basis of conservative boundary conditions and input data sets was in compliance with the state of the art. The licensing authority argued that the international development, especially the contributions of the OECD/NEA's Probabilistic System Assessment Group (PSAG), had lead to such a progress in probabilistic computer programs that their application within a licensing procedure had become possible. Therefore the licensing authority demanded their use in order to increase confidence in compliance of the safety case with the protection goal.

The proponent refused this demand as not justified. He reasoned that probabilistic calculations of one-dimensional radionuclide transport - as in the PSACOIN Level 1a Exercise - are state of the art, but not three-dimensional hydrogeological model calculations of ground- water flow. Further he referred to the diversity of his deterministic calculations. Their con-servatism was additionally confirmed by isotopic age examinations of the deep groundwater at the site.

The licensing authority did not further pursue its demand towards the proponent. Instead it requested a probabilistic uncertainty analysis by one of its consultants. The Federal supervision agreed to this procedure.

2.2 Gained experiences

There are good reasons for deterministic model calculations on the basis of conservative assumptions, boundary conditions and parameter values: they are comparatively transparent, and their relatively robust results can more easily be communicated to the public; they allow for detailed modelling, but also permit covering simplifications. Their relative simplicity corresponds - and does not artificially hide - our limited capability to predict the future.

But they also have serious disadvantages. Of decisive importance is the fact that con-servativity of the overall results cannot be demonstrated, even if every single choice within the safety analysis is made in a conservative way. This is even true if only the aspect of input data definition is considered. This realization, which can easily be proven in theory, was demonstrated through a couple of practical examples within the long-term safety analyses. For instance leads the assignment of higher permeabilities to hydrogeological layers to shorter groundwater travel times, but not necessarily to higher maximum radionuclide concentrations in the biosphere. There are also applications in which the most unfavorable results were not obtained with extreme input parameter values but with an unforeseen combination of values taken somewhere from the middle region of their respective range of values. Another difficulty arises when a "worst" value of a parameter cannot be defined but increasingly extreme values are associated with a diminishing likelihood.

It is just this weakness which is the strength of probabilistic consequence analyses. It allows for systematic and theoretically exhaustive examination of the parameter space. Effects of input parameter on output uncertainties can be fully explored as well as the results' sensitivity to variations in input data. It also allows for demonstration of the conservativity of a given input data set.

Unfortunately, enthusiasm for the probabilistic approach is calmed when it comes to the treatment of uncertainties due to different conceptual models consistent with the available site information or possible climatic changes in the future. Proposals to parametrize these uncertainties and thereby overcome the limitations did not prove practical. It therefore became increasingly doubtful whether the major uncertainties were addressed at all by probabilistic calculations.

The concept of a full psa for radioactive waste disposal systems might share its fate with validation: it fails in practical long-term safety analysis because of its high theoretical demands. Probabilities of occurrence for a certain "improbable" sequence of events can hardly be quantified on a scientific basis. It also appears almost impossible to imagine a long-term safety assessment which is not based on any simplifying assumptions as it would be necessary for a full probabilistic analysis. On the whole the claim to comprehensively assess by means of probabilistic calculations all conceptual models for a site without conservative assumptions, but with three-dimensional modelling of groundwater flow in combination with radionuclide transport, and also taking the uncertainties due to future site evolutions into account does not appear practicable within a licensing procedure.

It seems to make sense, though, to pursue a principally deterministic approach in the frame of which envelope scenarios and different conceptual models are considered, several computer codes with different numerical procedures are implemented, and the effects of input data uncertainties are quantitatively assessed through probabilistic consequence analyses. It must thereby be kept in mind that the obtained probability distributions are not unconditional, but conditional on the conservative assumptions and model simplifications which entered into the calculations.

3. TIME FRAME FOR LONG-TERM SAFETY ASSESSMENTS

3.1 Course of events in the Konrad licensing procedure

Performance assessment studies at the Konrad site revealed groundwater travel times in the order of several hundred thousands of years. Taking retardation into account it soon became clear that for a considerable part of the relevant radionuclides long-term safety analyses would have to be performed over several millions of years to see their calculated maximum exposition in the biosphere.

In 1988, the Reactor Safety Commission (RSK) and the Radiation Protection Commission (SSK) jointly issued a recommendation on the subject. They argued that a sufficiently accurate calculation of a potential exposure can only be performed during a period of 10000 years regarding changing conditions in the biosphere and the hydrological setting, e.g. due to glaciation. RSK/SSK therefore concluded that compliance with the protection goal - the individual dose limit of 0.3 mSv/a - is only to be demonstrated over a period of 10000 years (demonstration period). Beyond that time evaluation of the geological conditions may serve for a prognosis of the site-specific isolation potential.

The licensing authority did not agree to any time frame for the long-term safety assessment, neither to a cut-off time for the calculations nor to a point in time after which compliance with the protection goal need not be further demonstrated.

Therefore the proponent did not take credit of the RSK/SSK recommendation and carried out safety analyses up to some ten millions of years until the dose curves of all relevant radionuclides have passed through their calculated maxima. Based on an expected activity inventory the calculations showed that the individual dose limit was not exceeded at any point in time. During the comprehensive discussion of the plan with the intervenors the proponent, on demand of the licensing authority, accepted the interpretation of the expected activity inventory as nuclide-specific disposal limits.

3.2 Gained experiences

A general time frame is debatable. From a legal point of view there is no a priori limitation of the time period over which damage provision has to be demonstrated. Investigations of potentially harmful sequences of events have to be carried out up to the limits of practical reasoning. These may well depend on site-specific features, but mere lack of knowledge cannot justify termination of damage provision. Changes e.g. of the hydrological conditions due to glaciations may be represented in additional scenarios and hence assessed in their consequences. Last but not least any regulatory cut-off time is unacceptable to the public. It would not comply to the principle that a similar level of protection should be provided for future generations as that provided for the current generation.

On the other hand it is also debatable to limit the disposable inventory of a radionuclide based on a potential exposition after 10 millions of years calculated deterministically under present day conditions. Long-term safety analyses are inevitably affected with uncertainties which gradually increase with time and eventually make calculated results meaningless. Adequate interpretation of calculated performance assessment results must consider their decreasing reliability with time.

During the last years the usage of safety indicators has been proposed as a possible way to overcome the problem. A calculated dose may be interpreted as an indicator of safety rather than an individual dose in the classical radiological sense. This corresponds to a transition to stylized calculations with reference biospheres and circumvents the problem posed by relatively rapid changes in the environmental conditions and the agricultural and eating habits. Furthermore, other non-radiological safety indicators could complement the dose indicator, and different indicators may be appropriate in different time frames.

The key question, however, remains: how to assess the results - be it in terms of conventional dose or in terms of safety indicators - in a regulatory context? Concluding from the experience in the Konrad procedure neither a fixed time frame nor a deterministic criterion which is strictly applied to eternity are satisfying solutions. And introduction of safety indicators only shifts the problem of increasing uncertainties to another level. Furthermore, they require respective regulatory limits against which compliance can be judged.

4. CONCLUSIONS

Results of long-term safety assessments are inevitably affected with considerable uncertainties. This is already true for a quantitative modelling of present day conditions and holds the more, when the resulting statements refer to the farther future. It is therefore necessary and as experience demonstrates practicable, too, to adequately take these uncertainties into account and thereby achieve reasonable assurance to a degree that is sufficient in a licensing procedure.

The application of deterministic and probabilistic approaches do not exclude but supple-ment each other. According to today's understanding of the matter, neither a purely deterministic nor a purely probabilistic approach is recommended. Instead a sensible combination of both compensates for their respective deficiencies and contributes to build confidence in a sufficient understanding of possible evolutions of the disposal system.

It appears decisive that the character of decreasing reliability of calculated results is reflected in the regulatory decision. The calculated result for a time point in the future therefore should not be lookod at as a number but as an interval or - in terms of probability calculus - as a distribution. It would then be possible to principally apply a deterministic limit but simulta- neously allow for some exceedence of the limit by the upper tail of the interval or distribution. The tolerable exceedence of the limit could gradually increase with time, not because of a less rigid protection of future generations but because of the more and more fictitious nature of the calculated results. A qualitative application with a certain latitude of judgment seems more appropriate than a quantitative definition of this procedure.

These aspects, among others, are considered in a presently ongoing review of the existing regulatory framework regarding radioactive waste disposal in Germany. On this basis the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, together with its consulting experts in RSK and SSK and other competent authorities, will possibly initiate a new edition of the safety criteria.

Waste Isolation Pilot Plant (WIPP): EPA's Regulatory Approach

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Abstract

The Waste Isolation Pilot Plant (WIPP) will contain transuranic (TRU) waste that has resulted from the United States' nuclear weapons programs. There are many facets to the WIPP project. As independent regulator of the WIPP, the United States Environmental Protection Agency (USEPA) has the responsibilities of promulgating public health and environmental standards, determining if the WIPP meets the standards, certifying compliance of the WIPP, and periodically, re-evaluating the WIPP to assure continued compliance for meeting these standards. EPA's regulatory framework incorporates many Federal laws, the bases of the Agency's WIPP standards. EPA has been successful in finalizing the Radioactive Waste Disposal Standards (40CFR191), proposing the Compliance Criteria (40CFR194), and implementing a process for achieving acceptance through the public participation process in the WIPP rulemaking. EPA has incorporated four guiding principles that are implemented in the regulatory process. The principles of protection, good science, consultation, and commitment have been applied to the WIPP program. EPA has worked diligently to develop a program in which the public can believe that EPA will do the right thing regarding their safety, their environment, and their tax dollars. This trust has been difficult to build and remains fragile, easily broken. EPA will continue to regulate the WIPP efficiently and effectively to always protect the public health and the environment.

The Waste Isolation Pilot Plant (WIPP) will contain transuranic (TRU) waste that has resulted from the United States' nuclear weapons programs. Its radioactive contents will remain hazardous for thousands of generations. Ensuring the safe disposal of the nation's transuranic waste is of utmost importance for the future. If not disposed of safely, a dangerous legacy of nuclear pollution will be left to our grandchildren and their grandchildren.

There are many facets to the WIPP project. As independent regulator of the WIPP, the United States Environmental Protection Agency (USEPA) has the responsibilities of promulgating public health and environmental standards, determining if the WIPP meets the standards, certifying compliance of the WIPP, and periodically, re-evaluating the WIPP to assure continued compliance for meeting the standards. EPA's regulatory framework for the WIPP standards incorporates many Federal laws. EPA has been successful in finalizing the Radioactive Waste Disposal Standards and the Compliance Criteria, and implementing a process for achieving acceptance through public participation in the WIPP rulemaking [1].

The Waste Isolation Pilot Plant represents a potential solution to part of one of the United States' more intractable problems, the safe disposal of highly radioactive waste. It will also represent a major national and international regulatory precedent in the field of radioactive waste disposal. The WIPP is the first facility of its kind to undergo a formal regulatory approval process. If approved, the WIPP Project will be the first disposal site for large quantities of transuranic waste in the world [2]. EPA regulates the release of radioactivity from the management, storage, and disposal of radioactive waste in order to protect public health and the environment from the harmful effects of radiation exposure. Radioactive wastes are the result of government and commercial production of nuclear materials. The WIPP is a repository for the disposal of transuranic waste and transuranic mixed waste. Much of the waste destined for disposal at the WIPP is in the form of transuranic mixed waste, which is a combination of transuranic waste and hazardous chemical or metal components. The waste targeted for disposal at the WIPP has been produced since 1970 and is currently being stored above ground at various DOE sites across the United States [3]. The WIPP is designed to receive waste primarily from 10 DOE facilities over a 25-year period.

The WIPP is located near Carlsbad, New Mexico. The Federal government began site investigation of the area in 1975. Congress authorized construction of the facility in New Mexico in 1979. DOE is responsible for developing and managing the facility and the surrounding 16 square mile reserve of federally-owned land. DOE broke ground for the facility in 1981. EPA promulgated the first high level waste disposal standards in 1985 and was sued very soon by several states and environmental groups. The suit was due to the inconsistencies between the waste standards and the Safe Drinking Water Act (SDWA). The court vacated and remanded several portions of the standards in 1987. In 1992, Congress passed the WIPP Land Withdrawal Act (WIPPLWA) which named EPA as the independent regulator to ensure that the WIPP can safely dispose of nuclear transuranic waste. The WIPPLWA also reinstated the vacated parts of the waste standards and required finalization of the remanded portions [4].

The WIPP site contains deep salt beds, which are a good medium for disposal of radioactive wastes. Salt beds have several characteristics that make them attractive. They are geologically-stable areas that have little or no discernible earthquake activity. They usually lack underground water sources. They are relatively easy to mine and are capable of creeping to seal cracks that might develop in the surrounding earth. The disposal facility is designed to hold approximately 850,000 drums of transuranic waste which will be placed in rooms carved out of the salt rock. The remaining higher-level transuranic waste will be packaged in carbon steel cylinders placed in holes drilled in disposal room walls. The holes will then be plugged and the rooms and shafts sealed [5].

In regulating the WIPP, EPA must ensure that it complies with all other applicable Federal environmental laws which constitute EPA's framework for the WIPP standards. EPA's regulatory framework includes all of the laws in the following table [6].

FEDERAL LAWS	**YEAR PASSED**	**CONTENTS**
Atomic Energy Act (AEA)	1954	Generally applicable environmental radiation standards
National Environmental Policy Act (NEPA)	1969	Evaluation of Federal actions involving environmental issues
Clean Air Act (CAA)	1970	Airborne emissions of radionuclides
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	1972	Risk goals (10^{-6}) for pesticides in food
Safe Drinking Water Act (SWDA)	1974	Radionuclides in drinking water
Resource Conservation and Recovery Act (RCRA)	1976	Hazardous component of mixed waste
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA)	1980	Radioactive waste cleanup and radon
Superfund Amendments and Reauthorization Act (SARA)	1986	Radon surveys
Nuclear Waste Policy Act (NWPA)	1982	Generally applicable environmental standards for high level radioactive waste
Energy Policy Act	1992	Radiation standards for the Yucca Mountain, NV high level waste repository
WIPP Land Withdrawal Act (WIPPLWA)	1992	EPA regulator responsible for promulgating Radioactive Waste Disposal Standards and Compliance Criteria

Table 1. U.S. Environmental Laws

DOE must submit to EPA documentation demonstrating that the WIPP complies with the laws listed above and with radiation protection standards that apply to the management and storage of transuranic waste prior to disposal.

Many of the Federal laws contain specific concentrations of radionuclides, dose limits, and associated risk levels. The next table shows some of that information.

FEDERAL LAW	**CONCENTRATION**	**DOSE LIMITS**	**RISK**
RCRA/CERCLA			10^{-4} to 10^{-6}
CAA (NESHAPS)			~10^{-4}
SWDA:			
beta emitters		40 mSv/yr (4 mrem/yr)	10^{-4}
alpha emitters	555 Bq/m^{-3} (15 pCi/l)	60 to 300 mSv/yr (6 to 30 mrem/yr)	$2x10^{-4}$ to $1x10^{-6}$
radium	185 Bq/m^{-3} (5 pCi/l)	50 mSv/yr (5 mrem/yr)	10^{-4}
WIPP		150 mSv/yr (15 mrem/ry)	$3x10^{-4}$
Federal Guidance		1000 mSv/yr + ALARA (100 mrem/yr + ALARA)	$2x10^{-3}$
Uranium Mill Tailings Radiation Control Act (UMTRCA)	185 Bq/m^{-3} (5 pCi/l) and 555 Bq/m^{-3} (15 pCi/l)	150 - 1000 mSv/yr (15 - 100 mrem/yr)	$2x10^{-3}$ to $3x10^{-4}$
FIFRA (Pesticides)			10^{-6}

Table 2. Comparative Risks

EPA has four guiding principles that are implemented in the regulatory process [7]. These principles have been applied to the WIPP program as well. They are as follows:

- **Protection**
  To protect the present and future generations from risks posed by the disposal of waste.
- **Good science**
  To base decisions on the best available scientific and technical data.
- **Consultation**

To recognize the important roles played by state, local governments, citizens, environmental groups, industry, Federal agencies; and be committed to conducting an open public process.

- **Commitment**
  To establish and meet commitments to implement legislation effectively, consistent with EPA's legal authority.

Before beginning disposal of radioactive waste at the WIPP, DOE must certify that the facility will comply with EPA's radioactive waste disposal standards. The proposed compliance criteria, which are specific to the WIPP, will serve a means to implement EPA's radioactive waste disposal standards. The primary goal of the compliance criteria is to make compliance at the WIPP as straightforward as possible by setting forth requirements that will assure the quality of DOE's compliance application. The proposed criteria include general requirements, individual and ground-water protection requirements, and public participation requirements [8].

Under the WIPP Land Withdrawal Act, EPA's WIPP-related responsibilities fall into two basic categories, first EPA must issue standards to limit radiation releases to the environment that might result from radioactive waste disposal and then determine if the WIPP will meet them. Secondly, EPA must ensure that the facility complies with other applicable Federal environmental laws that protect human health and the environment. The Federal laws that DOE has to meet were previously shown in the regulatory framework. EPA's Radioactive Waste Disposal Standards consist of a series of requirements that are designed to protect the public health and the environment from the potential hazards of radioactive waste disposal. The containment requirements dictate that waste disposal systems be designed to minimize all releases for 10,000 years. These requirements prescribe that waste disposal systems be designed to provide a reasonable expectation that total releases of radionuclides from a disposal facility into the accessible environment will not exceed specified levels for 10,000 years after disposal. The proposed compliance criteria lay out reasonable assumptions and approaches that can be used for demonstrating compliance with the containment requirements. For instance, the criteria specify a process for assessing the likelihood and consequences of "human intrusion" into the repository, such as intrusion from oil drilling. The criteria also specify an approach to considering naturally-occurring processes and events that may affect the WIPP disposal system. The assurance requirements demand that the wastes be disposed of in a cautious manner that reduces the possibility of any radiation being released from the facility. The assurance requirements supplement the quantitative containment requirements with more qualitative provisions. DOE is required to design passive institutional controls to provide further assurance that the disposal standards will be met. Passive institutional controls include permanent markers placed at the site and record keeping/archiving systems to assure that information on the facility is passed on to future generations. Other types of assessment requirements include active institutional controls, monitoring systems, and engineered barriers for the waste. The compliance criteria describe the types of information and justification that DOE will need to provide to EPA that demonstrates DOE is properly complying with the assurance requirements. Individual protection requirements order that the site be designed to limit the amount of radiation to which an individual can be exposed. They require that radioactive waste disposal systems be designed to provide a reasonable expectation that, for 10,000 years after disposal, the annual radiation dose to any individual does not exceed 150 mSv (15 mrem) effective dose equivalent (EDE) per year. The ground water protection requirements establish rules to protect current and potential underground sources of drinking water from radiation contamination and they are consistent with the Safe Drinking Water Act (SDWA). These requirements state that disposal systems must be designed to provide a reasonable expectation that the waste facility does not contaminate underground sources of drinking water such that radionuclide levels in this water exceed those allowed under the SDWA. The compliance criteria clarify terms in the standards and describe the types of analyses that DOE will have to submit to EPA to demonstrate compliance with these portions on the disposal standards [9].

The Compliance Criteria establishes the level of confidence needed for certification of compliance and explain the procedural aspects of the rulemaking, such as the requirements for public participation. The criteria also establish procedures that will afford EPA access to the WIPP and its records so EPA can independently assess the performance of the facility. Finally, the criteria provide procedures so that the Agency can suspend or revoke certification if necessary [10].

EPA has conducted WIPP activities in an open process to build public trust in the regulatory decisions that are made. The public must know that the Federal government is spending tax dollars wisely and safeguarding their health and their environment. The public demands that EPA use the best science available in making decisions. EPA's public participation process has included encouraging ***open*** communication from the stakeholders, involving the stakeholders ***early*** in the regulatory process, providing public participation opportunities ***often,*** and making public participation ***required***. Some of EPA's stakeholders include the Department of Energy, the State of New Mexico, the City of Carlsbad, NM, New Mexico Environmental Groups, New Mexico Environmental Evaluation Group, Congress, the states possessing transuranic waste (ten states), the states with transportation routes for transuranic waste (22 states), and the general public.

As required by the Compliance Criteria, EPA has an established communications plan which outlines the public participation process. This plan includes public meetings and hearings held near the WIPP site, technical meetings between EPA and DOE are open to the public, and independent consultation through WIPP Review Subcommittee. EPA has several public outreach avenues for information dissemination. There are four dockets with all of the information pertaining to the WIPP rulemaking located in New Mexico near the site and in Washington, D.C. There is a toll-free telephone number (1-800-331-WIPP) with recorded information on WIPP activities. Fact sheets describing key elements of the WIPP program are available and EPA has an electronic bulletin board (919-541-5742).EPA maintains a WIPP mailing list that presently includes 750 interested parties [11].

In summary, WIPP represents a rare opportunity - it is a solution to a major radioactive waste problem. The WIPP started as a project to demonstrate the safe long-term disposal of radioactive waste, but it also represents an opportunity to show that government agencies can efficiently work together, that an open, public discussion of the scientific and policy issues surrounding radioactive waste disposal is possible and public trust can be built. EPA has worked diligently to develop a program in which the public can believe EPA will do the right things with their safety, their environment, and their tax dollars. This trust has been difficult to build and remains fragile, easily broken. EPA will continue to regulate the WIPP efficiently and effectively to always protect the public health and the environment.

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The U.S. Nuclear Regulatory Commission's Experience in the Licensing of HLW Waste Repositories

Remarks Prepared by

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During the U.S. Nuclear Regulatory Commission's (NRC's) experience with the U.S. Department of Energy (DOE), while DOE has been developing high-level waste (HLW) repository, a number of areas of concern have arisen. Three areas of concern are particularly appropriate for discussion in this forum. They are *technical integration, independent verification,* and *quality assurance.* I will provide a description of, cause (or causes) for, and resolution of, these three areas of concern next.

Technical Integration

Description

Clearly, scientists from diverse disciplines will need to closely interact to successfully predict the future performance of a HLW repository. For example, designers of the waste package must understand what its thermal, chemical, and mechanical environment will be. Likewise, geoscientists attempting to predict that environment will need to know how it will be affected by excavation and by the emplaced waste packages. NRC has been alert to the need for such integration while it has reviewed DOE's investigations of Yucca Mountain, as well as DOE's efforts to develop the data and analyses needed for a license application. During NRC's reviews, we observed that some groups and individuals within DOE did not appear to be fully integrated into the overall repository program. For example, some experimental hydrologists did not appear to be developing information needed by performance assessment modelers, nor did they appear to understand the limitations of the computer models of the hydrology of Yucca Mountain.

Cause

NRC considers that technical integration of any large project that requires different disciplines is challenging. The task of technical integration is more difficult, regarding DOE's development of a HLW repository, because the needed skills are distributed not only among numerous DOE laboratories and private contractors, but also, in many cases, at widely scattered geographic locations. NRC experienced similar problems with its own HLW technical program, in the early 198Os, when it sponsored work at a number of different laboratories and universities. In the absence of a strong integrating force, NRC's scientists tended to focus on more straightforward problems that lay within their own disciplines rather than on broader problems, involving multiple disciplines, that were usually more difficult to resolve.

Resolution

At NRC, technical integration became the responsibility of our performance assessment staff and contractors, as they began to identify the information needed to assess the overall performance of the repository. The staff's interactions with other NRC contractors improved both communications and those contractors' attention to the specific products needed to address NRC's regulations. However, they had not successfully integrated NRC's overall HLW program when the Commission created *the Center for Nuclear Waste Regulatory Analyses* (the Center) in San Antonio, Texas. The Center operates through a single management chain, with all its staff and most of its consultants at a single location. This single-location, single-management approach has improved integration of NRC's technical assistance program significantly. The opportunities for and management emphasis on interdisciplinary communication appear to have resulted in successful technical integration of the overall NRC HLW program. DOE's efforts, regarding having a single overall contractor responsible for managing its HLW efforts, also appear to be making progress. However, this area will require close NRC/DOE attention during the entire repository development process.

Independent Verification

Description

NRC's role as an independent regulatory agency requires that it independently conclude that the technical basis for DOE's license application is sound. NRC cannot duplicate all DOE data nor repeat all of its analyses, but DOE must provide enough information for NRC to be able to probe technical issues, as necessary. A simple test of the information that DOE will need to provide at licensing is the same test that applies to a peer-reviewed technical publication, namely is there sufficient information for a technically competent outsider to duplicate DOE's analyses and reach DOE's conclusions about the repository?

Occasionally, during DOE's investigations of Yucca Mountain, it has not met this test. For example, DOE did not provide all the information on "surface varnish," or weathering effects on rock, that NRC needed to independently conclude that surface erosion, as a potentially adverse condition at Yucca Mountain, would not affect the long-term performance of the repository. Based on additional information available to the NRC staff, NRC has subsequently been able to conclude that this issue has been resolved at the staff level. NRC recognizes that until DOE submits a license application, it has no obligation to provide all the information needed for an independent review. However, DOE and NRC are both interested in resolving issues as early as possible, to the extent practical, and that level of information is necessary for such resolution.

NRC notes that DOE's conclusions are generally sound. However, occasionally the technical basis for those conclusions is not available, or DOE has not always demonstrated that it has considered all reasonable alternatives to its conclusions.

Cause

The reasons that DOE has not always provided sufficient information appear to vary, and it may be that the principal cause is ineffective communications between the two agencies about NRC's expectations.

NRC's experience with other organizations that it regulates suggests that their failure to provide sufficient information may result from an incomplete understanding of NRC's requirements, or a lack of resources (including time), or a desire not to overdo an initial licensing submittal. NRC has also found that some organizations that are product- or results-oriented have developed cultures that emphasize successful technical results, rather than documentation of how those results were reached. For such organizations, becoming NRC licensees has occasionally required culture changes within the staffs.

Resolution

As the agencies work together, and the body of interagency communications grows, the problem of insufficient information appears to have decreased. NRC is working during this pre-licensing period to provide early feedback to DOE, through an issue resolution process, to clearly identify where information may be incomplete for licensing. Also, both Agencies' officials will continue to emphasize that NRC and the public must be able to independently verify DOE's conclusions. NRC recognizes that this may require culture changes for some groups and individuals.

Quality Assurance

Description

NRC's regulations define quality assurance as all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system that provide, a means to control the quality of the material, structure, component, or system to predetermined requirements.

In the past, NRC's review of the DOE HLW program identified a number of instances where DOE's quality assurance program did not meet NRC's standards. For example, in DOE's design and construction of the exploratory tunnel at Yucca Mountain, NRC had initial concerns about whether DOE's configuration control was ensuring that the tunnel was being constructed as designed. NRC also has had concerns about the application of quality assurance to DOE's decision-making processes. In particular, DOE does not always appear to have a clear, logical, and defensible record of the decisions it has made and why it has made them. NRC believes that DOE must be able to show that alternatives to its decisions were appropriately considered and rejected.

NRC seeks quality assurance so that it can have confidence that the repository will perform satisfactorily. However, a second factor driving NRC's reliance on quality assurance is the formal public process that the Agency uses to reach its licensing decisions, and its expectation that this licensing action will be strongly contested. Therefore, it is particularly important that DOE's information be developed using a rigorous quality assurance process.

Cause

NRC‘s experience with other licensees suggests that it is not easy to achieve a sound quality assurance program. It requires a strong management commitment and the development of a culture that recognizes that an appropriate quality assurance program leads to a more efficient, rather than a less efficient, operation. As mentioned above, it may be that DOE's past emphasis on technical success and its limited experience in the public resolution of technical issues are factors.

