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## RWMC Regulators' Forum (RWMC-RF)

# MAIN FINDINGS AND SUMMARY OF ANSWERS FROM THE REGULATORS' FORUM QUESTIONNAIRE ON REGULATION FOR GEOLOGIC DISPOSAL

**Support document to the Tokyo workshop, 20-22 January 2009**

*The last decade has seen significant progress in several countries on the siting of repositories for deep disposal of long-lived radioactive waste. In parallel with this, regulatory authorities have developed and expanded the regulations that will be applied, firstly in deciding applications to proceed with repository development and, secondly, to provide the basis for ongoing supervision of repository development work. A workshop to be held in Tokyo 20-22 January 2009 will examine current issues in regulation for geological disposal of long-lived radioactive waste. A questionnaire was developed and sent to regulatory organisations in order to collect relevant data and structure the workshop along the themes of highest interest. The questionnaire answers are summarised herein along with the main findings in order to inform the discussions that will be held in the Tokyo workshop.*

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## FOREWORD

The last decade has seen significant progress in several countries on the siting of repositories for deep disposal of long-lived radioactive waste. In parallel with this, regulatory authorities have developed and expanded the regulations that will be applied, firstly in deciding applications to proceed with repository development and, secondly, to provide the basis for ongoing supervision of repository development work. A workshop to be held in Tokyo 20-22 January 2009 will examine current issues in regulation for geological disposal of long-lived radioactive waste. A questionnaire was developed and sent to regulatory organisations in order to collect relevant data and structure the workshop along the themes of highest interest. The questionnaire answers are summarised herein along with the main findings in order to inform the discussions that will be held in the Tokyo workshop.

**TABLE OF CONTENTS**

## INTRODUCTION

In order to efficiently prepare the Tokyo workshop of 20-22 January 2008 on regulation for geological disposal, a questionnaire was set up and sent to RWMC members with 12 responses received during July and August 2008. The questions were divided into fifteen groups for purposes of comparison of responses. A summary of the responses, together with a synoptic table, is attached (Annex I and Annex II, respectively).

From the review of the responses, it can be seen that a large effort was devoted by the regulatory authorities in providing the requested information. Thanks to the quality of the responses, it is possible to outline major areas for exchange during the workshop. Overall, these are in line with the major findings of the NEA-6182 report on regulating the long-term safety of geologic disposal.

Based on the questionnaire responses, the programme committee decided on five main themes to be followed up at the workshop, as reflected in Sessions 2-6. The questionnaire also covered a number of other topics, and the responses on these topics may be used to contribute to the planning of future workshops.

The main findings of the questionnaire, as they relate to each Session of the workshop, are summarised next. More detailed information on the questionnaire responses is contained in Annex I and Annex II. The questionnaire itself is contained in Annex III.

## MAIN FINDINGS FROM QUESTIONNAIRE RESPONSES

### Session 2: Fundamental concepts and evolution of international guidance

This topic was touched on in several of the questions (I, II, VII, VIII and XI) in the questionnaire.

In some areas covered by the questions one may identify very similar views among the respondents, as in the following:

- Implementation of the IAEA Safety Fundamentals and the Joint Convention in regulations,
- Application of the precautionary principle, and
- Application of the concept of limitation of the transfer of responsibilities to future generations.

However, it is not clear that the practical interpretation of the fundamental principles is common to all. Although all countries agreed with the principle of avoiding undue burdens on future generations, most responses were at the level of principles. Specific guidance or requirements related directly to this principle were found in three distinct 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).

International guidance on fundamental concepts has been evolving in recent years, and national regulations do not always reflect these recent changes, for example:

- The concepts of potential dose, of constrained optimization, and recognition of the ICRP's warning that doses or risks in the long term should not be interpreted as a direct measure of health detriment, but only an indicator of safety, are not yet fully accounted for in some national regulations.
- There does not seem to exist a common view on how to balance protection between present and future generations.
- There is ambiguity in communication when dealing with definitions of safety and protection.

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. The variety of responses to some of the questions as described above suggests that further discussion and elaboration of these concepts would be useful in this regard. Some of the topics raised in these discussions will also provide a basis for further discussions in the remaining sessions.

**Session 3: Establishing regulatory criteria that account for the inherent difficulties associated with the long time frames for protection**

This was the subject of questionnaire group III. This session may be considered to be a continuation of the previous RF initiative on long-term safety criteria that is documented in the report NEA-6182 of 2007.

A major challenge in developing regulatory criteria lies in setting criteria for long time frames, when the results of safety analyses are most affected by the uncertainties, which are unavoidable over such long times. There are still different approaches in different countries, although some convergence may be noticed in the introduction of time scales. For example, if there is an upper limit to the time scale for which analysis is required, that upper limit is most often related to the geologic stability of the site and the impossibility of providing meaningful analyses on longer time scales. One million years seems to be a critical time scale for many countries and is sometimes used as a cut-off. Before this period, which may also be considered as a cut-off for strict regulatory compliance, one or several time scales may be defined depending on the country. When numerical criteria are quoted, sometimes they are seen initially as constraints and later on only as reference values or targets.

There is still considerable variation in the way different countries approach the issue of regulating on very long time scales. A discussion of the reasons behind this variation may prove illuminating and help further the transparency and effective delivery of regulatory decision making for long time frames.

**Session 4: Optimization, BAT and related topics**

This was the subject of questionnaire group IX. The responses revealed a wide range of approaches.

The concept of constrained optimisation in ICRP-81 seems to be reflected to differing extents in regulations, and a variety of positions exist on such principles as ALARA and BAT. Some countries view optimisation and BAT as a powerful means to deal with uncertainties in the long term and have developed detailed regulation on the subjects. In some European countries these views are reinforced by the presence of the concept of Best Available Techniques in the European environmental protection regulations. On the other hand, some countries believe that the closely-related concept of ALARA is not applicable in the long

term. The role of optimisation and the relationship between optimisation and the use of best available practices and techniques are areas where further evolution can be expected.

**Session 5: Regulatory Research and Development Activities**

This topic was only partially dealt with in questionnaire group XII, but it was felt that the topic could usefully be followed up in more depth at this workshop, in preparation for a future continuing study of this topic by the RF.

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 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 questionnaire answers suggest that in almost all countries, the responsibility for managing uncertainties is considered to be the operator's, with the regulator's role generally 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. The role of research and development in supporting the regulator's ability to fulfil this role and the relationship between these programmes and the research and development programmes carried out by implementers give rise to some interesting questions to be investigated having a bearing on the delivery of the regulatory function.

**Session 6: Human actions**

This topic was the focus of questionnaire group XIV.

A variety of approaches to deal with human actions is presented in the responses to the questionnaire, both as regards the analysis of human intrusion scenarios and as regards ways to reduce the likelihood of human intrusion (markers, records, etc.). Generally speaking, the time scale over which these methods can be expected to be effective is quite different from the geological time scales over which safety analyses are usually carried out. Reconciling these two time scales in the interests of transparency may prove to be an interesting challenge.

**Other topics from the questionnaire left for future follow-up**

All regulators seem to agree on the benefits of a stepwise approach for social acceptability of a waste disposal. Some countries consider reversibility or possibly retrievability of the waste as a legal obligation, at least for a period of time. The safety related aspects of reversibility and retrievability are reasonably well understood. Provisions for limitation of the retrievability period are often made, in recognition of the increase in difficulty of retrieval as repository development proceeds. A monitoring period after closure is envisaged in some countries.

The importance of sound engineering and quality management is stressed in most countries.

Non-technical aspects or issues were not commonly mentioned in the responses. Most of the responses confined themselves to technical aspects, e.g. alternate performance measures and technical

discussions of confidence building. The importance of the visibility of the regulator for public confidence has been stated by the Regulators' Forum in co-operation with the FSC, but this aspect was not very evident in the responses to the questionnaire. In many countries this topic was felt to be outside the remit of the regulator, but the results of the FSC study suggest that this may not always continue to be the case.

