Session 4

Optimisation, BAT and Related Topics

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Optimisation: an Overview of Concepts

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

Background

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

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

The International Guidance

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

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

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

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

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

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

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

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

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

Examples of National Regulatory Guidance

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

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

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

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

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

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

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

Towards Transparent, Proportionate and Deliverable Regulatory Framework

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

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

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

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

Conclusions

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

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

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

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

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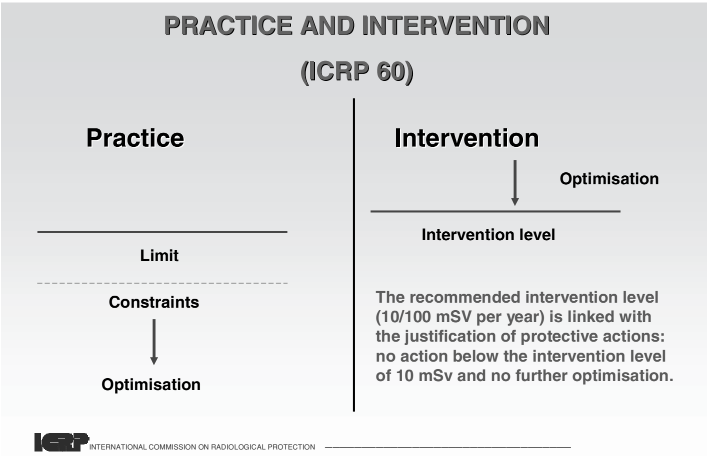
Introduction

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

Review of ICRP-60

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

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



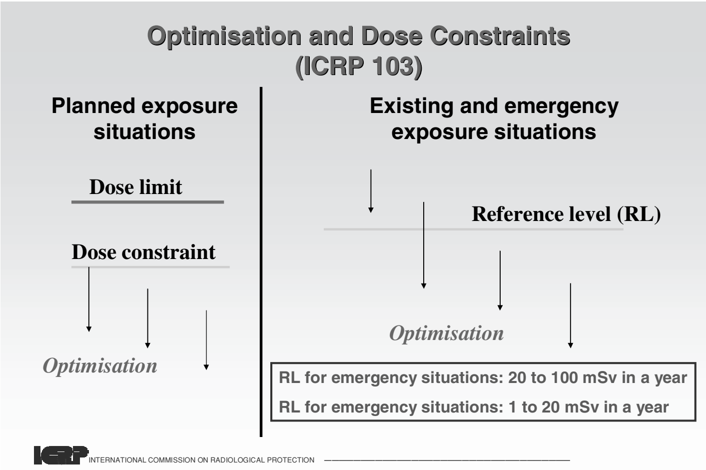
In an intervention situation (generic) optimisation is applied when intervention levels are selected. The intervention level is linked with the justification of protective actions following the identification of an intervention situation: below an intervention level no further optimisation is required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

Review of ICRP-103

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

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

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

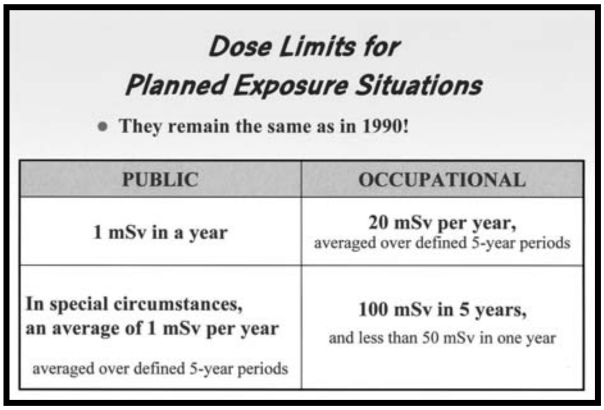


1. "Dose" is in fact "effective dose".

The Specific Issue of Geological Disposal

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

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



Dose Limits for Planned Exposure Situations

- They remain the same as in 1990!

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

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

Questions Raised by NEA

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

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

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

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

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

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

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

No, such a distinction should not be made.

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

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

The main types of stakeholders are:

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

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

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

ICRP recommends applying the approach of BATNEEC (best available technology not entailing excessive cost) rather than that of BAT. The principles of optimisation and BATNEEC complement each other. The control of residual doses (human health) is driven by optimisation, BATNEEC is applied as a means to control effluents in cases where humans are not directly affected.