Resolution

Senior NRC and DOE management are now paying close attention to quality assurance. Present DOE management appears to have a strong commitment to its success. For example, DOE has established its own audit process to determine whether its quality assurance program is being followed and NRC's quality assurance staff observe and comment on these audits. As a result, at this time, it appears that although quality assurance concerns continue to occur, they are being properly raised and addressed by both agencies.

Summary

Both NRC and DOE are responsible for addressing the three areas of concern I have just described. In asking that DOE meet NRC's standards, it is important for NRC to ensure that those standards are necessary for DOE to be able to make its licensing case. It is also necessary that the staffs of both agencies clearly understand what the licensing process will involve and what information is and is not necessary for the NRC to reach a decision on granting a license. Continuing public discussions with DOE on these topics will be necessary throughout the development of its license application.

Radioactive Waste Disposal in Canada: Judging the Safety Case

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Abstract

Experience

Canada has been involved with nuclear issues including radioactive waste for more than 50 years. As the federal agency with responsibility for regulating the safety of nuclear energy in Canada, the Atomic Energy Control Board is faced with regulating the full gamut of radioactive waste issues ranging from storage of low-level, short-lived hospital wastes to disposal of spent fuel. We have already licensed disposal facilities for uranium tailings, have reviewed a conceptual proposal for deep geological disposal of spent fuel and are reviewing a proposal for a near-surface low-and intermediate-level waste disposal facility. The objectives of radioactive waste disposal are to minimise any burden placed on future generations, to protect the environment, and to protect human health.

Criteria/regulatory expectations

The Canadian approach to regulation of radioactive waste disposal is governed by the need for a coherent, consistent set of criteria that is applicable to all types of disposal facilities, and is essentially non-prescriptive. There are three pivotal criteria on which radioactive waste disposal proposals are evaluated: the annual risk of fatal cancer and serious genetic effects from the facility must not exceed 10^{-6}; predicted future risks to humans or the environment must be no greater than those currently accepted; and compliance must be demonstrable over at least 10^4 years. If there is no practicable method of fully meeting these criteria, optimization arguments may be made in support of a proposed disposal facility. Such optimization arguments have been made, and accepted, in the case of uranium tailings facilities where long-term institutional controls are required to assure an appropriate level of safety. In such situations, the predicted risk to individuals must not exceed current risk from the wastes. Near-surface and deep geological radioactive waste disposal systems are expected to involve waste containment and isolation by means of multiple barriers.

Compliance

In attempting to demonstrate compliance with these criteria and regulatory expectations, proponents are expected to provide clear documentation on assumptions on system characteristics and

behaviour, use multiple lines of reasoning which will involve a range of qualitative, quantitative and semi-quantitative information. In addition to detailed, elaborate modelling, effective use has been made of qualitative arguments, such as comparison with natural and historical analogues, and semi-qualitative, bounding calculations that explore "worst-case" scenarios.

Lessons learned

There are two main lessons learnt from recent experience with radioactive waste disposal issues in Canada: Firstly, ongoing dialogue between the regulator and the proponent during all phases of the production of a proposal is essential. The regulator has to be able to provide regulatory expectations in a timely fashion and be prepared to discuss progress with the proponent on a regular basis, while the proponent has to be prepared to modify plans and take into account the information being received from the regulator.

A second lesson learnt is that in Canada, as in many other countries, there has a significant change in society's expectations with respect to decision-making. The public is no longer willing to leave technical decisions to the scientists, nor socio-political problems to the politicians. There are expectations that any decision-making process will be transparent and will accommodate public input and that decision-makers will be held accountable for their decisions. While there are many examples of this phenomenon, it has been particularly evident in the area of nuclear power and radioactive waste disposal.

It has been obvious from public hearings on nuclear issues in Canada, people operate in different modes and give different weight to different types of evidence. Those in the technical paradigm tend to seek factually-based information that can be used to construct linear, analytic arguments as proof of safety. The social paradigm tends to emphasise experience, examples and values. These different approaches have led to considerable frustration as each "side" tries to convey its message to the other. Scientists and technologists must accept that there are varying ways of communicating and demonstrating safety, if they wish to see their projects succeed. This does not mean that one should simply deluge the public with information about a project but rather that there should be open, and early, dialogue with all stakeholders to identify their issues and concerns and to initiate education of all parties. The communication of safety has to go beyond the technical basis for demonstration of safety. Such a process may be time-consuming and costly but would be a major step towards public acceptance of the long-term safety of radioactive waste disposal facilities.

For many years, the Atomic Energy Control Board and our licensees have operated strictly in a technical mode: producing and evaluating rigorous scientific and technical evidence to support safety concerns while placing little emphasis on ensuring that broader issues important to the potentially-affected society are addressed. Members of the public have felt that they are being ignored, that information is being withheld from them and that their issues are not seen as relevant. This perception has led to a reduction in the credibility of the regulator and the licensees.

For many years, the Atomic Energy Control Board and our licensees have operated strictly in a technical mode: producing and evaluating rigorous scientific and technical evidence to support safety concerns while placing little emphasis on ensuring that broader issues important to the potentially-affected society are addressed. Members of the public have felt that they are being ignored, that information is being withheld from them and that their issues are not seen as relevant. This perception has led to a reduction in the perceived credibility of the regulator and the licensees.

However, in the last few years we have started to take steps to help the public understand what the role of the Atomic Energy Control Board is and to increase our responsiveness to the public, not just in the area of radioactive waste disposal but in all areas of our mandate. We believe that these steps will increase our credibility with the public, therefore providing more assurance in our regulatory decision-making. Of course, public confidence has to be earned and our decisions must be based on sound science but, without public confidence the best science in the world will go uncredited if we do not get the message out to the main decision-makers: society at large.

Judging the Safety Case.
Compliance Requirements.

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1.- INTRODUCTION

The licensing process of radioactive waste disposal facilities in Spain is conducted, at the present time, on the basis of the legal framework existing in the field of nuclear and radioactive installations. The Nuclear Safety Council acts as the regulatory body and ENRESA is the national agency in charge of the radioactive waste management.

Briefly, the licensing process is divided into four main steps: the Prior Authorization, the official recognition of the site, the Construction Permit, the Operating Authorization and finally, when the facility stops its activities, a Closure Authorization is required. The procedure for the first three permits is well defined, while the procedure for the last one is not developed in detail at this time.

The Licensee, ENRESA in the cases of Radioactive Waste Management, must present a safety report in order to apply for any of these authorizations. The Nuclear Safety Council establishes the safety criteria used and verifies the compliance with the requirements reviewing the safety reports.

All these authorizations are granted by the Ministry of Industry and incorporate the preceptive and legally binding report of the Nuclear Safety Council on matters related to Radiation Protection and Nuclear Safety. In some cases, in the absence of national specific regulation, the Nuclear Safety Council have used technical regulations from other countries, namely USA, France and Germany, or from the International Atomic Energy Agency.

The radioactive wastes are managed according to the strategies defined in the General Radioactive Waste Plan. The Plan is proposed periodically by ENRESA, and presented by the Ministry of Industry to the Government for approval.

2.- REGULATORY AND LICENSING EXPERIENCE

The main activities developed by the Nuclear Safety Council regarding the final radioactive waste management, up to now, are the following:

- The Council has expressed its opinion about the First General Radioactive Waste Plan

- The Council has set up:

- The radiological criterion for radioactive waste disposal, which was defined as *"a level of risk to the individuals lower than 10^{-6} year^{-1} or the risk associated to an equivalent dose to individuals of the critical group lower than 0.1 mSv/year"*

- The general siting criteria for the geological disposal of radioactive waste (Table 1).

- The Council has reviewed the Safety Reports prepared for the following radioactive waste activities

  - Construction, and operating of El Cabril Low and Intermediate Level Waste facility

  - Andujar Uranium Mill in situ dismantling and site restoration

  - La Haba Uranium Mill in situ dismantling and site restoration

The work carried out by the Nuclear Safety Council along the lincensing of these activities, has provided an important experience to resolve relevant technical issues of the safety and environmental impact assessments. The existence of a fluid dialogue and cooperation between Authorities, Regulators, Implementers, and other Institutions has allowed to carry out these processes with a reasonable success.

We believe that the Council has acquired the know how to conduct the decision process in the absence of national specific regulations and the knowledge and competence required, in order to start the expected regulatory duties, related to the definition of criteria and the review of the safety assessment in the final management of high level waste.

3.- HIGH LEVEL RADIOACTIVE WASTE STRATEGIES

The spent fuel is considered as a radioactive waste in the General Radioactive Waste Plan which establishes the following management strategy:

- Interim storage

  - On-site storage

    - The storage capacity of the nuclear power plant pools is being increased by reracking to optimize their final occupation up to the year 2013 approximately

    - The licensing of a dual purpose cask is currently under way. This will allow Trillo nuclear power plant to increase its storage capacity after the year 2005 when its pool will be filled up

  - Centralized temporary storage

    - The construction of a centralized temporary storage for spent fuel is considered, to be able to operate around the year 2010

- Final disposal

    - The spent fuel will be finally disposed in a deep geological repository

    - Site characterization, conceptual design and the development of the technical characteristics of the repository are some of the main tasks of ENRESA.

4.- REGULATING THE SAFETY OF THE HLW MANAGEMENT

The availability of a centralized temporary storage will allow for a span of time to make the necessary decisions for the final disposal of radioactive waste. The process that will lead to this decision, has been initiated under three lines of action:

1. The Senate (High Chamber of the Spanish Parliament) has created an Inquiry Commission to discuss extensively the final solution to the radioactive waste management problem. The results of this discussion will serve to establish the bases of the legal system to regulate specifically the decision making on radioactive waste final management.

2. ENRESA is undertaking an extensive R&D Plan with the objective to get the scientific and technological information needed to assess the safety of the solution adopted in the future.

3. The Nuclear Safety Council is reinforcing its own capabilities for the review the safety assessment of the high level waste final disposal, and in this sense:

    - The Council has created a specific group responsible for the review of the safety assessments prepared by ENRESA, related to both the conceptual design and the actual projects.

    - The Council has initiated a process of acquisition of methodologies to assess the safety of geological disposal facilities, including:

        - A series of technical visits to research centres, underground laboratories, etc., in order to achieve a wide and updated view of the experimental works under development and the integrated safety assessment methodologies

        - A significant increment of the Spanish presence in international forum looking for the best knowledge of the state of the art. The following forum should be emphasized:

            - The Nuclear Energy Agency, particularly the Radioactive Waste Management Committee and its Working Groups PAAG and SEDE

            - The International Atomic Energy Agency, the WASSAC and the Working Group on the Principles and Criteria

            - The European Commission, participating actively in the projects:

    - "Building the safety case for a hypothetical underground repository in clay"

    - "Building the safety case for a hypothetical underground repository in crystalline rock"

- Broader contacts with regulatory bodies from other countries with active high level wastes management plans to share policies and regulatory practices

- Development of a training plan for the Nuclear Safety Council technical staff

- A number of projects in the Nuclear Safety Council Research Plan oriented specifically to increase our knowledge for the safety assessment of the radioactive waste disposal

5.- CONCLUSIONS

The activities mentioned have provided the Nuclear Safety Council with a first approach to the regulatory practices in other countries and the possibility to identify topics of special interest whose solution should be faced in the next years. Among these topics we would like to point out:

1. A wide spectrum of political, social, economical, technical and regulatory institutions must be involved in the decision making process.

2. The Nuclear Safety Council must focus its participation in:
    - Advising different institutions in matters strictly related with its functions
    - Assessing the safety of the selected option
    - Presenting the results to the Authorities in a transparent and clear way that avoids any doubt.

3. The development of a specific legal framework will be required in order to regulate the final high level waste management. This framework will need a wide consensus and must be sufficient to demonstrate that the proposed solution accomplishes the safety criteria adopted by the society.

4. However the differences existing in the licensing rules applicable in each country, the licensing procedure, derived from the legal framework, should be able to find a certain degree of coherence with practices followed in other countries.

5. The decision making process will require a close dialogue between regulators and implementers to attempt to reduce, in an appropriate way, the important level of uncertainties associated with the regulated process. This dialogue must be deep, open and transparent and will require a particular respect to the role of both parts.

6. The safety assessment, included in the licensing process, should pay special attention to the following topics, among others:
    - Long term radiological criteria and application

- Methodology to ensure compliance with the long-term safety
- Time frame for long-term safety assessment
- Waste acceptance criteria
- Monitoring programme during different stages of the repository lifetime
- Accident scenarios
- How the retrievability can be faced?
- Etc.

These considerations, and others resulting from the activities that the Nuclear Safety Council is carrying out, will be the basis to define our licensing procedure.

At this moment and taking into account the ideas exposed, we consider that events like this Workshop constitutes an excellent opportunity to know the main worklines in each country and their current status, the way in which the "regulatory dialogue" has been established and to open new ways to exchange information and experiences.

Table 1

GENERAL SITING CRITERIA	
1	*The shape and dimensions of the host rock body should be adequate to allow room for both the repository and also a sufficiently large protection zone around the repository to assure the waste isolation.*
2	*The repository shall be located in a host rock body having lithology and depth consistent with the cathegories and amounts of radioactive wastes to be disposed*
3	*The site shall be located is a way that the geological formations setting can be characterized to permit identification and evaluation of conditions which are potentially adverse or favorable to repository location and waste isolation*
4	*The repository should be located within a stable tectonic geological formation accordingly with the time required for fulfilling the objectives of the repository; therefore, active structures and potential faults must be avoided*
5	*The site shall be located in a zone of a nature such that any ground motion associated with potential earthquakes, in the mentioned zone can be shown to have no unacceptable impact on waste isolation*
6	*In the process of site selection, areas with abnormally high geothermal gradients or with evidence of recent volcanic activity should be avoided*
7	*The features of the site and its surrounding system should be entirely favorable for the waste isolation*
8	*The geochemical and physical-chemical features of the geological environment where the site is located should be such as to restrict the mobility of the radionuclides transport to the biosphere.*
9	*The geotechnical characteristics of the sites shall not unfavorably affect the basic objective of disposal. Geotechnical stability shall be ensured, taking into account the mutual influence between facilities, radioactive wastes, ground and potentially ground motions*

10	*The disposal facilities, as shallow ground, as deep ground disposals, should not be affected by any surface process or event that have an acceptable impact for the waste isolation*
11	*The site shall be located preferentially in areas of low population density with due consideration to urban, industrial and recreational areas, their expected growth and future development, so that, these do not prevent the objectives of the repository from being fulfilled.*
12	*The site shall be located avoiding areas of known forseeable future natural interest resources, which, if exploited, would result in an unfavourable effect on the waste isolation. The need of the repository, at a specific place and time, should be balanced against the need of, and value of resources now and in the future*
13	*The repository should be located in such a way that no significantly adverse alteration will be caused on environmental conditions*

Regulatory Issues Under Discussion in the Preparation of the Finnish Safety Regulations for Spent Fuel Disposal

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Abstract

Finnish Centre for Radiation and Nuclear Safety is preparing a general safety regulation for spent fuel disposal. In the course of this rulemaking, several regulatory issues have emerged that are even internationally still under discussion. These include use of different safety indicators depending of the time period of interest, how to judge the suitability of a proposed disposal site and what is required for a safety assessment intended for demonstration of compliance with safety goals. Our tentative approaches to these issues are described in the paper.

1. INTRODUCTION

In Finland, the spent fuel disposal programme is progressing towards the first formal licensing step, the so called Decision-in-Principle Process. Prior to that, the Environmental Impact Assessment Process will be carried out. The greatest challenge in the course of these processes will evidently be gaining the public and, in particular, the local acceptance for the disposal plans. Besides that, the processes will involve a regulatory review of the suitability of the proposed disposal concept and site.

To increase the credibility of the forthcoming regulatory reviews, the Finnish Centre for Radiation and Nuclear Safety has started the drafting of general safety regulations for spent fuel disposal. These regulations would later be issued by the Finnish Government, hopefully in due time prior to the submittal of the Decision-in-Principle applications by Posiva Ltd, our implementing organization for spent fuel disposal.

During the development of the safety criteria, certain regulatory issues that are even internationally still under discussion, were faced. Our tentative approaches to some of these issues are described below.

2. SAFETY INDICATORS

Individual dose or risk, or their combination, is the most commonly adopted safety indicator for the judgement of the acceptability of waste disposal. This is also our approach for the time period that is deemed as being reasonably predictable in the sense of calculating exposures due to the disposed radionuclides. The critical group, used for dose/risk calculations, would be a self-sustaining farming community deriving its water from local groundwater sources. The reasonably predictable time period is assumed to extend up to several thousands of years. Though there will be substantial environmental changes even in that timeframe due to e.g. global warming/cooling and land uplift, those changes are not likely to affect crucially, keeping in mind the other uncertainties involved in the calculations, the exposure of such subsistence community.

It is predicted that the next glaciation will reach Finland within 5000-20 000 years, bringing forth dramatic environmental changes. Estimation of actually occurring individual doses would then be meaningless. A more generic safety indicator (or indicators) must be introduced for that period, either based on reference biospheres representing typical interglacial conditions or indicators that are not very sensitive to environmental changes.

In the absence of internationally agreed reference biospheric scenarios, we have proposed to adopt the biospheric flux of disposed radionuclides as the main safety indicator for the time period that is not reasonably predictable. The limiting activity releases to the human environment would be nuclide specific and would be set on the basis of various considerations. These include comparisons with activity fluxes and radiological impacts that arise from naturally occurring radionuclides as well as typical individual doses arising from proposed limiting activity releases in environmental conditions of present kind. We also propose adopting only one main safety indicator, because the use of many parallel safety indicators would be confusing given the variety of relevant nuclides and scenarios to be analyzed.

3. SUITABILITY OF DISPOSAL SITE

The selection of the disposal site is planned to occur within about five years from amongst a few candidate areas, all representing crystalline rock type. These sites have for several years been subject to extensive investigations, including a number of deep drillings and borehole measurements. One of the main issues in the forthcoming regulatory reviews is the suitability of the proposed disposal site or sites, consequently specific criteria are needed for this purpose.

Our experience show that it is difficult to make a safety related ranking of sites, at least crystalline ones, in the present stage of site characterization. The sites seem quite similar from the geological point of view. Thus a set of criteria that define the desirable and adverse geological characteristics of a disposal would probably not result in any unambiguous ranking of the candidate sites.

The geological characteristics of the proposed disposal site must, as a whole, be favourable for the isolation of the waste to be disposed of. In our view, this should be demonstrated by means of a performance assessment that is site specific as far as reasonable taking account of the available investigation methods. It is also important that this performance assessment is based on, or supported by, mutually consistent conceptual models and datasets.

There are, however, a few geological factors that are crucial to safety and in this respect, the proposed site should meet at least minimum requirements to be specified. Such unqualifying factors may include proximity of exploitable natural resources, exceptionally high rock stresses, seismic or tectonic anomalies and very exceptional values for some groundwater chemistry parameters. It is also important that adequately large blocks of intact rock exist at the planned disposal depth for locating the disposal tunnels.

4. SAFETY ASSESSMENTS

Compliance with the radiation protection goals as well as the suitability of the disposal concept and site must be justified by means of a safety assessment that addresses both the expected evolution of the disposal system and unlikely events that may cause increased exposure to disposed waste.

The models and data introduced in a safety assessment shall be based on best available experimental data and expert judgement and on disposal conditions that may exist in each time period considered in the assessment. Up to the approach of the next glaciation, the geomodels and -parameters may, to a great extent, be derived from present conditions. But during the glacial period, the geological conditions (groundwater flow and chemistry, rock stresses) are likely to change substantially, thus a significantly broader range of conceptual models or geoparameters is required.

It is evident that in the forthcoming licensing stage the available experimental data are inadequate allow the use of statistical distributions for input parameters and probabilistic analyses. Thus deterministic analyses seem to be the appropriate approach for safety assessment in that context.

The relevance to safety of unlikely events that might cause increased radiation exposure, such as human intrusion scenarios, shall be discussed qualitatively and whenever practicable, their consequences and probabilities shall be assessed also quantitatively. The significance of the uncertainties involved in the safety assessment shall also be estimated e.g. by means of sensitivity analyses.

ISSUES IN ASSESSING SITE SUITABILITY AND IN COMPARING NATIONAL SAFETY APPROACHES TO DEEP GEOLOGICAL DISPOSAL

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Abstract

The step-by-step development of a deep repository includes a step where one or several sites have to be selected for further *in situ* studies in an underground laboratory.

This paper presents the assessment method that is being used by the IPSN to form its judgement about each site proposed by ANDRA for the construction of an underground laboratory, considering the preliminary state of knowledge obtained from surface investigations.

Two aspects are considered: firstly, a verification that the site, as characterised by data obtained from surface investigations, does not reveal features that are unacceptable, but presents, on the contrary, favourable features and secondly, an evaluation of the arguments supporting the applicant's declaration of confidence that the site is suitable for further *in situ* studies.

Pre-established site selection criteria are used as a basis for this verification, whereas the concepts of intrinsic robustness and engineered robustness form the basis of the evaluation.

In addition, generic issues are highlighted that call for more development and harmonisation between interested countries, with a view to enhancing credibility in safety judgements. These generic issues include: repository design rules in relation to acceptance criteria, the role of institutional control in safety assessments and the time frame to be considered in safety assessments.

1. INTRODUCTION

The step-by-step development of a deep repository includes a step where one or several sites have to be selected for further *in situ* studies. For this purpose, ANDRA, the French national waste management agency applied, in 1996, for the construction and operation of three underground laboratories, two in clay formations (East, Gard), and one in a granite formation (Vienne). The three sites were chosen from a series of potentially favourable candidate sites.

Section 2 of this paper describes the method used by the IPSN to form its judgement on the suitability of each site proposed, at the regulatory step in question. In other words, what degree of assurance can be obtained now, that if selected for building an underground laboratory, a site would be confirmed as suitable for deep geological disposal at the end of the *in situ* studies?

Although this degree of assurance can only be estimated qualitatively, it will, together with the number of sites selected, contribute to the probability of having, by the year 2006, an acceptable ANDRA proposal to build a repository at one of these sites.

This political deadline was fixed by the French law of December 1991 on waste management research.

Section 3 will highlight several generic issues relating to the safety approach to deep geological disposal where more development and international harmonisation appear necessary to enhance confidence in safety judgements.

2. METHOD FOR ASSESSING SITE SUITABILITY

2.1. Compliance with Site Selection Criteria

First of all, the characteristics of the site are examined in the light of pre-established criteria taken from the Fundamental Safety Rule [1] published in 1991 by the safety authority. These criteria are listed in Appendix 1 of this paper. As can be seen, they are essentially qualitative. However, a judgement of non-compliance with one of the essential criteria relating to site stability and hydrogeology would lead the safety authority to reject the corresponding site.

Comparison with the other criteria, and with recommendations relating to the disposal concept that have direct links with the properties of the host rock, allows the safety authority to evaluate the characteristics of the site as favourable or not.

Table 1 gives a broad idea of how the three sites proposed by ANDRA, as characterised from surface investigations, compare with site selection criteria. As a result of this review, the safety authority has reported to the government confirming that no site presents characteristics which would rule it out and concluding that the East site seems favourable while the Gard and the Vienne sites are more complex and less well-known. The regulatory step leading to the selection of sites for the construction and operation of underground laboratories is expected to take place at the end of 1997.

Site	East	Gard	Vienne
Host rock	clay	clay	granite
Depth (m)	400 - 600	400 - 800	several hundred
Thickness (m)	130	300	several hundred
Horizontal flexibility[a)]	high (continuous layer)	medium (lens)	low (surrounding large fractures)
Vertical flexibility[a)]	low	medium	high
Long-term stability	very good (low seismicity, limited effects of glaciation)	medium (medium seismicity, "messinian" phenomenon)	good (low to medium seismicity)
Permeability	very good	very good	good, contingent on spatial variability
Hydraulic gradient	low	low	low, possible disturbance due to water extraction
Mechanical and thermal properties	good; THM effects to be studied further	good, THM effects to be studied further	good
Geochemical properties	very good	very good	medium

Table 1. Compliance with Site Selection Criteria

a) flexibility for the final positioning of a repository

2.2. Assessment of Confidence in Site Suitability

Because the characteristics of the sites are not known in detail (this is the main objective of *in situ* measurements in the underground laboratories) and the features of a possible repository have not yet been defined other than in broad terms, an explicit performance assessment of the system as a whole is not possible.

Therefore, at this stage, confidence in site suitability can only be based on qualitative arguments and rough conservative quantitative assessments provided by ANDRA. However, a reasonably high level of confidence may be obtained if:

(i) qualitative arguments are convincing; in this case, the concepts of intrinsic robustness and engineered robustness may be useful,

(ii) rough quantitative assessments are shown to be reasonably conservative, taking into account the complexity of the system, and the possibility of adding extra safety features, if necessary.

Intrinsic Robustness

It must be remembered that, in principle, the deep geological disposal in porous rocks option is a reliable one, provided that groundwater motion is proved to be slow enough to allow for the decay of most radionuclides and to permit efficient sorption, dispersion and dilution of very long-lived radionuclides.

Thus, confidence in the suitability of a site should primarily be based upon confidence in the knowledge of the hydrogeological performances of the site over the time periods considered in the safety assessments (see Section 3).

In this respect, it must be recognised that in the kind of rocks considered for waste disposal, hydrogeological behaviour may be controlled by existing or induced heterogeneities in the rocks, difficult to characterise and model.

In view of the fact that confidence building is based on four principles:

(i) avoiding uncertainties, as far as possible,
(ii) evaluating uncertainties in items important for safety,
(iii) reducing uncertainties in these elements, and/or,
(iv) compensating for uncertainties through a conservative approach,

priority should, at the step in question, be given to the first principle. This principle leads to preference being given to sites which are only slightly subject or slightly sensitive to adverse features, events or processes (FEPs) likely to affect their hydrogeological behaviour. Such sites may be qualified as "intrinsically robust" as concerns their isolation capacity. Appendix 2 of this paper gives examples of sites which can be qualified in this way.

Engineered Robustness

Because it is not possible to completely avoid uncertainties in the knowledge of the hydrogeological behaviour of a site, and because a repository will disturb the site (THM effects) and add more uncertainty, engineered safety features including man-made barriers (waste packages, canisters, buffer and sealing materials) are currently integrated into repository designs. Moreover, at the underground laboratory site selection stage, these different types of uncertainties are not well-known. Therefore, to prevent any further difficulty, it is important to acknowledge that engineered safety features could be designed to compensate for uncertainties, as they are perceived at the time of decision making. These engineered safety features may be alleviated later on if uncertainties are found to be smaller than previously estimated.

In any case, they may be regarded as bringing an "engineered robustness" into the system in the sense that they would provide confidence that the system would fulfill its isolation function in the presence of uncertainties.

At the stage in question, it is not necessary, nor is it even possible, to describe the engineered safety features in detail, or the additional uncertainties that they themselves would bring into the system. The corresponding analysis will be part of the safety analysis report to be provided with the application for a licence to create a repository.

Illustration Using Conservative Performance Assessments

Confidence in site suitability may be enhanced through conservative performance assessments made by the applicant of a stylised repository system taking into account the characteristics of the waste to be disposed of. The geological barrier and the engineered barriers envisaged should be modeled both in a reference normal situation and in hypothetical situations (see Section 3). At this stage, hypothetical situations should be selected in such a way as to illustrate the main uncertainties mentioned above in the hydrogeological behaviour of the site; for example the existence in the host rock of a large defect undetected by the surface investigation results, the existence of a high permeability zone around disposal cavities, access galleries and shafts. Defining "what if" scenarios and estimating conservatively the order of magnitude of their consequences in a "standard biosphere" with "individual dose to a standard man" as the safety indicator, may be sufficient to illustrate the robustness of the system and contribute to building up a sufficient level of confidence in site suitability.

