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RWMC Regulators' Forum (RWMC-RF)

TOWARDS TRANSPARENT, PROPORTIONATE AND DELIVERABLE REGULATION FOR GEOLOGIC DISPOSAL

Main Findings from the RWMC Regulators' Forum Workshop, Tokyo, 20-22 January 2009

This document reports the main findings from the RWMC Regulators' Forum (RF) Workshop, as discussed and approved at the RF meeting in March 2009. The workshop was held in Tokyo on 20-22 January 2009 and was hosted by NISA, in co-operation with JNES, on behalf of the Government of Japan.

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FOREWORD

This document describes the main findings of the RWMC Regulators' Forum (RF) Workshop titled "Towards Transparent, Proportionate and Deliverable Regulation for Geologic Disposal", which was held in Tokyo on 20-22 January 2009 and was hosted by NISA, in co-operation with JNES, on behalf of the Government of Japan. The workshop focused on long-term safety regulation for geological disposal of radioactive waste and was attended by approximately 70 participants from 13 countries and including representation from the IAEA, the ICRP, and the NEA. The activities at the workshop will be described in detail in the workshop proceedings, to be published later in 2009. The findings are based on the workshop papers and deliberations. For completeness sake, the findings also include, in smaller type, quotes from report NEA/RWM/RF(2008)6, a pre-workshop survey that summarises regulatory positions in NEA countries on some of the workshop topics, which was provided to all participants in advance of the workshop.

The present document was discussed and approved by the members of the RWMC Regulators' Forum at their annual meeting in March 2009. Further information on the RWMC Regulators' Forum can be obtained from the NEA website (www.nea.fr/html/rwm/regulator-forum.html). The workshop programme is provided as an annex to the present document.

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MAIN FINDINGS

1. Workshop methodology

This method of work has proven to be successful.

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

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

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

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

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

2. National regulations and international guidance and bases for criteria and regulatory judgement

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

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

From the pre-workshop survey:

> The responses to the question [on ultimate safety objectives] were varied. Some specific responses of interest: (Finland) small fraction of background; (Sweden, Spain) protection of human health and the environment; (Germany) likewise, adding "without imposing undue burden…"; (Switzerland) ditto but with the additional word "permanently"; (UK) to safeguard the interests of people and the environment now and in the future, to command public confidence and be cost-effective; (US) ultimate objectives include multiple barriers as well as dose/release limits.
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> The UK's ultimate safety objective is stated very generally ("safeguard the interests"). This recognizes the ICRP/IAEA caution about using stylized calculations as predictions of actual health detriments in the distant future, and would allow for variability in quantitative criteria with time and/or the use of criteria other than dose and risk. Ultimate objectives which are defined in terms of dose/risk/release limits implicitly assume that dose calculations for all times represent health detriment equally well, and may to a greater or lesser extent preclude the use of other performance indicators or of variable criteria. This appears to be a significant difference in philosophy.

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

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

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

From the pre-workshop survey:

> Although all countries agreed with the principle of avoiding undue burden, most responses were at the level of principles. Specific guidance or requirements related directly to this principle were found in three areas: the requirement in several countries that risks or doses predicted to be experienced by future populations must not exceed levels that would be acceptable today; requirements for measures

related to institutional controls and record keeping; and financial requirements to ensure that there would be no economic burden. "Undue burden" was not defined, except implicitly (e.g. financial burden, and dose or risk constraints identical to current values).

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

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

International guidance is interpreted in different ways in each country.