Obligations of the operational management are to develop and provide internal policies, priorities, rules and procedures to ensure the existence of a vibrant safety culture at all levels of management and the workforce. Competent authorities are requested to establish clear policies and processes for decision making regarding the authorisation of proposed activities. Regulatory requirements should include the need for an active safety culture in both the authority itself and all regulated operating management.

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

The key issue in radiological protection in the context of radioactive waste disposal is the equity between generations. ICRP recommends that beyond timeframes of a few generations predicted doses should not play a major part in decision making.

ICRP Publication 103 (para.222) states: "… in the decision-making process, owing to the increasing uncertainties, giving less weight to very low doses and to doses received in the distant future could be considered … ICRP does not give detailed guidance on such weighting but stresses the importance of demonstrating in a transparent way, how any weighting has been carried out. A variety of approaches could be taken as long as they are properly justified by the regulator."

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NRC Position on Optimisation for a Potential Geologic Repository

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This afternoon, I would like to focus on the regulatory framework that the US Nuclear Regulatory Commission (NRC) is using to review the U.S. Department of Energy's (DOE) license application for a geologic repository at Yucca Mountain, Nevada, US. NRC will evaluate this application using regulatory criteria that protect public health and safety, the environment and common defence and security. Regulations governing the potential repository at Yucca Mountain are contained in 10 CFR Part 63, which covers both the pre-closure operational period and the period of time following closure of the repository.

I must note that, in response to a successful legal challenge in 2005, the safety standards for Yucca Mountain must be extended from 10,000 yr to 1 000 000 yr following closure of the potential repository. The 10 000 year requirements that previously were established remain essentially unchanged. By law, the U.S. Environmental Protection Agency (EPA) establishes the safety standards for Yucca Mountain. The NRC, in turn, must make its regulations consistent with EPA standards. EPA issued revised standards for the 10 000 to 1 000 000 yr performance period in October, 2008 (40 CFR Part 197). Following a public comment period on the proposed revisions, NRC is currently updating its regulations to be consistent with the revised EPA standards for the 10 000 yr to 1 000 000 yr post-closure period. In this talk, when I need to refer to safety standards after 10 000 yr, I will necessarily speak to the revised EPA standards.

One of the requirements in Part 63 for the pre-closure operational period is to meet the applicable requirements in 10 CFR Part 20 for radiation protection. Part 20 contains requirements for a program to reduce radiation exposures to As Low As Reasonably Achievable (10 CFR 20.1101) during the operational phase of the potential repository. Having a good ALARA program isn't the only requirement for safety during the pre-closure phase of operations. DOE also must produce an appropriately detailed safety analysis, which considers event sequences that have likelihoods as low as 1 in 10 000 of occurring during the approximately 100 year pre-closure period (i.e., annual frequencies of occurrence $>10^{-6}$). For event sequences that have annual frequencies of $>= 10^{-2}$, DOE must show that these event sequences would produce a dose of no more than 50 mSv/yr [5 000 mrem/yr] to a radiation worker, no more than 1 mSv/yr [100 mrem/yr] to any on-site person who is not a radiation worker and no more than 0.15 mSv/yr [15 mrem/yr] to any real member of the public located on or beyond the facility boundaries. Any event sequence that has an annual frequency of 10^{-2} to 10^{-6} must be shown in the pre-closure safety analysis to give doses of <50 mSv/yr [<5 000 mrem/yr] to a person located on or beyond the boundaries of the facility.

For the period following permanent closure of the repository, NRC has numerous regulatory requirements to protect public health and safety, the environment and common defence and security. These requirements represent an optimised approach that ensures our regulations are appropriately protective and provide a transparent basis to judge the safety of the proposed repository far into the future.

The first post-closure requirement is that the repository system must be constructed so that there is a system of both natural and engineered barriers. The applicant must demonstrate an understanding of the capability of these barriers in the total-system performance assessment, which is an integral part of the safety analysis report. An understanding of barrier performance is important to gaining confidence that the safety standards will be met by the proposed repository system.

A total-system performance assessment also must be used to demonstrate compliance with safety standards. This assessment must include appropriate uncertainties in both models and data, and propagate these uncertainties through the performance assessment. Performance assessment must consider events with annual likelihoods of occurrence as low as 1 in 100 million, if such events would affect the timing or magnitude of radionuclide release significantly. At the Yucca Mountain site, such events include very infrequent earthquakes and the potential eruption of a small-volume basaltic volcano.