3. GENERIC ISSUES IN BUILDING UP CONFIDENCE IN SAFETY JUDGEMENTS

3.1. Development of Harmonisation between the Various National Safety Approaches to Deep Geological Waste Disposal

The efforts of individual countries to build up confidence in safety judgements relating to deep repositories might not be sufficient as long as major differences exist between the various national approaches to the safety of deep geological waste disposal.

Harmonisation in the following fields appears necessary:

(i) Repository design rules in relation to acceptance criteria (deterministic-dose/probabilistic-risk approaches).

(ii) Role of post-closure institutional control in safety assessments.

(iii) Time frames to be considered in safety assessments.

3.2. Repository Design Rules in Relation to Acceptance Criteria

We firmly believe that a deterministic approach is more appropriate than a probabilistic one for a number of reasons already expressed [2] and because it is well adapted for defining simple and legible design basis rules, as in the case of other nuclear installations. Compliance with such rules means that there should be a reasonable assurance that the as-designed repository will meet safety objectives. The design rules are not based upon realistic representations of FEPs; rather, they include prudence and conservatism. A probabilistic approach might be used together with realistic representations of phenomena for design optimisation purposes.

The deterministic approach includes:

(i) the definition of a "normal" evolution scenario, based on the most likely course of events, and hypothetical" scenarios intended to represent reasonable envelopes of adverse conditions of natural or human origin, or resulting from the presence of the repository itself,

(ii) an analysis of the robustness of the system during these scenarios (see §2.2. for example and reference [2]),

(iii) the calculation of the values of relevant safety indicators for each scenario; by convention, the main safety indicator should be the "individual dose to a standard-man" (IDSM),

(iv) a judgement on the acceptability of the repository, taking into account the degree of likelihood of each scenario, IDSM level, nature, duration and extent of potential consequences,

The acceptance criteria proposed are summarised in Table 2.

Scenario	Criteria
Normal	- IDSM lower than 0.25 $mSv.a^{-1}$
Hypothetical	- multi-variable judgement as a function of degree of likelihood of scenario, IDSM level, nature, duration and extent of potential consequences, and - IDSM below levels liable to give rise to deterministic health effects

Table 2. Acceptance Criteria

3.3. Role of Post-closure Institutional Control in Safety Assessment

Active and passive institutional control would probably be maintained after repository closure. It is not possible to predict when this control would intentionally be changed - future generations would have to decide upon this.

However, a limited duration of the post-closure institutional control phase such as 500 years [1] may be taken into account in the safety assessment. Analysis of the institutional control of the situation left by past practices having led to hazards for future generations, such as the exploitation of underground quarries for extraction of plasterstone, suggests that efficient institutional control may be maintained over several centuries. Moreover, the efficiency of this control in preventing human intrusions is related to its social function of enhancing confidence in the entire safety provisions.

Therefore, it appears interesting to consider a multi-purpose institutional control including land use restrictions, monitoring, management of possible interventions, management of social acceptance and preservation of know-how on radioactive waste management at the repository [3].

3.4. Time Frame to be Considered in Safety Assessments

Although calculations of the behaviour of a repository and of the resulting impact may be extended to 10^8 years or more to have an idea of when long-lived insoluble radionuclides might in theory produce their maximum impact, it would be desirable not to unnecessarily extend the time frame over which calculational results are reported in the safety report, taking into account, on the one hand, the radioactive decay of most radionuclides and the low level of residual risk, and on the other hand, the growing unpredictability of geological and biosphere evolution as a function of time. The time frame upper limit is, however, dependent upon the specific repository under consideration and the method used for the safety case.

Therefore, the complete time frame could be defined as shown in Table 3, taking into account that over a period of a few tens of thousands of years, stability should be proved, making predictions reliable.

Time after closure (years)	0	500	a few tens of thousands	upper limit
Biosphere	today's local	regional biosphere types	regional biosphere types	
Human intrusion	no	yes	yes	
Glaciation	no	Würm	Riss	
Value of calculational results	reliable		indicative	

Table 3. Time Frame in Safety Assessments

4. CONCLUSION

The main issue in the selection of sites for further *in situ* studies in underground laboratories is to obtain a sufficient level of confidence despite the lack, at this stage, of detailed information, both on site characteristics and on repository design features.

However, a reasonable level of confidence can be built up:

(i) in the intrinsic robustness of the sites due to their relatively low sensitivity to adverse FEPs which results in a low sensitivity to uncertainties, as far as their hydrogeological behaviour is concerned,

(ii) in the availability of engineered safety features which may compensate for uncertainties, thus bringing to the system an engineered robustness. Special attention must be given to possible uncertainties in hydrogeological behaviour due to THM effects induced by a repository in the host rocks considered.

Limited conservative performance assessments using deterministic scenarios, including "what if" scenarios, may be sufficient at this stage of the decision process to illustrate confidence in the overall robustness of a repository system at the sites envisaged.

More generally, generic issues have been selected as they call for increased harmonisation between national safety approaches. Harmonisation would enhance confidence in and public acceptance of safety judgements on deep geological disposal. Items that we propose for consideration are repository design rules in relation to acceptance criteria, the role of institutional control in safety assessments and the time frame to be considered in safety assessments. Proposals are made for these three items.

References

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Appendix 1 - Site Selection Criteria

1. Essential criteria

(i) Site stability: possible modifications of initial conditions due to glaciation, earthquakes or neotectonic movements shall remain acceptable for safety; stability including a limited and predictable evolution, shall be proved for a time period of at least 10,000 years.

(ii) Hydrogeology: the site must show a very low permeability in the host formation and a low hydraulic gradient; a low hydraulic gradient should also be sought for neighbouring geological formations.

2. Important criteria

(iii) Mechanical and thermal properties: these properties condition the feasibility of the repository, that is to say the possibility of conceiving a repository without significantly impairing the geological barrier. Moreover, the host rock must be chosen to allow the design of cavities stable enough to prevent maintenance during operation to maintain gauges. Models shall be made available to determine cooling time and density of waste arrangement.

(iv) Geochemical properties: the geochemical properties shall be described quantitatively so as to enable analysis of radionuclide transfer conditions.

(v) Minimum depth: the site must be chosen so that the depth envisaged for a repository ensures that the performance levels of the geological barrier will not be significantly affected by erosion phenomena (in particular due to glaciation), by the effect of earthquakes or following current human intrusions. One shall therefore consider that a depth of 150 to 200 metres below ground level is disturbed and inefficient for isolation purposes.

(vi) Sterilisation of underground resources: the site shall be chosen away from zones of known or possible exceptional interest.

3. Design constraints

(vii) Host block: the repository shall be positioned:

- in a crystalline formation, within a host block without large fractures subject to possible preferential groundwater circulation. The disposal cavities shall be located away from medium size fractures; access galleries may interfere with these fractures,
- in sedimentary rocks, within a medium exempt from large heterogeneities and at a sufficient distance from aquifers.

(viii) Thermo-mechanical effects: the presence of heat generating wastes and of structure and back-filling materials shall not significantly affect the containment properties of barriers. Disturbances resulting from the excavation of cavities shall be limited as far as possible.

(ix) Access shafts: the design and positioning of access shafts shall, on the one hand, limit the risk of underground water circulation and on the other hand, take into account the objective of an effective sealing at the end of the operating life of the repository.

Appendix 2 - Examples of Intrinsically Robust Sites

1. A deep sedimentary argillaceous layer of regular geometry and simple geological history could rarely be subject to the occurrence of faults which would allow the passage of large groundwater flows. This could be confirmed by the interpretation of salt concentration measurements in surrounding aquifers. A site with such features could be judged as robust as regards the risk of hydrogeological short circuiting due to spatial variability.

2. A geological formation, the past history of which has left no trace of damaging events and can be explained over a much longer period than that considered for the safety assessment of the disposal facility, could be judged to be robust as regards the risk of disturbance of its hydrogeological behaviour as a function of time due to unstability of natural origin.

3. A host formation, the geometry of which, along with the location of major faults, allows flexibility in the final positioning of the repository, could be judged to be robust as regards the risk of significant geological shortcomings being detected later on.

4. A site far from resources of exceptional interest could be judged to be robust as regards the risk of human intrusion.

5. The possibility of positioning the repository deep down, presuming that there is an overburden 150 to 200 metres thick, makes it possible to confirm robustness as regards the risk of common underground workings and as regards the effects of seismicity or erosion.

6. A host formation large enough to allow physical separation of wastes could be judged as robust as regards both the effects of human intrusions and THM effects.

Judging the Safety Case: Compliance requirements
- Some Discussion Notes -

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Development/Application of Compliance Criteria

- Overall safety criteria:
  - ◊ when judging acceptability/feasibility of total system
  - ◊ applied to overall system evaluation (Total System PSR)
  - ◊ e.g. SSI dose criteria, SKI release criteria

- Functional requirements:
  - ◊ when judging application for system components
  - ◊ derived from Total System PSR
  - ◊ applied to components of the system, e.g. encapsulation plant, canister and repository.

- Technical criteria:
  - ◊ derived from functional requirements
  - ◊ applied when judging application for operation, e.g. properties of buffer, quality of canister welds

- Technical specifications:
  - ◊ when defining conditions for operation, e.g. settings of equipment, process parameters and quality control methods

SKI's Role in Pre-licensing Phases

- Build Competence for up-coming license applications
  - ◊ R&D programme
  - ◊ development of PA capability (Project-90, SITE-94)
  - ◊ international cooperation

- Provide guidelines to the implementer
  - ◊ review of SKB's R&D programme
  - ◊ dialogue with SKB
  - ◊ inspection of site investigations
  - ◊ issuing general regulations on safety criteria, safety assessments and safety reporting

Basic Requirements for Successful Evaluation of the Safety Case

- QA of site investigation
  - ◊ documentation of data and models used and associated uncertainties

- QA of the EBS components
  - ◊ manufacturing, non-destructive testing etc.

- Comprehensiveness and quality of PA
  - ◊ scientific basis (validation aspects, applicability of models etc.)
  - ◊ system description (PID, RES)
  - ◊ selection of scenarios
  - ◊ evaluation of uncertainty

Strategic Philosophical Issues

- Acceptability of high consequence - low probability scenarios

- Judgement of consequences in different time frames

- Treatment of human intrusion

- Choice of safety indicators (doses, fluxes...)

Input/discussions with different parties (public, EIA-parties, international cooperation)

Concluding Remarks

- Development and application of regulatory criteria - stepwise process

- Dialogue between regulator and implementer and other actors within the framework of EIA

- Evaluation of compliance requires qualified regulatory assessment
    - ◊ need for competent and prepared regulator

- PA as a regulatory tool when judging the safety case
    - ◊ extent of independent regulatory PA?

Swiss Experience in Judging Safety Cases

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Abstract

Two important reviews of safety cases for the disposal of radioactive waste have been conducted so far in Switzerland. The first concerned Project Gewähr 1985 which is a huge study aimed at demonstrating the feasibility of the safe final disposal of all kinds of radioactive waste. The second is the review of the general license application for a low- and intermediate-level waste repository at the Wellenberg site. The subjects, conduct and outcomes of these two reviews are presented. Finally some issues are addressed, which were raised in relation with the reviews and which may be of interest to the international community.

1. INTRODUCTION

It is well known that, for the time being, Switzerland has no repository for radioactive waste. It is well known too, that despite this fact, the Swiss implementing organization Nagra has a great expertise in making safety cases for disposal facilities. Also the Swiss regulators, the Swiss Federal Nuclear Safety Inspectorate HSK, have some experience in judging such safety cases. This experience was mainly gathered on the occasion of two important reviews conducted by HSK. The first concerned Project Gewähr 1985 and the second was related to the proposed LLW/ILW repository at the Wellenberg site.

In the following sections 2 and 3 the subjects of these two reviews and the way the reviews were conducted are briefly described. Emphasis is put on the outcome of the reviews, i.e. on the results and on what was done with them. The last section 4 gives a summary of what could be called lessons learned. The issues addressed there are important in relation to the circumstances prevailing in Switzerland and may be of interest to the international community.

2. REVIEW OF PROJECT GEWÄHR 1985

Legal Request

The Federal Ruling of October 1978 stipulates that the license for new nuclear power plants will only be granted if the permanent, safe management and final disposal of radioactive waste is guaranteed. In addition to that, the extension of the operation licenses of the existing nuclear power plants beyond the year 1985 was made dependent upon the demonstration of the feasibility of the safe final disposal. For the purpose of this demonstration, a huge study named "Project Gewähr 1985" was conducted by Nagra, the Swiss National Cooperative for the Storage of Radioactive Waste. The result of the study [1] was presented to the Government on January 1985.

Contents of the Study

The study covers all types of radioactive waste, but emphasis was given to high-level waste (HLW). An essential part is the safety analysis which was focused on the long-term aspects of the post-closure phase. The data used for the safety analyses are based on experimental results, especially those obtained from exploratory drillings.

A so-called type C repository is considered for the disposal of HLW and certain alpha-bearing intermediate-level waste (α-ILW). The repository is assumed to be situated 1200 m deep in a stable granite formation in the crystalline basement of northern Switzerland. The vitrified HLW is enclosed in an 15 cm thick steel canister which is emplaced horizontally within a 1.35 m thick layer of highly compacted bentonite on the axis of mined tunnels. The α-ILW packages would be stacked into concrete silos with bentonite lining.

For all the remaining ILW and low-level waste (LLW) a type B repository consisting of a system of mined disposal caverns is considered. This repository is assumed to be situated in an alpine marl formation in a mountain side with horizontal access tunnel.

The main conclusions of the study are that safe final disposal of all kinds of radioactive waste is feasible with existing technology and that suitable geological options are available in Switzerland. The results further allowed to identify the questions which must be answered in view of the realization of a definite repository.

Conduct of the Review

HSK reviewed Project Gewähr 1985 in the years 1985 and 1986. HSK prepared itself for that task well in advance. The methodology to be applied and the computational tools necessary for the conduct of a safety assessment were developed on the occasion of so-called model studies. In such exercises HSK analyzed the safety of fictitious repositories.

The requirements concerning the long-term post-closure safety of a repository were defined in the first issue of the guideline HSK-R-21 [2] from 1980. A basic deterministic approach for safety assessment is requested. The safety requirements are formulated as protection objectives which apply to the disposal system as a whole. The individual dose shall at no time exceed 0.1 mSv per year. The safety shall be ensured by a system of passive barriers.

An independent assessment was aimed at. It started with an own model representation of the geological settings and especially of the crystalline basement of northern Switzerland. In order to achieve this, the geological investigations conducted by Nagra were closely followed by HSK or its experts. An own analysis of the processes and events which could possibly act on the disposal system was performed and the relevant scenarios defined. Also the conceptual modeling of important processes, particularly of the migration of radionuclides through the geosphere was done independently from Nagra. Dose calculations with own computer codes and input data were done mostly for enveloping cases and as parametric studies.

HSK always uses the expertise of external contractors. For the review of Project Gewähr 1985 this use was increased and extended to experts from abroad (France, United Kingdom and Canada). Not every element of Project Gewähr 1985 was reviewed in detail, but HSK is confident that no important aspect was missed.

Outcome of the Review

The review resulted in almost, but not totally positive conclusions. The technical feasibility of the disposal projects is doubtless. HSK also concluded that the requested demonstration was given for the disposal of LLW and ILW (without α-ILW from reprocessing). It recommended therefore that the remaining open questions be resolved in the frame of the realisation of an effective repository for these waste types.

Considering the sparse knowledge on the crystalline basement obtained from the few exploratory drillings, the question concerning the disposal of HLW was split in two parts. The first part concerned the demonstration of the safety under the assumption that the host-rock properties derived from the observations in the bore-holes are representative of a volume of rock large enough to host the repository. This first question was answered positively. The second part of the question is, if a volume of rock with the requested properties large enough to host the repository exists and can be found in the crystalline basement of northern Switzerland. This second question could not be answered with the available information. HSK considers the prospects to be poorer than Nagra does. HSK therefore recommended that research and field investigations, including other host-rocks, be continued; time enough is available.

These conclusions were accepted by the Federal Government. Its decision was fully in line with the recommendations of HSK. The operation licenses of the nuclear power plants were not canceled. The review work done by HSK was also acknowledged by such scientists that are critical against nuclear energy. Some of them however drew other conclusions concerning the requested demonstration and maintaining the operation licenses of the nuclear power plants.

3. REVIEW OF THE WELLENBERG REPOSITORY

Licensing Step

Each new nuclear installation needs a general license as a prerequisite for the construction and operation licenses. The general license fixes the site and the general layout of the installation and, for a repository, the nature and approximate amount of the radioactive waste to be disposed of at the facility. The application shall include a demonstration that operational and long-term post-closure safety can be achieved. Confidence in long-term safety shall be based on knowledge about the site gained by previous field investigations. Such field investigations by means of exploratory drillings, shafts or galleries are subject to a special license for so-called preparatory measures. A positive decision of the Government on a general license application has to be approved by the Parliament.

Four sites have been investigated by Nagra in view of the realization of a repository for LLW/ILW. Based on the results of the geological investigations, Wellenberg in Central Switzerland was selected by Nagra in June 1993 as the preferred site. The authorities concerned and the Federal Government approved this choice. In June 1994, the application for the general license for a disposal facility at Wellenberg was submitted.

Project Description

The repository is designed for all Swiss radioactive waste other than the high-level and the long-lived intermediate-level waste arising from the reprocessing of spent fuel. It should accommodate a volume of about 100'000 m^3 of conditioned waste. The facility consists of a system of parallel disposal caverns with a horizontal access tunnel. It is situated in an alpine marl formation in a mountain side. The system of technical barriers comprises the waste solidification matrix (cement, bitumen, polymers), the concrete container in which the waste packages are emplaced, the special backfilling concrete and the cavern liner.

The long-term safety of the repository relies primarily on the technical barriers in combination with slow water movement. The large amounts of cement ensure a long-lasting alkaline environment in the near-field of the disposal caverns. Under such chemical conditions, the retention of radionuclides is very strong, thus allowing for the decay of short-lived nuclides within the repository. Long-lived radionuclides, which are present in the waste in limited amounts, will be released only at a very low rate. The main role of the geosphere is to ensure a very low waterflow through the repository in order for the technical barriers to function as described above. The overburden also protects the repository against intrusions and other processes at the ground surface.

Conduct of the Review

In the review of the license application, HSK again aimed at an independent assessment. The review was conducted with the help of the regular external experts. Since the general license fixes the site and since the site specific geological conditions largely influence the long-term safety in the post-closure phase, the review was concentrated on this aspect.

The actual geological and hydrogeological conditions will only be fully recognized with the construction of the underground cavities. Only at that time can predictive safety assessments be based on proven characteristics. This means that the demonstration of safety for the general license is preliminary. The incomplete knowledge must allow a reasonable assurance that the safety requirements will later be met. The possible radiological consequences of the repository have been evaluated independently by means of own conceptual models, computer codes and input data. Similarly to the applicant, a fully deterministic approach was used; no attempt at probabilistic risk calculations was made. One problem was to decide to what extent pessimistic assumptions should be combined in assessing the range of variation of the final results. In some cases individual doses higher than the specified limit of 0.1 mSv per year were calculated.

Outcome of the Review

Owing to the early stage in the long-lasting licensing and realization process, many questions remain open. These questions shall progressively be answered in the course of the subsequent licensing stages (construction, operation, closure). In spite of these still open questions, HSK drew positive conclusions concerning the safety: From the available knowledge it is expected with the requested reasonable assurance that a safe repository can be built at the Wellenberg site. HSK therefore recommends to grant the general license with three obligations. These obligations aim at improving the basis for decision-making regarding the next licensing step (construction license).

The review report prepared by HSK was made public in July 1996 without a significant response in the media. This is probably because the licensing procedure is blocked due to a missing authorization at cantonal level. According to the cantonal legislation, a concession for the use of the underground is requested before excavations can take place. In June 1995, a corresponding application was refused by the citizens of the canton on the occasion of a popular referendum. Discussions at the political level took and will continue to take place in order to decide on further procedures.

4. IMPORTANT ISSUES

The waste management branch of HSK is fully in line with the corresponding international community. In particular, we totally agree with the conclusions of the collective opinions published by NEA concerning the demonstration of long-term safety for a repository [3] and the environmental and ethical basis of geological disposal [4]. In the light of our experience with judging safety cases for radioactive waste disposal and communicating the results to whom it should or may concern, we would like to stress following issues. These issues are important for us and may be of interest to the international community.

Independence of the Regulatory Body

From the beginning HSK wanted to be able to perform safety assessments for disposal facilities independently from implementing organizations. This is certainly more difficult in a small country with limited human and financial resources. We think that we achieved this goal up to now. We also think that the public opinion broadly recognizes this independence. This is a necessary but not sufficient condition for the acceptance of our work and recommendations.

Communication of the Findings

The work done at a regulatory agency like HSK is at a high technical and scientific level. The conclusions arise from objective and rational reasoning. The reports in which this work is documented are generally understandable only for specialists. Since the findings must be explained to a broader audience, a reporting must occur at lower levels of complexity. In communicating the findings and seeking acceptance of their review work, regulators must take care not to be misunderstood as being advocates of the project under review.

Contacts with Others

Regulators should not work in isolation. HSK has frequent contacts, mostly pertaining to technical and scientific issues, with the implementers. This allows to avoid diverging views on the basic features of the projects. The regulator has however to carefully preserve his independence of view. For that reason he should be open to the matters of concern of political authorities and of the general public.

Surveillance and Retrievability

The prevailing principle in Switzerland is that any measures taken to facilitate surveillance and repair of a repository or retrieval of the waste shall in no way compromise the passive safety. Several people, among them politicians, have requested that the disposal concept be changed: A repository shall be monitored and allow for the retrieval of the waste, at least for a certain time period. Discussions on that matter will start soon in relation with the Wellenberg project.

Opposition against Final Disposal

Some persons do not believe that safe final disposal of radioactive waste is feasible without permanent surveillance and maintenance of the repository. This opinion appears to be a matter of faith, thus no rational arguments would convince them. The sound basis of geological disposal should however periodically be reminded in public in order to avoid too many people to get mislead by the wrong views.

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SESSION IV: CLOSING SESSION

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CLOSING SESSION

Summary and Conclusions
Chairman: Lars Högberg

Following the presentations made during the previous sessions on the general state of the art in long-lived radioactive waste disposal safety, the preparation of safety cases and the regulatory review process, most of the discussions took place on the last day of the workshop, on the basis of introductory remarks by rapporteurs in the following closely related areas:

- Waste disposal objectives and criteria (Rapporteur: A. Duncan, UK)
- Trends in performance assessment (Rapporteur: P. Zuidema, Switzerland)
- The conduct of the regulatory process (Rapporteur: M. Knapp, USA)

In addition, items for further work were identified, and they are mentioned below, after a summary of the discussions and conclusions of session IV.

I Radioactive waste disposal criteria

A great deal of information has been published in the past at national and international levels on the need to consider disposal criteria essentially as references or indicators, addressing the ultimate safety objectives of disposal, rather than limits to be interpreted strictly, notably in a legal context. This interpretation was confirmed, but many views were presented regarding the various possibilities to express safety criteria in regulations and to apply them in practice, notably with regard to protection of human health and the environment and the timescales involved.

a) Risk/dose criteria for protection of human beings

It was recognised that risk is in principle a more fundamental and perhaps more appropriate criterion than dose since analyses of radioactive waste disposal will yield ultimately estimates of potential exposures, with varying degrees of probability of occurrence of exposure. However, the risk concept is difficult to understand and use in practice when applied to far future events, the probability of which may be affected by large uncertainties. Suggestions were made to use dose as the main indicator/criterion for the most likely evolution scenarios; and to consider risk for more uncertain scenarios with the recommendation that risk figures should be disaggregated into probabilities and consequences in order to give a better perspective of the two components of risk. Such scenarios may be judged more appropriately on the basis of relatively “soft” information, with multiple lines of reasoning.

It was noted in this respect that, in a decision making context, single “high-level” criteria like dose or risk indicators, coupled with a pass/fail decision process, have the appeal of being transparent and easy to understand by the public, but that a more sophisticated approach taking account of multiple factors is more appropriate.

In such an approach, consideration of the following information may be useful and would deserve further work:

- the time and duration of effects from releases of radionuclides
- the size of the potentially affected populations
- the possibility of contamination of water resources.
- the exposure of current populations, including workers
- the risks of conventional accidents, for example including during transport
- the other management alternatives, including the "zero option" which would correspond to leave waste at the surface and might be a less acceptable option than disposal from a safety and ethical perspective.

Furthermore, approaches with multiple lines of reasoning to assess repository performance (using for example different models and methodologies, or even soft qualitative information) need to be clarified. In the context of this discussion, it was remarked that a hard, pass/fail interpretation based on numerical criteria might suggest the notion of "disqualifyers" for a repository system, but many views stressed the need to be very cautious on such a notion, and to avoid premature decisions which would not be based on truly prohibitory conditions tied to actual safety.

Finally, the ICRP concept of the critical group, as well as the usefulness of collective dose calculations were discussed, and it was remarked that their interpretation was sometimes pushed too far. In particular, given the uncertainties involved in the long-term, rejection or acceptance on this basis alone would not appear justified, and even discrimination between options may not be possible. Nevertheless, it was suggested that further work on the concept of critical groups in a risk context would be valuable.

b) Protection of the environment

Although not discussed in much detail, this area was recognized as needing further clarification, notably because of the current interest for the protection of the environment per se. The protection of humans against radiation may be generally sufficient to protect the fauna and flora constituents, at least at the level of living species which is probably the essential concern, but not necessarily at the individual level. There is a certain amount of information available in this field, including in some recently published performance assessments or environmental impact statements (for example in Canada). The results of current work within ICRP might be also very valuable.

It was mentioned that it would be useful to develop guidance on the protection of the environment (on how to measure impacts, set possible standards and enforce them), taking into account, also, what might be done in other environmental assessments of far future consequences. In the meantime, it might be desirable to consider, on a case by case basis, whether there could be any potential for environmental damage as a result of future geological disposal activities.

c) Timescales

Considering the expected very gradual evolution of long-lived waste isolation systems located in suitable deep geological formations, the workshop participants agreed that there is no real justification for a "hard" cut-off time or times from a technical and scientific perspective for the conduct of safety assessments. Recognizing the increasing uncertainties with time, they agreed that safety assessments will have to move from an essentially quantitative approach to more qualitative considerations in the very long-term. In particular, while it may be possible to assess quantitatively the geosphere behaviour over periods above 10^4 - 10^5 years, the biosphere may be difficult to evaluate quantitatively for timescales longer than 10^4 years. Consequently, there seems to be no a priori justifiable and obvious transition time in this respect, since it will depend largely on the reliability of the technical information available and the limits of practical reasoning for each specific case.

However, it was also remarked that it may be judged desirable to propose specific "end-points" to assist in the regulatory process, notably given public understanding and administrative and legal issues. No agreement exists on such end-points which are to some extent arbitrary and related to social and cultural national backgrounds. It would nevertheless be useful to clarify the meaning and interpretation of proposed timescales or cut-off times, particularly in relation to potential disruptive events such as glaciations, and to the use of specific safety indicators, such as the reference to concentrations of natural radionuclides in the very long-term.

In this context, a majority of participants agreed that, as long as it is understood and clearly stated that long-times (for example after 10 000 years) cannot be ignored in safety assessments, the question of specifying fixed timescales in the drafting of regulations appeared essentially a matter of pragmatism in the conduct of the regulatory process, and much less as the subject of a fundamental technical debate between regulators and implementers.

Furthermore, on all the above issues, it was pointed out that scientists and implementers are sometimes interpreting quantitative criteria beyond what regulations really require; hence the need for a continuous dialogue between implementers and regulators.