There was a wide range of responses to the questions on protection of the environment, and this appears to be a subject in transition. In almost all countries, it was stated that protection of the environment is a requirement. In a few countries, there are now specific requirements for protection of the environment and non-human species, but many still consider that protection of humans is sufficient to ensure protection of the environment. In those countries that do impose requirements related to non-human species, the goal is generally protection of biodiversity, i.e. protection of populations. One or two responses (UK, Sweden) mentioned additional concepts such as sustainable use of biological resources and preservation of habitat quality. In general, "protection of the environment" still seems to be at the level of a statement of principles rather than imposition of detailed criteria. Avenues to practical implementation may remain to be developed.

# ANNEX I

## SYNTHESIS OF QUESTIONNAIRE RESPONSES

**I.** *On IAEA Safety Principles[1] (2006) and former Safety Fundamentals[2] of 1995*

- **Is it intended that your regulatory approach will be updated to reflect the new IAEA Safety Fundamentals? If so, what steps are planned to implement this? If you have it, please provide a list of what are, in your assessment, the major changes.**
    - ***Most responses indicated that the member countries had no plans to change their regulatory requirements following the issuing of SF-1, as they believe they are consistent with the previous fundamentals. Most countries considered that their requirements were consistent with the earlier IAEA Safety Fundamentals and Safety Principles. Those countries that had recently developed or were in the process of developing new regulations or guidance (Belgium, Finland, Japan, UK) indicated that they had taken or would take SF-1 into account during the development of those regulations and guidance.***

**II.** *From The Joint Convention[3] Article 1*
*From IAEA Fundamental Safety Principle*

- Do your regulations include some consideration in order to apply the *precautionary principle* intrinsically related in paragraph 3.29 of the IAEA Safety Fundamentals to the requirement to avoid imposing an undue burden to future generations?

*All countries where requirements and guidance for disposal have been developed say they respect the principle of avoiding undue burden on future generations. Only some countries mentioned the precautionary principle: Japan indicated that it was felt that the requirement not to hinder prevention of hazard reflects the precautionary principle. In Sweden the precautionary principle applies to disposal through the general "rules of consideration" in the Environmental code.. The UK does not include the precautionary principle in its draft guidance, but does include several other principles intended to avoid imposing undue burdens. The new German regulations require that there must not be a need for surveillance or maintenance in the long term.*

- How do your regulations deal with the Joint Convention objectives and safety requirements "in such a way that the needs and aspirations of the present generation are met without compromising the ability of future generations to meet their needs and aspirations"?
    - How do your regulations "aim to avoid imposing undue burdens on future generations" vis-à-vis their long-term "needs and aspirations"?

[1] http://www-pub.iaea.org/MTCD/publications/PDF/Pub1273_web.pdf

[2] http://www-pub.iaea.org/MTCD/publications/PDF/Pub989e_scr.pdf

[3] http://www.iaea.org/Publications/Documents/Infcircs/1997/infcirc546.pdf

- Are long-term responsibilities towards future generations described in national law or reference national documents?

*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.*

- How do your regulations deal with the issue of balancing protection of future generations vs. protection of the present generation?
  - Are there examples of situations where these considerations compete?
  - How do these relate other factors in the optimization process, if it is required?
  - Is the concept of sustainability defined or mentioned in your regulation on in the context of disposal of long-lived radioactive waste?

*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.*

*Several of the responses mentioned sustainability as one of the principles underlying their requirements.*

**III.** *From ICRP-103*[4] "(222)
*From NEA-6182*[5]

- How do your regulatory requirements for the post-closure phase reflect changing timescales (or are they independent of timescale)?

*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 cutoff chosen to include the time of maximum expected consequences (a number of countries seem to have settled on one million years). In another*

[4] The 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication 103

[5] http://www.nea.fr/html/rwm/reports/2007/nea6182-regulating.pdf

*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.*

- If you fixed a cut-off in time for the application of regulation, how is this cut-off justified? How are the potential long-term hazards communicated and dealt with?

*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 ask for a description of the evolution of long-term radiological toxicity (irreducible long-term hazards have to be dealt with when selecting strategy for waste management).*

*Geological stability seems to be an underlying criterion for both soft and hard cutoff.*

- If a cut-off in time for the application of regulation is not fixed, how are the potential long-term hazards to be dealt with by the applicant over increasingly long time scales?

*There were only a couple of answers that seemed to attempt to deal with this beyond the period of post-closure institutional controls. The UK response mentioned the need for multiple lines of evidence in the very long term.*

- Do numerical criteria such as dose or risk constraints change over different time scales?

• ***Responses 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.***

- Is the same weight given in regulatory decision making to exposures to persons in the distant future as is given to exposures to persons in the present or near future? If not, how has the weighting been carried out?

*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.*

**IV.** *From IAEA Fundamental Safety Principle 1.* "3.7.

*From NEA-6182*

- Do your regulations elaborate on the actual responsibilities of the regulator in the post-closure phase?

*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.*

- Do your regulations recognize a possibility of transfer of some obligations from the producer or implementer to other bodies (WMOs or national or local government) in the long term?

*The Swedish, Finnish, German, Japanese and Spanish responses 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.*

- How does regulation take into account the decreasing capability of control over time?

*The responses as a whole did not really deal with this question 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.*

- How does the regulator(s) 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 suggests (see Section VIII below) that dose estimates should not be regarded as measures of health detriment?

*Most responses 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.*

**V.** *From IAEA Fundamental Safety Principle 5* "3.24. The resources devoted to safety by the licensee, and the scope and stringency of regulations and their application, have to be commensurate with the magnitude of the radiation risks and their amenability to control. Regulatory control may not be needed where this is not warranted by the magnitude of the radiation risks."

- In what way(s) are the scope and stringency of your regulations commensurate with the magnitude of the radiation risks and their amenability to control? Is an explanation officially documented?

*This question appears to have been confusing to some responders. In two cases the response referred specifically to clearance of materials from regulatory control, and in several others the responses related to procedures for licensing practices, but in a number of the responses it was not clear how this applied to the subject of geological disposal. The Japanese and German responses indicated that*

*requirements for different types of waste were different, reflecting the different levels of hazard posed by the wastes.*

**VI.** *From IAEA Fundamental Safety Principle 4* "3.18.

- Does justification of the disposal activity play any role in your regulatory requirements for waste disposal? If so, please describe.

*This question was interpreted in two different ways: (1) justification of a practice, as in the BSS, does not apply to waste disposal – the question of justification must be dealt with at the stage of waste generation; or (2) justification of disposal vs. other potential strategies, to which the most common response was that disposal has been adopted as a national strategy and therefore justification no longer applies at the point of regulatory decision-making. Some of the responses did indicate that justification was one of the arguments that would need to be considered in the event that a management option other than geological disposal was considered.*

**VII.** *From IAEA Fundamental Safety Principle 5 "*3.21.
*From IAEA WS-R-4*[6] "2.14.
*From IAEA WS-R-4* "A.2. …
*From ICRP-81* "(23)
*From ICRP-81* "(24)
*From ICRP-81* "(49)
*From ICRP-81* "(78) …
*From ICRP-103* "(218)
*From ICRP-103* "(219)

- Do your regulations make reference to the concept of potential dose or risk as described in ICRP-81?

*Regarding the concept of potential dose, countries where a risk criterion (Spain, Sweden, UK) is used recognized the concept of potential dose. Japan, in its requirements for intermediate depth disposal, uses criteria that vary with the likelihood of the scenario being assessed, and may do likewise for HLW disposal in future. Some other countries refer to dose estimates or potential doses in stating requirements.*

- Does your regulatory approach use a constrained optimisation approach for radiological protection as defined in IAEA standards (WS-R-4) or ICRP-81?

*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.*

[6] http://www-pub.iaea.org/MTCD/publications/PDF/Pub1231_web.pdf

- Do your regulations make reference to the term reasonable assurance when in relation to the use of the dose or risk and constrained optimisation in the long term (as in IAEA standard WS-R-4)? If yes, how is this concept interpreted or defined?