For Yucca Mountain, uncertainties about future changes in human society or key biosphere components, which cannot be constrained by current scientific understanding, have been addressed through rulemaking. In the performance assessment, expected doses are calculated for a stylised individual, called the "reasonably maximally exposed individual" (RMEI), who represents a small group of people that are most likely to receive a maximum dose. The RMEI lives above, and withdraws water from, the centre of the plume of contamination, and has the habits and lifestyles of individuals currently living in the accessible environment near Yucca Mountain. In addition to using water withdrawn from the plume of contamination for crop irrigation, the RMEI drinks 2 liters of this water each day. Thus, the RMEI approach for performance assessment avoids undue speculation about long-term changes in future societies or biosphere characteristics, while still allowing consideration of biosphere uncertainties in the performance assessment.

The numerical standard for the performance assessment is a probability-weighted expected annual dose to the RMEI. Thus, the likelihood of the RMEI receiving a dose from an event is factored into the conditional dose associated with the event. The performance assessment analyzes the uncertainties associated with data and models, and calculates a range of probability-weighted annual doses. The mean of those calculated doses to the RMEI is used to assess compliance with the post-closure dose standard.

For the post-closure period up to 10 000 years, expected annual doses to the RMEI cannot exceed 0.15 mSv/yr [15 mrem/yr]. EPA has recently specified that doses to the RMEI cannot exceed 1 mSv/yr [100 mrem/yr] from 10 000 yr to 1 000 000 yr post closure. NRC is in the process of updating its 10 CFR Part 63 regulations to conform to the EPA post-10 000 yr standard for individual protection.

In addition to the individual protection standard, for the first 10 000 yr following repository closure, a groundwater protection standard limits doses to the RMEI to less than 0.04 mSv/yr (4 mrem/yr) and sets some concentration limits for radium and some alpha emitters. The groundwater protection analysis, however, only needs to consider events that have a greater than 1 in 10 chance of occurring during the 10 000 yr period. Human intrusion is evaluated using a stylised scenario in which a driller penetrates a waste package and forms a pathway to the water table. This stylised event is evaluated for a future time when the waste package has degraded to the extent that a driller wouldn't recognise a drill bit has hit an engineered barrier. Doses to the RMEI that result from this stylised scenario cannot exceed 0.15 mSv/yr [15 mrem/yr] in the first 10 000 years, or 1 mSv/yr [100 mrem/yr] after 10 000 years.

Confidence that the geologic repository is optimised to protect public health and safety and the environment also is achieved through a performance confirmation program. If NRC grants DOE an authorisation to construct the repository, DOE must conduct a series of investigation to confirm that site characteristics encountered during construction are within the range of conditions considered in the license application. In addition, DOE must conduct additional investigations to confirm that barriers important to waste isolation are functioning as intended.

Repository oversight must continue following permanent closure. In order to close the repository permanently, DOE must have a program in place to continue monitoring the repository system, establish permanent land-use controls, construct permanent markers over the repository site, and preserve all applicable records of the repository and its contents.

NRC concludes that the regulatory requirements I've outlined provide a rigorous basis to determine if the proposed geologic repository at Yucca Mountain will be safe. Compliance with these requirements is sufficient, and appropriately optimised, to ensure public health and safety. The ALARA principle, while appropriate for pre-closure and decommissioning operations, does not apply to post-closure. If the repository system is shown to be safe, further design modifications incur additional costs with values that are difficult to judge against speculative changes in future societies and economies. As an additional consideration, deep geologic disposal, by its very nature, already is viewed as ALARA. There are few technological alternatives in repository design (10 CFR Part 63). Thus, NRC concludes that its post-closure regulatory requirements represent a sufficiently optimised approach to protecting safety.

In summary, safety of the potential geologic repository at Yucca Mountain will be evaluated by considerably more than compliance with a numerical dose standard. NRC concludes that the current US regulatory framework provides sufficient and optimised protection of public health and safety, the environment and common defence and security. The principle of optimised protection (i.e., ALARA) is being applied for pre-closure operations and decommissioning of the potential repository. However, long-term safety is optimised through compliance with the post-closure regulatory requirements.

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The Current Regulatory Requirements on Optimisation and BAT in Sweden in the Context of Geological Disposal

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Legal Framework

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

The environmental code defines general rules of consideration with requirements on both siting and use of best available technique (BAT). The siting rule states that a proposed site should be selected with the goal to give the least disturbance and negative impact on human health and the environment. This means that the proposed site should be compared to other plausible sites presented in the environmental impact statement, or otherwise available. Similarly, the requirement on BAT aims at preventing or counteracting damage to human health and the environment. Both BAT and the siting rule should be applied to the extent it cannot be considered unreasonable. In making this judgement the effectiveness of the protective and precautionary measures should be related to cost, as well as aspects of sustainable development.