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

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

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

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

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

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

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

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

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

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

From the pre-workshop survey:

> The expression “other than technical indicators of safety” [in a question asking whether national regulations explicitly take into account factors other than technical indicators of safety] was interpreted diversely. The actual examples given were mainly technical (use of natural analogues, use of environmental safety indicators, requirements on technical barriers). The Swedish response stated explicitly that purely ethical issues are not considered to be within the regulatory framework. However, sustainable development was seen as a point of departure for the derivation of the regulatory risk constraint. The Spanish response stated that purely non-technical aspects are considered and the main instruments to accomplish this are the EIA and SEA legislation incorporating the corresponding European Directives and the Aarhus Convention.
>
> As conclusion [from this and other questions] it seems to be that the regulatory requirements themselves are thus confined to technical issues, i.e. the social aspects such as acceptance within the community are dealt with outside the formal licensing process, whether during siting, during environmental impact hearings, or in a national or regional debate on waste management strategy. The role of the regulator during such debates was not mentioned, perhaps because it is usually not spelled out in regulations.

3. Optimization processes

The fundamental goals of optimization need to be clarified.

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

From the pre-workshop survey:

> All countries recognize the basic principle of optimization of exposures, and all countries apply the constraint of limitation of individual doses during time frames where uncertainties are not so large as to prevent meaningful interpretation of dose calculations. Differences are evident in the way optimization is applied when dose estimates are below the constraint, and/or for very long time frames where uncertainties dominate. In Sweden, in situations where uncertainties are large, the application of BAT is prioritized over optimization. In Japan, in the case of intermediate depth disposal a number of different constraints or guide values are applied depending on the relative likelihood of the scenarios.
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> In the majority of cases there is some form of optimization requirement, i.e. simple compliance with a numerical dose or risk criterion is not considered sufficient. However, such optimization requirements are not always quantitative or rigorous. The German response indicated that other factors such as long-term geological stability and consequences of human intrusion are taken into account during the course of optimization. In the US, ALARA beyond licensing criteria is not required, for reasons described in the response: Optimization of future doses is considered problematic and introduces intergenerational equity issues. The question is dealt with by the use of constraints well below current dose limits to ensure that future doses are reduced well below currently accepted values.
>
> Optimization of design (including BAT as a qualitative form of optimization) is recognized in only a few countries as a regulatory requirement. Even where design optimization is a requirement, specific techniques and criteria may not be prescribed (e.g. Sweden, Germany, Spain). In the UK, current BPM and BPEO requirements are being replaced by BAT, and guidance will be developed further.

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

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

Opinions did vary on the relative weight to be given to the distant future and to the near future with regards to optimisation and regulatory decision-making, and the conclusion was that there is, at present, no generally applicable answer to the question. There might be arguments of principle for weighting far-future risks higher than, lower than or the same as near-future risks, depending on the circumstances. Different stakeholders may well have different views on such arguments. It was pointed out that the strategy of

concentrating and containing waste for disposal intrinsically gives priority to protection of current and closely-succeeding generations against actual risks over protection of future generations against potential risks, although there is clearly also an intent not to expose future generations to harm. Practical issues related to the choice of workable protection criteria for the far future, and the balance between risk criteria and design criteria such as the use of best available techniques (BAT), may also contribute to the discussion.

From the pre-workshop survey:

> In response to the question about balancing the needs of current and future generations, most of the responses were not very specific. In Sweden the implementer should report potential conflicts between operational and post-closure safety but the guidance does not provide specific criteria. The response to this question is also related to the next question about criteria vs. timescale. The Swiss and US responses indicated that both present and future generations must be protected to the same safety standards. In Swiss guidance, conflicting situations are consistently resolved in favour of future generations. In the UK, on the other hand, the risk levels used as constraints for the near future are treated as risk targets at long time scales, i.e. are not applied equally strictly, in recognition of the increasing difficulty in interpreting results of calculations with increasing time scale.
>
> No country uses formal methods of weighting of exposures or other indicators. Most countries indicated that the same weight is given to protection of present and future generations. The Swedish response recognized that exposure scenarios in the near and distant future might be evaluated differently with a shift from radiological risk at early times to more robust measures of repository performance for the distant future, and some other responses indicated a general shift from prediction of numerical indicators (dose/risk) towards qualitative indicators (e.g. multiple lines of argument) with increasing timescale, although not an actual change in weighting as such.

