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Work in Support of Biosphere Assessments for Solid Radioactive Waste Disposal

1. Performance Assessments, Requirements and Methodology; Criteria for Radiological Environmental Protection

Statens strålskyddsinstitut
Swedish Radiation Protection Authority

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TITLE/ TITEL: Work in Support of Biosphere Assessments for Solid Radioactive Waste Disposal. 1. Performance Assessments, Requirements and Methodology; Criteria for Radiological Environmental Protection/ Utvecklingsarbete av biosfärsanalyser vid slutförvaring av radioaktivt avfall. 1. Säkerhetsanalys, krav och metodik; kriterier för miljöskydd

SUMMARY: The first part of this report is intended to assess how the recent Swedish regulatory developments and resulting criteria impose requirements on what should be included in a performance assessment (PA) for the SFR low and medium level waste repository and for a potential deep repository for high level waste.

The second part of the report has been prepared by QuantiSci as an input to the development of SSI's PA review methodology.

The aim of the third part is to provide research input to the development of radiological protection framework for the environment, for use in Sweden. This is achieved through a review of various approaches used in other fields.

SAMMANFATTNING: Syftet med den första delen av rapporten är att analysera vilka krav som ställs på en säkerhetsanalys av ett slutförvar för använt kärnbränsle och kärnavfall genom SSI:s nyligen utfärdade föreskrifter om miljö och hälsoskydd (SSI FS 1998:1).

Andra delen av rapporten har tagits fram av QuantiSci som ett underlag för utvecklandet av granskningsarbetet på SSI.

Målet med den tredje delen var att ge ett forskningsunderlag till utvecklandet av radiologiska miljöskyddskriterier i Sverige. Detta har uppnåtts genom att granska tillvägagångssättet inom andra områden.

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Förord

1988 fick Svensk Kärnbränslehantering AB (SKB) tillstånd till ett begränsat drifttagande av slutförvaret för radioaktivt driftavfall. Efter att SKB skickat in ett par kompletterande rapporter gav Statens strålskyddsinstitut (SSI) och Statens kärnkraftinspektion (SKI) sina slutliga driftmedgivanden 1992. Som villkor till de driftmedgivanden som SSI utfärdade både 1988 och 1992 anges att SKB ska inkomma med en uppdaterad säkerhetsredovisning vart tionde år. En sådan redovisning inkom till myndigheterna hösten 2001. Inför den förestående granskningen av denna rapport såg SSI att det fanns ett behov att uppdatera både modelleringsverktygen och granskningsstrategin inom området. (En bakomliggande orsak till detta behov är den precisering av kravbilden som erhållits genom utfärdandet av SSI:s föreskrifter (SSI FS 1998:1) om skyddet av hälsa och miljö vid slutförvaring av använt kärnbränsle och kärnavfall.) Med anledning av detta fick QuantiSci 1998 i uppdrag av SSI att:

- utveckla arbetsmetoderna för det kommande granskningsarbetet, dels utifrån SSI:s skyldigheter som landets strålskyddsmyndighet, dels utifrån ovan nämnda SSI-föreskrifter om skyddet av hälsa och miljö vid slutförvaring av använt kärnbränsle och kärnavfall
- utveckla grunderna för oberoende analyser och biosfärsmodelleringar, bland annat genom framtagande av modelleringsverktyg
- ge stöd i utvecklandet av en förteckning över vilka förhållanden, händelser och processer (FEP, från engelskans features, events and processes) som är av betydelse för biosfärsmodellering.

Delar av de modelleringsverktyg som tagits fram har integrerats med verktyg som SKI låtit utveckla i ett parallellt projekt, och kommer att utgöra en av grunderna i den myndighetsgemensamma granskningen av SKB:s uppdaterade säkerhetsanalys.

Projektet har mynnat ut i fem stycken QuantiSci-rapporter. Dessa är sammanställda i två SSI-rapporter, varav detta är den ena. I denna rapport diskuteras säkerhetsanalys, krav och metodik samt kriterier för miljöskydd. I SSI Rapport 2001:22 diskuteras biosfärsmodellering och utvecklingen av en FEP-lista för biosfären. Författarna svarar ensamma för rapportens innehåll, varför detta ej kan åberopas som Statens strålskyddsinstituts ståndpunkt.