Although the requirements on BAT and siting in the Environmental Code apply to radiological protection, they aim at a broader system optimisation. The more specific requirements on optimisation and BAT of radiological protection of geological disposal systems are given in the regulations associated with the radiation protection act. These regulations are the basis for the discussion in the remainder of this note.

Supplementary Requirements to Dose and Risk

The Swedish radiation protection regulations (SSM, 2009) comprise three cornerstones:

- A risk target: the repository should be designed so that the annual risk of harmful effects does not exceed 10^{-6} for a representative individual in the most exposed group.
- Environmental protection goals.
- The use of optimisation and BAT.

The risk target relating radionuclide releases to consequences for humans provides a yardstick by which the acceptability of the repository can be determined. Dose and risk calculations provide numbers for evaluating compliance with the target. However, risk analyses for geological repositories will always be associated with uncertainties, especially for distant time periods after closure and regarding climate, biosphere conditions and human society. Therefore there is a need for additional arguments in the safety case in support of decision making.

It is in this context that the requirements on optimisation and BAT should be seen as supplementary to the risk target, in providing evidence that the developer as far as reasonably possible has taken into consideration measures and options for reducing future doses and risks. Both principles focus on the proponent's work on developing the repository system and should be applied to the whole process of developing a disposal system, i.e. all steps from siting, design, construction, operation to closure of the repository. However, the application of these principles is subject to societal and economical boundary conditions as will be discussed later.

However, as mentioned above, risk and dose calculations will always be associated with uncertainties when looking far into the future. For these situations, and also for early stages of repository development when there is limited data from sites and the engineered barrier system (EBS), the concept of BAT is a more appropriate. BAT focuses on more robust measures of repository performance, aiming to hinder, reduce and delay releases of radioactive substances from both the engineered and the geological barriers, and is therefore less sensitive to speculative assumptions on climate and biosphere conditions in the distant future.

In case of a conflict between BAT and optimisation, measures satisfying BAT should be prioritised. For example, the risk analysis may suggest that a repository solution leading to early releases is acceptable if the radioactive substances are diluted in a large lake or the sea. In such a case a repository solution providing containment, according to the principle of BAT, should be prioritised.

Application of Optimisation and BAT on Different Timescales

The conditions for estimating risks from a geological repository are different for different timescales. Some elements of the risk analysis become speculative already after few hundred years after closure, for example human society and living habits. After a few thousand years the uncertainties regarding the human environment (the biosphere) will increase, which renders calculation of radiation doses and risk even more uncertain. In the time perspective of 100 000 years one could expect dramatic climatic changes with glaciations and large sea level fluctuations in the Scandinavian region. Other elements of the risk analysis, such as the evolution of the basement rock and the engineered barriers, can be expected to be more stable over long time periods. These are some of the considerations behind SSM's guidance on the reporting of risk analyses and other radiation protection arguments for different time periods, summarised in Figure 1.

Figure 1. **Summary of SSM's guidance on compliance demonstration for different time periods after closure of a geological repository**

<table>
<tr><th>Time after closure (yrs)</th><th>Safety case reporting</th><th>Compliance measure</th></tr>
<tr><td>0-1 000</td><td>• Risk analysis based on today's biosphere
• Special reporting on early barrier transients</td><td rowspan="2">• Calculated risk
• Description of environmental impact
• Application of optimisation and BAT</td></tr>
<tr><td>0-100 000</td><td>• Risk analysis based on illustrative scenarios for climate and biosphere
• Complementary safety indicators to support risk calculations</td></tr>
<tr><td>100 000-1 000 000</td><td>• Simplified risk analysis
• Analysis of long-term barrier performance and effects of major detrimental events
• Reasoning of protective capability based on risk and complementary safety indicators</td><td>• Application of BAT</td></tr>
<tr><td>> 1 000 000</td><td>• Description of radiological toxicity of the repository</td><td>• Basis for comparison with alternative waste management options</td></tr>
</table>

Three main compliance periods can be identified. The first is the period over which calculations of dose and risk has a meaning for compliance evaluation. The length of this time period may vary depending on country and setting of the repository site, but in Swedish guidance quantitative risk calculations are expected for the time period of one glaciation cycle or approximately 100 ka (for spent nuclear fuel repositories). For this time period the proponent should present quantitative risk and dose calculations for comparison with the risk standard. The calculated risk (and environmental impact) is the main compliance measure for this time period, but the application of optimisation and BAT are important supplementary arguments.