II Performance Assessment trends

Performance assessment calculations are generally regarded as the most significant and essential part of the technical and scientific basis to be provided in support of safety cases for deep underground repositories. They imply the need for a sufficient understanding of the behaviour of repository systems with time, and care in the use of quantitative approaches in a context of uncertainty. They therefore do not pretend to be predictions but rather conservative illustrations of the long-term behaviour and safety of repository systems which they help to test and assess. They may be done for different purposes - e.g. to identify R&D priorities, make bounding calculations, evaluate parameter sensitivities, or support licence applications - and can always be complemented by useful qualitative information. R&D efforts may help to reduce some uncertainties, but there will always be irreducible uncertainties which, in extreme cases, may suggest that consequence targets may be exceeded. Accordingly, performance assessment results will always need to be interpreted with caution and appropriate qualifications regarding, for example, expert judgements made to compensate for limited data or to decide between design options.

In spite of a well advanced state of the art in performance assessment, there are areas requiring further discussions, clarifications or improvements. They concern technical and scientific aspects, methodological issues, and interpretation and communication of the results, particularly in a public participation and decision-making context, with various types of uncertainties affecting the whole area and different ways of compensating for them.

a)Technical and scientific aspects:

They concern mainly:

- the quantification of event probabilities, notably for natural events, for which there is sometimes little scientific basis;
- the debate on whether it makes sense to attempt to quantify the probability of potential future human intrusions at repository sites;
- the desirability and definition of "stylized approaches" for sufficiently representative and credible scenarios, particularly concerning future reference biospheres and human intrusions;
- the integration of quantitative and qualitative information, particularly concerning the characterisation of geological disposal sites, where the collection of representative data and the development and use of appropriate models incorporating complex physical, chemical and geological processes is of considerable importance;
- the identification and handling of various types of uncertainties;
- the overall confidence in the performance assessment results.

b) Methodological issues:

They include:

- the respective pros and cons of deterministic and probabilistic calculations , with an increasing consensus that the two approaches complement each other and may be used both;
- the use of "robust", sometimes overconservative, designs and performance assessments, as opposed to realistic ones, and the need therefore to have a "soft" multi-criteria approach to avoid the risk of too extreme single results contributing to reject a proposed disposal system otherwise acceptable.
- the elicitation of expert judgements which is not only a methodological issue but also a matter of transparency in performance assessment.
- the meaning and limitations of an optimisation approach, which seems to be essentially a matter of common sense in a broad context rather than a question of formal application of ALARA methodologies (see previous section on criteria);
- the respective weight to be given to performance assessment results and more qualitative/intuitive information, particularly in the earth sciences area.

c) Interpretation and communication of performance assessment results:

Many questions were raised which are mostly centred around the actual role of performance assessment results as a support to licence applications and decision making. Performance assessment is a tool used also by regulators to assess long-term safety, either independently for full or partial verification of the results, or as a general indication that the implementer's proposal corresponds to the state of the art and that its conclusions appear reliable enough. Performance assessments are conducted primarily to address complex, technical and scientific safety issues, and they have to be judged from the point of view of compliance with regulatory criteria by independent national authorities with a high degree of professional competence. Performance assessment results are not therefore easily interpretable and understood by non-technical readers, and this is why, among other reasons, continuous efforts are required to improve transparency, traceability and presentation of all the information presented in performance assessments. This concerns many aspects such as:

- project specific designs which may differ considerably from one country to another;
- the integration of advances in scientific and technical knowledge and update needs;
- the transfer of information between implementers, regulators, decision-makers and the general public. In particular, the responsibility of the transfer of technical information to the public is not always clear. In general, it is undertaken by the implementers but, in a few cases (SKI, in Sweden, and EPA, in USA) the regulators have made separate attempts to respond to it;
- the approaches used by regulatory authorities to judge compliance (see below);
- the use of performance assessment as a means to test the long-term safety and robustness of disposal systems and not as an exact prediction of the future;
- the extent and quality of the technical information available at a given time, which has to be consistent with the relative importance of the interim decisions taken in a stepwise process;
- the concept of reasonable assurance in a stepwise implementation process which has to be undertaken with the participation of various stakeholders not necessarily briefed on all technical and scientific aspects.

III The conduct of the regulatory review process

This process has to be based primarily on technical and scientific elements which are provided, on the one side, by the national regulations, and on the other side by the safety analyses made by proponents of disposal systems when a decision is needed or a request for a licence is presented to the regulatory authorities. From this standpoint, the previous sections illustrate the main technical issues involved, and what remains to be addressed here is how the process is conducted in practice by regulators to judge compliance with regulatory requirements and, ultimately, acceptability of the proposed waste disposal facilities from a technical point of view.

The other important feature of the regulatory review process is that it cannot be strictly limited to technical and scientific issues, since its objective is to lead to decisions which have to be taken according to a broader range of considerations including social and political inputs from the public and various other stakeholders. Although the workshop was not supposed to cover non-technical issues in detail, their importance was recognized and their influence on the conduct of the regulatory review process was discussed.

a) The technical review process

There was a general consensus among workshop participants to recognize that a step-wise process is necessary, with interim decisions as may be appropriate based on a continuing relationship between regulators and implementers. This relationship helps in promoting information transfer from both sides, better mutual understanding of the technical issues involved both on technical and procedural aspects of regulations and on safety issues themselves. It can be both informal and formal, but it should not be seen as a situation which could compromise the independence of the regulators, or lead to loss of trust in regulators by the public. In some countries, it is the subject of a memorandum of understanding between the main partners, which provides for observation/participation by representatives from the public.

Such a relationship may facilitate the early development of specific requirements and guidance for the regulatory process and a clear presentation of the resulting strategy. For example, a strategy could consist in having detailed specifications and guidance in the regulations (i.e. on time-scales, sub-system performance indicators or stylized reference situations) rather than leaving most of the issues involved open for discussion at the time of licensing. Such an approach has been followed in the past, in the United States, with some difficulty. It was designed in such a way as to avoid entering later into lengthy discussions having finally little influence on long-term safety. However, this type of approach is sometimes misunderstood and may be interpreted as the sign of a prescriptive attitude. In this respect, the opinions of the workshop participants on the balance between what should be prescribed in the regulations compared to what should be left to the licensing debate were divided. Finally, the point was made that the "rules of the game" for the regulatory process should be known as far as possible prior to its start, and in any case, well in advance of license applications.

Similar to the previous question, is the degree of independent review and verification of performance assessment calculations which the regulators are going to make. In some countries, full recalculations are envisaged with separate tools when available , while in some others only partial checks are foreseen. In most cases, when a real dialogue has taken place, it would seem sufficient to check the important aspects of the work done by the implementers without duplicating it in an independent way.

Two related aspects concern first, the high professional competence of regulators which appears as a must (certain countries have to conform to quality standards from ISO for regulatory activities and regard this situation as beneficial to the process); and, second, the extent of independent R&D activities needed or sponsored by regulators in support of their review functions. On the second aspect, different situations may be observed depending notably upon the size of national nuclear power programmes and financing systems set up for the back-end of the fuel cycle.

More specific technical issues have also been mentioned about the review process, as requiring attention in the future, notably the question of completeness in the identification of scenarios, the handling of possible extreme events or situations and, as already noted, the need to develop more guidance on "stylised approaches" for future biospheres and human actions at repository sites.

Institutional control measures, are usually regarded as reliable for only a limited period of time after closure of a deep repository, and some countries believe that a post-closure safety case should not depend on them. However, future generations may decide to maintain them and attention might be given to the additional safety margin they may provide, in order to promote consistency, notably for possible post-closure administrative control and retrievability requirements. In particular, the credit given to institutional control measures may vary in time depending whether such measures are "active" or "passive". So far, there has been no agreement at the international level to formalize the credit which could be given to measures designed to prevent human intrusion. More generally, it would seem desirable to develop in some detail a description of the whole safety approach for disposal, integrating technical aspects and others less technical, such as the role of institutional control measures.

b) Non-technical aspects and their impact

In a difficult socio-political context, one of the recurring topics of the workshop was the actual and perceived position of regulatory authorities vis-à-vis both the implementers and the public. It was stressed that the regulators had to preserve their integrity and their independence and achieve public trust. This could be obtained through a clear definition of responsibilities and procedures in advance of the regulatory process and in conformity with good practices and standards, the nature and transparency of the decisions taken during the stepwise process including direct or indirect participation of the public, a record of the decisions taken and the way they have been implemented, and an open public information attitude. Alternatively, some concern was also expressed about the fact that regulators might be subjected to some pressure from the public in the conduct of their professional responsibilities, which might result into the risk of "diluting good engineering practice to have better relations with the public".

This debate raised the question of what should be the exact role of the public in the regulatory process and who should communicate with the public - the implementers, the regulators, or both? In this respect, an effort may be made jointly by implementers and regulators, in order to present the appropriate information to the public in a form which would facilitate a debate on the issues of direct public interest rather than on unnecessary technical or academic details. Furthermore, it was suggested that there is perhaps no other way but to work towards a stepwise approach, which would contribute to build confidence in the overall regulatory process on the basis of well structured and formalized exchanges between the implementer, the regulator, political decision-makers and the general public. In other words, the regulatory process is part of a broader decision making system, the practical application of which has still to be improved, taking into account of the national institutions and cultures.

The discussions covered also specific communication aspects, such as the use and value of making comparisons with other risks, for which there was only limited support; the need to maintain continuity in information transfer and experience during the regulatory process which is likely to be relatively long, and the education of the public about the concept or risk.

Given the apparent discrepancies in the way national regulations are specified, notably for dose or risk criteria and timescales, it was suggested that it might also be useful to promote a greater harmonisation in this respect.

IV General remarks and main topics for further work

After the general discussion, as reported above, a short summary of the main topics for further work was presented by Lars Högberg. The topics identified included:

a) On criteria development and clarification

- clearer guidance on basic dose/risk targets, indicators and limits, in the context of soft/hard approaches;
- the meaning and interpretation of the concept of risk, notably the disaggregation of risk into probabilities and consequences, and its usefulness in the safety assessment and regulatory context;
- clarification of multiple lines of reasoning and multi-factor approaches, as mentioned in I.a. above;
- guidance on the way the protection of the environment should be approached from a regulatory and safety assessment perspective.

b) On performance assessment issues

- clarification of the meaning of performance assessments used for different purposes and at different steps of the process: system choice, design, site selection, licensing,..., stressing that they will never pretend to be predictions of future but rather the most appropriate tool to judge the potential long-term behaviour and safety of disposal concepts;
- improvements in state of the art in specific areas/methods of performance assessment, notably the treatment of probabilities and the elicitation and use of expert judgements.
- clarification of what is involved in, and what is meant by confidence building and reasonable assurance concepts concerning the results of performance assessments;
- improvements in the presentation of methods and results, notably to political decision-makers and the general public.

c) On the regulatory process

Development and publication of clear regulatory review approaches and criteria well in advance of licensing applications ("The rules of the game") and in particular:

- regulatory guidance on stylized approaches for some long-term scenarios: reference biospheres and human intrusion reference scenarios, which should perhaps remains simple enough to be credible;
- development, at national level, of a stepwise approach for the regulatory process, taking account of the need for interim steps and decisions from the point of view of both regulators and implementers. It was mentioned that this approach should be seen in the context of a well structured dialogue/interface between the implementer, the regulator, political decision-makers and the general public, and contribute to information exchange and building confidence in the process.

These suggestions for further work have to be seen in a context of growing experience, where it appears that, from a scientific and technical perspective, there is no fundamental difference in the approaches recommended or used by implementers and regulators to assess long-term safety of radioactive waste disposal facilities. There is indeed a common basis in terms of the methods used and the understanding of the main issues, even if differences and difficulties remain when it comes to practical application and specific cases, notably at the compliance verification stage where unavoidable uncertainties will continue to exist.

Some of the issues are relatively “generic”, for example those related to stylized approaches and decision aids in a context of uncertainty, or to the risk concept, and would therefore benefit from additional work at international level. The programmes of work of the NEA and other international organisations active in the field cover already several of them.

Others are perhaps more influenced by the national administrative, legal and cultural contexts, notably concerning regulatory frameworks, the interface with the public, and decision-making procedures. They may require specific choices and measures at national level, which may not appear in line with the practices adopted in other countries. This should not be seen necessarily as a major issue, as long as their background is clearly explained and a certain degree of harmonisation is achieved at the level of the overall safety objectives, rather than in the detailed regulatory texts.

As a follow up, the results of the workshop are going to be submitted to the NEA competent committees which will have to decide to incorporate them, when appropriate, in the NEA programme of work.

CLOSURE OF WORKSHOP

Chairman : J.M. Kindelan
CSN, Spain

Mr. Allègre (RWMC Chairman):

I - After three very busy days, many questions have been raised. We have not solved all of them, but it has certainly been useful to meet to increase mutual understanding, and to clarify our own ideas through discussions. Before giving you my remarks, I would like to proceed to my final conclusion: it will be up to NEA to decide how, but my personal conclusion is that we will need some kind of a strong follow up.

When starting to give you my remarks, I am a little disturbed because I have just heard Mr. Zurkinden saying things very similar to the things I wanted to say, but I will try anyway. As preliminary remarks, I would say that there are some things which seem obvious but it's better to say them anyway. First, we all think that an underground repository is the solution and must be a stepwise solution; we also think that other options like indefinite surface storage or "do nothing" are not solutions or are to be clearly rejected because they would leave the burden to future generations and that's what we want to avoid. Such things are very obvious to all of us, but I think we have to repeat them again and again, and we have to ask our governments, our responsible politicians to take clear positions on these points.

I now come to the subject: a few things struck me specially and I will keep in mind three words: "the public", "dialogue" and "robustness", and I will elaborate a little around those three words.

1) The first word is **public**. I remember in the opening session that Jean-Pierre Olivier told all of us that we will not discuss public, public acceptance and so on, and I have seen that the public has always been present. That does mean something. We noticed that there is a tendency of the public to want to participate more and more in the decision making process, but if I may be a little provocative, it seems to me that some regulators, maybe, are encouraging such a tendency and are prepared to respond to that tendency in such a way that, maybe, it could become a tendency among regulators to transfer to the public part of their responsibility. I am conscious that I am very provocative in saying that, and my English does not allow me to give a more diplomatic presentation, but I am sure you understand what I mean. I think that direct democracy in that case is not workable and that the regulators are the technical power in very highly sophisticated scientific matters, and they have to take their responsibilities and to say yes it is good, or no it is not good. We, as implementers, have to convince regulators, and then both of us have to convince the public that what we have made is sound. Nevertheless, there are two remaining challenges. Firstly: to explain in simple and concise terms to the public those difficult matters that we have been discussing together, and this is a very big challenge: who will do that, how, and what will be specially the role of the regulators? I am not speaking of the implementers because anyway they have to be in the

front line. These are still open matters for me. The second challenge is up to what point will external experts be allowed to evaluate the work done by the implementer and the regulator. These matters raise the question of the credibility and competence of the independent regulator. This is also for me a kind of open matter which we will have to think about.

2) The second word I mentioned is **dialogue**. I mean of course dialogue between implementers and regulators. May I say that after the workshop I will not see the regulators in exactly the same way as before, because now I am convinced that we are all in the same boat. We are human beings of course, and we are in the same situation. We have, both, regulators and implementers a very difficult problem to solve. We have to do things which have never been done before and to solve these difficult challenges. There is a strong necessity for continuous dialogue to be sure that regulators will be asking the right questions and that the implementers will be presenting the right solutions. But the dialogue will have to maintain some distance to preserve the integrity and independence of the regulators of course.

3) The third word is **robustness**, which was heard several times a few minutes before. The problem is the robustness of a complex system, I mean a repository, whose unique objective is a very low release to the biosphere. All what we have said about performance assessment and so on can be translated into testing robustness of the system in order to get a good answer to very difficult questions such as disruptive events and many difficult things. This notion of robustness must be elaborated and can be the key for answering relevant questions and giving good explanations to the public because it is probably a simple notion which people outside can understand better. We have never to forget that we are speaking of a system, given that the repository is a system. We have also been speaking very little of the three barrier system, but the three barrier system of a repository is not exactly the same as a three barrier system of a power plant, and we have to explain why.

II - Now, I will come to some specific items which I have divided into three categories. The first category encompasses the subjects which in my opinion represent real problems, which are still problems after three days of discussion. The second category concerns problems which are not so much real problems and which are more or less semantic or presentation problems. The third category concerns what I term potentially troublesome issues.

1) In my first category, undoubtedly, the keypoint to evaluate the quality of a repository is the question of dose/risk approach, and all the discussions related around that and to probabilistic/deterministic questions, critical group definition, evolution scenarios and disruptive events, human intrusion and so on. I will not give a summary of the discussion we had on that, but I am sure we still have to think and to talk about it, because I think that not all of us agree on a purely risk approach and that the quotation by Mr. Vira from Finland of a UK expert (Neil Chapman)* , that it is not possible to give a priori probability to human

* Quoting from Chapman et al. "it is not possible to analyse the mathematically possible combinations of future possibilities for all components of the disposal system and the natural environment and it is thus not possible to calculate scenario probabilities... we see scenarios as simply a means of illustrating possible behaviour of the system and exploring how such behaviour might arise. This information then assists in making decisions on the acceptability of a disposal option..."

intrusion is something which we have to draw conclusions on. So I think there is room for further discussion on this very key point.

The second keypoint, which is probably not so sensitive an issue as the first one and could be to some extent simply a matter of understanding and semantic, is the time frame question. Mr. Zurkinden has already spoken much about this. For me there is one time limit which is easy to understand; this is roughly one thousand years or maybe a little less. At the end of this period the gamma radioactivity will have gone, and probably, we cannot completely rely on institutional control, as the memory of the repository can be lost. So these one thousand years or several hundred years are something which have a concrete sense for me, but after that, really, I don't see any reason to have a definite cut-off. I have been discussing that with our US colleagues who have very simple answer, and so I am asking myself: are we creating a problem in Europe, or have not our American colleagues adopted the right attitude towards the public? They say that the American people are, excuse me, short-sighted; they think that for them 10 000 years are infinite. But do we think that Europeans are more clever than Americans, and for them 10 000 years are not enough? I do not know. So maybe it's only a question of explanation, simple explanation to the public. Maybe there is a real problem underneath, I am not yet sure, but I know there is room also for more discussion between us.

2) The second category concerns semantic or presentation problems. Our Russian colleague mentioned that there was a need for some definitions, harmonisation in the definition of certain words. I agree with him and I just want to point out this qualitative/ quantitative debate. For me this is not real debate. When you do modeling, when you decide to simplify, to over simplify complex phenomenon such as geology and so on, you introduce obviously qualitative elements. When you decide some parameters and you introduce them in the model, this also is qualitative. So what are we doing? we are doing simulations. This is the right word, not prediction. We try to simulate what could be the reality, that's all. Everybody should know that we should not believe what comes out of the computer without knowing what we initially put into it. This is also something very evident, but many people forget it, so we have to be conscious of that. I think that this qualitative/quantitative debate is not so important.

3) Then I come to what I called potentially troublesome issues. The two questions I have in mind are retrievability and the protection of the environment. Why do I think these may be potentially troublesome issues? Retrievability, because this comes mainly from political pressure. We have to define it and to give it a definition which will not be harmful to general safety, because if we give to this word the meaning of a kind of underground storage, in which the waste would be shelved underground, why not to put them on the surface, and then you are back to indefinite surface storage. The other issue is defence of the environment. Frankly speaking I do not understand the meaning of this issue, but I am very frightened if one day we have to take care of the genetic effects on butterflies in one hundred thousand years from now.

Now I come to my final conclusion. We cannot expect to unitize our views completely, at least for two reasons. As well as specific sites and solutions to find, just think about the completely different approaches you may have with hard rock sites and clay sites for instance. The second reason is that we are in different countries, with very different historical and cultural backgrounds. We cannot react the same way, and this is specially true for the whole decision process, and for all questions related to contact with the public. To come back to Mr. Zurkinden, we have to be consistent altogether. If I were an intelligent opponent I would go to the main countries, ask for their approach to the regulatory problems, and try to put them in contradiction. This is something it could be difficult for us to answer and maintain our credibility. I mean it will be difficult for both implementers and regulators to protect against that. So I am not asking that we all take exactly the same solutions, I am asking that we meet again first to know exactly what we are doing, why we are doing that, and to find ways either to converge a little more or to have good explanations to explain why different countries, different problems, give way to different solutions. However, these different ways are not incompatible, inconsistent, or in contradiction. This is my wish, and this is why I think a continuous dialogue must take place and I ask the NEA to organise it. Thank you.

Chairman:

- Thank you very much Mr. Allègre for your remarks. They were really outstanding and maybe provocative in some ways; and now Mr. Högberg.

Mr. Högberg (CRNA Chairman):

- Thank you Mr. Chairman. As Chairman of CNRA, I really want to thank my colleague Chairman of RWMC for a very good summing up of the issues, in a very clear and also sometimes very provocative way. I think I can agree with almost all he has said in that respect, and I want to amplify just one or two points. One about the question of time frames. I think we have to be very clear to explain why we use a time cut-off if we are going to use it, such as 1 000 years, 10 000 years or something else. Are we using it because we cannot predict what is going to happen afterwards? or are we using it because no human generation up to now has taken any responsibility for time spans like that? The first question is accepting defeat; the other one is moral and ethical reasoning. We have to be very clear on that, or also if we discuss in some way or another longer time frames. That was one idea which came to my mind.

Secondly, the quantitative/qualitative question is a semantic issue. What came to my mind is a definition of performance assessment as a numerical simulation of qualitative expert judgment on incomplete data, but doing the best that we can; and it's the same we do in a number of cases.

Finally I fully agree that what was said in the end, it's the same as it was said at the opening statement: it is dangerous if we do not work on more convergence, consistency and approaches even if there are national differences. We may use various, different disposal concepts, but, we have to explain that we have had consistency in our approaches. We have very large differences when it comes to formal regulations of reactor safety, but I think in the NEA context we will always be able to demonstrate that. It is urgent because one consequence of the stepwise disposal approach is that we have to start that stepwise approach now and we have to find consistency and convergence very soon. I fully agree with the Chairman of RWMC, that we will have to take that back to our respective Committees and take some initiatives for further work in this area.

Well, ladies and gentlemen these were my final remarks. I have spoken at length, specially today, but again as the Chairman of the Programme Committee, I cannot finish without expressing the thanks not only of the Programme Committee, but I think of all the participants to our Spanish hosts who have organised this workshop so excellently, and have displayed such enormous hospitality and made the stay here so very pleasant; as someone said it yesterday, can any country even dare to offer to host a workshop after this. We probably can, but again I think this is a very good sign of the appreciation we have. So, we should all join with a warm hand for the organisers of this conference, Mr. Kindelan at CSN and his colleagues, and ENRESA.

Chairman:

- Thank you very much indeed Mr. Högberg, for your kind words. It is my duty now to close the meeting, and I will do it very briefly. As was said by my friend, commissioner Martin, at the opening of the workshop, we were very glad to host this meeting and see various countries, like many of us, which are now starting to consider the procedures and the rules for licensing a future repository for high level waste. Now at the end of these three days of fruitful work, I must express my satisfaction for the work which has been done. I'm not going to repeat now what has been said by Mr. Allègre, Mr. Högberg, Mr. Olivier and all the others. I would only like to finish with, three or four, very short, general remarks that are the personal views of somebody who has been almost ten years the Head of an implementing agency and is now at the chair of a regulatory body. First, I am very glad to see that there is a broad consensus in the different technical issues that are in front of us, both regulators and implementers. We could say very strongly that the problem of disposing of high-level waste is not a dramatic one, and certainly a problem which can be solved with the present technical knowledge. Nevertheless, and this is my second point, there is still a lot of work to be done, and the purpose of this seminar was precisely to specify how this work should be done with the collaboration of organisations and people concerned. Thirdly, I am glad to see that the dialogue between regulators and implementers is going ahead softly. I must refer to the earlier remarks of Mr. McCombie and Mr. Allègre, and consider that one of the fruitful results of this meeting is that, for the first time in a formal way, we have been together to start this dialogue. It is important that we understand each other and that we are speaking a common language. Communication between us must improve, and we, as regulators, should increase the transparency of our ideas towards the implementers and also to the general public. Finally it is evident for me that international collaboration and consensus are basic, both to optimise our efforts and also to help reassuring the public opinion about the success of the task to be done. Now I pass the words to Mr. Olivier.

Mr. Olivier (NEA):

- Thank you Mr. Kindelan. I just wanted to express my thanks to many people; first to all of you who are here, and have contributed to the discussions. We wanted to restrict participation at the meeting, but we still had a large meeting which nevertheless was very productive, and I would like to thank all participants. I would like to thank the Chairman of the Programme Committee, Lars Högberg, and its members who helped to organise the meeting. As we said, we tried to avoid discussing certain issues (notably the involvement of the public) knowing perfectly that we would deal with them and that was finally OK. If we had said at the beginning that we would deal with these issues, we would have probably dealt with them only.

I would also like to thank the local organisers, ENRESA and the Nuclear Safety Council for their assistance. I am not going to repeat what Lars Högberg said, but this is well appreciated by everybody. In particular, I would like to thank two persons: Eugenio Gil and Javier Reig, from the Council, and the secretariat staff who assisted us all through that week.

Finally, I would like to express also the hope that NEA is going to be in a position to follow up a number of suggestions made at this workshop. This is still open; the NEA Committees will have to discuss it soon, in particular, at the Radioactive Waste Management Committee meeting, next March, in Paris.

Thank you very much to everybody on behalf of the Nuclear Energy Agency.

COMPILATION:

SUMMARIES OF NATIONAL REGULATIONS

ON THE DISPOSAL OF

LONG-LIVED RADIOACTIVE WASTE

Legal Framework and Licensing Procedure in Belgium

1. Introduction

The construction and the operation of nuclear installations are regulated by the Federal Government. These regulations have been laid down by the Royal Decree of February 28, 1963 and have been amended several times. The current version is based on the European Basic Safety Standards for Radiological Protection (Council Directive 80/836/EURATOM, as amended by Council Directive 84/467/EURATOM).

These regulations are currently under revision in order to implement the law of April 15, 1994 on the protection of the population and the environment against the hazards of ionizing radiation and the establishment of the Federal Agency for Nuclear Control.

In the following paragraphs, the most relevant elements of these regulations are summarised. However, it must be kept in mind that these regulations deal with the radiological hazards only, and that other regulations, e.g. with respect to building activities and to mining activities, must also be complied with.

2. Licensing Procedure

Nuclear installations are classified into four categories, depending on the nature and the degree of the hazards involved. The facilities for storage, treatment, conditioning and disposal of radioactive waste belong to class 1, the operation of which must be authorized by Royal Decree.

In general, the license application is drafted by the future operator; it must contain the elements listed in the General Regulations for the protection of the general public and workers against the hazards of ionizing radiation (a.o. an environmental impact assessment).

This application is sent to the Governor of the province involved, who transmits it to the local authorities for advice (in principle to be given within 60 days). The local authorities have to inform the public about the subject of the application and they have to take account of the comments made by the public when they draft their advice to the Governor.

The Governor then sends the application and the advice of the local authorities to the permanent deputation of the province for advice (in principle to be given within 30 days).

The application and all advices are then sent to the Special Commission, composed of senior officers of the ministries involved, as well as experts in nuclear science and radiological protection. A rapporteur is designated, to examine the application and to report to the Commission; this report also includes a proposal for decision. The Special Commission has the right to consult other experts. In cases where a potential radiological hazard for neighbouring countries exists, the Special Commission has to submit the application to the European Commission who consults the group of experts set up under article 37 of the Euratom Treaty.

The Special Commission has to give a preliminary advice which is sent to the operator, who is given the opportunity to comment within a period of 30 days. Taking these comments into account, the Special Commission then gives its definitive advice, in most cases accompanied by a set of proposed special operating conditions.