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Requirements for Performance Assessments Based on Swedish Regulations and Criteria

1 Background, Scope and Objectives

The Swedish Radiation Protection Institute (SSI) has issued Regulations concerning the protection of human health and the environment in connection with final management of spent nuclear fuel and nuclear waste [SSI, 1998a]. These Regulations have evolved against a background of on-going regulatory development:

- by the SSI over ten years and more, for example SSI [1995];
- by other Swedish bodies, e.g. SKI [1997];
- in the wider Nordic community, e.g. the Radiation Protection and Nuclear Safety Authorities in Denmark, Finland, Iceland, Norway and Sweden [1993, 1989 and 1986];
- by international bodies such as the International Commission on Radiological Protection [ICRP, 1985 and 1997] and the International Atomic Energy Agency, e.g. IAEA [1995];
- and by other national authorities, as informally recorded in presentations at a Nuclear Energy Agency workshop [NEA, 1997], and nationally relevant recommendations and guidance, e.g. in the USA [CTBYMS, 1995] and in the UK [EA et al, 1997].

As part of a wider project being undertaken by QuantiSci in support of SSI's (post-closure) biosphere assessments for solid radioactive waste disposal, this Sub-Task Report is intended to assess how the recent Swedish regulatory developments and resulting criteria impose requirements on what should be included in a performance assessment (PA) for the SFR low and medium level waste repository and for a potential deep repository for high level waste (HLW). This includes a review of previous PAs to explore how they have addressed the regulations extant at the time they were produced and wider radioactive protection principles as applied to solid waste disposal. Specific lessons are then drawn from an SSI regulatory perspective for on-going review of the SFR, and for deep repository PA. In particular, proposals are made for the development of an "assessment context" [BIOMASS, 1998a] for PA related to SSI's regulatory interests in solid waste disposal facilities. Then, preliminary recommendations are made on specific biosphere assessment modelling issues. While the scope of the report is limited to post-closure PA, overlapping issues relevant to operations before repository closure are mentioned.

A great deal of literature exists on the subject. The method of work here is not to try to review chronologically or by organisation all that has happened in the past, which would be tiresome and largely fruitless. Instead, attention is focused top down on the issues arising from the latest Swedish requirements, notably in SSI [1998a] and SKI [1997], and the relevant experience in Sweden and elsewhere that addresses those issues. At the same time, consideration is given to identification of any apparently important omissions or divergences between recent Swedish regulations and other authoritative guidance. Results from this review can then contribute to development of an assessment context for biosphere calculations. The following steps are therefore involved:

- identification of biosphere modelling issues arising from SSI [1998a] and other Swedish inputs, notably SSI [1998b, and 1999];
- comparison with recent international guidance;
- comparison with other recent national guidance;
- review of biosphere modelling in PAs for SFR and Swedish HLW projects;
- review of wider biosphere modelling developments;
- recommendations and conclusions for current biosphere modelling requirements.

2 Biosphere Modelling Issues Arising from Swedish Inputs

2.1 SSI Regulations

SSI [1998a] sets out SSI's regulatory requirements. It is brief. Account is also taken of a commentary provided by SSI [1998b], and SSI [1999]. Issues are considered under the same subheadings as in the Regulations.

Definitions

SSI [1998a] includes specific regulatory definitions of some important terms. These definitions contribute to the definitions of quantities that can form the 'endpoints' of biosphere models, i.e. they form part of the assessment context as described in BIOMASS [1998a].

It is noted here that harmful effects are limited by definition to cancer and hereditary *effects in humans* caused by ionising radiation, but that protective capability and best available technique both refer to protection of human health and the environment from the harmful effect. There is a clear intent to protect the environment, but the regulatory definition of harmful effects excludes harmful environmental effects, except those on humans.

Similarly, optimisation is defined in SSI [1998a] much as by ICRP in Publication 60, notably with consideration limited to keeping doses *to humans only* to levels that are As Low As Reasonably Achievable (ALARA), economic and social factors being taken into account. This definition is therefore not as widely scoped as the Swedish Radiation Protection Act 1988:220, which has the stated aim 'to protect humans, animals and the environment from the harmful effects of radiation' [SSI, 1998b]. On the other hand, the Best Available Technique (BAT) is defined as the most effective measure to limit the release of radioactive substances and harmful effects on human health and the environment that does not entail unreasonable costs.