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

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

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

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

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

From the pre-workshop survey:

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

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

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

4. Technical indicators for safe performance

The relative importance of different safety indicators varies with time scale.

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

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

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

From the pre-workshop survey:

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

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

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

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

From the pre-workshop survey:

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

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

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

From the pre-workshop survey:

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

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

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

From the pre-workshop survey:

> The responsibility of the regulator terminates either with licensing of closure or with the end of a post-closure monitoring or institutional compliance period of up to a few hundred years.
>
> The Swedish, Finnish, German, Japanese and Spanish responses [to the question on transfer of responsibilities in the long term] recognize that the ultimate responsibility rests with the national government (in Sweden, the fact of ratifying the Joint Convention was seen as acknowledging this fact). Other responses did not deal with this question.
>
> The responses as a whole did not really deal with the question [on how regulations take into account decreasing capability of control over time] beyond a short period immediately after closure.

For the most part, they appeared to assume that issuance of approval for closure, based on the applicant's submission, would be sufficient to overcome any questions that might arise.

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

5. Regulatory research and development activities

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

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

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

It was widely agreed that in order to maintain technical competence, regulatory staff need to be familiar with current research and development themes and issues of safety significance. It was also agreed that regulatory staff need to sponsor, and be closely involved in, research projects to achieve this; reading about and attending presentations on research carried out by others may not be sufficient. There is a need for independence of the regulator from the implementer, but the quality of the work is pre-eminent, and joint participation with implementers and support organizations should not be ruled out.

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

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

From the pre-workshop survey:

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

6. Human actions

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

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

From the pre-workshop survey:

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

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

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

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

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

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

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

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

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

CONCLUSIONS

Starting from a set of well targeted questions, the workshop allowed a very broad exchange of views among participants. All of the participants were able to give their points of view and share their experience with others. The judgment from the speakers and participants at the closing session was that the workshop accomplished what it was intended to do, as described in the workshop programme:

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

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

- Evaluate and update the current regulatory position in the past decade, namely since the output of the NEA Córdoba workshop of 1997, and add more recent developments/international guidance;
- Complete the current understanding of the process for establishing long term safety criteria and the major motivation for differences;
- Establish areas of agreement/disagreement (e.g., duties to future generations, timescales for regulation, step-wise decision making, roles of optimisation and BAT, multiple lines of reasoning, safety and performance indicators and limitations, recognition of uncertainties, importance of stakeholder interactions, etc.);
- Identify the elements of a successful process of regulation for the long term; and

- Carry out the first phase of a RF project to study the regulator's needs for research and development on regulatory-related issues."

Coupled with the results of the the pre-workshop survey of member countries positions, the workshop findings help complete our understanding of the status of long-term safety regulations worldwide and provide the basis for judging which issues deserve the highest priority and which ones are closer to solution at the international level.

These findings are in line with the outcomes of previous work by the Regulators Forum, namely the NEA-6182 report of 2007 on Long-Term Safety Criteria, and they will serve as a basis for future work, whether in following workshops, at topical sessions at regular RF meetings, or by task groups in special projects. One workshop session in particular, on regulatory research and development activities, has paved the way for the topical session on this subject at the present RF-12 meeting. The second RF workshop, planned for late 2009 or early 2010, will follow up on many of the other issues.

Acknowledgements

The Regulators' Forum expresses its gratitude to NISA and JNES and to the Government of Japan for hosting and organizing this excellent workshop and all participants for their enthusiastic and constructive participation.

APPENDIX

FINAL PROGRAMME OF THE WORKSHOP

"Towards Transparent, Proportionate, and Deliverable Regulation for Geologic Disposal"

Hosted by the Government of Japan through its
Nuclear and Industrial Safety Agency (NISA),
in co-operation with Japan Nuclear Energy Safety Organization (JNES)

Programme

Background

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

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

Structure and modus operandi:

Session 1 will provide the opportunity to be informed of the Japan institutional scene on geologic disposal as well as to acquaint the Japanese dignitaries and workshop participants on the RWMC Regulators' Forum, on the challenges we face and on the aims of the workshop.