*The US recognizes this as a means of introducing multiple lines of reasoning and/or alternate performance measures (particularly measures which are less quantitative). The German response indicated an emphasis on the reliability of the safety demonstration more than on compliance with criteria. Most other countries do not mention this or similar terms.*

- Do your regulations expect protection to be optimized further when predicted exposures are below the constraint, or is compliance with regulatory limits considered to be sufficient?

*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.*

**VIII.** *From ICRP-81* "(81) …

*From ICRP-103* "(265) …
*From NEA-6182*

- Do your regulations explicitly recognize that dose and risk in the long term are not to be viewed as measures of health detriment?

*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.*

- Which are the recognized/documented "ultimate safety objectives" in your regulation or approach?

*The responses to this question 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.*

*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.*

**IX.** *From IAEA WS-R-4* "3.35. …
*From ICRP-81* "(86)
*From NEA-*

- Do you have precisely defined terms for requirements related to optimization of design or use of best available techniques (such as BAT, ALARP, etc.)? What are they?

*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.*

- If your approach involves both optimization of design and a stepwise development process, how do these interact?

    - Is optimization of design evaluated at different stages of the programme?

*There were more "yes" answers to this question than to the previous one, indicating that optimization of design is evaluated by the regulator even (in many cases, although not all) when it is not a formal regulatory requirement.*

    - If so, how do the criteria differ (and the judgment of compliance) for each stage?

*None of the responses to this question indicated any change in criteria; most considered the question to be not relevant.*

    - Is there a point at which design optimization is considered to be complete or sufficient?

*The responses to this question were not particularly clear or direct. It appears that for the most part, if optimization of design is part of the process, it is considered to be complete at the time a licence is issued.*

    - Are economic factors included as a consideration in optimization of design?

*There were a number of "yes" answers to this question, plus a few others that considered the question not relevant (because there were no requirements for optimization).*

    - Are formal quantitative methods used/required for optimization of design? If so, please describe?

*There were no responses that indicated the use of formal quantitative methods. Most considered the question to be not relevant. In the UK, simple approaches rather than formal methods appeared to be preferred. Swedish guidance states in general terms that risk analysis should be used for optimizing overall design choices (more focus on BAT solutions for the distant future). Detailed technical design solutions should be justified by design basis cases specifying the load conditions each component should withstand. In Germany, the use of such methods would be up to the implementer's choice.*

**X.** *From IAEA Fundamental Safety Principle 3* "3.12. Leadership in safety matters
*From ICRP-81* "(65) …

- Do your regulations require effective leadership and management?

*All the responses to this question were "yes".*

- Do your regulations address "safety culture"?

*All the responses to this question were "yes" (at least implicitly).*

- Do you have requirements related to "sound technical and managerial principles" of ICRP-81?
    - How are these related to BAT and optimization (if also required)?
    - How are they related to, or deemed to support, safety assessment?

*Most countries referred to QA or Safety Management requirements that apply to all licensed practices. Some applied the concept only to operation. Only the UK response indicated a particular interest in aspects of management and safety culture that are unique to disposal (specifically, "environmental safety culture" requirements).*

**XI.** *From ICRP-103* "(224)
*From NEA-6182*
*From NEA-6182* "

- Does your regulation explicitly take into account considerations other than technical indicators of safety (e.g. dose and risk)?

*The expression "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 non-technical aspects were taken into account – the main instruments to accomplish this were EIA and SEA legislation.*

*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.*

- Does your regulation define and use the terms "safety" and "protection"? If yes, can you provide the definitions?

*Few of the responses had much to say about this, 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).*

- Has the interpretation and application of international guidance in your regulations been agreed or discussed with your national stakeholders and documented?

  *The majority of responses said either that this had been discussed or that there were plans to do so.*

**XII.** *From NEA-6182*

- Does your regulation allow for, or require, a stepwise or phased approach to repository development, decision-making, or licensing?

*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.*

- Do your regulations require (or otherwise take into account) retrievability or reversibility?

*Reversibility or retrievability is a requirement pre-closure in several countries (France, Hungary, Japan, Switzerland, US), but few if any extend this requirement beyond a limited period of post-closure institutional control, and none have requirements specifically related to retrieval.*

  - In your regulations, are reversibility and/or retrievability considered to be safety-related issues?

*This question was ambiguous. All countries that responded to the question indicated that reversibility was safety-related in some way, if only in that reversibility must not endanger safety. Some noted that reversibility requirements were not necessarily motivated by safety concerns (e.g. the Finnish and French responses indicated that reversibility requirements were politically imposed).*

  - Do you have safety criteria for the necessity of retrieving and relocating waste packages during the operations phase? In a monitored post-operations phase? After closure?

*None of the countries has requirements specifically related to the necessity of retrieving and relocating waste packages during the operations phase (other than the regulatory requirements that apply to waste management generally), although the Japanese response indicated that this would be included in future regulations.*

- What do you feel are long-term uncertainties that can and should be reduced through research or design by the time a license is granted? Are these documented?

*In general, most responses appeared to consider the answer to this question to be site and concept-specific, i.e. they would have to be dealt with on a case by case basis. Most responses avoided going into details about specific safety cases and specific issues. The Japanese response referred to information about natural external events such as earthquakes and to geological information about the site (site-specific) as examples of reducible uncertainty.*

- What do you feel are uncertainties that cannot be reduced even by the time a license is granted? Are these documented?

*In general, the responses appeared to consider the answer to this question to be site-specific, i.e. they would have to be dealt with on a case by case basis. Most responses avoided going into details about specific safety cases and specific issues. The Swedish response mentioned that three illustrative examples might be future climate and evolution of man and the environment, but a list of irreducible uncertainties has not been documented. The Japanese response referred to human intrusion as an irreducible uncertainty.*

- What is the role of the regulator in uncertainty reduction?

*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.*

*The Japanese comments on the questionnaire (received some time before the response to the questionnaire) indicated a keen interest in developing the regulator's role with respect to some quite detailed technical questions, at a level of detail which most of the other responses did not appear to address. In Japan as in other countries, the implementer has a responsibility to demonstrate the safety assessment through the license application. However, the Japanese response indicated that the regulator should prepare his own safety evaluation methodologies in order to review the safety assessment in the license application, and that this contributes to overall public acceptance.*

- How does the regulator deal with irreducible uncertainties?

*The responses to this question included the use of judgment on acceptability, the use of stylized approaches, safety margins or "what if" scenarios, and withholding of approval if uncertainties are too large. It appears in most cases to be up to the proponent to make a case that is sufficiently convincing to carry the day despite remaining irreducible uncertainties. The diversity of response may reflect difficulty in dealing with the question.*

**XIII.** *From IAEA Fundamental Safety Principle 8* "3.30.
*From The Joint Convention Article 1*

- Do your regulations for disposal facilities address protection against accidents?

*The question did not appear to be clear. Most of the responses indicated that they felt that this requirement from the Safety Fundamentals applied only pre-closure. This may be a terminology issue – a question about "disruptive events" (instead of "accidents") might have received more detailed responses.*

*The responses from Finland, Japan and the US mentioned requirements for analyses of disruptive events or design basis accidents.*

**XIV.** *From ICRP-81* "(83)

- How are human intrusion scenarios addressed in regulations? Does the assessment of human intrusion scenarios differ from that of naturally-occurring scenarios (as in ICRP-81)? If so, how?

*There was a range of responses on this question, 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.*

- Do your regulations include requirements for measures to reduce the likelihood of intrusion (e.g. physical markers, institutional controls)?

*Almost all responses 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.*

**XV.** *From IAEA Fundamental Safety Principle 7* "3.28.

- Do your regulations require protection of the environment (other than prevention of environmental effects that would result in dose to humans)?

*In almost all countries, it was stated that protection of the environment is a requirement. In a few countries, there are now specific requirements for protection of the environment and non-human species, but many still consider that protection of humans is sufficient to ensure protection of the environment, i.e. in those countries protection of the requirement may impose no additional requirements other than procedural ones (requirements for EIAs, for example).*

- Do your regulations require protection for populations of a species (as distinct from individual organisms)?