When the advice of the Special Commission is favourable, a Royal Decree is then drafted and submitted for signature to the competent Minister(s) and the King.

When the advice of the special Commission is not favourable, the authorization cannot be given.

3. Particular Provision

If the waste installation is considered as an extension of another licensed class 1 installation, the applicant may be exempted from part of the administrative procedure.

RADIOACTIVE WASTE MANAGEMENT IN CANADA

1. GENERAL STRATEGY

1.1 Overall Strategy and National Policy

Radioactive waste produced in Canada at all stages of the nuclear fuel cycle is managed according to a comprehensive set of policies and programs. The overall objective is that radioactive waste be managed such that: the human population and the environment are protected from any harmful effects; any burden placed on future generations is minimized; all applicable radiological and other criteria are satisfied; and all social and economic factors are taken into account. The overall strategy is to hold the waste in interim storage, and then dispose of it permanently.

The utilities discharge their responsibility for managing radioactive waste, including spent fuel, by storage on their own sites. AECL Research operates a major low- and intermediate-level radioactive waste management facility at its Chalk River Laboratories, where wastes from its own research and development activities, and wastes from the Canadian isotope production industry and from the use of radioisotopes in medicine, industry and research are stored. Construction is planned of an intrusion-resistant underground disposal structure (IRUS), which will allow disposal of low- and intermediate-level radioactive wastes with hazardous life-times of up to 500 years.

1.2 Organizational Structure

AECL Research, a crown corporation owned by the government of Canada, has been responsible for the generic research for permanent disposal of nuclear fuel waste. Ontario Hydro, a utility owned by the Government of Ontario, has been responsible for research on transportation and storage of such waste. Research into storage and disposal of LILW is carried out by both organizations.

The Low Level Radioactive Waste Management Office was established by the federal government in 1982, and attached to AECL, with a mandate to discharge the federal government’s responsibilities for management of low level radioactive waste including historic wastes.

The Atomic Energy Control Board (AECB) is the nuclear regulator in Canada with a mandate to Responsibility for Canadian nuclear policy issues rests with Natural Resources Canada.

2. DISPOSAL SYSTEMS

2.1 National Policy

The acceptability of the concept of disposal of nuclear fuel waste is being reviewed under the federal Environmental Assessment and Review Process. In 1989, an eight-member Environmental Assessment

Panel was appointed by the federal Minister of the Environment to conduct this review. Following AECL's submission of documentation of its disposal concept in 1994, public hearings started in 1996 and are scheduled to conclude in early 1997 with the Panel's report anticipated later in that year. Ontario Hydro has announced its intention to take responsibility for implementation of a spent fuel repository, if the Panel recommends that such a step be taken. (The transcripts of the public review are available from the Canadian Environmental Assessment Agency.)

According to the concept being assessed, used fuel will be buried in a vault 500 to 1000 m deep in plutonic rock of the Canadian Precambrian Shield. It is expected that there will be one central disposal facility which could accommodate all used fuel produced over almost a century of nuclear power generation in Canada, at the present rate of production.

A multiple-barrier approach, which includes both engineered and natural barriers, has been developed for isolating the used fuel. The waste form, containers, buffer, backfill and the rock mass between the disposal vault and the biosphere are the barriers. The performance of the entire disposal system has been assessed by predictive computer modelling, using a wide variety of information from field and laboratory studies..

National policy encourages waste producers to establish LILW disposal facilities for their own needs; so far only AECL, with the IRUS disposal project, has taken firm steps in that direction.

2.2 Regulations

The siting requirements for a geologically acceptable disposal site are specified in the AECB's regulatory document R-72. These are: the host rock and geological system should have properties such that the release of radioactive material from the disposal vault and its subsequent transport is retarded; there should be little likelihood that the host rock will be exploited as a natural resource; the geological system should be capable of withstanding stresses without significant structural deformation or fracturing; and the dimensions of the host rock should be such that the disposal vault can be deep underground as well as removed from major geological discontinuities.
AECB's Regulatory Document R-104 deals with the long-term aspects of radioactive waste disposal. It specifies that the radiological risk to individuals in the most exposed group from a waste disposal facility shall not exceed 10^{-6} fatal cancers and serious genetic effects in a year. This document also states that the time-frame of concern for quantitative compliance is 10,000 years, while also requiring that longer periods be addressed qualitatively to ensure that no sudden increase in risk would occur.

2.3 Disposal Vault Concept; LILW:

The Intrusion Resistant Underground Structure (IRUS) will be the first facility in Canada for the permanent disposal of LILW produced by radioisotope users and nuclear reactors. The IRUS concept is based on reinforced concrete in-ground modules, each of which will be 30 m long, 20 m wide and 9 m deep. The site has been selected in a free-draining sand deposit above the groundwater table at the site of the Chalk River Laboratories.

Each module will have a capacity of 2000 m^3 of packages waste in the form of 200-L steel drums, bales and standardized boxes. Spaces between the waste packages will be filled with sand and the base of each unit will be of compacted buffer material.

During the operating phase the IRUS will have a light building over it and a crane for handling the waste packages. After the modules are filled this structure will be removed to be used on other modules and the IRUS will be covered with a concrete cap overlain by an engineered cover containing barrier and drainage features.

2.4 Experience/Status

For over 40 years Canada has been managing the storage of radioactive waste. While no disposal facilities have yet been constructed, Canadian regulatory agencies, potential implementers and the general public have given much consideration to technical and social issues associated with siting, design, construction and operation of such facilities.

National Regulations on the Disposal of Long-Lived Radioactive Waste

CZECH REPUBLIC

LEGAL FRAMEWORK

1. Law No. 28/1987 Coll., on State Supervision of Nuclear Safety of Nuclear Facilities

Licensing process for siting, construction, operation and decommissioning of nuclear facilities has been defined in this law. Safety documentations (safety assessment reports) are required to be submitted by licensee to regulatory authority in every step of this process.

2. Regulation No. 67/1987 Coll., on Asssurance of Nuclear Safety in Radioactive Waste Management

The regulation provides the basic technical and organizational requirements for the preclusion of the release of radioactive substances into the atmosphere, waters and soil in handling radioactive wastes. The requirements have been also given on ensurance of nuclear safety and radiation protection at collecting, record keeping, segregation, treatment, conditioning, storage and disposal of radioactive waste in provisions of this regulation. One part has been devoted to limits and conditions of radioactive waste final disposal.

3. Regulation No. 59/1972 Coll., on Health Protection against Ionizing Radiation

The regulation formulates the basic principles of radiation protection based on ICRP and IAEA recommendations, which are safety handling of sources of ionizing radiation, primary and secondary limits and regulation of the exposure of workers and members of public.

4. Decree CSAEC No. 4/1979 Coll. on General Criteria for Sitting Nuclear Facilities

The purpose of the regulation is to determine the general acceptance criteria as well as excluding criteria for ensuring nuclear safety in siting nuclear facilities.

5. Law No. 17/1992 Coll. on Environmental protection

The environmental impact assessment is required for the licensing processes of the facilities including the nuclear and radioactive waste disposal ones. For specific cases, international discussion is also required.

6. Law No. 244/1992 Coll. on Environmental Impact Assessment

Detailed requirements on the content of environmental impact assessment studies including nuclear and waste storage or disposal facilities are given in this law.

7. Regulation No. 99/1992 Coll. on Establishment, Operation, Ensurement and Liquidation of Facilities for Underground Waste Disposal

The basic principles and requirements for site selection, site investigation, design, construction, operation and decommissioning of underground waste disposal facilities are determined by this regulation mainly from the geological point of view.

Regulatory Guides:
1. SNF CSAEC No. 4/1986 on Acceptance Criteria for Disposal of Radioactive Wastes in Shalow Land and Rock Cavities

The basic recommendations for the setting of acceptance criteria for disposal of radioactive waste are given in this document.

2. SNF CSAEC No. 6/1991 on Safety Principles and Technical Criteria for the Underground Disposal of High Level Radioactive Wastes

The basic safety principles and technical criteria for siting and design of deep geological repository of high level waste are described in this document. The main attention is paid to the long term radiation protection aspects.

Recently some basic changes are being prepared in the Czech Republic in relation to so called atomic legislation. The act on the Peaceful use of nuclear energy and ionizing radiation has been submitted to parliament for approval. It is supposed that this act will come to force at the second half of this year. This act will substitute act No. 28/1984 Coll.. Some regulations will be amended with regard to this change e.g. documents which are mentioned above as points 2),3) and 4).

Organizational structure

State Office for Nuclear Safety (SONS) is a regulatory authority in all areas of the use of nuclear energy and ionizing radiation. One part of its activities is supervision on the safety of radioactive waste management. It also means that SONS is the licensing authority for all nuclear facilities including repositories of radioactive waste. All important decisions in licensing process are made with a support of an independent expert judgement. Peer reviews are also used in decision-making in licensing process.

Practical experiences

At the beginning of eighties first activities related to deep geological disposal were started in the Czech Republic. These first steps were devoted to development of site selection criteria and evaluation of potential areas. Then a discussion on integration of financial and research capacities, organizational structure, content of the future project and time schedule of works followed. The results of this discussion were a base for a preparation of Underground Disposal Programme when the main aim was to develop a basic concept ,applicable technologies, to select a final site for a deep geological repository for radioactive waste , to perform safety assessment studies.

In parallel with these activities a number of investigations relating to Deep Geological Disposal Programme were carried out. The results obtained were used as an introductory part of geological investigations of promising regions for geological disposal. The selection of 27 perspective regions was made from studies of archived documentation and became a starting material for discussion on deep geological repository siting in the Czech Republic.

The proposal deep repository concept was reviewed by IAEA WATRP mission. The recommendations of this mission were implemented into the revised Programme of Deep Geological Disposal in 1993. This programme is co-ordinated by Council which was established from representatives of six bodies which are Ministry of Industry and Trade, Ministry of Environment , Ministry of Economy, State Office for Nuclear Safety, Czech Power Company plc. and Nuclear Research Institute plc.

Nine activity areas are identified within the Programme of Deep Geological Repository: design and construction activities, economic studies, safety assessments, source terms and near-field interactions, far-field interactions, repository siting, QA and QC programme, public involvement programme, information system, international programme.

FINLAND

1. Implementing and regulatory responsibilities

The Nuclear Energy Act and Decree define the responsibilities, licensing procedures and supervisory rights concerning nuclear activities, including nuclear waste management. The two NPP utilities have the financial and operational responsibility for nuclear waste management in Finland. They have founded a joint company, Posiva Ltd, for the research, development, planning and later implementation related to spent fuel disposal.

The Government is the licensing body for nuclear facilities. The Ministry of Trade and Industry oversees that implementation of waste management and related R&D complies with the national policy. Finnish Centre for Radiation and Nuclear Safety is responsible for the control of nuclear safety and for the technical and safety related review of licence applications and other important documents.

The objectives and milestones for spent fuel management were defined in the policy decision made by the Government in 1983 and were later reaffirmed by the Ministry of Trade and Industry with minor modifications. This decision defines three reporting - regulatory review milestones, taking place in 1985, 1992 and 2000. (The latest review is described in report STUK-B-YTO 121: ”Review of TVO’s spent fuel disposal plans of 1992”). The selection of disposal site and the first formal licensing step, the so called Decision of Principle process, would occur around the year 2000. Prior to this, the Environmental Impact Assessment process will be carried out. The construction and operating licence applications would be submitted to the authorities in 2010 and 2020, respectively.

2. Regulations

While the Nuclear Energy Act and Decree include only very general statements concerning the safety of nuclear activities, they authorise the Government to issue general safety regulations and the Finnish Centre for Radiation and Nuclear Safety to issue detailed safety regulations. Such regulations have already been issued for the disposal of low and intermediate level waste (Reports in English by the Finnish Centre for Radiation and Nuclear Safety: STUK-B-YTO 87 and Guide YVL 8.1).

The Finnish Centre for Radiation and Nuclear Safety has recently prepared the first draft for a general safety regulation concerning disposal of spent fuel. The long-term safety criteria, included in that document, are given below.

General objectives

The health detriments and other effects on the environment, arising from waste disposal, shall be low and not greater than the maximum levels that would be currently acceptable. The judgement of the safety of disposal shall be based on all radiological impacts irrespective of any national boundaries.

The burden on future generations shall be limited by implementing waste disposal in a safe manner, at an appropriate time and so that no long-term institutional control or remedial actions are required to meet the safety goals.

Radiation protection goals

Up to reasonably predictable time periods *(around 10 000 years)*, the radiation dose to the most exposed individuals from the expected evolution of the disposal system, shall be constrained 0,1 mSv per year. The relevance to safety of unlikely events that might cause increased radiation exposure shall be discussed qualitatively and whenever practicable, assessed in quantitative terms in relation to the risk of death corresponding to the dose constraint given above.

Beyond the reasonably predictable time period *(around 10 000 years)*, the quantities of radioactive substances migrated from the repository to the human environment, averaged over long time periods, shall be less than nuclide specific constraints. These constraints shall imply radiological impacts that are insignificant on a large scale and even at the disposal site not more than the level of radiological impacts that arise from natural radioactive substances.

Suitability of the disposal concept

The safety of disposal shall be based on passive multiple barriers so that deficiencies in one of the barriers do not substantially impair the overall safety of disposal, and realistic changes in disposal conditions are likely to impair substantially the performance of only one barrier, or to have only minor effects on the performance of more than one barrier.

The repository shall be located at a sufficient depth in order to mitigate the effects of surfical events and to render inadvertent human intrusion into it very difficult.

Suitability of the disposal site

The geological characteristics of the planned disposal site shall, as a whole, be favourable for the isolation of the waste to be disposed of. At the planned disposal depth, there shall exist adequately large intact blocks of bedrock where the repository can be constructed. In comparison with the typical crystalline bedrock in Finland, none of the most safety relevant characteristics of the planned disposal site shall not be significantly unfavourable.

The suitability of the disposal site shall be justified by means of a safety assessment based on or supported by models and data which are mutually consistent and specific to the planned disposal site as far as reasonable taking account of the available investigation methods.

Safety assessments

Compliance with the radiation protection goals as well as the suitability of the disposal concept and site shall be justified by means of a safety assessment. It shall address both the expected evolution of the disposal system and unlikely events that might cause increased exposure to disposed waste. The safety assessment consists of a numerical safety analysis based on experimental studies and complemented by qualitative expert judgement whenever quantitative analyses are not feasible or too uncertain.

The models and data introduced in a safety assessment shall be based on the best available experimental data and expert judgement and on disposal conditions that may exist in each time period considered in the assessment. The safety assessment shall aim at overestimating the radiation impact really to occur. The significance of the uncertainties involved in the safety assessment shall also be estimated.

The Control of the Safety of Radioactive Waste Management in France

Radioactive waste management encompasses all activities aiming at ensuring the protection of human health and the environment, now and in the future, without imposing undue burdens on the future generations.

From the very beginning of the design of nuclear installations, the radioactive waste issues have to be addressed, the main objective being the limitation of the volume and toxicity of the waste generated. Radioactive waste management includes treatment, conditioning, storage and disposal activities. These activities shall be designed according to the nature of the waste generated and are interdependent. Interdependency among and between these steps shall be taken into account to optimize, from the safety point of view, the overall system.

The primary responsibility for safety relies to the waste generators and operators of radioactive waste management facilities.

The Regulatory body, Nuclear Installations Safety Directorate, regulates these radioactive waste management activities, for waste produced in nuclear installations subject to the Decree of December 1963 establishing the licensing process, and within the legal framework based on the Law of December 1991 related to the research on management of high level waste and medium level long lifetime waste.

Radioactive waste classification

The objective of the classification is to identify the waste that will, after treatment, conditioning and eventually interim storage, be disposed of in the same way, according to the hazards associated. Two main parameters characterize the risks : the total activity and the lifetime.

The new classification in France is as follows :

Activity/lifetime	**short lived**	**long lived**
very low level	under study	under study
low level	surface disposal	under study
intermediate level	surface disposal	under study according to the Law of December 1991
high level	under study according to the Law of December 1991	under study according to the Law of December 1991

The main responsibilities

Radioactive waste management involves waste generators, operators of waste treatment and conditioning facilities, operators of interim storage facilities and operators of repositories as well as research and development institutes.

According to the Law of December 1991 and the Decree of December 1992 related to the organization of the French Agency for the management of radioactive waste (ANDRA), this Agency is in charge of the long term management of radioactive waste and of the design, construction, operation and closure of repositories. ANDRA is also in charge of establishing waste acceptance criteria, in accordance with the basic safety rules (BSR I-2 and BSR III-2-e) and the safety assessment of the disposal facilities, of the approval of each type of waste packages and of ensuring that the waste producers comply with the conditions set out in the approval documents including the waste acceptance criteria. The approval procedures shall be agreed upon by DSIN.

Moreover, pursuant to the legal provision of the ministerial order of August 1984, dealing with quality assurance system, ANDRA shall consider the waste producers as service organizations and shall ensure, particularly by means of audits and inspections, that a quality management system has been put in place by the waste producers, allowing them to guarantee that the waste packages are produced in compliance with the corresponding specifications the Agency has set down.

In accordance with the provisions of the law of July 1975, the waste producers are responsible for their management until the waste are correctly disposed of. The producers must in particular implement means of satisfying the requirements which result from the basic safety rules issued by DSIN, either directly or through the requirements of ANDRA. This includes means of limiting the volume and activity of waste produced, as early as the design phase of the installations.

In addition to the responsibility for the overall safety of the waste management with a view to ensuring the safety of the disposal, the operators involved in any radioactive waste management activity are also responsible for the safety of their waste management facilities.

The regulatory functions assigned to DSIN include establishment of regulations that assign responsibilities to each actor and implementation of the licensing procedure, verification of compliance with the requirements and implementation of necessary enforcement actions. For the control of safety, DSIN controls the safety of the installations by direct inspection of the different installations involved and controls also ANDRA either to ensure safety of its own activity, such as operation of repositories, or to control the efficiency of the verification carried out by ANDRA of the producers activities.

Legal framework and status for the disposal of high level waste and intermediate level - long life waste

The law of December 30th 1991 sets the main orientations for the research on management of high level waste, and medium level and long lifetime waste. This law requires the implementation of a fifteen years research programme along three different ways :

- research of solutions to separate and transmute long life radionuclides in the waste.
- studies of retrievable and non retrievable disposal in deep geological layers with the help of underground laboratories.

- studies of processes for conditioning and long term surface storage of these waste.

As set out by the law of December 1991, a National Review Board is in charge of evaluating the progress made in the three ways of research. Its first report was provided to the Government and the Parliament in July 1995 and the second one in June 1996.

Various decrees detail the precise application of the law. One of them sets the missions of the mediator in charge of discussions with local elected officials, associations and local populations. Another fixes the conditions under which the underground laboratories will be created.

The discussion and information process conducted by mediator Christian Bataille and the favorable geological characteristics lead to the choice in January 1994, by the government, of four geological areas in the departments of GARD (clay), VIENNE (granite), HAUTE MARNE (clay) and MEUSE (clay).

Preliminary surface investigations carried out by ANDRA allowed this agency to select three potential sites for the location of a deep geological laboratory. One is located at the border between the two departments of Meuse and Haute-Marne and is now called East site. The two others are located in Gard and in Vienne.

During this preliminary phase, the results of the investigations have been examined by DSIN, its technical support IPSN and by the standing group of experts dealing with radioactive waste disposal in February 1996. As a result of this review, DSIN reported to the Government in April 1996, confirming that no site present redhibitory characteristics and concluding that the East site seems favorable while the Gard and the Vienne sites are more complex and less well known.

In June 1996, the government allowed ANDRA to apply for the creation of laboratories in this three sites. ANDRA applied for the East, Vienne and Gard sites mid 1996. DSIN sent the application to the Prefets of the Departments who will organize the local consultation which involve the public and the local administrations, as well as elected representatives. At the same time, the applications provided by ANDRA will be submitted to a review by IPSN and the standing group of experts, planned for March 1997. At the end of the licensing procedure, planned for end 1997, and according to the results of the inquiry and the review, sites should be chosen to build deep geological laboratories.

In this process, DSIN is particularly concerned with :

- the priority that must be given to safety,
- the necessity to avoid delays and to respect the schedule of the law of Dec. 91,
- the need that the research developed in the laboratories are operational and not academic. After the research programme has been performed, one of the selected site for a deep geological laboratory could be proposed to the Parliament as the location for a waste repository.

Safety and radiation protection objectives for geological disposal

Dose versus risk indicators, other safety indicators, normal and hypothetical situations, time frame to consider

The safety and radiation protection objectives are described in the Basic safety rule n° III.2.f related to the objectives to be adopted in the design and construction phases of the creation of a deep geological formation radioactive waste repository with a view to ensuring safety after the repository has been closed :

Objective

The protection of people and the environment in the short and long terms constitutes the Basic objective of a deep geological waste repository. The protection must be provided against risks associated with the dissemination of radioactive substances in all the considered situations, without depending on institutional control which may not be guaranteed beyond a limited period of time. With respect to this, the concept chosen for the repository must make it possible "to limit the radiological impact to levels which are as low as reasonably achievable in view of the technical, financial and social factors" (the ALARA principle of the International Commission for Radiological Protection).

The characteristics of the selected site, the setting up of the repository, the design of the artificial barriers (packages an engineered barriers) and the quality of their construction form the bases of the safety of the repository.

As concerns the assessment of safety, adequacy must also be checked in terms of the above objective and principles. To this end, assessments of the radiological impact will be made to verify that the objective is met under all the considered situations.

Radiation protection criteria

The safety assessments will include determination of potential individual exposures expressed as effective doses. The characteristics of human being will be considered to be constant (sensitivity to radiation, nature of food, contingency of life, and general knowledge without assuming any scientific progress, particularly in the technical and medical fields). A distinction must be made between potential exposures resulting from the repository in the normal reference scenario and that which would result from random events which might disturb the repository.

Reference situation

Individual effective dose must be limited to 0.25 mSv/year for extended exposure associated with events which are certain or highly probable. This value corresponds to a fraction of the annual limit of exposure of the public in a normal situation, in accordance with the possibility of exposure from several sources. The assessments are based on modelling the evolution of the repository, with particular reference to the barriers, and modelling the circulation of ground-water and the transfer of radionuclides. For a period of at least 10,000 years*, the stability (covering limited and predictable evolution) of the geological barrier must be demonstrated. The value of the results of the forecasts may then be checked objectively, in particular on the

* Cf. The Goguel report. Whatever the case, the period of stability of the geological barrier must be estimated on the basis of the results of geological studies conducted at the site.

basis of explicit studies of uncertainties. The **limit** of 0.25 mSv/year will be applied for determining the acceptability of the potential radiological consequences.

Beyond this period of stability of the geological barrier, on the one hand uncertainty concerning the evolution of the repository progressively increases with time, and on the other hand the activity of the waste will have significantly decreased. Quantified estimates of the individual effective dose must then be made. These may be supplemented by more qualitative assessments of the results of these estimates, as regards the geological barrier evolution factors, so as to verify the release of the radionuclides does not result in an unacceptable individual effective dose. In this verification, the same 0.25 mSv/year limit shall be used as a **reference** value. After a period of 100,000 years, it is not considered that there is still a normal evolution. The evolution after this period of time is then assessed as an hypothetical situation.

Hypothetical situations corresponding to random events

Some random events, either of natural origin or associated with human activity, may disturb the evolution of the repository and possibly result in higher individual exposure than that associated with reference evolution of the repository. To maintain consistency between potential exposure in the reference situation and potential exposure associated with hypothetical situations, consideration may be given to using the risk concept (the product of the probability of the occurrence of an event and the effect of the associated exposure) to allow for the probability of occurrence of each situation giving rise to exposure. However, the establishment of a criterion based on an individual risk limit requires caution, as it may imply a debatable equivalence between reducing the probability and reducing the exposure. Furthermore, it can be expected to be difficult, or even impossible, to estimate the probabilities of events which can result in exposure.

Under these conditions, the acceptability of potential individual exposures associated with the occurrence of random events is assessed with allowance made for the nature of the considered situations, the duration and the nature of the transfers of radioactive substances to the biosphere, the properties of the pathways by which man can be affected and the size of the groups exposed.

Furthermore, the possibility of implementing interventions to mitigate the consequences, should they occur, must not be made allowance for in the design of the repository. Therefore, potential individual exposure expressed as an effective dose, associated with hypothetical situations for which allowance must be made in the design of the repository must be maintained well below levels liable to give rise to deterministic effects.

Role of post-closure surveillance

As a safety objective, the protection must be provided against risks associated with the dissemination of radioactive substances in all the considered situations, without depending on institutional control which may not be guaranteed beyond a limited period of time. This relates particularly to the minimum lapse of time before human intrusion might occur.

For such a situation, the minimum date has to be fixed before which involuntary human intrusion would not occur due to the memory of the existence of the repository. This memory would depend on the durability of the measures implemented: archiving, institutional documents resulting from regulations, surface markers etc. Under these conditions, the loss of the memory of the existence of the repository will not reasonably occur before 500 years. This value of 500 years shall be taken as the minimum lapse of time before human intrusion might occur.

The determination of the characteristics of the human intrusion situations adopted shall be based on the following conservative hypotheses:

- the existence of the repository and its location is forgotten,
- the level of technology used is the same as that at the present day.

Another aspect of the post-closure surveillance is the implementation of measures to verify the efficiency of the multiple-barriers system for both its protection function and its confinement function.

GERMANY

National policy

Radioactive waste disposal policy has been based on the decision that all types of radioactive waste are to be disposed of in deep geological formations.

The Atomgesetz (Atomic Energy Act /1/) gives the responsibility for disposal of radioactive waste to the Federal Government, with the Bundesamt für Strahlenschutz (BfS, Federal Office for Radiation Protection) as the responsible authority. The Atomic Energy Act was amended in 1994. The important change in radioactive waste manage-ment is that the priority for reprocessing spent nuclear fuel has been substituted by making the reprocessing and direct disposal route legally equivalent. As a consequence the direct disposal of spent fuel has been taken into consideration in long term safety assessments.

Organizational structure

The Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (**BMU**, Federal Ministry for the Environment, Nature Conservation and Nuclear Safety) is the supervisory body for the licensing authorities in the Federal States. In carrying out its duties, the BMU is advised by the Reaktorsicherheits-Kommission (**RSK**, Reactor Safety Commission) and the Strahlenschutz-Kommission (**SSK**, Commission on Radiological Protection).

The **Federal States** are the licensing authorities for all nuclear installations, including repositories, except interim storage facilities for nuclear material. With regard to a licensing procedure, the Federal Government can give directives to the Federal States.

The **BfS** was established on November 1, 1989, and has been charged by law as the competent authority for construction and operation of federal installations for the disposal of radioactive waste, acting on behalf of the Federal Government. BfS is a Federal Agency in the portfolio of BMU.

Legal framework

The disposal of radioactive waste in a repository is, in particular, governed by the following specific regulations:

/1/ Atomic Energy Act, Gesetz über die friedliche Verwendung der Kernenergie und den Schutz gegen ihre Gefahren (Atomgesetz-AtG), Bundesgesetzblatt I, zuletzt geändert 1994

/2/ Radiological Protection Ordinance, Verordnung über den Schutz vor Schäden durch ionisierende Strahlung (Strahlenschutzverordnung-StrlSchV), Bundesgesetzblatt I, zuletzt geändert 1996

/3/ Federal Mining Act (Bundesberggesetz-BBergG), Bundesgesetzblatt I, zuletzt geändert 1995

/4/ Safety Criteria for the Disposal of Radioactive Waste in a Mine (Sicherheitskriterien für die Endlagerung von radioaktiven Abfällen in einem Bergwerk), Bundesanzeiger, Jahrgang 35, 1983

The general safety objetives for construction and operation of a repository for radioactive waste are prescribed in /1/ and /2/. The basic aspects that must be taken into account to achieve these objetives are compiled in /4/. The Federal Mining Act /3/ regulates all aspects concerning the operation of a disposal mine. According to /1/, a licence is required for the construction and operation of a repository. This so-called plan approval procedure concentrates the examination, evaluation and licensing of all relevant radiological and environmental aspects into one single licensing procedure. More specific licensing requirements are elaborated e.g. by means of ordinances, safety criteria, general administrative regulations, guidelines and technical standards. As part of the licensing procedure public participation is required.