Risk is defined in the regulations as the 'product of the probability of receiving a radiation dose and the harmful effects of the radiation dose'. SSI [1998b and 1999] says that ICRP Publication 60 risk coefficients should be used and helpfully discusses the probability of a harmful effect arising from a given dose. It would clarify interpretation of the regulatory definition of risk to assume the words 'probability of' in front of 'harmful effects'.

While the definitions referred to above contribute to endpoint definitions and other matters relevant to biosphere modelling, they are insufficient in themselves for the current assessment and modelling review purposes. Further components of definition and explanation are provided within the rest of the Regulations.

Holistic Approach (and Optimisation)

The Holistic Approach is not specifically defined but requires that human health and the environment shall be protected from detrimental effects of ionising radiation *during waste management operations* as well as in the future. No mention is made of a time limit here.

Optimisation 'must be performed'. This includes a specific requirement to assess collective doses, but given the definition of optimisation discussed above, not the collective dose to non-human biota. The collective dose is to be assessed integrated over 10,000 years, for expected outflows arising within the first 1,000 years. No specification is given in the regulation for the exposure group receiving the collective dose. However, SSI [1998b and 1999] indicates that 'global collective dose' is (to be) calculated.

Also within the Holistic Approach, the Best Available Technique has to be taken into consideration in solid waste management. This is defined as requiring consideration of non-human biota.

A definition is required within the PA for 'outflows', both where outflow is defined to occur and what it includes. For example, this could be from the repository into the geosphere or from the geosphere into the biosphere. In the latter case, this will involve definition of the geosphere-biosphere interface (GBI). Outflows could include man-made radionuclides in the waste, other radionuclides in the waste and/or other radionuclides in the repository/geosphere. This should be made clear before the biosphere assessment starts, either in the assessment context for the overall PA or in the context applied specifically to the biosphere part of the assessment. However, the two should be consistent. Discussion of intrusion in SSI [1998b and 1999] sets some limitations on what might be included with the assessment context.

SSI [1998a] requires impacts outside Sweden to be less than those accepted within Sweden. This requirement suggests that collective doses have to be assessed within Sweden and outside it. The results of this requirement may contradict the conclusions of optimisation and may also suggest the adoption of something other than the BAT. In addition, since no one has actually approved HLW/deep repository waste disposal, it cannot be known yet what impacts are accepted within Sweden. Even with respect to SFR, which is operational, it is not clear who constitutes the accepting constituency. Such difficulties are endemic to solving the problem of radioactive waste disposal in other countries. The implication is that future PAs should be more broadly scoped than in the past in order to provide wider input to the decision. However, this should not be confused with a requirement for greater details.

SSI [1998b] refers to the application by the Swedish utilities, after consultation with SSI, of a norm of MSEK 4 per manSv saved. This in turn was based on assumptions about what would constitute reasonable measures to prevent a statistical fatality. As reported, this does not respond to recommendations in ICRP Publication 77 and elsewhere of timing issues, intergenerational equity, and individual dose rates at which the collective dose is delivered. It also implicitly relies on an assumption that you can determine detriment based on assessments of collective dose, which in turn has specifically been recommended against by Lars Eric Holm *at the individual levels of dose likely* (SSI News, May 1998). SSI [1999] leads one into the same quandary, although explicit reference to an implied value of about MSEK 80 for a saved statistical facility is removed. Again, this is not just an issue in Swedish radioactive waste management decision making.

The relationship between optimisation and identification of the BAT is discussed in SSI [1998b and 1999]. Significantly, this recognises the difficulties of calculating long-term impacts and quantification of environmental impacts. In the short term, demonstration of protection of human health, BAT and optimisation can be treated similarly with respect to protection of human health and quantitative application of cost-benefit analysis is suggested. Such quantitative methods may not be needed with respect to protection of the environment. For the longer term, BAT may be demonstrated without a strict quantification of the relative detriments and benefits and collective doses may be calculated in a relatively simple fashion (compared with individual risks).