*In those countries that do impose requirements related to non-human species, the goal is generally protection of biodiversity, i.e. protection of populations. One or two responses (UK, Sweden) mentioned additional concepts such as sustainable use of biological resources and preservation of habitat quality.*

## ANNEX II: SYNOPTIC TABLE OF ABRIDGED RESPONSES

| | I. IAEA SF-1 | II. Undue burden | III. Timescales | IV. Responsibilities | V. Graded approach |
|---|---|---|---|---|---|
| Belgium | Regulations under revision – will comply with SF-1 | Brief reply refers to economic burden only | Regulations for post-closure phase under development | Long/term responsibility is assigned to ONDRAF/NIRAS | General regulations follow graded approach according to type of facility; disposal is in the highest class |
| Canada | Requirements are believed to be consistent with IAEA fundamentals. | Policy requires that future impacts not exceed currently acceptable limits. No mention of sustainability. A review of international standards is being conducted to see whether national regulations should be updated. | Requirements not yet developed. | Licensee remains responsible. Licences are issued for relatively short periods and renewed periodically, which allows for the possibility of change of ownership and/or responsibility. | No response. |
| Finland | Ongoing renewal of requirements – SF-1 will be considered | Future impacts must not exceed currently acceptable limits. Principle of avoiding undue burden is recognized in law, but there are no other specific requirements. | Four timescale regions with soft boundaries (operation, up to ~$10^4$ a, up to ~1 Ma, after ~1 Ma). Desired level of protection does not change but the focus of assessment shifts from individual exposures to overall impacts and qualitative considerations. | Responsibility is transferred to the State after completion of closure and after the regulator transfers necessary information. Confidence based on assessment of licensing analysis. | Brief response on general process, not specifically on grading. |
| France | Various laws dealing with individual aspects mentioned. SF-1 is | Responsibilities towards future generations mentioned as a principle in the law. Requirements | Before 10 ka, constraint is treated as a limit. After that time it becomes a reference value. No | Regulatory role is for licensing. Responsibilities for the post-closure are implied but no yet | Brief response on general process, not specifically on grading. |

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| | explicitly considered by new regulations. | intended to reduce future burden and allow needs and aspirations to be met relate to funding, the overall process, and research. Sustainability is one of the objectives. | changes in weighting. | developed. Confidence should originate from the demonstration of a safe conception and realisation complying with the safety requirements. | |
| Germany | Consistent with WS-R-4 and guide DS-334, the need for a further revision will be checked after publication of the new Safety Requirements. | Requirement for no need for future surveillance or maintenance. Sustainability is not mentioned but intrinsically implied by the site selection criteria and the requirements of long term safety. | Time cutoff of 1 million years, justified by the ability to predict the future of the geologic host formations. Exposures to persons in the present or near future limited by the regulations for radiation protection. Requirements for the post-closure phase in the new "German Safety Requirements" stipulate the same level of protection. | Regulatory responsibility for 500 years concerning prevention of unintended intrusion. Long term responsibility is federal. For confidence, emphasis is on geological stability and isolation from the biosphere. | Separate regulations for HLW vs. LILW (heat-generating and non-heat-generating). |
| Hungary | Compliant with older principles – refinement of requirements is foreseen | Addressed only as a basic principle in the Atomic Act l – no interpretation or guidelines. Economic burdens dealt with through a fund. | Timescale issues not yet dealt with in regulations. | No regulation yet. | Response refers only to clearance. |
| Japan | Regulations were revised in 2007, basically taking SS No.111-F into consideration and other regulations (Government decrees and | Requirement for "no hindrance to prevention of the hazard" is considered to reflect the precautionary principle. Specifics related to burden on future generations include record-keeping, prohibition of | No change in requirements with time scale for intermediate depth disposal. No cutoff times. Requirements for HLW yet to be developed. | Post-closure requirements exist but responsibility is primarily the implementer's. Regulations recognize the possibility of a need for transfer of responsibility from NUMO to the State | Examples given of grading of regulatory approach for different types of waste. |

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| | ordinances) took SF-1 and SS No.111-F into consideration. | excavation of land, annulment of mining rights, etc. Sustainability is not mentioned. | | | |
| Spain | Regulations are largely consistent with SF-1. There is an ongoing process of development of binding Safety Instructions. | Avoidance of undue burden involves radiological protection criteria, financing and responsibilities. Present and future generations must be adequately and effectively protected against radiological risk. Sustainability is addressed through EIA and SEA requirements. | No change with time scale, no formal weighting. | Regulator's responsibility ends at closure, but state responsibility is recognized post-closure. Confidence building is based on regulator's independence and competence. | Scope of prevention and monitoring measures is required to be based on the risks. |
| Sweden | Requirements are consistent with earlier safety principles | Burden is reduced by requiring the energy producer to take the necessary actions to safely dispose of the nuclear waste. Repository should not impose restrictions on future way of life. Sustainability is the basis for the risk criterion. The precautionary principle applies to disposal through the general "rules of consideration" in the Environmental code. | Three different time periods identified. Higher weight on risk calculations gives way to BAT for longer time scales, and for very long time scales both give way to a general comparison of radiotoxicity with existing alternatives (e.g. ore bodies), in recognition of the inability to provide meaningful estimates. The risk criterion does not change with time, but it is only applied strictly during the first time period. Weighting shifts | It is recognized that overall responsibility shifts from the operator to the State after closure. It is foreseen in the Environmental Code that the operator's responsibility may be extended to include a period after closure, which implies that also the regulatory responsibility will remain. | Guidance differentiates between repositories for spent fuel/long lived waste and other types of waste, reflecting the different time-scales of hazard posed. |

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| | | | from risk calculations to more robust function indicators. Cutoff time 1 Ma. | | |
| Switzerland | Largely compatible, no general update planned | Prevention of undue burdens is a regulatory requirement. This includes measures to enable rapid closure if necessary. Specific requirements to protect future needs and aspirations are included (e.g. institutional controls). Present and future generations must both be protected. In case of conflicts, the guidance favours long-term safety. Sustainability is included in the principles. Preservation of information and use of durable markers mentioned. | Requirements are independent of timescale, but after one million years, only qualitative assessments are performed. There is no change in weighting of factors with time. | Licensee responsibility ends at the end of any post-closure active monitoring period. No specific regulatory responsibility after that time. Confidence building by long-term safety demonstration according to state-of-the-art. | Scope and stringency depend on the magnitude of risk in order to achieve the protection criteria. |
| UK | Guidance has been cross-referenced to SF-1. No significant changes required. | Fundamental objective is to safeguard the interests of people and the environment now and in the future, to command public confidence and be cost-effective. This is supported by requirements not to exceed currently acceptable risk limits in the future, without requiring significant protective | Detailed response. No timescale cutoffs after the end of institutional control (or closure if no institutional control). Multiple lines of reasoning required at very long time scales, as quantitative analysis is not considered sufficient. | Regulatory and all other institutional responsibility ends at the end of institutional control. Detailed discussion of confidence building during the regulatory approval process, e.g. by thorough safety demonstration and information of the public at different hold or decision points. | No specific differentiation. New guidance expected to be applied appropriately according to the hazard of the waste. |