Safety features

- Objectives

The fundamental objective of radioactive waste disposal in repositories is to ensure that waste is disposed of in such a way that human health and the environment are protected. Radioactive waste shall be managed in such a way that the predicted impact on future generations will not exceed the relevant levels of impact which are acceptable today.

Possible dangers and harms must be identified on the basis of the state of science and technology and precautionary measures must be taken within the limits of practical reasoning.

In the licensing procedure possible dangers and harms have to be identified. It has to be distinguished between expected events, likely events and events which are very unlikely. Precautionary measures are requested for the first and second kind of events. For the third kind of events the licensing authority may only require comparative measures of damage provision.

- Radiation protection criteria

The safety of a geological repository must be deomonstrated by a site specific safety assessment which includes the whole system of barriers and technical elements and considers possible failures and developements of the barriers in the future.

After termination of the operational phase the total repository must be closed off safely from the biosphere. Even in the post-closure phase, radionuclides which might reach the biosphere via water path as a result of not completely excludable transport processes must not lead to individual annual doses which exceed the limits specified in the criteria (0,3 mSv/a).

- Time frame

No time frame for safety assessments is given by the regulations. Safety assessments rely firstly on geological prognosis and secondly on calculations of individual doses. As to the latter, RSK/SSK hold the opinion that the required demonstration of compliance with the 0,3 mSv/a criteria has to be performed by a safety assessment over a time period of about 10.000 years. A period of 10.000 years is likely to be free of major geologic changes, such as renewed glaciation, tectonic movements, or volcanism. Beyond that period the safety assessments should demonstrate that no unacceptable risks or harm will result from radioactive waste. Safety indicators as toxicity, radionuclide release, or groundwater flow velocities can be used to demonstrate the isolation potential of the site and the potential risks. Calculated doses, interpreted as safety indicators, could also provide useful information in building confidence in the safety case.

- Technical safety principles

According to existing experience technical safety principles have been set up to ensure completeness, robustness, diversity of concepts and conservatism of safety assessment methodologies.

The safety is assessed based on the performance of the disposal system as a whole. Consequence calculations should use input data which are as realistic as possible.

Safety assessments have to use state of the art methodology. They should use conservative and deterministic models for subsystems. Uncertainty and sensitivity analyses are required. Site investigation should consider all aspects which are available and applicable for building confidence in the conservatism of planning and safety assessments. Paying attention to the risk concept and natural analogues as diversity concepts is part of the confidence building process.

Weaknesses or possible failures of the barriers including human actions have to be worked out and included in the safety cases. Design of the barriers and modelling of the barrier functions should be robust. The function of one barrier should not be dependent on the effectiveness of another barrier.

Practical experiences with regulation of long term safety

Konrad: Disposal of radioactive waste with negligible heat production. The 1990 compliance report was declared sufficient for public participation by the State licensing authority of Lower Saxony. Objections raised against the project were discussed with the intervenors and the proponent on 75 days from September 1992 to March 1993. Subject to the decision of the licensing authority, the proponent is not aware of any unresolved problems regarding the long term safety of the site.

Morsleben: Disposal of low- and intermediate level waste with relatively low concentrations of alpha-emitters. The repository has been in operation since 1981. An extended compliance report was written in 1989. A peer review was carried out by the RSK/SSK 1991 confirming the long term safety of the site.

HUNGARY

Legal framework

In Hungary, the regulations dealing with the applications of nuclear energy and sources of ionizing radiation are based on the principle of shared responsibility among various authorities. There are acts, decrees, orders and standards which are issued at various levels by different regulatory bodies. At the highest level, legislation is conducted by the Acts of Parliament, while separate issues in specific areas are covered by ministerial decrees. The regulations will be revised, because, presently a new Atomic Energy Act (AEA) is being passed by Parliament.

Waste management and disposal activities are mainly regulated by the Act No. 1/1980, which states the responsibilities of the various ministries involved in the regulatory and licensing processes. So the different ministries are responsible for nuclear safety; radiation-, environmental-, water-, soil protection; agriculture (radioactivity of food)-, fire-, transport-, defense-, security-, trade-, and local (municipal) questions.

The Decree No. 7/1988, issued by the Ministry of Public Welfare, contains some stipulations concerning the radiation protection requirements for the final disposal of radioactive wastes.

Regulatory structure

The Hungarian Atomic Energy Commission (HAEC) plays a central role in the various task associated with the use of atomic energy. The Commission has been assigned the responsibility for regulating, licensing and inspecting installations in respect of nuclear safety, technological and waste management aspects. It coordinates the regulatory tasks distributed among the ministries involved.

The Ministry of Public Welfare is responsible for developing radiation protection standards and for licensing and regulating waste disposal facilities. Its responsibility is discharged through the State Public Health and Medical Officer Services (SPHAMOS) with expert advice and technical assistance provided by the "Frederic Joliot - Curie" National Research Institute for Radiobiology and Radiohygiene.

The Ministry for the Environment and Regional Policy is responsible for establishing air and water quality standards, including derived concentration limits in releases from nuclear and radioactive facilities, as well as for controlling the releases at the facilities and their environment.

The Ministry of Internal Affairs is responsible for the security, emergency preparedness and fire protection.

The Ministry of Transportation, Telecommunication and Water Management is responsible for regulating the water usage and transportation.

Radioactive waste management activities

The radioactive wastes generated in Hungary mainly arise from the operation of the Paks Nuclear Power Plant. Also, although in a smaller proportion, wastes are being produced in the application of radioactive isotopes, as well as in the operation of the existing research and training nuclear reactors.

The Püspökszilágy Radwaste Treatment and Disposal Facility has until now been the only facility in Hungary providing final disposal for low and intermediate level wastes. This facility, situated some 40 km north of Budapest, was opened by the HAEC in 1976 and is now operated by the Capital Institute of SPHAMOS of the Ministry of Public Welfare.

In 1992, a national project aimed at solving the problems in the management and disposal of the NPP waste was launched. This project contemplates the creation of an overall waste management scheme, including all related issues of conditioning, disposal, development of legislation and assignment of responsibilities. The main goals of the project are:

- development and approval of a long term comprehensive strategy for the management and disposal of all kind of wastes,
- development of screening criteria for L/ILW and HLW disposal sites,
- selection of disposal technologies and suitable sites,
- assuring the financial basis for waste management,
- development of the licensing criteria and procedures,
- development of the legal framework to provide for public involvement,
- review and updating of the current regulatory and legal framework,
- construction of a L/ILW disposal facility.

Basic prescriptions for radiation protection and radioactive waste management

The basic regulation is Decree No. 7/1988 stating that radiation prescription must be applied to all activities involving the use of atomic energy and ionizing radiation. This decree is supplemented with 12 Annexes, which are dealing with values for limitation of radiation doses of both workers and public members (Table 1), workplace safety regulations, education, dosimetric control, accident situation, radiation protection service, accident prevention, licensing form, participating authorities in license procedure, nuclear power plant and disposal of radwaste. The Standard MSZ 62 covers the special items of radiation protection (derived dose limits, annual limits on intake, emergency levels,...).

According to the Standard MSZ 14344, the waste classification on the basis of activity concentration is the following:

Low level	less than $5.\ 10^5$ kBq/kg
Medium level	$5.\ 10^5$ - $5.\ 10^8$ kBq/kg
High level	greater than $5.\ 10^8$ kBq/kg

If the determination of the radioactive concentration of solid waste could not be applied in connection with reactor and accelerator facilities and except alpha bearing waste, then the base of surface dose rate measurement is accepted for classification:

Low level	less than 300 µGy/h
Medium level	300 µGy/h - 10 mGy/h
High level	geater than 10 mGy/h

According to the Annex No. 11 of Decree No. 7/1988, the requirements for the final disposal of radwaste are the next:

1. The disposal can be accepted as a final one only if it lasts at least twenty times the half-life of the longest lived dominant radionuclide.
2. Final disposal of radwaste can be licensed only in a manner and on site that does not cause unacceptable risk to the society and does not harm human life, the health of present and future generations, the human environment and goods.
3. Members of the public living in the neighbourhood of the facility should not be exposed to a yearly effective dose equivalent above 0,25 mSv.
4. A shallow ground disposal facility can be sited only in a geological environment acceptable from the point of view of tectonics, seismology, etc. and at least on 1 km distance from densily populated areas, recreational districts, surface waters (river, lake), dams, mines and factories producing dangerous and explosive goods.
5. If the natural parameters of the site are not quite adequate, the selected site should be improved by engineered structures.
6. The facility of the final disposal of radwaste - taken into account the natural characteristics of the site, the packaging and conditioning of the waste - shall be designed in such a way that the radiation protection of the surrounding public should be assured even in extraordinary and accidental situation. The fulfillment of these requirements must be proved in the preliminary and final safety analysis report.
7. The site shall be surrounded with an appropriate fence. In addition to that a safety zone must be established around the site of 0,5 km width, marked by appropriate signs.
8. The capacity of the facility for the final disposal of radwaste shall be sufficient for the quantity of waste arising in ten years with the possibility to increase further the capacity.
9. On the site of the facility the disposal area serving for the waste should be separated from the area where the workers of the facility are staying.
10. The operator has to make an inventory and a recording of the quantity, properties of the radwaste, time, place and method of disposal.
11. The radwaste disposed in the facility must be prepared according to the relevant safety and technological requirements.
12. The monitoring of radiation on the site and in the environment is the task of the operator. The authority supervises the fulfillment of this task.
13. In the post-sealing period the operator has to provide for the supervision of the facility for the monitoring of radiation in the environment and the prevention of the intrusion of persons and animals for at least 50 years and after that date as long as the authority requires it.

The regulation of Hungarian radiation protection is based on ICRP 26 (today a 'new edition' of Decree No. 7/1988 is being prepared on the basis of ICRP 60).

Management of high level waste and long-lived radionuclides

Annually, only 1-2 m^3 of high level radioactive waste are generated in the NPP and in the other facilities in Hungary. Now, 470 spent fuels during 3 - year fuel cycle are produced in a year at the Paks NPP.

A preliminary investigations for the solution of disposal of the high level radwaste, including long-lived, alpha bearing waste are being performed in the Mecsek Mountain area, in the south part of Hungary.

The Upper Permian claystone formation covers an area of 150 km^2 and its thickness ranges from 700 to 900m. At present, this formation is being investigated and the on-site test area is accessible from the uranium mining area.

The examinations include geological surveying, geochemistry, hydrogeology, geotechnology and geophysics studies. The temperature of host rock in the depth of 1100m is about 49 ^oC and the pressure of rock ranges from 40 to 50 bar. Hydraulic conductivity of the bulk rock is 10^{-10} m/sec. Because, this area has a lot of fracture and fault zone, a comprehensive studies of hydrology and geology are needed to carry out in the future.

Table 1. Radiation protection values for workers and public members in

(external and internal exposure summed in the case of whole body, not including medical and

Parts of body	Exposed worker (> 18 old years)					Pupils/ students
	working condition A				working condition B	
	men			women (2)	men, women	boys, girls
	normal	extraordinary		normal	normal	normal
	1 year	1year/ 1 event	life	1 year	1 year	1 year
whole body	50 (1)	100	250	50	5	0.5
lens of eye	150	-	-	150	15	-
other organs	500	-	-	500	50	5

Remarks:

1; $H_E / 50 + \Sigma (Ij / Ij, k) \leq 1$

H_E - external exposure

I_j - intake of radioactivity

$I_{j,k}$ - annual limits on intake

2; Pregnant woman is not permitted to work in radiation workplace, nursing mother is not allowed to work with unsealed radioisotope.
During conceiving period equal dose burden is expected, without any extraordinary situation.

Highlights of the Revised Version of Italian Fundamental Safety Rules concerning the Management of Radioactive Waste

The Italian Directorate for Nuclear Safety and Radiation Protection, now belonging to ANPA (the new Italian State Agency for the Environmental Protection), issued, as a draft, in April 1985, the Technical Guide n. 26 "Radioactive Waste Management".

According to the established procedure, the final version has been published in 1987 after the comments from the relevant national operators.
Within this Technical Guide:

- radioactive wastes are classified into three categories, on the basis of the identities and concentrations of radionuclides and taking into account their final destination (Table 1);
- for the wastes belonging to the Second Category (whose final destination is a near surface disposal), a detailed list of requirements for the waste form, the waste container and the waste package has been set forth (Table 2 and 3).

At the time when the T.G.26 was issued, the main national problem concerning radwaste was the safe management of large volumes of radioactive wastes produced by the ENEL nuclear power stations and the ENEA research facilities, as well as by universities, research centers, hospitals.

In this connection the attention of the regulatory authority was mainly focused towards the management of these wastes, mostly belonging to the Second Category, so that the requirements for the safe management of Second Category wastes were very well defined in the TG 26, which, on the contrary, contains little details as far as the management of Third Category wastes is concerned.

After the closure of the Italian nuclear power stations and fuel cycle experimental facilities, the safe management of spent fuel and of high level and long lived intermediate level wastes became a very important problem to solve, together with the safe management of the conditioned wastes to be returned to Italy by BNFL after reprocessing at Sellafield of spent fuels coming from ENEL power stations.

Therefore, the Italian Regulatory Authority has been engaged in preparing a new revised version of the Technical Guide n.26, mainly focused on the safe management of the "Third Category" radioactive wastes, and with very little changes as far as the management of I and II Category Waste is concerned.
The main improvements concerning the management of III Category wastes are now illustrated.

The III Category has been subdivided into the following three sub-categories:

Category III-a: wastes that decay to radioactivity levels comparable with the natural radioactivity background within thousands or millions of years, but with little or negligible heat output (for example: transuranic wastes, cemented ILW);

Category III-b: wastes that decay to radioactivity levels comparable with the natural radioactivity background within thousands or millions of years, but with high heat output (for example: first cycle raffinates from reprocessing plants, vitrified HLW):

Category III-c: spent fuel to be directly disposed of.
It is worthwhile to point out that, in the present (not revised) version of TG 26 the management of spent fuel, being not considered a radioactive waste, is completely missing, since, during the past Italian nuclear programme, reprocessing was considered as the only option to be adopted.

At present, the strategy of management of spent fuel still stocked in Italy is under revision, and the "direct disposal" (without reprocessing) seems to be the preferred option.

The main general requirements for the III-a and III-b Category conditioned wastes to be fulfilled before their final disposal are shown in the Tables 4 and 5 respectively.

As already established for the II Category conditioned wastes, a test programme must be performed to assure compliance of III Category waste forms with a set of specified characteristics (Table 6).

The management of spent fuel (in the case of the "direct disposal" option) is also defined in a special chapter.

The revised version of TG 26 will be issued as a draft (to be submitted to national operators for comments) within the end of this year or within the first quarter of the next year.

Table 1
RADIOACTIVE WASTE CLASSIFICATION IN ITALY
TECHNICAL GUIDE No. 26

Category	Definition	Present Disposal Option
I	Wastes which decay in a few months to radioactivity levels lower than values derived from current Italian law (mainly hospital and research waste with T1/2 < 1 year)	---
II	Wastes which decay to radioactivity level of about 370 Bq/g within a few centuries. Activity of several specific radionuclides shall not exceed given values (e. g. alpha emitters of T1/2 > 5 y shall not exceed 370 Bq/g, on the average, for the whole repository and 3700 Bq/g per package)	near surface disposal
III	Long-lived wastes, not included in categories 1 and 2; High level waste from reprocessing of spent fuel and alpha bearing waste from the fuel cycle and R&D activities	deep geological formations (clay)

Table 2

Radioactivity Concentration limits

for conditioned II Category wastes

Radionuclides	**Concentration**
alpha emitters T1/2 > 5 years	370 Bq/g*
Beta/gamma emitters T1/2 > 100 years	370 Bq/g*
Beta/gamma emitters T1/2 > 100 years in activated metals	3.7 KBq/g
Beta/gamma emitters 5 < T1/2 < 100 years	37 KBq/g
Cs137 and Sr90	3.7 MBq/g
Co 60	37 MBq/g
H3	1.85 MBq/g
Pu241	13 KBq/g
Cm242	74 KBq/g
Radionuclides T1/2 < 5 years	37 MBq/g

* Those values are average values for the wastes contained in the disposal site; limit values for each waste package is 3.7 KBq/g.

Table 3

MINIMUM REQUIREMENTS FOR CATEGORY II CONDITIONED WASTE FORMS

Parameter	Minimum Waste Form Requirements
Compressive strength	at least 5 MPa (UNI - Destructive tests for concrete)
Thermal cycling	after 30 thermal cycles (-40°C - +40°C) compressive strength must be at least 5 MPa
Radiation Resistance	after an absorbed dose of 10^8 rads compressive strength must be at least 5 MPa
Fire resistance	incombustible or self extinguishing according to the ASTM D 635-81 test method
Leaching rate	measurement according to long term leaching test ISO 6961, 1981
Free liquids	measurement according to ANSI/ANS 55-1
Biodegradation resistance	compressive strength > 5 MPa after biodegradation test ASTM G21 and G22
Immersion resistance	compressive strength > 5 MPa after 90 days of water immersion
Radionuclide concentration	not exceeding values of the TG 26 table (see next Table)

Table 4

RADIOACTIVE WASTE
CLASSIFICATION IN ITALY

III CATEGORY
CONDITIONED WASTE

IIIa Category main features:

- radionuclide concentration exceeding limits for conditioned II Category waste;
- final disposal in deep geological formations;
- heat output negligible or absent (0-50 mW/Kg);
- embedding matrix normally cement.

Radionuclide concentration limits
for conditioned IIIa category waste

average values for all the IIIa Category waste contained in the interim and/or final storage site:

- **total alpha: 0,3 T Bq / t**

- **total beta-gamma: 100 T Bq / t**

Limit values for each waste package:

- **total alpha: 1 T Bq / t**

- **total beta-gamma: 1000 T Bq / t**

Table 5

RADIOACTIVE WASTE
CLASSIFICATION IN ITALY

III CATEGORY
CONDITIONED WASTE

IIIb Category main features:

- radionuclide concentration exceeding limits for conditioned II Category waste;
- final disposal in deep geological formations;
- heat output not negligible (> 0,1W/kg ; < 6,3 W/kg);
- embedding matrix borosilicate glass.

Radionuclide concentration limits
for conditioned IIIb category waste

Limit values for each waste package:

- **total alpha: 0,9 T Bq / kg**

- **total beta-gamma: 115T Bq / kg**

average values for all the IIIb Category waste contained in the interim and/or final storage site:

- **total alpha: 0,3 T Bq / kg**

- **total beta-gamma: 80 T Bq / kg**

Table 6

Specified characteristics for III Category conditioned wastes.

Sub-Category 3-a

- surface contamination
- specific activity (radionuclide inventory)
- dose rate
- heat output
- hydrogen generation
- density
- water permeability
- microporosity
- impact strength
- compressive strength
- tensile strength
- thermal cycling
- radiation resistance
- leaching rate

Sub-Category 3-b

- surface contamination
- specific activity (radionuclide inventory)
- dose rate
- heat output
- density
- homogeneity
- thermal conductivity
- thermal capacity
- transformation temperature
- liquidus temperature
- Young's modulus
- volatility
- thermal expansion
- fragmentation
- radiation resistance
- leaching rate

JAPAN

In Japan, the disposal of Low-Level radioactive waste has been implemented since 1992, and the disposal of the other radioactive waste such as High-Level radioactive waste, TRU waste, and uranium waste, which are managed at storage facilities, is under examination. Backend measures to be taken is decided in "The Long-Term Program for Research, Development and Utilization of Nuclear Energy."

1. Long-Term Program

"The Long-Term Program" states that radioactive waste has different levels of activity and includes different kinds of radioactive materials, and that each type of waste is to be disposed of in a rational manner meeting the kind of waste. It also states individual measures to be taken about each type of waste.

(1) High-Level radioactive waste

Basic policy regarding disposal of high-level radioactive waste is to solidify it into stabilized form, to store it for 30~50 years to be cooled, and to dispose of it deep in the ground (geological disposal).

In disposing of high-level radioactive waste, the national government bears responsibility to ensure that it is disposed appropriately, and shall take the necessary means for it. At present, Power Reactor and Nuclear Fuel Development Cooperation (PNC) is performing R&D to study geological environment and to establish the geological disposal technology. In addition to securing the necessary funds for disposal, the electric power companies need to participate in the R&D.

R&D on geological disposal will be carried forward as an important national project, in which the PNC will play a role as the core promotional body. R&D items include performance evaluation study on the geological disposal system, R&D on disposal technology, survey and study on geological environmental conditions and other fields involved in the geological environment, and scientific research on the deep geological environment.

(2) TRU waste

The reprocessing licensee and the MOX fuel fabrication licensee who generate TRU waste, and the electric power companies who are closely concerned with generation of it are responsible for the disposal. Who is responsible for the disposal will examine implementing schedule, implementing structure, procurement of funds and so on.

Approximately 1 GBq/t of alpha nuclides is appropriate as the tentative threshold value to classify waste containing in alpha nuclides. Waste in which the concentration of total alpha nuclides is below the threshold and that of beta and gamma nuclides is relatively low can be disposed of in a shallow land with engineered barriers. As for the other waste, which cannot be disposed of in a shallow land, technical studies will be performed to obtain a definite disposal concept by the year 2000.

(3) Uranium waste

Uranium conversion and fabrication business licensee and uranium enrichment business licensee who generate uranium waste and the electric power companies who are closely involved in the generation of it are first responsible for the disposal. Those responsible for the disposal will examine implementing schedule, implementing system, procurement of funds and so on.

Most of the waste are of relatively low uranium concentration. Therefore, it can be disposed of in a shallow land without engineered barriers and in a simple way that does not include de-escalated management. Its institutional control is reduced according as activity decays.

2. Current Status of Regulation

High-Level radioactive waste, TRU waste, uranium waste and so on are managed at storage facilities, according to the requirements of laws. Regulatory process of the business of radioactive waste management is almost same as that of the other nuclear facilities. The regulation includes the following items:

- safety review of the location and facility by the government
- re-evaluation (double-check) of the safety review by the independent commissions
- approval of detailed design and construction method by the government
- inspection before use
- approval of welding method
- inspection of welding method
- safety regulation by a business licensee and confirmation by the government, and so on.

Regulations on the Disposal of Long-Lived Radioactive Waste in the Netherlands

Regulatory and policy framework

All activities relative to the import, transport, use, storage, disposal and export of radioactive material are subject to the provisions of the *Nuclear Energy Act*[1] and its enacting decrees. This includes the construction and operation of nuclear power stations but also of other nuclear facilities such as radioactive waste disposal facilities. The establishment of any nuclear facility requires a license issued by the regulatory body which in the Netherlands is represented jointly by the minister of Energy, the minister of Social Affairs and the minister of the Environment. Procedures for the application of a license, the documentation to be provided in support of the application and a timetable specifying limits to the duration of each of the different phases in the licensing process are prescribed in a framework act, the *Environmental Protection Act*[2]. One of the requirements which an applicant for a license for a nuclear facility has to meet is the obligation to carry out an Environmental Impact Assessment.

Specific regulations for the construction of a radioactive waste disposal facility do not exist yet. The reason is that the national policy on radioactive waste management as laid down in a position document[3] presented by the Netherlands' government to parliament in 1984 envisaged a temporary storage of all radioactive wastes for a period of 50 - 100 years. This interim storage facility is established in the south-west of the country in Borsele and is operated by COVRA, the Central Organisation for Radioactive Waste. For the future disposal of the radioactive waste a comprehensive research programme was set up (OPLA programme) which focused on the examination of the possibility of long-term disposal of radioactive waste in salt formations. Although it is envisaged that an underground disposal facility would accommodate both the high and the low/intermediate level radioactive waste, the safety studies focussed on the integrity of the high level waste galleries. After completion of the phases 1 and 1a of the OPLA programme in 1993 it was concluded that from a safety point of view there are no prohibitive factors which would prevent the deep underground disposal of radioactive waste in salt.

Also in 1993 the government adopted a position[4] on the long-term underground disposal of radioactive and other highly toxic wastes, which was presented to parliament, and which now forms the basis for the further development of a national radioactive waste management policy: an underground disposal facility shall be constructed in such a way that retrieval of the waste is always possible.

On the strength of this position it was decided that follow-up research be adjusted and concentrated on the elaboration of disposal concepts which meet the requirement of retrievability. It was also decided that the research be extended to host rocks other than salt.

Main features of the regulations

Although, as was mentioned before, no specific regulations exist on the establishment of a radioactive waste disposal facility and as a consequence no long-term radiological safety criteria for such facilities have been developed yet, some general remarks can be made.

According to Principle 4 of the IAEA Safety Fundamental on Radioactive Waste Management[5] *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 an explanatory note to this principle it is observed that: *This principle is derived from an ethical concern for the health of future generations. In the establishment of acceptable levels of protection, the latest recommendations of international organizations, for example the ICRP and the IAEA, are typically taken into account.*

In the earlier mentioned OPLA study several accident scenarios have been considered which lead to an eventual release of radioactive material from its underground repository in a salt formation by failure of one or more of the different engineered or natural barriers. It was found that for none of these scenario's the released radioactivity would give rise to an incremental radiation dose of more than 0.1 mSv. In this case the calculated dose was compared with current radiation protection standards and with prevailing background radiation levels, and it was concluded that this value constitutes an adequate protection level.

Another approach could be derived from the individual risk target values for exposure to hazardous material as set out in the national risk management policy. This policy has as regards its application in the area of radiation protection recently been implemented in national law by a revision of the Radiation Protection Decree[6]. In this policy the maximum allowed risk individual for exposure to all sources of radiation is set at 10^{-5}/y. Assuming that persons will be exposed to more than one, but generally less than ten sources, the maximum individual risk due to exposure to one source is set at 10^{-6}/y. The band with a risk range between 10^{-6}/y and 10^{-8}/y is considered as representing a conditionally acceptable region. However, efforts have to be undertaken to reduce the risk below the lower limit of 10^{-8}/y. The region representing a risk value below 10^{-8}/y is considered as an area where further risk reductions are not practicable.

Taking account of a dose conversion factor of 2.5´10^{-2}/Sv according to present radiation risk data, the abovementioned risk limits correspond to an upper dose limit of 40 mSv/y and a lower dose limit to 0.4 mSv/y.

Consequently, the long-term safety assessment carried out for the hypothetical repository in the OPLA study would also meet the standards set by the risk management policy.

A third approach could be the establishment of acceptable concentration levels for the radionuclides which are still present at the moment that a postulated accident would cause a release of radioactive material from the repository into the biosphere. This approach is based on the assumption that it is impossible to determine whether at the moment of release of radioactive material there is still human life to protect. In that case it is not useful to apply criteria which have been developed specifically for the protection of man. An acceptable limit for the concentration is a more species-independent measure. Safe levels could be derived from current concentrations of radionuclides in the soil at ground level above the repository.

In view of the plans for a long interim storage of the radioactive waste at the COVRA establishment and consequently, failing great urgency to transfer radioactive waste to an underground disposal facility, no decision has been taken yet on which approach for the safety assessment would be most appropriate in the Netherlands. Neither has it been determined whether a cut-off time should be maintained in the assessment of the long-term radiation impact.