For the time period beyond 100 ka, after a glaciation, risk calculations become more speculative due to large uncertainties in climate and biosphere conditions, hence compliance demonstration based exclusively on a comparison of calculated risks with the risk target will not be meaningful. The compliance discussion for this second compliance period may instead be based on a combination of arguments including more robust measures of the repository's protective capability, such as different measures of barrier performance and activity fluxes. Indications of disturbances of the repository's protective capability should be reported together with a discussion on potential measures for improving the repository performance. Hence, for these long time periods SSM's evaluation of compliance will focus more on the application of BAT than on the uncertain results of a quantitative risk analysis.

At some point in the distant future, even analyses of more robust repository performance measures become speculative and meaningless. Further, it is hard to foresee any measures that could be taken in the design of the repository that would counteract the very long-term global geological processes, for example repeated glacial erosion that eventually may expose the waste to the human environment. Therefore SSM does not ask for a reporting of radiological consequences after 1 million years after closure of the repository. However, a simple analysis of the fate of the repository and the very long-term consequences of concentrating uranium in geological formations may provide an important basis for high-level comparison with alternative waste management options.

Future Human Intrusion

The potential for future human action (FHA), and the special case of human intrusion into the repository, is a direct consequence of geological disposal, and any attempt to estimate probabilities and consequences will be very speculative. Therefore Swedish guidance states that FHA scenarios should be reported separately and should not be included in the risk summation. Only inadvertent intrusion needs to be considered. FHA scenarios provide a basis for identifying measures to reduce the probability and consequences of the human disturbances, according to the principle of BAT, e.g. by increasing repository depth, avoiding mineral deposits and preservation of information. FHA scenarios may also serve to illustrate irreducible risks associated with geological disposal, and thus provide a basis for comparison with other waste management options.

Boundary Conditions for Application of Optimisation and BAT

There are of course limits for what can be expected in terms optimisation and BAT. The principle of voluntary participation in the Swedish Nuclear Fuel and Waste Management Co's (SKB) site investigations on part of the municipalities is one example of a government decided societal limitation on site selection. Cost considerations also set boundaries to SKB's optimisation process. In Sweden, it is the full responsibility of the waste producer (through SKB) to ensure that sufficient funds are available for the development of an acceptable geological disposal solution. However, society may provide feedback to SKB on optimisation and BAT considerations during the development process, through the recurrent regulatory reviews and subsequent government decisions on SKB's programme for research, development and demonstration (RD&D programme). Finally, technical constraints could be availability of technology and the effectiveness of various measures for enhancing the repositories protective capability.

Regulatory Review of Optimisation and BAT

Demonstrating compliance with Swedish radiation safety regulations involves demonstrating (1) that the risk and environmental protection targets are satisfied for at least the period of one glacial cycle, or approximately 100 000 years and (2) that optimisation and BAT have been applied as far reasonably possible during the process of developing the disposal system. It is the responsibility of SKB to motivate the balancing between radiological protection and societal and economical factors.

Because we cannot foresee exactly what issues that will appear in SKB safety case it is more or less impossible to, a priori, define a comprehensive set of acceptance criteria for BAT and optimisation. In this respect, SKB will not get the final answer to what is an appropriate level of optimisation and BAT until the licensing review. However, a stepwise process of developing a repository makes it possible to provide guidance along the way. As already mentioned, one example is the Swedish system with regulatory review and subsequent government decision on SKB RD&D programme every third year – where design choices and other important decisions in SKB programme are scrutinised. The government has also established a series of consultation meetings between SKB and the regulator with the aim of clarifying regulatory expectations on the license application. Recurrent regulatory reviews of SKB's preliminary safety assessments are another way of providing regulatory feedback to SKB, prior to the license application.

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

Summary

Optimisation and BAT are important regulatory (societal) tools for ensuring an attitude of doing as good as reasonably possible, i.e. important supplements to the quantitative yardsticks dose and risk. Critical BAT and optimisation considerations may become an important part of the decision basis and should consequently be presented in an understandable way to the decision makers. However, as the date for license application and review quickly is approaching there is a need for SSM to develop and communicate a strategy for how to evaluate these lines of argumentation. Examples of issues that may need further clarification include:

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

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