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| | | action, human intervention or active engineered systems. Risks must be ALARA. Dose constraints pre-closure, risk targets post-closure. There is explicit mention of sustainability in the requirements. | | | |
| US | Largely consistent, updates not considered necessary | Several of the regulatory requirements are intended to ensure that there is no undue burden (e.g. institutional control measures). Balancing generations achieved by using the same exposure limits. Future generations not directly considered as part of the optimisation process – prospective dose constraints are already low. No mention of sustainability. | Cutoff at 10 ka – new regulations for Yucca Mountain out to 1 Ma. Constant criteria within each time period. No variation in weighting. | Implementer (DOE) has long-term responsibility. Regulatory confidence is based on safety evaluation report submitted for licensing. | Prospective limits commensurate with public dose limits. No commensuration consideration regarding to different magnitudes of radiation risk mentioned. |

| | VI. Justification | VII. Optimization of dose | VIII. Health detriment | IX. Optimization of design | X. Management |
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| Belgium | General requirement for waste generation but not for waste management on its own. | Constrained optimization is mentioned, but specifics are under development | To be addressed in regulations under development. | No specific requirements related to application – reference is to optimization of protection. | To be addressed in regulations under development. |
| Canada | No response. | No response. | No response. | No response. | No response. |
| Finland | Justification principle is included in law generally. Options other than disposal are excluded, thus no real justification of waste management itself required. | Potential dose/risk concept not mentioned. Reasonable assurance not mentioned. Safety related optimization (SAHARA – Safety As High As Reasonable Achievable) is a requirement, but rigorous assessment to demonstrate compliance is not required. There is no explicit use of the term reasonable assurance. | ICRP caution about the role of dose for the long-term not explicitly recognized. Ultimate objective is small fraction of natural background radiation. | Regulations do not include terms of Optimisation, BAT and ALARAP, but only the term SAHARA. | General safety management and safety culture requirements by government decree. Sound technical and managerial principles are not addressed explicitly. |
| France | Part of waste generation rather than waste management. Response also refers to choice of disposal as a justification-related issue. | Regulations refer to potential dose but not to dose constraint. Constrained optimisation is used, but it is dominated by an ALARA requirement. Compliance with regulatory limits is not sufficient, optimization is expected. There is no use of the term reasonable assurance. | Regulations do not recognize ICRP caution about about the role of dose for the long-term. Ultimate objectives are not really documented. | ALARP is a regulatory requirement. No mention of BAT. Optimisation is re-evaluated at different stages. Economic factors are taken into account, but quantitative optimisation methods are not used. | Yes. Licensees are responsible for the safety of their facilities and the procedures to reach this objective. New regulatory requirements under development, reinforcing these requirements. Requirements related to technical and managerial |

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| | | | | | principles exist. |
| Germany | No justification requirement – given by the Act. | No reference to potential dose directly, but risk concept is used. Constrained optimization required. Exposures below the constraint are part of the safety requirements but emphasis is on reliability of proof, geological stability and other factors rather than strictly on exposures. | The long-term limitations of dose calculations are recognized in the annotations to the requirements. Ultimate objectives are protection of humans and the environment and avoidance of undue burdens. | Optimization of design is a requirement and is evaluated at each stage. Formal methods may be used by the implementer but are not required. | Only general requirements. Federal responsibility for disposal and regulations valid for authorities. |
| Hungary | Required for interim storage but not for disposal | Response describes the dose and risk limits for LILW but not the concepts (potential dose, dose constraints, optimization beyond limits, reasonable assurance). | Not considered. | Fairly lengthy response, suggests that BAT will be one of the requirements, but no specific criteria. | General quality management requirements. |
| Japan | Justification of disposal was a government decision. | Potential dose terminology not used, but for intermediate depth disposal, constraints vary according to probability. Constrained optimization and reasonable assurance not used. Requirements for HLW still to be developed. | Not considered for intermediate depth disposal (HLW requirements not yet developed). Ultimate objectives defined in terms of dose. | Not considered for intermediate depth disposal (but HLW requirements yet to be developed, ongoing discussion). 10 uSv/a used to terminate optimization of dose. Economic factors and relevant quantitative methods not considered. | General QA and safety culture requirements apply, not yet developed specifically for disposal. |
| Spain | RWM policies and strategies are government policy matters. Radiological | Potential exposure is accounted for through risk criterion. Constrained optimization is implied (ALARA). Reasonable | Not explicitly recognized, regulatory approaches yet to be defined. Safety objective is protection | Optimization of design is required during nuclear facility licensing, including repositories. | Safety management and safety culture requirements applicable to all nuclear facilities. |

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| | protection requirement for justification applies. | assurance is not used. | of people, things and environment against risk, achieved through adequate isolation. | | |
| Sweden | Part of energy production rather than waste management. Zero option and alternatives considered as part of EA. | Risk standard takes into account potential dose. Optimisation and BAT are both required, with BAT taking precedence in the case of a conflict. Optimisation is required even after risk criteria have been met. | Regulations recognize the decreasing value with time of dose as an indicator. Robust indicators of performance take precedence at longer times. Ultimate safety objective is protection of human health and the environment. | BAT and optimisation are both required in parallel. More weight to optimisation at early times, BAT is prioritised in the distant future. Design optimisation and safety assessment are reviewed during stepwise process. Economic factors are taken into account. Specific techniques are not prescribed. | Requirements on organisation, management and control of nuclear activities are the same for all nuclear facilities (including sufficiency of resources, well-defined responsibilities and safety objectivies, a documented management system, periodic audits etc.) |
| Switzerland | Radiation Protection Act applies – benefits from any activity involving exposure must justify the risks involved | Concept of potential dose or risk is implicitly included in the guidance. Optimisation is part of radiation protection requirements. Reasonable assurance terminology is not used. Long term safety is to be optimised in addition to compliance with the regulatory constraint. | No explanation of the ICRP caution in the new guideline HSK-G03. Overall safety objective is to permanently protect humans and the environment, without imposing unreasonable burdens or obligations on future generations. | Design optimisation is not mentioned explicitly in the regulations but regarded as inherent part of the stepwise licensing and review process. | General managerial principles and safety culture addressed in guideline HSK-G07. |
| UK | Justification applies to waste generation, not to waste management as a separate activity | Potential dose: dose constraint during the period of authorization; use of risk guidance level after the period of authorization. Optimisation is consistent | Use of risk guidance levels recognizes the caution about using dose in the long term. Ultimate safety objective is to | Developers are expected to take guidance on BPM and BPEO into account. Authorities are considering replacing these with BAT. | Specific requirements on strong leadership, safety culture and sound technical and managerial principles for the developer. |

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| | | with ICRP and IAEA. Reasonable assurance terminology is not used. ALARA is required beyond meeting dose constraints. | safeguard the interests of people and the environment now and in the future, to command public confidence and be cost-effective. | Optimisation is evaluated at each decision-making stage. Economic and social factors are taken into account. Quantitative optimisation methods may be used, but a simple approach is preferred. | |
| US | Disposal is a national policy and does not require justification | Potential exposure: Reference to dose estimates and potential doses. Constrained optimisation: Time frames set in recognition that uncertainties preclude meaningful calculations at longer times. Reasonable assurance: Detailed response defining and describing the concept – less than absolute proof required, accounts for long-term uncertainties, allows imprecisely quantified parameters, focus on the full range of values rather than extremes. ALARA beyond the licensing limits is not required for long-term performance; a detailed explanation of the reasons for this is given. | No explicit discussion of health detriments in regulations, long-term dose prediction is one of the requirements. Ultimate objectives include multiple barriers as well as dose/release limits. | No optimisation requirement per se. Stepwise licensing process but only one licence. | Generic quality assurance requirements |

| | XI. Social values | XII. Stepwise decision-making | XIII. Accidents | XIV. Human intrusion | XV. Environment |
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| Belgium | To be addressed in regulations under development. Stakeholders (ONDRAF/NIRAS) to be involved, including on international guidance | To be addressed in regulations under development. | Requirements under development | To be addressed in regulations under development. | EIA ToC under development |
| Canada | No response. | No response. | No response. | Human intrusion is treated as a disruptive event. No regulatory requirement for institutional control. | The environment must be protected against radiological and non-radiological hazards. |
| Finland | Regulatory requirements are technical, but take into account social acceptability of risk. Safety and protection are not defined explicitly. Stakeholders have the opportunity to give input into regulation making process, but there has been no particular input into application of international guidance. | Four step process: siting, construction, operation and closure licensing. Reversibility is no longer a requirement and is not solely considered a safety issue. Operator must assess uncertainties through both monitoring and evaluation of confidence. Regulator input is via dialogue with the operator. Multiple safety functions used to address uncertainties. | General requirement for assessment of disruptive events. The acceptability of the expected radiation impacts caused by such events shall be assessed in relation to the dose and release rate constraints | Human intrusion is treated as a disruptive event. Institutional control is through land use control. | Impacts on species of fauna and flora shall be examined. Assessment of the typical radiation exposures of populations in the environment, assuming the present kind of living populations. Biodiversity and populations are to be protected. |
| France | Public consultation (local and national) and a national debate are parts of the process. Nuclear Safety is defined as technical and organizational | Stepwise approach is required. Reversibility is required, but more on political grounds than for safety reasons. Reducible | Pre-closure only, same regulation as for any nuclear facility. Occurrence of accidents | Intrusion to be addressed and treated like other abnormal situations. Consequences for | Safety objectives include protection of the environment. However, it is assumed that |