Organisational/institutional structure

As mentioned before the regulatory body in the Netherlands is represented jointly by the minister of Energy, the minister of Social affairs and the minister of the Environment. The involvement of these ministers arises from responsibilities for the continuity of the electricity production, the protection of he workers and the protection of the public and the environment respectively.

The operator is COVRA, a private organisation which currently runs a facility for the storage of low - and intermediate level waste at the Borsele site and is in the process of revising its licence to enable the construction and operation of a facility for the interim storage of the high level waste which will be returned shortly after reprocessing. Shareholders in COVRA are the nuclear facilities (60 % in total), the Energy Research Foundation in Petten (30 %) and the State (10 %), represented by the minister of the Environment.

The tasks of the regulatory body regarding radioactive waste management disposal can be described as policy-setting and facilitating and consequently focus on aspects which bear on the creation of favourable conditions for the realization of a disposal facility. This will generally entail a direct control of the site selection process because of the public acceptance and political implications involved. Also the research required for the assessment of the long-term safety of the waste disposal facility is usually commissioned by the regulatory body as well as the bordering conditions under which such disposal is to be carried out. The condition of retrievability of the waste from disposal facilities for radioactive and other highly toxic wastes is a typical example of this function of the regulatory body (see next section).

The responsibilities of the operator are primarily on the executive level. The operator's main concern is to take care that the radioactive waste generated is being collected and removed from the sites where it is produced in a safe and efficient way. Another responsibility is the good management of the collected waste which includes processing operations such as compaction and conditioning aimed to ensure the creation of adequate first-level protection barriers, the interim storage on its establishment, maintaining monitoring procedures and finally the management of all disposal operations.

Specific compliance requirements

The Netherlands' government aims at close international co-operation between researchers, policy makers and institutions involved in radioactive waste management so as to place the envisaged disposal options in a wider international perspective and to subject the validity of the safety assessments to peer reviews of recognized experts involved in the subject matter. As an example, the final report of phase 1a of the OPLA study, in which it was concluded that underground disposal of radioactive waste can be achieved safely in salt formations, was submitted for review to a committee of experts from the NEA and the EC. Guidance was obtained which has been taken into account in setting up the follow-up research programmes which are ongoing now. The NEA/EC review also contributed to the increased international interest for retrievable disposal concepts for radioactive waste as evidenced by the incorporation in the scope of the EC Fourth Framework Programme.

Experience obtained so far

Since the Netherlands' government has decided to keep the radioactive waste for an envisaged period of 50 - 100 years in an interim storage facility, no experience has been gained with the licensing - and other procedures applicable to a disposal facility. However, since it is not expected that the procedures *per se* will differ very much from that for a waste storage facility a brief account will be given of the licensing procedure which is presently going on for the interim storage facility of COVRA.

When COVRA was founded in 1984 a temporary location at the premises of the ECN at Petten was utilized for the storage of the low - and intermediate level waste. A site selection procedure was undertaken from which at least five locations emerged as suitable sites for the interim storage facility. Much of the effort in the final site selection, leading up to the choice of the present site at the location Borsele, was devoted to mitigating the concerns from the local administration and the population at the different sites and to providing adequate information on the impact (perceived or real) of the facility on each individual's personal life. A site-independent Environmental Impact Assessment (EIA) was made which described the generic consequences for the environment of the envisaged facility design. Once the consent of the local administration had been obtained and Borsele could be appointed as the best site in view of all aspects considered, another EIA was made for that specific site and using the features of that site. The latter EIA was part of the information required in the licensing process of the interim storage facility for radioactive waste. Due to very strict procedures and a rigid time-table applied to all phases in the licensing process, the actual time required for licensing is in principle restricted to 6 months from the receipt of the license application and the issuance of the license. For complex situations with much involvement of the public as is usually the case for the construction of waste management facilities this time period is slightly longer. A diagram with all relevant phases in the licensing process is appended (see Figure).

The retrievability option

As already stated before, in 1993 the Netherlands' government has determined a clear position on the underground disposal of highly toxic wastes including radioactive waste. Although the conclusions from the OPLA study were adopted to the extent that the salt formations considered are, in principle, suitable for the disposal of radioactive waste, it was also demanded that such disposal should not result in an irreversible situation. The effect of this requirement is that the waste should be disposed of in such a manner that it can be retrieved if deemed necessary.

The reasons for this additional imposition originate from the basic principles governing waste in general as agreed in the national waste management policy:

- The arisings of waste should be prevented where possible, and if that option can not (yet) be fully realized they should be restricted as much as is reasonably achievable using state of the art techniques.

- Where waste does arise the possibility of recycling into the production process or of reuse for other purposes should be examined with the aim to close the life cycles of raw materials to the maximum extent possible.

The retrievability requirement is consequently imposed with the following objectives:

- To keep the waste available for improved processing techniques should these become available in the future. It is conceivable that for instance a further development of actinide partitioning and transmutation techniques could reduce the amount of long-lived radionuclides and thus achieve a reduction of the long-term radiotoxicity of the waste.

- In the case of direct disposal of spent fuel to keep the door open for the extraction of valuable material when in a later stage reprocessing would be chosen as the most suitable management option.

- To verify the continued validity of the safety assessment for the particular design of the waste disposal facility by appropriate monitoring programmes under realistic conditions.

In the current research programmes which are undertaken within the EC Fourth Framework Programme on Waste Management by research institutes from the Netherlands, Belgium and France special attention will be given to some derived issues in connection with retrievability such as:

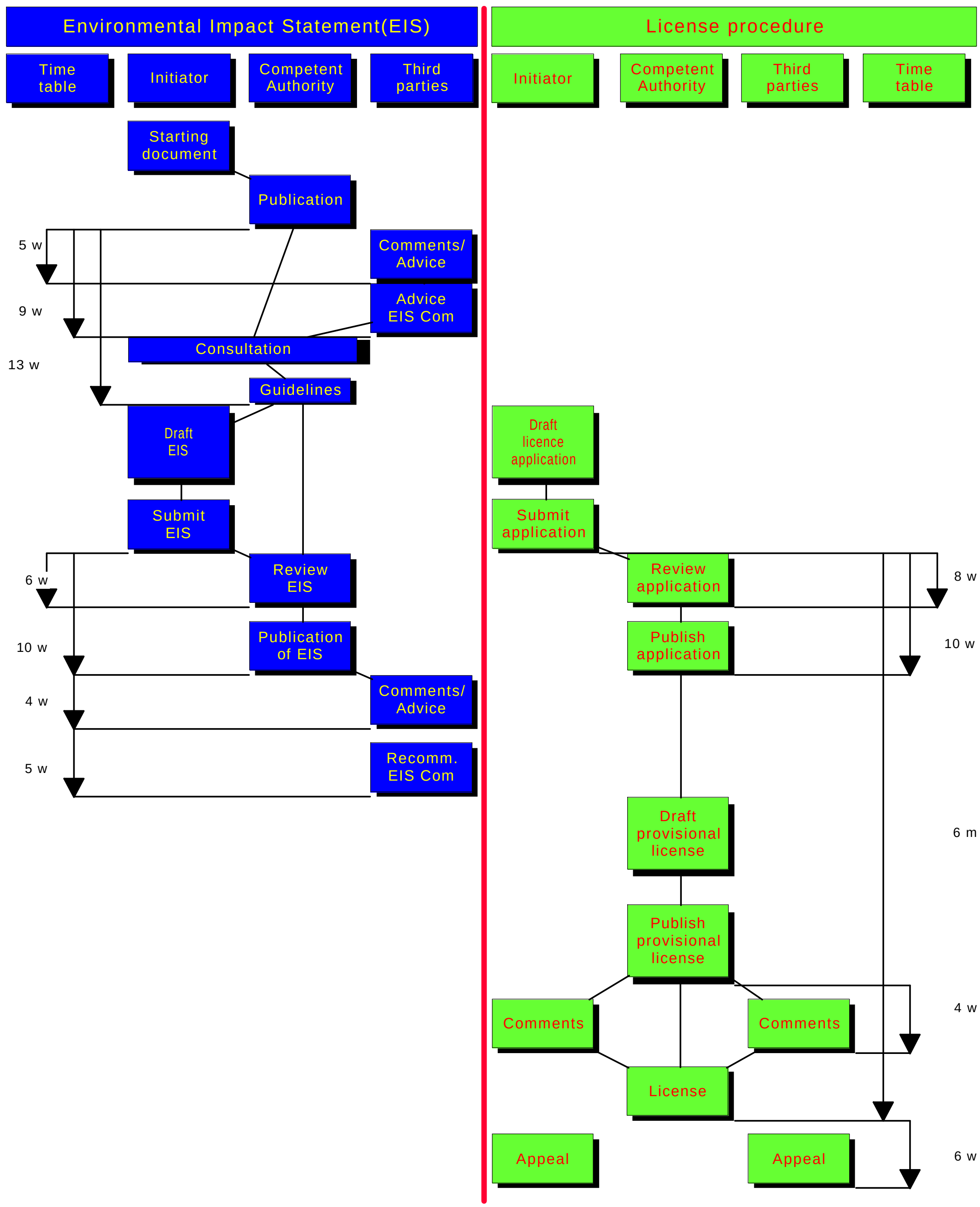
- The specific objectives to be achieved, functional requirements for deep disposal and applicable constraints.

- Selection of feasible technical concepts of retrievability.

- An estimation of the costs of the selected concepts.

- The impact of the retrievability concept on the safety performance of the envisaged design for the underground disposal facility.

The research which is currently in progress will consider other host rock materials than salt. In particular for the situation in the Netherlands clay will be covered by the scope of the study.


Environmental Impact Statement(EIS)
License procedure
Time table
Initiator
Competent Authority
Third parties
Initiator
Competent Authority
Third parties
Time table
Starting document
Publication
5 w
Comments/ Advice
9 w
Advice EIS Com
Consultation
13 w
Guidelines
Draft EIS
Draft licence application
Submit EIS
Submit application
Review EIS
Review application
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8 w
Publication of EIS
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4 w
Recomm. EIS Com
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Draft provisional license
6 m
Publish provisional license
Comments
Comments
4 w
License
Appeal
Appeal
6 w

Figure 1

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2. Environmental Protection Act, Bulletin of Acts Orders and Decrees, 283, 1993

3. Lower House, 1983-1984, 18343, no. 2

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SPAIN

¨ **Latest regulations and regulatory guidance documents**

⇒ The Spanish nuclear and radiation practices and facilities are under the following regulations:

◊ A set of nuclear regulations including general laws, licensing procedure for nuclear facilities, radiation protection standards, specific regulations on particular problems, safety guides, etc.. The main regulations are:

- Nuclear Energy Act, Law 25/1964
- Nuclear Safety Council Creation Act, Law 15/1980
- Regulations of Nuclear and Radiation Facilities, Decree 2869/1972
- Health Protection Standard against Ionizing Radiation, Royal Decree 2519/1982, Royal Decree 53/1992 (modification of RD 2519/82)

◊ Spain, as Member of the European Union, is a Contracting Part of the EURATOM Treaty and requires the compliance with the European regulations, directives, etc.

◊ The regulation on Environmental Impact Assessment, contains some reference of the Radioactive Waste Management (RWM).

- Royal Decree Legislative 1306/1986
- Royal Decree 1131/1988

◊ The National Electric System Reorganization Law includes reference to the radioactive waste definition

- Law 40/1994

⇒ Regarding the long-lived radioactive waste management, the following specific regulations has been set up:

◊ Creation of ENRESA as the Spanish RWM agency. ENRESA is obliged to prepare and to review the National Radioactive Waste General Plan (PGGR) and to summit it to the Ministry of Industry for his approval by the Government.

- Royal Decree 1522/1984

◊ The Nuclear Safety Council set up the general siting criteria for the geological disposal of radioactive waste in Spain

- Nuclear Safety Council Resolution, 1985

◊ The Nuclear Safety Council set up the radiological acceptance criteria for radioactive waste disposal facilities

- Nuclear Safety Council Judgement on the first PGGR, 1987

◊ In December 1994, the Government approved the 4th General Radioactive Waste Plan (the 5th edition is under has been submitted to the Ministry of Industry)
- Government Approval 9, Dec., 1994

◊ In December, 1995, a Royal Decree reorganized the Nuclear Safety Council and created a the General Subdirection for Cycle and Waste to coordinate the RWM regulatory activities.
- Royal Decree 2209/1995

◊ The Senate (High Chamber of the Spanish Parliament) established a Inquiry Commission "to study the Problem of the Radioactive Waste".
- Commission of Industry, Trade and Tourism Agreement, 15, Oct. 1996

¨ **Main features of the regulations**

⇒ Most of the Spanish RWM regulations are oriented to organize the RWM National System. Only the Nuclear Safety Decisions include qualitative and quantitative criteria for radioactive waste disposal.

⇒ The Senate Commission objective is to review and discuss the legal basis for the long-term RWM taken into account: political, social, technical, financial, regional compensation, etc. aspects, to solve the long term RWM.

¨ **Regulatory and implementing interactions**

⇒ The Nuclear Safety Council (Regulatory Body) and ENRESA (RWM Implementing Agency) have initiated a number of informal and regular meetings and workshops to define the regulatory dialogue regarding the R+D plans and long-term management of high level waste.

¨ **Specific compliance requirements**

⇒ No specific requirements has been established yet

¨ **Practical experience**

⇒ Licensing process of the following facilities has been performed

◊ LILW facility "El Cabril" construction permit. Ministry of Industry Order (31, Oct., 1989)

◊ LILW facility "El Cabril" operation permit. Ministry of Industry Order (9, Oct., 1992). Ministry of Industry Order (8, Oct., 1996) (Extension)

◊ Andujar Uranium Fabrication Plant in situ dismantling and site restoration authorisation. Ministry of Industry Order (1, Feb., 1990)

◊ La Haba Uranium Fabrication Plant in situ dismantling and site restoration authorisation. Ministry of Industry Order (15, Nov., 1994)

⇒ The Nuclear Safety Council has participated in the CEC exercises:

◊ "Building the safety case for a hypothetical underground repository in clay"
◊ "Building the safety case for a hypothetical underground repository in crystalline rock"

⇒ The Nuclear Safety Council has participated in the OIEA Peer Review:

◊ "WATRP Review Team on the Management of Short-Lived Waste in France as seen through the Centre de l'Aube Experience"

¨ **Other aspects**

⇒ An intensive programme of contact with regulatory agencies from other countries and presence in International Working Groups has been started:

◊ to acquire a wide view of the regulatory frames and practices
◊ to know the regulatory participation in the R+D plans for long term HLW management
◊ to establish specific relations in the field of HLW management from the regulatory standpoint.
◊ to develop a training plan of regulatory staff.

The Swedish Nuclear Power Inspectorate (SKI)
The Swedish Radiation Protection Institute (SSI) 1996-12-

SWEDISH REGULATIONS ON THE DISPOSAL OF LONG-LIVED RADIOACTIVE WASTE

Regulations and regulatory guidance documents on disposal of long-lived radioactive waste

Basic legislation

Three main Swedish acts regulate the nuclear program:

The Act (1984:3; 1992:1536) on Nuclear Activities defines nuclear materials, nuclear waste, nuclear installations and nuclear activities, requiring licensing. This act asigns the full responsibility to the licensee for the safety of nuclear activities, including safe handling and final disposal of spent fuel and nuclear waste. Pursuing a timely and comprehensive research development and implementation program to achieve the final disposal goals is stated a legal requirement for continued operation of the reactors. ***The act also establishes the legal authority of SKI as the regulatory body.***

With respect to final disposal of spent fuel, the act requires periodic regulatory reviews to be performed every three years to ensure that the Swedish nuclear utilities, through their jointly owned implementer, the SKB company, pursue the required comprehensive research development and implementation program in a timely and technically satisfactory manner to achieve the final disposal goals. The most recent review was performed in 1995-96, by SKI, which in the process solicited comments from a number of government authorities and research institutions.

The Act (1981:669) on Financing of Future Costs for Spent Fuel and Nuclear Waste requires the nuclear power plant owners to submit, each year, estimates of all future costs for management and final disposal of spent fuel and nuclear waste, including decommisioning, and their time distribution. This act furthermore requires the cost estimates to be reviewed by SKI as a basis for a government decision on a fee per produced nuclear kWh to be paid into interest-bearing funds managed by the government. Finally, the act establishes the procedures for reimbursing the utilities for costs incurred for waste management and disposal.

The Radiation Protection Act (1988:220) specifies general radiation protection requirements with regard to protection of workers, the public and the environment. All types of potentially harmful radiation are covered, not only ionizing radiation. The act establishes the legal authority of the Swedish Radiation Protection Institute (SSI) as the regulatory body. Moreover, Sweden being a member of the European Union, the Euratom Basic Safety Standards are applicable in Sweden.

The basic legislation is supplemented by government ordinances, further defining the regulatory tasks of SKI and SSI, for example with regard to the processing of licensing applications. Also, the government has recently appointed a special coordinator, reporting directly to the government, to facilitate coordination between SKB, local communities, county administrations and regulatory

authorities in the process of siting the facilities needed for encapsulation and final disposal of spent fuel.

Amendments to the legislation are presently under consideration by the government. These amendments would cover requirements related to the consultation process needed as a component in the development of an environmental impact assessment (EIA) prior to the filing of an licensing application for facilities to be used for encapsulation and final disposal of spent fuel.

Regulatory guidance documents

In 1989, the Nordic safety and radiation protection authorities issued a joint consultative document, Disposal of High Level Waste - Consideration of Some Basic Criteria. It provides general guidance on safety and radiation protection objectives for final disposal of spent fuel and high-level waste, as well as on demonstration of reasonable assurance of compliance with the objectives by means of performance assessments.

In 1995, SSI issued, and circulated for comments, preliminary radiation protection criteria for disposal of spent fuel and long-lived waste.

The regulatory review reports resulting from the periodic reviews of the SKB R&D program, and the subsequent government decisions have provided extensive general regulatory guidance on the step-wise process of assessing technical options and finding a suitable site for final disposal of spent fuel, as well as on the conduct of performance assessments supporting this process.

Main features of regulations

In general, the regulatory guidance documents referred to above use the ICRP radiation protection principles as a basis. Thus the principles of optimization and dose limitation are to be applied. For potential releases from a repository the probability of a certain dose to occur has to be taken into account.

In principle, the risk generated by a repository for spent fuel should be evaluated up to the time the repository activity content becomes comparable to an naturally existing uranium ore, i.e. up to some hundred thousand years. The risk evaluation should be done using state-of-the art performance assessment methods, recognizing and discussing the increasing uncertainties in the assessments with increasing time perspectives. For the first thousand years dose calculations will be essential for assessing the repository performance. For long-term exposures (>10 000 y) comparison with the natural turnover of naturally occurring radionuclides can be a complementary criterion. Although such long-term calculations should be performed, it is understood that with increasing time perspectives, quantitative results, with associated uncertainties, should be regarded as safety indicators. Using such indicators, it is recognized that the final risk assessment will involve a substantial amount of qualitative judgements.

No subsystem criteria are given in regulations. However, when an application to construct a repository is presented to SKI, it must include specifications on sub-systems shown to be consistent with system behaviour assumed in the performance assessment. Moreover, SKI has proposed that SKB should present geological and hydrological evaluation criteria, based on a comprehensive performance assessment, as a basis for the exploratory drilling program envisaged in the site selection process.

Organisational/institutional structure

The Swedish utilities have set up a joint company, the Swedish Nuclear Fuel and Waste management Co. (SKB), to act as the implementer of the legal obligations of the utilities with regard to final waste disposal. SKI and SSI are responsible for supervising safety and radiation protection.

As already indicated, the legal requirement for periodic reviews of the SKB R&D program, provides for an ongoing formal and public dialogue between the regulatory authorities on the step-wise process of assessing technical options and finding a suitable site for final disposal of spent fuel, as well as on the conduct of performance assessments supporting this process. There are also other fora for this dialogue, including joint participation in several international research cooperation projects.

Compliance requirements

Although little formal regulatory guidance on compliance requirements have been issued so far, it appears obvious that a strict comparison of calculation results with criteria is not meaningful. Calculation results, e.g. doses, with associated uncertainty estimates should be regarded as indicators of the level of safety and radiation protection achieved rather than dose predictions. Thus it appears that "reasonable assurance " is the only justifiable approach.

A systematic approach regarding expert judgement will be needed. The screening and grouping process of FEPs and the subsequent formulation of scenarios is a good example where systematic use of expert judgement, including a careful process for documentation of all steps in that process, will be required.

International peer reviews have to be used in the licensing process. In 1983, the SKB safety assessment reports on the KBS-3 spent fuel disposal concept were subjected to an extensive national and international peer review as a basis for the government decision to grant operating licenses to the Forsmark 3 and Oskarshamn 3 nuclear power plants. In SKI's last review of the SKB R&D programme, SKI has proposed that SKB now should carry through a new comprehensive performance assessment of the repository system, and that this performance assessment report should be subjected to an international peer review.

Practical experience - the SFR repository for low and intermediate level waste

No repository for long-lived radioactive waste has been licensed in Sweden. However, a repository for operational radioactive waste from the nuclear power plants has been licensed, the SFR-facility near the Forsmark nuclear power plant. In the analysis made by SKI and SSI, it was found that, in a realistic case, the resulting radiation dose would likely be considerably lower than that man receives from natural sources. However, under pessimistic assumptions, some combinations of circumstances were identified where in a longer time perspective (~ 1000y), a few persons drinking water from a well drilled downstream the repository might receive individual doses in the range 1-10 mSv/year. In the SFR assessment, the appearance of such doses was estimated to be improbable, as this presumes that a combination of mutually independent, pessimistic assumptions are simultaneously fulfilled. However, quantitative probability estimates were not considered meaningful as a basis for decisions.

In summary, and considering the pessimistic assumptions, SKI and SSI concluded that the SFR facility presented a risk profile with respect to probability of exposure of limited groups that did not deviate significantly from what the Swedish society accepts today with respect to exposure from naturally occurring radioactive substances without requiring special measures to be taken by the society. Based on these findings and conclusions the SFR operating licence was granted. As a licence condition, the licensee was required to take certain measures to reduce the most important of the uncertainties that might contribute to doses in a longer time perspective.

SWISS REGULATIONS ON THE DISPOSAL OF RADIOACTIVE WASTE

A. Zurkinden, HSK, November 1996

1. Legal Framework

The Swiss federal legislation concerning the disposal of radioactive waste consists mainly of the following laws and ordinances:

- Atomic Energy Law, 23 December 1959
- Federal Act on the Atomic Energy Law, 6 October 1978
- Nuclear Liability Law, 18 March 1983
- Radiological Protection Law, 22 March 1991
- Atomic Energy Ordinance, 18 January 1984
- Ordinance on Preparatory Measures, 27 November 1989
- Radiological Protection Ordinance, 22 June 1994

This legislation is partly outdated and does not contain detailed provisions on the disposal of radioactive waste. The elaboration of a totally new Nuclear Energy Law is under way.

The main features of this legislation concerning radioactive waste disposal are as follows:

- For disposal facilities, as for other nuclear facilities, licenses to be granted by the Federal Council (Federal Government) are requested.
- A general license which has to be approved by the Parliament is requested prior to the licenses for construction and operation of a facility.
- Geological investigations of a potential disposal site by deep drillings and exploratory shafts or galleries (so called preparatory measures) require a license.
- The producers of radioactive waste are responsible for its safe and permanent disposal.
- The Federal State takes over the responsibility for the collection, conditioning, storage and disposal of radioactive waste generated by the use of radioisotopes in medicine, industry and research.
- Imports and exports of radioactive waste for the purpose of disposal are not allowed.

A disposal facility requires further authorisations (for instance, a mining concession) according to cantonal legislation.

2. Organisational Structure

The producers of radioactive waste, i.e. the operators of nuclear power plants and the Federal State (for the waste from medicine, industry and research) formed the National Cooperative for the Disposal of Radioactive Waste (Nagra) which is responsible for the planning for the disposal of all kind of radioactive waste. Dedicated companies domiciled at the site are responsible for the construction and operation of disposal facilities. The company GNW (Genossenschaft für Nukleare Entsorgung Wellenberg) is responsible for the proposed LLW/ILW repository at the Wellenberg site.

The licensing authority is the Federal Council (Federal Government). It is supported in its decisions by the Federal Office of Energy which organises the licensing procedures. The Swiss Federal Nuclear Safety Inspectorate (HSK) is part of the Office of Energy and has the three main tasks to elaborate safety requirements, review license applications and supervise the facilities. This regulatory organisation is complemented by several advisory bodies.

There are frequent contacts mostly pertaining to technical and scientific issues between the implementers (Nagra/GNW) and the regulators (HSK). This allows to avoid diverging views on the basic features of the projects. The problem for a small regulatory body is to preserve its independence of view.

3. Safety Requirements

More precise safety requirements are set in the guidelines issued by the nuclear safety authorities. The guideline HSK-R-21 from November 1993 relates to the long-term safety in the post-closure phase of a repository. It applies to all methods of geological disposal and to all categories of radioactive waste. Another guideline relating to the operational phase is in preparation.

The overall objective of radioactive waste disposal and the principles to be observed which are stated in the guideline HSK-R-21 are derived from the internationally agreed IAEA Safety Fundamentals for radioactive waste management (SS 111-F, 1995). As a concretisation of the overall objective and the associated principles, the safety requirements are expressed in the form of three protection objectives:

PO 1 The release of radionuclides from a sealed repository subsequent upon processes and events reasonably expectable to happen, shall at no time give rise to individual doses which exceed 0,1 mSv per year.

PO 2 The individual radiological risk of fatality from a sealed repository subsequent upon unlikely processes and events not taken into consideration in PO 1 shall, at no time, exceed one in a million per year.

PO 3 After a repository has been sealed, no further measures shall be necessary to ensure safety. The repository must be designed in such a way that it can be sealed within a few years.

One recognizes following main features:

- A basic deterministic approach is required for the safety assessment.
- Where useful or necessary, the deterministic calculations should be complemented by probabilistic analyses.
- The requirements apply to the disposal system as a whole.
- Calculations should be carried out at least for the maximum potential consequences (no axiomatic cut-off time).

4. Compliance Requirements

The guideline HSK-R-21 gives a number of indications concerning the safety assessment:

- A safety assessment is needed at each stage of the licensing process. The corresponding calculations must be based on information collected throughout the characterisation, construction and operation phases.

- The results of the calculations are not to be interpreted as effective predictions of radiation exposure of a defined population group. They are indicators for evaluating the impact of a potential release of radionuclides into the biosphere and are compared with the limits specified in the protection objectives.

- For such calculations, reference biospheres and an affected population with, from a current point of view, realistic living habits should be assumed. The population group most likely to be affected is meant to be a limited number of people. The calculation should pertain to the potential exposure of an average individual of that group.

- Processes and events with extremely low probability of occurrence or with considerably more serious non-radiological consequences, as well as intentional human intrusion into the repository system, are not required to be considered in the safety assessment.

- Each computer code used in the safety assessment has to be verified. Further, confidence has to be provided that the models used are applicable for the specific purpose. The applicant has to give the possible ranges of variation in the data used in the models and of the results of the calculations. Where uncertainties remain, conservative assumptions must be made.

5. Practical experiences

Two important reviews have been conducted so far. The first (1985-87) concerned Project Gewähr 1985, the second (1994-96) was related to the proposed LLW/ILW repository at the Wellenberg site.