All this only reflects that there are major difficulties in the area of optimisation, and the related role of collective dose and individual protection issues. Nevertheless, there is a direct require-

ment to assess collective dose of some form or other within a clear time-frame. The problem is that measures taken to reduce collective dose occurring today can be more easily understood and more confidently estimated in terms of cost and health consequences than those which are intended to reduce collective doses in the far future. Given also the uncertainties in dose-risk relationships at low individual dose rates, this suggests that collective dose should be assessed across different temporal and spatial scales.

Protection of the Individual

SSI [1998a] sets a limit on annual individual risk of $1 \cdot 10^{-6}$ to a representative individual in the group exposed to the greatest risk. The explicit averaging within this (critical) group across risk and not dose is important and significantly affects decisions on Features, Events and Processes (FEPs) which are not certain to occur in a year or in a lifetime. Furthermore, SSI [1998b and 1999] says that the size of the hypothetical group is allowed to have a risk range of 100 from highest to lowest. Characteristics of exposure groups are not defined a priori, but the range in risk within the group is so large that the group could be large relative to assumptions used in some previous assessments. The quantity to be calculated and compared with the risk limit is the risk to a representative individual within the group. It is not said how you identify the representative individual within that group. Given the large range in risk, that may not be trivial. Either you decide in advance on particular assumptions for the representative individual, guessing that the risk distribution around the person within the group is two orders of magnitude, or you have to calculate the distribution within the group and then think about it. Or you might do both. This has implications for the biosphere assessment, as regards level of detail in the description of exposure groups.

While it does not say so in SSI [1998a], SSI [1998b] says and SSI [1999] confirms that this criterion applies only to undisturbed performance, i.e. not affected by human or other types of intrusion. Again, this significantly affects treatment of biosphere FEPs.

SSI [1998b] refers to just a single risk coefficient of 0.073 per sievert, which implies ignoring those genetically at greater risk than the average, or those at greater risk because of age or other factors.

Environmental Protection

SSI [1998a] explicitly requires protection of bio-diversity and sustainable use of biological resources from harmful effects. 'Biological effects of ionising radiation in *habitats and ecosystems* concerned shall be described.' The regulation may intend this to be limited to the effects of outflows from the repository. However, comparisons with background effects in the same area may also be of interest. These may contribute to informed regulatory decisions. In any event, the description shall take account of 'available knowledge of the ecosystems' *(but not the habitats?)* concerned. Given the difficulty with obtaining new and reliable information about future ecosystems, this wording could be regarded as a considerable limitation on requirements. Essentially, it is saying that you have to assess long-term impacts, but if you cannot do that without spending more money on researching future changes, you can limit your consideration to what you know already. (Such an apparent relaxation regarding the requirements for human protection does not arise.) Nevertheless, the description shall take particular account of the 'existence of genetically distinctive populations such as isolated populations, endemic species, species threatened with extinction and in general any organisms worth protecting.' The biosphere assessment therefore has to address a number of genetic and population related issues for non-human biota, but it is not explicit that these issues have to be addressed on a site specific basis. If the part on isolated populations applies within species (and it does not say it doesn't) then the level of consideration is higher than that required for humans!

Intrusion and Access

The consequences of human intrusion on the protective capability have to be reported. Thus, while the risk limit only applies to undisturbed release, the dose (and other) consequences of human intrusion do require assessment, including the effects on the intruders and the effects arising from modified outflows from the disturbed repository.

Time Periods

An assessment of the repository's protective capability shall be reported for two time periods, up to 1,000 years after closure and for the period after 1,000 years. The assessment will include a case based on assumption of biosphere conditions that exist at the time of licence application. However, there is no intent to 'freeze' the current state of biodiversity [SSI, 1999].

Quantitative analyses of impacts on human health and the environment are required of protective capability in the first 1,000 years. General discussion suggests that the risk criterion quantity would not necessarily represent a complete measure of the impact on human health. Some stakeholders may wish to know who will be effected and how. It may be suggested that the wider human health issues are covered by the requirement to assess collective doses. However, such a calculation does not address how people will be affected in health terms; the translation of collective dose estimates into health impacts in the long-term has been much criticised, but if this is not done, how is the health impact to be assessed? This is a difficult issue for waste management generally, not just SSI.

After 1,000 years, it does not say that the assessments should or should not be quantitative. But it does say that the assessment shall take account of various possibilities for the development of the repository's properties, its environment and the biosphere.