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| | measures taken to prevent accidents or minimize their impact. Protection refers to radioactive and chemical hazards. Stakeholders have not yet been involved on international guidance related to geologic disposal. | and irreducible uncertainties not documented yet. Role of the regulator is to identify uncertainties and identify them to the operator. | excluded for the post-closure phase. | surrounding population must be tolerable. Likelihood is reduced by site depth and by requiring that site avoids mineral or geothermic resources. | protection of humans will protect most other species. |
| Germany | Non-technical aspects would be dealt with during site selection (procedure not yet defined). Safety and protection are defined in terms of technical risk factors - probability and consequences, dependent on the likelihood of scenarios. | Stepwise approach is envisaged. Reducible uncertainties are to be addressed by optimization. Irreducible uncertainties (e.g. geological) have to be demonstrated and evaluated by the implementor. | Pre-closure only | Intrusion to be addressed, but limiting values for dose and risk are not defined. Likelihood and consequences are to be reduced. Institutional control for 500 years. | Assumption is that protection of humans will protect other species. |
| Hungary | Public involvement in environmental hearings. Public communications programme required. | Retrievability required pre-closure. Other aspects not addressed. | Generic requirements for accidents and emergency response | No specific regulation. | Regulations require protection of the environment. |
| Japan | Non-technical indicators not used. Safety and protection not defined. There has been public consultation before application of international guidance. | Normal licensing phases. Retrievability required pre-closure. Reducible uncertainties include site-specific geological knowledge. Irreducible uncertainties include the likelihood of human intrusion. The regulator's role is to identify uncertainties and to carry out research, both of which the regulator thinks | Safety assessment required for operational phase. Extremely unlikely scenarios are considered in the post-closure safety evaluation. | Yet to be decided. Avoidance requirements exist including land use controls, records, markers, etc. | Regulations based on protection of humans. |

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| | | necessary. For intermediate depth disposal, uncertainty affects criteria and safety margins – yet to be decided for HLW. Comments received on the questionnaire suggest a more direct role for the regulator and regulatory research than is apparent in most other responses – issues raised are more specific and technical than in other responses | | | |
| Spain | No technical aspects other than dose and risk, but non-technical aspects (environment, social issues, communications) are dealt with through EIA/SEA processes. Safety and protection are not defined in regulation, but regulator uses safety for source-related and protection for recipient-related measures. Stakeholders are involved in development of guidance. | Standard licensing steps. No mention of reversibility or retrievability in regulations, but retrievability was a feature of the El Cabril LILW repository. No responses to questions on uncertainties. | General requirements applicable to all nuclear facilities. | Human intrusion is not specifically addressed. Siting must avoid locations where there are mineral resources. | Environmental protection is required. Details not given. |
| Sweden | Purely ethical issues are not included in the regulatory framework, but sustainable development is the starting basis for the risk constraint. Safety is maintained by avoiding faults, misconduct, | No specific regulatory requirements for either a stepwise process or retrievability. Retrievability must not compromise safety and must not be used to | General safety analysis requirements - restricted to the pre-closure phase. | Human intrusion scenarios are assessed separately and not included in risk calculations. Likelihood of intrusion is reduced | Environmental protection is required. Main objective is to protect ecosystems, e.g. to protect biodiversity and sustainable use of |

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| | etc. that may lead to a radiological accident, and by preventing unauthorized handling of nuclear materials. Protection is defined as avoidance of harmful effects (cancers and genetic effects). Stakeholders are involved in development of guidance. | compensate for a lack of safety. Lists of reducible and irreducible uncertainties arise from the licensing review process. The regulator's role is to identify critical uncertainties, to carry out research on uncertainties not identified by the proponent, and to keep track of international developments. The regulator must ensure that all uncertainties are put on the table for decision making. | | through application of BAT. | biological resources. |
| Switzerland | Supportive arguments including natural analogues are mentioned (additional technical arguments). Protection and safety implicitly defined by related terms in HSK-G03. Consultation precedes the publication of guidelines. | Usual licensing steps. Retrievability is a requirement pre-closure, and would be carried out for safety reasons. Uncertainties are considered on a case-by-case basis. Regulatory role is to review uncertainty in the operator's safety assessment. | Pre-closure only | Inadvertent human intrusion is not addressed explicitly, but contained by a systematic FEP analysis. Markers and land use controls are required. | The environment must be protected. Biodiversity must not be endangered. Protection criteria based on protecting humans. |
| UK | Response mentions multiple lines of reasoning (additional technical arguments). No specific definition of safety. Public consultation during development of guidance | A stepwise approach is allowed but not required. Retrievability is not required; it must not adversely affect safety. The existence of | Pre-closure and closure phase only. | Detailed guidance on human intrusion. Intrusion scenarios are part of the optimisation process. No requirements for | Protection of the environment is a requirement, including effects on non-human species such as damage to |

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| | through workshops. | uncertainties is allowed for; the operator must account for them. The operator is responsible for management of uncertainties. Regulatory research is not aimed at reducing uncertainties. Regulatory guidance recognizes uncertainties and suggests means for the applicant to deal with them. | | physical markers or institutional controls. | habitat quality. |
| US | In addition to dose/release limits, there are requirements for multiple barriers and for a performance confirmation programme. "social safety" issues not directly addressed in regulation. No specific definitions for safety and protection. Development of regulations includes public input for comment prior to finalizing the regulations. | Regulations provide for a stepwise approach. Reversibility is a requirement, foreseen only for safety reasons. Reducible and irreducible uncertainties are considered site-specific and addressed during the licensing review and public hearing. The applicant is required to address uncertainties and to conduct a performance confirmation programme to ensure that parameters are within assumed values. Primary responsibility for dealing with uncertainty is the licensee's. | General requirement for design basis accident analyses | Stylized human intrusion scenario to be analyzed. Regulations require markers, record-keeping and institutional controls. | Only environmental protection requirement is for protection of groundwater. |

## ANNEX III

## QUESTIONNAIRE IN PREPARATION OF THE TOKYO WORKSHOP

**I.** Several of the following questions refer to the latest Safety Principles[7] (2006). Current national regulations may be implementing the earlier Safety Fundamentals[8] of 1995, which are the ones mentioned in the Joint Convention.

- **Is it intended that your regulatory approach will be updated to reflect the new IAEA Safety Fundamentals? If so, what steps are planned to implement this? If you have it, please provide a list of what are, in your assessment, the major changes.**

**II.** *From The Joint Convention[9] Article 1* "Objectives … to ensure that during all stages of spent fuel and radioactive waste management there are effective defences against potential hazards so that individuals, society and the environment are protected from harmful effects of ionizing radiation, now and in the future, in such a way that the needs and aspirations of the present generation are met without compromising the ability of future generations to meet their needs and aspirations;" *and from Articles 4 and 11* "General Safety Requirements …aim to avoid imposing undue burdens on future generations."

*From IAEA Fundamental Safety Principle 7* "3.29 Radioactive waste must be managed in such a way to avoid imposing an undue burden on future generation; that is, the generation that produce the waste have to seek and apply safe, practicable and environmentally acceptable solutions for its long term management[10]"

- Do your regulations include some consideration in order to apply the *precautionary principle* intrinsically related in paragraph 3.29 of the IAEA Safety Fundamentals to the requirement to avoid imposing an undue burden to future generations?
- How do your regulations deal with the Joint Convention objectives and safety requirements "in such a way that the needs and aspirations of the present generation are met without compromising the ability of future generations to meet their needs and aspirations"?