Project Gewähr 1985 (Nagra Project Report NGB 85-09, June 1985) was aimed at showing the feasibility and safety of final disposal of all kinds of radioactive waste, this being a prerequisite to the extension of the operation licenses of the existing nuclear power plants beyond the year 1985. Project Gewähr 1985 comprises two model repositories, a type C for HLW and certain alpha waste in the crystalline basement and a type B for all remaining LLW/ILW in a marl formation. HSK prepared itself for such a review for several years. The expertise of external contractors also from abroad was used for the review. An independent evaluation based partly on own conceptual models, computer codes and input data could be achieved. The review resulted in positive conclusions concerning the technical feasibility and long-term safety. The question, if an adequate site for the type C repository exists and could be found in Switzerland, was however considered to remain open. These conclusions were accepted by the political authorities and the public. The operation licenses of the existing nuclear power plants were extended beyond 1985. The Federal Council however requested the research work to be continued and also sedimentary rocks to be evaluated as possible host rock for a type C repository.

In June 1994 the application for a general license for a LLW/ILW repository at the Wellenberg site was made. The accompanying safety assessment is based on the results of extensive laboratory research and site investigations. The applicant used a fully deterministic approach; no attempt at risk calculations was made. HSK conducted the review with the help of its regular external experts. The review was concentrated on the long-term post-closure safety. Again the reviewers achieved an independent evaluation. Many questions remain open; these questions should be answered in the course of the subsequent licensing stages. One problem was to decide to what extend pessimistic assumptions should be combined in assessing the range of variation of the final results. In some cases doses higher than the limit of 0,1 mSv per year were calculated. Despite such results, positive conclusions concerning the safety were drawn from the review. HSK therefore recommends to grant the general license with a few conditions. For the time being the licensing procedure is however blocked, because the mining concession requested by the cantonal legislation has been refused.

UNITED KINGDOM'S NATIONAL REGULATIONS ON THE DISPOSAL OF LONG-LIVED RADIOACTIVE WASTE

POLICY AIMS

The UK's policy aims set out in the White Paper, Review of Radioactive Waste Management (Cm 2919)[1] are as follows:

> "Radioactive waste management policy should be based on the same basic principles as apply more generally to environment policy, and in particular on that of sustainable development. Most societies want to achieve economic development to secure higher standards of living, now and for future generations. They also seek to protect and enhance their environment, now and for their children. Sustainable development tries to reconcile these two objectives. A widely quoted definition of this concept is "development that meets the needs of the present without compromising the ability of future generations to meet their own needs." This principle is outlined at greater length in Sustainable Development - the UK Strategy (Cm 2426), which also sets out the following supporting principles:
>
> - decisions should be based on the best possible scientific information and analysis risks;
> - where there is uncertainty and potentially serious risks exist, precautionary action may be necessary;
> - ecological impacts must be considered, particularly where resources are non-renewable or effects may be irreversible;
> - cost implications should be brought home directly to the people responsible - the polluter pays principle.
>
> "More specifically, and consistent with the above, radioactive wastes should be managed and disposed of in ways which protect the public, workforce and the environment. The radiation protection principles and criteria adopted in the UK and applied by the regulatory bodies are designed to ensure that there is no unacceptable risk associated with radioactive waste management. In defining these principles and criteria and in their application by the regulators, it is recognised that a point is reached where additional costs of further reductions in risk exceed the benefits arising from the improvements in safety achieved and that the level of safety, and the resources required to achieve it, should not be inconsistent with those accepted in other spheres of human activity."

Within this approach, the White Paper makes a clear identification of the parties involved in radioactive waste management and sets objectives appropriate to each. It says:

> "(1) the Government will maintain and continue to develop a policy and regulatory framework which ensure that:

a) radioactive wastes are not unnecessarily created;

b) such wastes as are created are safely and appropriately managed and treated;

c) they are then safely disposed of at appropriate times and in appropriate ways;

so as to safeguard the interests of existing and future generations and the wider environment, and in a manner that commands public confidence and takes due account of costs;

(2) the regulators, including in future the Environment Agencies, have the duty to ensure that the framework described above is properly implemented in accordance with their statutory powers;

(3) within that framework, the producers and owners of radioactive waste are responsible for developing their own waste management strategies, consulting the Government, regulatory bodies and disposal organisations as appropriate. They should ensure that:

a) they do not create waste management problems which cannot be resolved using current techniques or techniques which could be derived from current lines of development;

b) where it is practical and cost-effective to do so, they characterise and segregate waste on the basis of physical and chemical properties and store it in accordance with the principles of passive safety (i.e. the waste is immobilised and the need for maintenance, monitoring or other human intervention is minimised) in order to facilitate safe management and disposal;

c) they undertake strategic planning, including the development of programmes for the disposal of waste accumulated at nuclear sites within an appropriate timescale and for the decommissioning of redundant plant and facilities. These programmes should be acceptable to the regulators and discussed with them in advance.

The producers and owners of radioactive waste are responsible for bearing the costs of managing and disposing of the waste, including the costs of regulation and those of related research undertaken both by themselves and by the regulatory bodies. They should cost radioactive waste management and disposal liabilities before these are incurred and make appropriate financial provisions for meeting them. They should regularly review the adequacy of these provisions."

REGULATION

The disposal of radioactive waste is regulated under the Radioactive Substances Act 1993 (RSA 93). Following the passing by Parliament of the Environment Act 1995, regulation has become the responsibility of two new bodies, the Environment Agency and the Scottish Environment Protection Agency (SEPA), which have taken over the functions of respectively Her Majesty's Inspectorate of Pollution (HMIP) in England and Wales and Her Majesty's Industrial Pollution Inspectorate (HMIPI) in Scotland. In Northern Ireland, the regulatory body is the Environment and Heritage Service of the

Department of the Environment for Northern Ireland. The creation of the Environment Agencies has made the distinction between policy and regulation more transparent and completes a process begun by the Environmental Protection Act 1990, which introduced a separation of functions between the Secretaries of State and the Chief Inspectors of HMIP and HMIPI in respect of radioactive waste management.

Nuclear sites

The disposal of radioactive waste from "nuclear licensed sites" - i.e. sites, such as nuclear power stations, licensed by the HSE under the Nuclear Installations Act 1965 as amended (NIA 65) - is authorised by the Environment Agencies. However, the management of radioactive waste on such sites is regulated by HSE's Nuclear Installations Inspectorate (NII). This responsibility covers all ILW, since there is currently no disposal route for this waste in the UK. There is close liaison between the regulatory bodies under the terms of memoranda of understanding, which set out the lead roles of the organisations and the requirements for timely liaison and consultation. To place such consultation on a more formal basis, provisions were included in the Environment Act to make HSE a statutory consultee of the Agencies for disposal authorisations for nuclear licensed sites and to make the Agencies statutory consultees of HSE for the waste management implications of licences granted under NIA 65. Such consultations are therefore a legal requirement.

Before granting an authorisation for disposal of waste from a nuclear site, the Agencies are also legally required to consult relevant local authorities, water undertakings and other public or local bodies as appropriate. When appropriate, they also invite comments from local interest groups and environmental organisations.

The Environment Act also introduced a simplification to the authorisation arrangements. Before the Environment Agency was created, the Ministry of Agriculture, Fisheries and Food (MAFF) (and in Wales the Welsh Office) were joint authorisers with HMIP of disposals from nuclear licensed sites. Instead, they are now statutory consultees of the Agency. MAFF has continued its role in assessing critical group doses and in monitoring for radioactivity in the environment. In order to protect MAFF's responsibilities for ensuring the safety of the food chain, the Minister of Agriculture, Fisheries and Food shares with the Secretary of State joint powers to call in applications, to determine appeals and to issue directions to the Agency.

Ministry of Defence sites

MOD sites are excluded from statutory regulation under RSA 93, although the regulatory bodies exercise similar controls by administrative means. Statutory regulation is, however, applied to the naval Dockyards at Devonport and Rosyth and the Atomic Weapons Establishment sites at Aldermaston and Burghfield, which are operated by civilian contractors. Devonport and Rosyth also include nuclear licensed sites, and Aldermaston and Burghfield are due to be licensed as such in 1997. MOD's radioactive waste management practices are subject to periodic review by RWMAC.

In the interests of greater openness, the Government included a provision in the Environment Act which allows relaxation of the scope of directions made under RSA 93 prohibiting the release of information on the grounds of national security.

Non-nuclear sites

For sites other than nuclear licensed sites (e.g. hospitals), RSA 93 requires the keeping and use of radioactive materials and the use of mobile radioactive apparatus to be registered, and the accumulation and disposal of radioactive waste to be authorised. Registration and authorisation certificates issued by the Agencies set out limitations and conditions relating to the control of radioactive materials and waste.

The primary concern of the Agencies is to control radioactive waste. Occupational exposure to ionising radiation and any direct exposure to other persons arising from a work activity is regulated by HSE under the Health and Safety at Work Act 1974 and the Ionising Radiations Regulations 1985 (IRR 85), although in some cases local authorities are the relevant enforcement body. HSE requires prior notification of all work with ionising radiations (except where that work is exempt from reporting) and receives notice of material changes in the work. HSE is considering with the Environment Agencies whether the memoranda of understanding between them should include one describing their respective roles in relation to non-nuclear sites to ensure that these complement each other and do not overlap.

DISPOSAL ROUTES

High-Level Waste

High-level liquid waste from the reprocessing of spent fuel is being converted by BNFL into glass cylinders to make it safer and easier to manage. The policy prior to last year's White Paper had been to defer a decision on disposal until the vitrified waste had been allowed to cool for 50 years. However, the White Paper affirmed that disposal to geological formations on land was the favoured option in the long term for dealing with HLW, once it had been allowed to cool and said that the Government would shortly be initiating work on a research strategy for the disposal of HLW and the direct disposal of spent fuel, if the owners of the fuel were to decide not to reprocess it.

The aim is to produce a UK national statement of future intent in this area, setting out the decisions to be taken and the milestones to be achieved by particular dates in developing an HLW repository, and the supporting research that will be necessary to achieve this. The strategy will be subject to periodic review and updating. Although the statement is ultimately a matter for the Government, its implementation will involve research by the industry and the regulators; they will therefore be involved closely in its formulation. The strategy will be able to draw on international research and on the results of research in the UK into the deep geological disposal of ILW. However, it will be carried forward as a separate project. Implementation of the policy will be a matter for the producers and owners of the waste in accordance with the "polluter pays" principle.

Intermediate-Level Waste

In 1982, the nuclear industry formed a company, the Nuclear Industry Radioactive Waste Executive (Nirex), to develop a disposal route for ILW. Nirex's shares are owned by BNFL (39.5%), Magnox Electric (35%), UKAEA (14.7%) and British Energy (10.8%) with the Department of Trade and Industry holding a single "special share". The parties are bound by a Shareholders' Agreement which establishes the basic operating regime for Nirex and sets out the various duties of the shareholders, including an obligation to provide the required funding. The proportions in which the shareholders provide the funding required by Nirex are based on the volumes of waste which each of them expects to dispose of rather than on their shareholding percentage. The Government believes that ownership by the industry is important, not only because, under the polluter pays principle, it is responsible for dealing with the waste it creates, but also because this is the best means of ensuring that Nirex operates efficiently. However, the Government must have a means of ensuring that its radioactive waste management policies will be implemented, and the Shareholders' Agreement contains a specific undertaking that the company will abide by Government policy; this will be enforced by means of the Government's special share in the Company.

When Nirex was established by the nuclear industry in 1982, its task, in line with the Government's policy at that time, was to develop two disposal routes for ILW and LLW:

(a) deep disposal of long-lived ILW in an underground repository; and

(b) shallow burial of LLW and short-lived ILW in engineered trenches 20 to 30 metres below the surface.

Initially, Nirex explored the possibility of developing a disused ICI anhydrite mine at Billingham in Cleveland as a deep repository, but in 1985, following local and national controversy, ICI decided not to make the mine available to Nirex. At the Government's request, Nirex then concentrated on finding a site for a shallow repository for LLW and short-lived ILW.

Elstow in Bedfordshire had originally been identified in 1983 as the potential site for a shallow repository, but in 1986 Nirex's investigations were widened to include three other locations in the clay geology of Eastern England. The same year, the Government accepted the recommendation of the House of Commons Environment Select Committee that no ILW should be disposed of in near-surface facilities. In 1987, the proposals for a shallow repository were dropped and Nirex concentrated instead on identifying a suitable location for a deep multi-purpose facility for both ILW and LLW. This, it argued, would now be the most cost-effective solution.

Nirex's investigations are currently concentrated on a site near Sellafield. In addition to drilling a number of boreholes, they have applied for planning permission to construct a "rock characterisation facility" - or rock laboratory - around 650m underground. The application was rejected by Cumbria County Council and Nirex's appeal against the Council's decision was considered at a public inquiry which ran from September 1995 to February 1996. The inquiry Inspector submitted his report in November 1996, which recommended that the appeal be dismissed. The Secretary of State for the Environment agreed with the inquiry Inspector's recommendation and announced his dismissal of Nirex's planning appeal on 17 March 1997.

REQUIREMENTS FOR AUTHORISATION

Disposal of Solid Waste

The criteria used by the regulators in determining applications to dispose of radioactive waste in land-based facilities were set out in a 1984 publication, Disposal Facilities on Land for Low and Intermediate-Level Radioactive Wastes: Principles for the Protection of the Human Environment[2]. This has recently been revised and following two rounds of public consultation the Environment Agencies will shortly be publishing a new document, Disposal Facilities on Land for Low and Intermediate-Level Radioactive Wastes: Guidance on Requirements for Authorisation.

The new document contains guidance on the principles and requirements against which the Agencies will assess any application for authorisation under RSA 93 relating to a specialised disposal facility on land for low and/or intermediate level solid radioactive wastes. This may be a deep underground or near surface disposal facility, but the document does not cover the disposal of high-level waste, or the disposal of LLW by controlled burial with other waste at non-specialised landfill sites, or the mixed disposal of very low-level waste with non-radioactive waste.

The principal criterion used to assess the safety of a disposal facility is the risk target of 10-6 per year set out in the Government's White Paper. This is the risk, after institutional control of the repository has been withdrawn, that a representative member of the potentially most exposed group will develop either a fatal cancer or a serious hereditary defect. It is a target rather than an absolute limit, since the nature of the disposal system makes it less amenable to the quantified risk assessments used in the case of, for example, new nuclear reactors. Where the regulators are satisfied that best practicable means have been adopted by the operator to limit risks and the estimated risks to the public are below this target, then no further reductions in risk will be sought. However, if the estimated risk is above the target, then the regulators will need to be satisfied not only that an appropriate level of safety is assured, but also that any further improvements in safety could be achieved only at disproportionate cost.

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UNITED STATES REGULATIONS

Introduction

By law, the responsibility for the regulation of the geologic disposal of spent nuclear fuel (SNF) and other high-level radioactive waste (HLW) in the United States is divided among 3 Federal agencies - the U.S. Department of Energy (DOE), the U.S. Environmental Protection Agency (EPA), and the U.S. Nuclear Regulatory Commission (NRC). DOE is responsible for developing general guidelines for the siting of a repository in geologic formations, EPA is responsible for promulgating generally applicable standards necessary to protect the public from radioactive material in the geologic repository, and NRC is responsible for developing the technical criteria and requirements necessary to license a geologic repository.

U.S. Department of Energy - 10 CFR Part 960

Section 112(a) of the Nuclear Waste Policy Act (NWPA) of 1982 (Public Law 97-425), as amended, directed DOE to develop general siting guidelines for the recommendation of potential sites as candidates for geologic repositories for SNF and HLW. DOE's final siting guidelines - in Part 960 of Title 10 of the Code of Federal Regulations (10 CFR Part 960) - were published in the *Federal Register* in December 1984.

10 CFR Part 960 is divided into three major categories: implementation guidelines, post-closure guidelines, and pre-closure guidelines. The implementation guidelines, found in Subpart B of the regulation, establish general rules to be followed in the process of selecting a site for repository development, and govern the application of all other Part 960 siting guidelines.

The post-closure guidelines, found in Subpart C, govern the siting considerations that deal with the long-term behavior of a geologic repository - that is, its behavior after permanent closure. The post-closure guidelines establish a performance objective (one system guideline) and technical conditions important to meeting those objectives (eight technical guidelines).

The pre-closure guidelines, found in Subpart D, govern the siting considerations that deal with the construction and operation of the repository. The Subpart D guidelines focus on three areas: (1) pre-closure radiological safety; (2) environmental, socio-economic, and transportation-related impacts; and (3) the ease and cost of repository siting, construction, operation, and closure. These guidelines are divided into three system guidelines and eleven technical guidelines.

To improve compatibility with NRC's regulation, DOE referenced or repeated many of the applicable provisions of NRC's regulations in 10 CFR Part 60. Thus, both the post-closure and pre-closure siting guidelines make reference *to favorable and potentially adverse (siting) conditions* found in Subpart E of 10 CFR Part 60.

Before passage of the Nuclear Waste Policy Amendments Act (NWPAA) of 1987 (Public Law 100-203), DOE was to use its siting guidelines for any preliminary decisions for selecting candidate repository sites, as required by NWPA. To implement these and other provisions of NWPA, DOE's process of selecting a repository site was envisioned to take place in four stages: (1) site screening; (2) nomination of at least five sites for characterization; (3) recommendation, to the President, of three of the five sites for characterization; and (4) recommendation of one of the three characterized sites for repository development. DOE was to apply its siting guidelines at each of these stages.

At the time the guidelines were developed (ca. 1984), DOE had begun the site screening process and was considering nine sites in six States as potentially acceptable. DOE prepared draft environmental assessments (EAs) for each of the nine sites nominated for public review and comment, based on its siting guidelines. After preparation of the final EAs, in 1986, DOE began the second step in the NWPA site-selection process. However, in its 1987 amendments to NWPA, Congress directed DOE to characterize only the Yucca Mountain (Nevada) site.

U.S. Environmental Protection Agency - 40 CFR Part 191

In September 1985, EPA established generic standards for the management, storage, and disposal of SNF, HLW and transuranic waste (TRU) in 40 CFR Part 191. 40 CFR Part 191 establishes containment requirements that limit releases of radioactive material to the accessible environment, weighted by a factor approximately proportional to radiotoxicity, and integrated over a period of time (10,000 years is the current regulatory requirement) after permanent closure of the geologic repository.

In its 1985 form, 40 CFR Part 191 specified three broad quantitative performance requirements for the overall geologic repository system:

- Limits on the cumulative release of radioactivity at the boundary of the accessible environment over 10,000 years (i.e., containment requirements).

- Limits on dose to individuals for the first 1000 years (i.e., individual protection requirements).

- Limits on permissible concentrations of radionuclides in special sources of ground water for the first 1000 years (i.e., ground water protection requirements).

Because the EPA standard is probability-based, the demonstration of compliance must also be probability-based. Accordingly, the measure of total system performance for a geologic repository under 40 CFR Part 191 would be expressed by the complementary cumulative distribution function (CCDF) for cumulative normalized radioactive releases to the accessible environment over 10,000 years. The representation of repository performance by a CCDF thus incorporates:

- Consideration of the various parameters affecting the performance of the geologic repository; and

- Consideration of a range of anticipated and unanticipated processes, conditions, and events that could affect future geologic repository performance.

In March 1986, several petitions for review of 40 CFR Part 91 were filed by a number of States and environmental groups. They were consolidated in the U.S. Court of Appeals for the First Circuit Court in Boston. In July 1987, the court remanded the standard to EPA for reconsideration of several of its provisions. Principal among these was Subpart B, the individual and ground water protection requirements. The court requested further notice and comment on these provisions as well as their inter-relationship to the Safe Drinking Water Act of 1965 (Public Law 93-523), as amended[1] . In October 1992, the Waste Isolation Pilot Project (WIPP)[2] Land Withdrawal Act (WIPP LWA - Public Law 102- 579) was enacted which reinstated all of Part 191 except for those provisions that were the subject of the remand by the court. Moreover, the WIPP LWA also required issuance of new standards to replace those that were the subject of the judicial remand and exempted the Yucca Mountain site from the 40 CFR Part 191 standards. Final disposal standards in 40 CFR Part 191 were issued in December 1993[3] .

Since then, EPA has been working to develop new environmental standards for Yucca Mountain. However, before EPA could complete its work, Congress enacted the National Energy Policy Act (EnPA) of 1992 (Public Law 102-486), dated October 1994, that changed EPA's standard-setting authority, as discussed later.

U.S. Nuclear Regulatory Commission - 10 CFR Part 60

NRC's geologic disposal regulation - 10 CFR Part 60 - is structured around the Commission's principles of defense-in-depth, and primarily focuses on the repository performance objectives. Moreover, 10 CFR Part 60 provides for a two-step licensing process - first, a construction authorization decision and second, a license to receive and emplace waste. The regulation consists of 9 subparts, designated A through J, and was promulgated in the early 1980's. The principal technical substance of NRC's regulation is contained in Subpart E; other subparts address contents of a potential license application, quality assurance (QA), consultation with States, Indian Tribes, and affected units of local government.

As the potential applicant, DOE must demonstrate compliance with the performance objectives of Subpart E, with "reasonable assurance[4] ", to receive a construction authorization. 10 CFR Part 60 sets out a number of general siting and design criteria to facilitate the demonstration of compliance. There are no specific site suitability or exclusionary criteria. If potentially adverse conditions are identified (i.e., evidence of Quaternary-age igneous or seismic activity, perched water bodies), they must be thoroughly analyzed and it must be demonstrated that the condition(s) can be compensated for by the geologic repository design and or by favorable conditions (i.e., minimum waste emplacement depth, host rock with low vertical or horizontal permeability) present in the geologic setting. Although the multiple barrier concept allows for the use of certain engineering measures to contain and isolate waste, the technical criteria in Subpart E are structured to favor the selection of a candidate site with certain favorable (natural) waste isolation capabilities. Thus, because of site- and design-specific considerations, the language in 10 CFR Part 60 is intentionally non-prescriptive; that is, it leaves to

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1 Implemented by EPA, the goal of the Safe Drinking Water Act is to set standards for safe drinking water and to protect drinking-water aquifers from contamination resulting from waste.

2 WIPP was developed to accept *only* TRU from the defense nuclear program. WIPP is not regulated by the NRC.

3 In its 1993 form, Part 191 now recognizes a 10,000-period of regulatory interest for both the individual and ground water protection requirements.

4 The Commission recognized that over the temporal and spatial scales of interest, proof in the ordinary sense of the word, would not be possible and therefore set a standard of "reasonable assurance".

DOE the opportunity and responsibility to determine how to design a geologic repository for a particular geologic setting.

Subpart E of Part 60 implements the EPA HLW standard (discussed in the previous section, above) as the overall performance requirement for a geologic repository. The performance objectives in Subpart E specify an overall system performance objective that amounts to meeting EPA's requirements, whereas certain other requirements in Subpart E set forth quantitative subsystem performance objectives consistent with the Commission's defense-in-depth concept which were intended to enhance confidence that the overall system performance objective would be met.

As for the subsystem performance objectives, the regulation currently establishes specific performance objectives for the following repository subsystems: (1) the engineered barrier system (EBS); and (2) the geologic setting. These subsystem performance objectives require the following:

- Substantially complete containment of waste in the waste packages for a minimum period of 300 to 1000 years after closure.

- Controlled release-rate from the EBS (e.g., one part in 100,000 per year of the inventory of radioactive waste that remains in the repository 1000 years after closure).

- Pre-waste-emplacement ground water travel time of at least 1000 years.

After completing construction of the geologic repository, DOE would apply to NRC for a license to receive and possess SNF and HLW. The conditions under which the Commission would grant such a license are also specified in 10 CFR Part 60.

Recent Developments

Congressional re-direction through EnPA and severe budget reductions have had a significant impact on the regulatory framework in the U.S. The following summarizes recent developments with respect to the aforementioned regulations.

10 CFR Part 960 As of September 1996, DOE plans to revise its siting guidelines to respond to policy changes and to reflect DOE's increased understanding of the Yucca Mountain site since the guidelines were issued in 1984.

Overall, the revision DOE is proposing is limited to amending the existing Part 960 by adding a new subpart (designated Subpart E) to address only the Yucca Mountain site. Under the proposed change, DOE would perform a total-system performance assessment and compare it to a single qualifying condition for both the pre-closure and the post-closure periods of performance to determine whether the Yucca Mountain site is suitable for development as a repository. The qualifying condition in both cases would provide that the proposed geologic repository be capable of meeting EPA's radiation protection standard and NCR’s geologic disposa1 regulation (both of which are not yet issued).

DOE's current plans call for completing this rulemaking effort in calendar year 1997.

New Regulatory Standards for Yucca Mountain Through EnPA, Congress mandated a new and different process for developing the HLW disposal regulations for the proposed repository at Yucca Mountain. EnPA directed the National Academy of Sciences (NAS) to evaluate the scientific basis for a Yucca Mountain standard and directed EPA to promulgate new environmental standards based on and consistent with the findings and recommendations of the NAS. Moreover, once the final standards are promulgated, EnPA directs the NRC staff to modify its requirements at 10 CFR Part 60 to conform to the new EPA standards[5] .

EnPA directed the NAS to provide EPA with recommendations on the following issues:

- Whether health-based standards based on doses to individual members of the public from releases to the accessible environment... will provide a reasonable standard for protection of the health and safety of the general public.

- Whether it is reasonable to assume that a system of post-closure oversight of the repository can be developed, based on active institutional controls, that will prevent an unreasonable risk of breaching the repository's engineered or geologic barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits.

- 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, over a period of 10,000 years.

In August 1995, the NAS issued its findings and recommendations on an environmental standard for HLW specific to Yucca Mountain. Among the NAS findings and recommendations was a key recommendation that the revised standard limit individual risk to a member of the public and abandon the existing quantitative release limit with its implied population-protection basis. Specifically, the NAS has recommended that the level of protection provided for in the new environmental standard should be comparable to that level of risk that may be acceptable to society at large, given that society currently tolerates certain *involuntary* risks (e.g., in the range of 10^{-5} to 10^{-6} per year). To demonstrate that the geologic repository can be designed to provide comparable protection to society, the NAS recommended that assessments of individual risks be conducted for certain target populations, in the Yucca Mountain vicinity, using the approach specified by the International Commission on Radiological Protection (e.g., "critical groups").

Other NAS findings and recommendations included:

- Consider an alternative compliance assessment period of up to 10^6 years;
- Re-consider the need for quantitative subsystem performance objectives;
- Treat human intrusion separately by a stylized calculation; and
- Assume that there would be no post-closure oversight beyond 100 years following permanent closure of the repository.

Important differences exist between the NAS findings and recommendations and prior EPA standards for SNF and HLW as well as the existing geologic disposal regulations at Part 60. The NRC staff is currently cooperating with EPA to ensure the development of reasonable and implementable HLW standards, considering the recommendations of the NAS. Once the EPA issues its final standards, the NRC must conform its regulations within one year. It is understood that EPA's Yucca Mountain-

5 In addition to the recent NAS recommendations, Congress is contemplating other legislative proposals that would affect the regulation of SNF and HLW at Yucca Mountain.

specific standard will be designated 40 CFR Part 197. The NRC staff anticipates that a final EPA standard specific to Yucca Mountain will be issued sometime in 1997.

For its part, the NRC is considering the development of simplified implementing regulations specific to a Yucca Mountain repository. The NRC staff have performed a preliminary review of Part 60 to identify areas of potential changes needed to be consistent with a new dose-based standard and sensitive to the findings and recommendations of the NAS. Moreover, the staff plans to recommend options to the Commission for implementing EPA's new 40 CFR Part 197 in NRC's regulations in the near term.

Practical Experience

The development time for the geologic repository is expected to take several years, if not decades to complete. Because of this long timeframe, there will be an increased emphasis on QA and documentation of decisions regarding the design of the repository and the collection of data. Because many of the staff who collect the data and make decisions may not be available at the time of licensing, DOE will need to maintain a robust QA program as well as the means to document important decisions. NRC is working with DOE to ensure that the Department has adequate plans in place to meet these objectives.

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