While the above points are duly noted, it may be noted that it is sometimes practical and relevant to take account of some changes within the first 1,000 years and that some features can best be dealt with effectively even after 1,000 years.

2.2 Swedish Nuclear Power Inspectorate (SKI) Inputs

SKI [1997] sets out premises for regulations concerning safety in connection with the final disposal of spent nuclear fuel, etc.

The focus is on technical features of the repository system, engineered barriers and the geosphere. However, it notes that the waste hazard does not fall to the level of the equivalent natural ore for about $1 \cdot 10^5$ years, inviting, according to SKI, safety analysis for up to $1 \cdot 10^6$ years. Structured scenario analysis is proposed to determine the behaviour of the disposal system and the kinds of release mechanisms to be assessed. Application of 'reference biospheres' is suggested for dose assessment, especially for these longer time-frames.

While different regulators have different primary responsibilities, it is reasonable to assume that Swedish regulatory authorities would wish to develop a consistent basis for regulatory supervision. There would therefore appear to be a strong incentive for some form of dose assessment, albeit not necessarily quantitative, out to $1 \cdot 10^6$ years, and hence for biosphere modelling to cover this range of time-frames.

Swedish/SKI related presentations to the NEA workshop [NEA, 1997] emphasise the use of safety indicators.

2.3 Other Swedish Inputs

Smith and Hodgkinson [1988] attempted to identify a full list of types of impact that might be addressed in a Swedish repository PA based on a review of radiological and other protection objectives. Practically, the general form of protection objectives listed does not differ from those in SSI [1998a]. The types of impact also largely correspond with those requiring assessment according to SSI [1998a].

Two additional points raised by Smith and Hodgkinson [1988] are noted here as potentially relevant. Firstly, the intent to protect the environment could reasonably include protection from non-radiological impacts. Thus the PA should address non-radiological impacts. These are not explicitly mentioned in SSI [1998a], but previous proposals (e.g. SSI [1995]) and the apparent overall intent would suggest that they ought to be addressed. See also Persson [1988]. Secondly, long-term safety and implications for environmental protection and human health could be assessed semi-quantitatively on the basis of assessed fluxes of radionuclides into the biosphere. If the repository fluxes are less than natural fluxes, then some measure of the impact of repository fluxes is obtained through comparison with the natural impacts. This point is emphasised here because of the emphasis also given to it in the ‘Nordic Flagbook’ of 1993 [Radiation Protection and Nuclear Safety Authorities in Denmark, Finland, Iceland, Norway and Sweden, 1993]. Thus, while a quantitative ‘flux’ criterion may not be helpful, information on likely fluxes of radionuclides from the repository could be useful for the longer time-frames.

3 Comparison with Recent International Guidance

IAEA's radioactive waste principles [IAEA, 1995] are specifically discussed in SSI [1998b] showing how the Regulations address each principle.

ICRP Publication 77 ICRP [1997] limits consideration to protection of man. It discusses optimisation, suggesting that collective doses should not be ignored, but should be broken down into groups exposed at different individual exposure rates and time intervals. It also says that it may be possible to disregard the collective dose from small doses to large numbers of people as may arise from widely dispersed material. It does not discuss how one might use the results of collective dose assessments beyond comparison between options. That is, no absolute requirement is defined.

Clarke [1999] discussing the ICRP Committee 4 draft Task Group report on disposal of long-lived radioactive waste has recently said that further work is required in just three areas: clearer specification of risk; the application of risk criteria to disruptive events; and more on the application of optimisation when individual risk criteria are specified. These are all very difficult areas. Concerning the latter point, a difficulty arises concerning the dose and risk assessment. ICRP have been clear in past advice that *dose assessment in optimisation should be realistic and not employ conservative assumptions*, so as to avoid misallocation of resources. Then, ICRP also say dose/risk constraints are to be used in optimisation, and dose/risk constraints are to be compared with assessed doses/risks calculated for critical groups. But then, critical group doses are to be assessed using 'cautious but reasonable' assumptions. This has been interpreted as advice to use conservative assumptions in critical group dose assessment. The overall advice from ICRP is difficult to interpret for modelling purposes because it suggests using realistic assumptions simultaneously with cautious assumptions for the parametric definition of critical groups. Proposals from Roger Clarke discussed at the International Radiation Protection Association conference in Southport (June 1999) could provide a resolution of this issue, but they also involve such wide revision of the focus of radiation protection policy that it is difficult to anticipate the outcome. The confusion on this aspect is not ameliorated in the text of a recent ICRP consultation document [ICRP, 1999]. However, ICRP do advise in this draft that it is not necessary to look at doses to different human age groups. Also, on homogeneity, they say that this should not be a major concern if due attention is paid to the choice of habits and characterisation of such a group. This latter advice would be very useful if the advice on cautious versus realistic assumptions for critical groups were clearer.