Sessions 2-6 will start with three to four brief (10-15 minute) presentations in plenary session. Following these presentations, participants, who will be grouped at tables about 8-10 people each, will discuss the subject. These discussions will be guided by lists of questions prepared in advance. A spokesperson from each table will moderate the discussions and will present the results to the plenary at the end of each session. The session chair will wrap up the session. A rapporteur for each session will document key points of the discussion, both for the stocktaking in the final plenary session and for the workshop proceedings.

Sessions 2, 3 and 4 will occupy a half day each, while sessions 5 and 6 will together make up another half day.

Sessions 7 and 8 will close out the workshop. Session 7 will present the views of three external specialists on what they have heard during the workshop. Session 8 will be a recap of the discussions in Sessions 2-6 and the drawing up of the workshop's main conclusions and recommendations.

Workshop General Chair is Mr. Georg Arens, the Chairperson of the RWMC-RF

Jan. 20 (day 1)		
Session 1	**Introduction** Session 1 will provide the opportunity to be informed of the Japanese institutional scene on geologic disposal as well as to acquaint the Japanese dignitaries and workshop participants with the RWMC Regulators' Forum, the challenges we face and the aims of the workshop. A lecture on accomplishments and issues in long-term safety regulation will prepare for the next two days' discussions.	
10:00-12:00 without break	**Opening remarks** from Session Chair **Opening remarks** on behalf of Japanese hosts **The role and work of the RWMC-RF** **The Japanese HLW management scene** - 4 presentations (1 hour) by Japan on its programme for geologic disposal, covering all aspects but with an emphasis on regulation. **Accomplishments and issues in long-term safety regulation**	Session chair: *Uichiro Yoshimura* *Eiji Hiraoka* *Georg Arens* *Hiromichi Matsuo* *Keigo Kajita* *Tomio Kawata* *Kazuyuki Kato* *Allan Duncan and Claudio Pescatore*
Lunch		
Session 2	**Fundamental concepts and evolution of international guidance**	
14:00-18:00	What are the ultimate safety objectives that we are trying to achieve through regulation? The preparatory work for the workshop within the RF did not provide an unequivocal and clear answer to this question. There were also very varied views on what would constitute "undue burden". Finally, there is ambiguity on the meaning of "dose" in the long term, in particular whether estimated dose constitutes, as it may for the short term, a measure of health detriment. These topics are the fundamental basis for most of what follows in regulation. Transparency requires that the ultimate goals and the terms used be agreed upon and understandable now and in the future by the general public, regulators and implementers.	Session Chair : *Marie-Pierre Comets* Session Rapporteur: *Carmen Ruiz*
	Presentations: • International guidance, evolution and trends • Dose concepts and the achievability of protection	 *Carmen Ruiz* *Annie Sugier and*

	according to ICRP • Fundamental concepts used in national regulation: need for clarity in terminology and interpretation? • Ethical issues and societal expectations	*Thierry Schneider* *Richard Ferch* *Dan Metlay*
15:20	The table discussions will address the following questions: • *How should "undue burden" be interpreted? In practice, what are our responsibilities towards future generations and the environment that can be fulfilled?* • *Are "safety" and "protection" the same concept?* • *What do you consider to be the most important, workable long-term objectives in regulation?* • *How should regulator(s) and implementers achieve and communicate confidence in their long-term safety decisions in the absence of controls, in the presence of uncertainty, and for situations where international guidance (ICRP) suggests that dose/risk estimates should not be regarded as measures of health detriment?* • *Should we communicate the difference between safety in the sense of meeting criteria and in the sense of freedom from risk, or can a common ground be found?*	
16:30	*Break*	
17:00	Reports from tables spokespersons and closure of the session around 18:00	
Jan. 21 (day 2)		
Session 3	**Establishing regulatory criteria that account for the inherent difficulties associated with the long times frames for protection**	
8:30-12:30	The issue of time frames for regulation catalyzes many of the questions that arise when formulating criteria for long-term protection of man and the environment. A common finding is that the period of geological stability is being cited as the defining time for cut-offs (soft or hard). Important ancillary issues are, however: (a) equal protection for all and at all times? (b) Should regulatory criteria change with in time? If so, how? Should several kinds of "yardsticks" be used?	Session Chair: *Walter Blommaert* Session Rapporteur: *Esko Ruokola*
	Presentations: • Planning for the long-term: perspectives of the Canadian citizens • What do implementers need in the way of understandable and usable criteria	*Atika Khan* *Bruno Cahen*