[7] http://www-pub.iaea.org/MTCD/publications/PDF/Pub1273_web.pdf

[8] http://www-pub.iaea.org/MTCD/publications/PDF/Pub989e_scr.pdf

[9] http://www.iaea.org/Publications/Documents/Infcircs/1997/infcirc546.pdf

[10] The same requirement is included in the Joint Convention; but the interpretation provided in the second part of the sentence in 3.29 is new.

- How do your regulations "aim to avoid imposing undue burdens on future generations" vis-à-vis their long-term "needs and aspirations"?
- Are long-term responsibilities towards future generations described in national law or reference national documents?
- How do your regulations deal with the issue of balancing protection of future generations vs. protection of the present generation?
    - Are there examples of situations where these considerations compete?
    - How do these relate other factors in the optimization process, if it is required?
    - Is the concept of sustainability defined or mentioned in your regulation on in the context of disposal of long-lived radioactive waste?

**III.** *From ICRP-103*[11] "(222) In Publications 77 and 81, the Commission recognised that both the individual doses and the size of the exposed population become increasingly uncertain as time increases. The Commission is of the opinion that in the decision-making process, owing to the increasing uncertainties, giving less weight to very low doses and to doses received in the distant future could be considered. The Commission does not intend to give detailed guidance on such weighting, but rather stresses the importance of demonstrating in a transparent manner how any weighting has been carried out."

*From NEA-6182*[12] "The design and implementation of a repository involves balancing of risks and responsibilities between generations. The obligations of the present generation toward the future are complex, involving not only issues of safety and protection but also of freedom of choice and of the accompanying burden of responsibility, and of the need to transfer knowledge and resources. Our capacity to deliver these obligations diminishes with distance in time, which complicates the setting of criteria to be used today in order to demonstrate that obligations to the future will be met."

- How do your regulatory requirements for the post-closure phase reflect changing timescales (or are they independent of timescale)?
    - If you fixed a cut-off in time for the application of regulation, how is this cut-off justified? How are the potential long-term hazards communicated and dealt with?
    - If a cut-off in time for the application of regulation is not fixed, how are the potential long-term hazards to be dealt with by the applicant over increasingly long time scales?
    - Do numerical criteria such as dose or risk constraints change over different time scales?
    - Is the same weight given in regulatory decision making to exposures to persons in the distant future as is given to exposures to persons in the present or near future? If not, how has the weighting been carried out?

**IV.** *From IAEA Fundamental Safety Principle 1*. "3.7. Since radioactive waste management can span many human generations, consideration must be given to the fulfillment of the licensee's (and regulator's) responsibilities in relation to present and likely future operations. Provision must also be made for the continuity of responsibilities and the fulfilment of funding requirements in the long term."

[11] The 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication 103

[12] http://www.nea.fr/html/rwm/reports/2007/nea6182-regulating.pdf

*From NEA-6182* "While there is agreement on the need to provide a high level of protection in the long term, the fact that there cannot be ongoing active control to assure safety poses difficulties for regulators."

- Do your regulations elaborate on the actual responsibilities of the regulator in the post-closure phase?
- Do your regulations recognize a possibility of transfer of some obligations from the producer or implementer to other bodies (WMOs or national or local government) in the long term?
- How does regulation take into account the decreasing capability of control over time?
- How does the regulator(s) 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 suggests (see Section VIII below) that dose estimates should not be regarded as measures of health detriment?

**V.** *From IAEA Fundamental Safety Principle 5* "3.24. The resources devoted to safety by the licensee, and the scope and stringency of regulations and their application, have to be commensurate with the magnitude of the radiation risks and their amenability to control. Regulatory control may not be needed where this is not warranted by the magnitude of the radiation risks."

- In what way(s) are the scope and stringency of your regulations commensurate with the magnitude of the radiation risks and their amenability to control? Is an explanation officially documented?

**VI.** *From IAEA Fundamental Safety Principle 4* "3.18. For facilities and activities to be considered justified, the benefits that they yield must outweigh the radiation risks to which they give rise. For the purposes of assessing benefit and risk, all significant consequences of the operation of facilities and the conduct of activities have to be taken into account. 3.19. In many cases, decisions relating to benefit and risk are taken at the highest levels of government, such as a decision by a State to embark on a nuclear power programme. In other cases, the regulatory body may determine whether proposed facilities and activities are justified."

- Does justification of the disposal activity play any role in your regulatory requirements for waste disposal? If so, please describe.

**VII.** *From IAEA Fundamental Safety Principle 5 "*3.21. The safety measures that are applied to facilities and activities that give rise to radiation risks are considered optimized if they provide the highest level of safety that can reasonably be achieved throughout the lifetime of the facility or activity, without unduly limiting its utilization".

*From IAEA WS-R-4*[13] "2.14. Constrained optimization is the central approach adopted to ensure the radiological safety of a waste disposal facility. In this context, the optimization of protection is a judgemental process, with social and economic factors being taken into account, and it should be conducted in a structured but essentially qualitative manner, supported by quantitative analysis (see the Appendix)."

[13] http://www-pub.iaea.org/MTCD/publications/PDF/Pub1231_web.pdf

*From IAEA WS-R-4* "A.2. … protection can then be considered optimized provided that ... There is a reasonable assurance that the assessed doses and/or risks resulting from the generally expected range of the natural evolution of the disposal system do not exceed the appropriate constraint, over time frames for which the uncertainties are not so large as to prevent meaningful interpretation of the results …"

*From ICRP-81* "(23) … In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or on the risks to individuals in the case of potential exposures (risk constraints) so as to limit the inequity likely to result from the inherent economic and social judgements. …"

*From ICRP-81* "(24) … The term 'potential exposures' refers to situations where there is a potential for exposure but no certainty that it will occur, i.e. the type of situations of concern in the long term following closure of a solid radioactive waste disposal facility. …"

*From ICRP-81* "(49) Formal optimisation techniques for application to potential exposure remain to be developed…"

*From ICRP-81* "(78) … the Commission's view is that provided that the appropriate constraint for natural processes has been satisfied, that reasonable measures have been taken to reduce the probability of human intrusion, and that sound engineering, technical, and managerial principles have been followed, the radiological protection requirements can be considered satisfied."

*From ICRP-103* "(218) The best option is always specific to the exposure situation and represents the best level of protection that can be achieved under the prevailing circumstances. Therefore it is not relevant to determine, a priori, a dose level below which the optimisation process should stop[14]. Depending on the exposure situation, the best option could be close to or well below the appropriate source-related constraint or reference level."

*From ICRP-103* "(219) Optimisation of protection is not minimisation of dose. Optimised protection is the result of an evaluation, which carefully balances the detriment from the exposure and the resources available for the protection of individuals. Thus the best option is not necessarily the one with the lowest dose."

- Do your regulations make reference to the concept of potential dose or risk as described in ICRP-81?

- Does your regulatory approach use a constrained optimization approach for radiological protection as defined in IAEA standards (WS-R-4) or ICRP-81?

- Do your regulations make reference to the term *reasonable assurance* when in relation to the use of the dose or risk and constrained optimisation in the long term (as in IAEA standard WS-R-4)? If yes, how is this concept interpreted or defined?

- Do your regulations expect protection to be optimized further when predicted exposures are below the constraint, or is compliance with regulatory limits considered to be sufficient?

[14] There may be some uncertainty about how to interpret the statement in the previous quote from ICRP-81 (para. 78) in the light of this sentence.

**VIII.** *From ICRP-81* "(81) … protection of future generations should be achieved by applying these dose or risk criteria to the estimated future doses or risks in appropriately defined critical groups. These estimates should not be regarded as measures of health detriment beyond times of around several hundreds of years into the future. In the case of these longer time periods, they represent indicators of the protection afforded by the disposal system."