Overall, this makes it very difficult to justify particular choices of critical and other exposure group assumptions. The point is discussed in Smith and Kessler [1999] and the issue is addressed in BIOMASS [1999a]. The general trend emerging is to assess the distribution of doses and risks rather than trying to pin down exposure of just one arbitrary group.

4 Comparison with Other Recent National Guidance

Yucca Mountain recommendations [CTBYMS, 1995] include risk based homogeneity like SSI [1998a], but this is perhaps the only other example. Interpretation of what this means for biosphere modelling is interesting. For Yucca Mountain, this has been taken to mean for assessment purposes that it is acceptable to assume that the contaminant plume, which might arise in the aquifer(s) below ground at Amargosa Valley, is uniformly spread across the whole aquifer. In fact some parts of the plume would probably be effectively clean and other parts much more highly contaminated than the assumed average. This at least dilutes the risk, if not the contamination. Arguably, it also saves having to characterise the aquifer sufficiently to determine where the contamination would actually go.

Recent Finnish regulations [Finnish Radiation and Nuclear Safety Authority, 1998] include some important features similar to SSI [1998a], such as no quantitative limitation on disruptive events but a requirement to consider them. It does require assessment of doses to the most exposed and also an evaluation of doses to other exposure groups, or at least a demonstration that their doses are insignificantly low. The most exposed group is defined as 'such self-sustaining community in the vicinity of the disposal site that receives the highest radiation exposure' from expected evolution, i.e. excluding, it would seem, disruptive events. However, it is not clear what is intended by 'expected evolution'. While disruption in any particular year may be unlikely and therefore unexpected, disruption at some time in the future is, perhaps, readily expected. Self-sustaining is another term which is difficult to interpret when it comes to data assumptions for the model. BIOMASS [1999b] suggests using assumptions for critical groups such that all food etc., is obtained from local (contaminated) sources, consistent with a 'self-sustaining community', but also assuming modern farming practice consistent with current conditions, as commonly required in guidance, e.g. in SSI [1999a] under discussion of Time Periods.

The Finnish Regulations also require that 'potential impacts on species of fauna and flora shall also be discussed'. Radionuclide fluxes from the repository (excluding the natural component) to the environment are to be constrained so that impacts are less than those occurring naturally and that in any event they remain insignificantly low.

5 Review of Biosphere Modelling in PAs for SFR and Swedish HLW Projects

Previous biosphere models for Swedish PAs have focussed on assessment of doses to individuals in critical groups, e.g. Charles and Smith [1991].

Consequences to intruders have been considered for SSI [Charles and McEwen, 1991], but not consequences for the protective capability of the facility.

Flux/concentration/dose calculations have been considered in the context of HLW disposal and the implications of the environmental protection principle. These are discussed in Annex 1 of Radiation Protection and Nuclear Safety Authorities in Denmark, Finland, Iceland, Norway and Sweden [1993].

Collective doses have been considered for SFR, e.g. in SSI [1988]. There are relatively few recent examples of long-term collective dose calculations done for other countries. However, a recent example is provided in Channell and Neill [1998] in relation to the WIPP site, albeit the title of the report implies interest only in individual doses.

Direct impacts on the environment and non-human biota have not been considered.

6 Review of Wider Biosphere Modelling Developments

The IAEA's BIOMASS project is developing a Reference Biosphere Methodology and practical examples [BIOMASS, 1998b]. The Reference Biosphere concept is described in BIOMASS [1998a].

The Methodology identifies a major starting point as the assessment context, which provides basic input without which the biosphere and other parts of the PA cannot readily proceed. The components of an assessment context identified in BIOMASS [1998a] include:

- purpose;
- endpoints;
- assessment philosophy (concerning use of cautious or more realistic assumptions);
- repository type;
- site context;
- source term;
- geosphere-biosphere interface;
- time-frame;
- societal assumptions.