	• Regulatory viewpoint – The Finnish example on dealing with different time scales	*Esko Ruokola*

9:30	The table discussions will address the following questions:
	• *Should safety and protection be defined the same way in the short-term as in the long term? If so, why? If not, why not?*
	• *How should regulatory requirements for the post-closure phase reflect different timescales (or should they be independent of timescale)? Namely,*
	  • *How reasonable is it to fix a cut-off in time? Based on what considerations?*
	  • *Should numerical criteria such as dose or risk constraints change over different time scales?*
	  • *Should the same weight be given in regulatory decision-making to potential exposures to persons in the distant future as is given to actual exposures to persons in the present or near future? If not, how should this be reflected in regulation and criteria?*
	• *If estimated dose and risk in the long-term are not measures of health detriment, may they still be useful for regulatory acceptance purposes, e.g., as indicators of containment or isolation capability, as attributes for optimisation?*
	  • *Which other indicators could also be used for regulatory acceptance purposes?*	

11:00	*Break*	
11:30	Reports from tables spokespersons and closure of the session around 18:00	
Lunch		
Session 4	**Optimization, BAT and related topics**	
14:00-18:00	The terms "as low as reasonably achievable", "optimization", "sound technical and managerial principles", "best available techniques or technology", "constrained optimisation" or similar terms appear variously in international and national guidance. The meaning, interpretation and the degree of guidance provided vary significantly from country to country. There is sufficient breadth in the international guidance, perhaps, to accommodate much of this variation. It is, however, an open question whether this situation is as it should be. What is wished, and what is possible in the field of optimisation?	Session Chair: *Juhani Vira* Session Rapporteur: *Ian Barraclough*

	Presentations: • Optimisation: an overview of concepts • Optimisation of protection as applicable to geological disposal: the ICRP view • The position on optimisation of the US NRC in the context of geologic disposal • The current regulatory requirements on optimisation and BAT in Sweden in the context of geologic disposal	 *Philippe Raimbault* *Wolfgang Weiss* *Brittain Hill* *Björn Dverstorp*

15:20	Note that a supporting document is provided for this session. The table discussions will address these questions:
	• *What kinds of check and balances or factors that would be needed to be considered for an "optimal" system? Can indicators be identified?*
	• *Should a distinction be made between system optimization (in the sense of taking account social and economic as well as all types of hazards) and optimization of radiological protection? What could be criteria?*
	• *How can "optimisation" or best practice aspects be made visible in the regulatory process?*
	  • *Does the process of stepwise decision making constitute a part of system optimisation? To what extent? Is this best practice?*
	• *How should factors like stakeholder acceptability (e.g. in selecting a site) taken into account in the concept of optimisation?*
	  • *Should the same weight be given to the distant future and to the near future with regards to optimisation and regulatory decision-making? If not, how should this be reflected in regulation?*	