*From ICRP-103* "(265) … Considerable uncertainties surround exposures taking place in the far future. Thus dose estimates should not be regarded as measures of health detriment beyond times of around several hundreds of years into the future. Rather, they represent indicators of the protection afforded by the disposal system. …"

*From NEA-6182* "There is agreement that calculations of dose and risk in the future are illustrations of possible system behaviour rather than predictions of outcomes, and there is consensus that, in the long term, numerical criteria for radioactive waste disposal should be considered as references or indicators, addressing the ultimate safety objectives, rather than as absolute limits in a legal context."

- Do your regulations explicitly recognize that dose and risk in the long term are not to be viewed as measures of health detriment?

- Which are the recognized/documented "ultimate safety objectives" in your regulation or approach?

**IX.** *From IAEA WS-R-4* "3.35. … Care needs to be exercised in using the criteria beyond the time where the uncertainties become so large that these criteria may no longer serve as a reasonable basis for decision making. For such long times after closure, indicators of safety other than dose or individual risk may be appropriate, and their use should be considered."

*From ICRP-81* "(86) Demonstration of compliance with the radiological criteria is not as simple as a straightforward comparison of calculated dose or risk with the constraints, but requires a certain latitude of judgement. Neither should estimated transgression of a constraint necessarily oblige rejection, nor should numerical compliance alone compel acceptance of a waste disposal system. The dose or risk constraints should increasingly be considered as reference values for the time periods farther into the future, and additional arguments should be duly recognised when judging compliance."

*From NEA-6182* "There is continued and increasing recognition of the importance of the role of safety functions of the repository system, and of performance indicators related to those functions. Performance indicators other than dose and risk, the use of multiple lines of reasoning, the application of constrained optimisation and demonstration of the use of best available techniques can all contribute to regulatory decision making..."

- Do you have precisely defined terms for requirements related to optimization of design or use of best available techniques (such as BAT, ALARP, etc.)? What are they?

- If your approach involves both optimization of design and a stepwise development process, how do these interact?

    - Is optimization of design evaluated at different stages of the programme?

    - If so, how do the criteria differ (and the judgment of compliance) for each stage?

- Is there a point at which design optimization is considered to be complete or sufficient?
- Are economic factors included as a consideration in optimization of design?
- Are formal quantitative methods used/required for optimization of design? If so, please describe?

**X.** *From IAEA Fundamental Safety Principle 3* "3.12. Leadership in safety matters has to be demonstrated at the highest levels in an organization. Safety has to be achieved and maintained by means of an effective management system. This system has to integrate all elements of management so that requirements for safety are established and applied coherently with other requirements, including those for human performance, quality and security, and so that safety is not compromised by other requirements or demands. The management system also has to ensure the promotion of a safety culture, the regular assessment of safety performance and the application of lessons learned from experience."

*From ICRP-81* "(65) … The Commission recommends that technical and managerial principles for potential exposure situations should be applied during the disposal system development process to enhance confidence that radiation safety will be maintained throughout the post-closure period. These principles should be applied to disposal systems in a manner consistent with the inherent hazard level of the waste as well as with the level of residual uncertainty identified in the assessment. …"

- Do your regulations require effective leadership and management?
- Do your regulations address "safety culture"?
- Do you have requirements related to "sound technical and managerial principles" of ICRP-81?
  - How are these related to BAT and optimization (if also required)?
  - How are they related to, or deemed to support, safety assessment?

**XI.** *From ICRP-103* "(224) Societal values usually influence the final decision on the level of radiological protection. Therefore, while this report should be seen as providing decision-aiding recommendations mainly based on scientific considerations on radiological protection, the Commission's advice will be expected to serve as an input to a final (usually wider) decision-making process, which may include other societal concerns and ethical aspects, as well as considerations of transparency. This decision-making process may often include the participation of relevant stakeholders rather than radiological protection specialists alone."

*From NEA-6182* "…Social and ethical dimensions of safety affect regulatory criteria as well as other stages of policy setting and implementation. As a result, regulatory policies and decision making are not solely based on technical matters. They take into account expectations of civil society, international experience, ethical considerations and practical needs of implementers."

*From NEA-6182* "There is agreement that decision making and the criteria and methods on which it is based need to be clear and transparent. Societal considerations are involved in discussions of tolerance of risk, and there is a need to provide a role for society and affected communities to participate in discussions of safety."

- Does your regulation explicitly take into account considerations other than technical indicators of safety (e.g. dose and risk)?

- Does your regulation define and use the terms "safety" and "protection"? If yes, can you provide the definitions?

- Has the interpretation and application of international guidance in your regulations been agreed or discussed with your national stakeholders and documented?

**XII.** *From NEA-6182* "The increasing importance of stepwise decision making, and of reversibility and retrievability, are changing the nature of repository design to a process that may itself span several generations. This poses difficulties for the regulatory decision-making process, and for the ability to maintain transparency."

- Does your regulation allow for, or require, a stepwise or phased approach to repository development, decision-making, or licensing?

- Do your regulations require (or otherwise take into account) retrievability or reversibility?

    - In your regulations, are reversibility and/or retrievability considered to be safety-related issues?

    - Do you have safety criteria for the necessity of retrieving and relocating waste packages during the operations phase? In a monitored post-operations phase? After closure?

- What do you feel are long-term uncertainties that can and should be reduced through research or design by the time a license is granted? Are these documented?

- What do you feel are uncertainties that cannot be reduced even by the time a license is granted? Are these documented?

- What is the role of the regulator in uncertainty reduction?

- How does the regulator deal with irreducible uncertainties?

**XIII.** *From IAEA Fundamental Safety Principle 8* "3.30. … to ensure that the likelihood of an accident having harmful consequences is extremely low, measures have to be taken: —To prevent the occurrence of failures or abnormal conditions (including breaches of security) that could lead to such a loss of control; —To prevent the escalation of any such failures or abnormal conditions that do occur; —To prevent the loss of, or the loss of control over, a radioactive source or other source of radiation."

*From The Joint Convention Article 1 "...* to prevent accidents with radiological consequences and to mitigate their consequences should they occur during any stage of spent fuel or radioactive waste management…"

- Do your regulations for disposal facilities address protection against accidents?

**XIV.** *From ICRP-81* "(83) … Assessed doses or risks arising from natural processes should be compared with a dose constraint of 0.3 mSv per year or its risk equivalent of around $10^{-5}$ per year. With regard to

human intrusion, the consequences from one or more plausible stylised scenarios should be considered in order to evaluate the resilience of the repository to such events. (84) The Commission considers that in circumstances where human intrusion could lead to doses to those living around the site sufficiently high that intervention on current criteria would almost always be justified, reasonable efforts should be made at the repository development stage to reduce the probability of human intrusion or to limit its consequences. In this respect, the Commission has previously advised that an existing annual dose of around 10 mSv per year may be used as a generic reference level below which intervention is not likely to be justifiable. Conversely, an existing annual dose of around 100 mSv per year may be used as a generic reference level above which intervention should be considered almost always justifiable. Similar considerations apply in situations where the thresholds for deterministic effects in relevant organs are exceeded."

- How are human intrusion scenarios addressed in regulations? Does the assessment of human intrusion scenarios differ from that of naturally-occurring scenarios (as in ICRP-81)? If so, how?

- Do your regulations include requirements for measures to reduce the likelihood of intrusion (e.g. physical markers, institutional controls)?

**XV.** *From IAEA Fundamental Safety Principle 7* "3.28. Whereas the effects of radiation exposure on human health are relatively well understood, albeit with uncertainties, the effects of radiation on the environment have been less thoroughly investigated. The present system of radiation protection generally provides appropriate protection of ecosystems in the human environment against harmful effects of radiation exposure. The general intent of the measures taken for the purposes of environmental protection has been to protect ecosystems against radiation exposure that would have adverse consequences for populations of a species (as distinct from individual organisms)."

- Do your regulations require protection of the environment (other than prevention of environmental effects that would result in dose to humans)?

- Do your regulations require protection for populations of a species (as distinct from individual organisms)?