16:30	*Break*	
17:00	Reports from tables spokespersons and closure of the session around 18:00	
Jan. 22 (day 3)		
Session 5	**Regulatory Research and Development Activities**	
8:30-10:15	The regulator needs to acquire and maintain the capability for independent review of the implementer's submissions and safety assessments. The role of research and development	Session Chair: Y*utaka Kawakami*

	carried out by and on behalf of the regulator contributes to transparent and effective regulation by equipping the regulator with the knowledge to test the arguments presented by an applicant. The session at this Workshop is intended to prepare the ground by starting a wide-ranging discussion on the role of regulatory research within the RF.	Session Rapporteur: *Hans Wanner*
10 min each	Presentations: • Needs of research for regulatory purposes • An example of the R&D programme of a regulatory support organization • The Japanese programme of regulatory R&D	*Hans Wanner* *Christophe Serres* *Shinichi Nakayama*
9:00	The table discussions will address the following questions: • *What are the main current research needs related to establishing long-term safety criteria* • *What are regulatory competences and research capabilities needed to review the implementer's R&D plans and results, and how to maintain those competences.* • *One of the purposes of R&D is to reduce uncertainties in areas where knowledge is lacking. What is the role of the regulator in requiring, sponsoring and/or carrying out such R&D?* • *Should a regulator undertake R&D on safety assessment methodology necessary in order to develop an independent means of judging long-term safety?* • *What research is needed by regulators to develop an understanding of which aspects of a long-term safety case require greatest levels of scrutiny?* • *On what basis can it be determined that uncertainties have been reduced sufficiently?* • *Is regulatory research needed to support the stylization of human actions, biosphere, and climate change scenarios?*	Tables 1, 2, 3 will address the first 3 questions; Tables 4,5,6 will address the three remaining questions
9:45	Reports from tables spokespersons and closure of the session around 10:15	
Break		

Session 6	**Human actions**	
10:45 – 12:30	A variety of approaches to deal with human actions is presented in the responses to the questionnaire, both as regards the analysis of this scenario and as regards ways to reduce human activities (markers, etc.)	Session Chair: *Daniel Schultheisz* Session Rapporteur: *Klaus Fischer-Appelt*
	Presentations: • IGSC perspective on human intrusion • German viewpoints on integration of human intrusion scenarios in safety cases • Means to reduce human activities at the site: markers, records … Where do we stand?	*Hiroyuki Umeki* *Klaus Fischer-Appelt* *Saïda Engström-Laârouchi*

11:15	The table questions will address issues related the session topics that have arisen from the RWMC-RF survey and work:
	• *Should regulations require measures to reduce the likelihood and/or consequences of intrusion (e.g. Physical markers, institutional controls or design features)?*
	  • *What are appropriate criteria for judging acceptability of intrusion scenarios?*
	  • *Should the consequences to the intruder be considered?*
	• *What is the role of the regulator in specifying human intrusion scenarios?*
	  • *Which stylised human intrusion scenarios should be considered in a safety case?*
	• *Have regulatory requirements evolved in the last decade?*	

12:00	Reports from tables spokespersons and closure of the session around 12:30	
Lunch		
Session 7	**What was heard so far: the view from outside**	
14:00 - 15:30	Following the NEA FSC model for workshops, two interested parties other than regulator: an independent scientist, a university professor, and expert in repository management, will each make a roughly 20 minutes presentation providing their perspective on what they heard at the workshop.	Session Chair: *Phil Metcalf* Speakers: *Michael Sailer* *Carl-Reinhold Brakenhielm*
Break		

Session 8	**Stocktaking and closure of the meeting**	
16:00 – 17:30	**Stocktaking**: A brief session in which each session rapporteur will make a 10-minute presentation of the main observations from his/her session, followed by 10 minutes for discussion in plenary. **Closure of the meeting**: The RWMC-RF Chair will make a final wrap-up presentation covering the main results of the workshop and suggesting directions for further RWMC-RF work, followed by a brief closing address from a host organisation representative and the NEA.	Session Chair: *G. Arens* *Rapporteurs from sessions 2 to 6* *Georg Arens* *Shin Aoyama* *Uichiro Yoshimura*