Input to any of the above may come directly from Regulations, or it may come from regulatory guidance or other guidance. Past assessment practice may also be relevant. BIOMASS does not make specific recommendations for any of the above but does address the modelling issues associated with alternative choices with respect to alternatives for each component.

BIOMASS has produced one fully documented Example Reference Biosphere [BIOMASS, 1999b]. Although applying only to a simply defined assessment context, it does demonstrate all the components of the Reference Biosphere Methodology.

7 Recommendations for Current Biosphere Modelling Requirements

7.1 Assessment Context Derived from the Regulations and the Background and Comments Document

The following bulleted comments arise directly from SSI [1998a], but also takes account of SSI [1998b and 1999] as discussed in Section 2. They are related to the components of assessment biosphere context, as set out in BIOMASS [1998a].

Purpose

- The purpose of the assessment is not specified in the regulations. This may be thought of as self-explanatory. However, specific consideration could be given to this issue within the SSI review programme. Notably, reporting and documentation of the review could be different in terms of level of explanation according to who is expected to read the review; and differences may arise between SFR review (licensing) and HLW PA (concept development) that in turn affect the relevant level of detail.

Endpoints

- The following endpoints should be included in the assessment. Fuller definitions are required than the short forms given here:
  - annual individual risks from expected releases from undisturbed facility;
  - collective doses from outflows in first 1,000 years integrated over the first 10,000 years;
  - radiological impacts on environment habitats and ecosystems.

Assessment philosophy (concerning use of cautious or more realistic assumptions)

- No guidance is given.

Repository type

- Not specified, no difference for deep or shallow facilities.

Site context

- Not specified, no difference for deep or shallow facilities.

Source term

- Not specified, no difference for deep or shallow facilities.

Geosphere-biosphere interface

- Not specified, no difference for deep or shallow facilities.

Time-frame

- Quantitative assessment for first 1,000 years, qualitative thereafter.

Societal Assumptions

- Assume at least a calculation case in which the conditions are the same as those at the time of licence application.

7.2 Assessment Context Derived from Wider Considerations

The next set of bullets on assessment context arises from a need for the biosphere assessment to be given a context, but where the SSI Regulations and Background and Comments [SSI, 1999] do not provide it. In this case, other inputs such as international guidance and possible expectations of stakeholders arising from previous assessment practice have been taken into account. Note that, while it is not necessary for the Regulations to provide all the features of the assessment context, it is difficult to begin the biosphere model development without these issues being addressed. The following suggestions are made as preliminary suggestions. Note however, that if SSI disagrees with the suggestions, then this could have implications for the suggestions for biosphere modelling made in Section 7.3.

Purpose

- For SFR, the purpose of the assessment is demonstration of regulatory compliance.
- For HLW, a wider range of issues arise concerning approval for site selection and development, which may have less stringent requirements associated with them at this stage, but may also require a wider range of issues to be addressed.

Endpoints

- Annual individual effective doses and annual individual radiation risks to adults who are representative members of exposure groups among those likely to be at higher risk because of habits and location. Risks to be determined from the probability of doses arising and the probability of cancer or hereditary health effect arising from those doses. Release modes to the biosphere to include undisturbed performance of the disposal system and disturbed performance. However, for disturbed performance, only doses need to be assessed and some qualitative consideration of the probability of occurrence provided. A range of hypothetical exposure groups to be considered corresponding to the range of release modes from the geosphere, including the alternative geosphere-biosphere interfaces. The range of risk within each exposure group to be 100. Exposure group definition should include how many people fall within each group. An indication should be provided of the distribution of dose within the groups assessed.
- Collective dose from outflows to the biosphere occurring within 1,000 years of site closure for the undisturbed system to be assessed and integrated out to 10,000 years after site closure. Such integral to be broken down in time-frames 0–1,000 years, 1,000–10,000 years, and also spatially, inside and outside Sweden, and also in individual dose rate bands, above 1 mSv/ year, from 0.01 mSv/y year to 1 mSv/ year, and below 0.01 mSv/ year. The lower value is chosen because of the relationship to exemption criteria used by IAEA and elsewhere.

- Environmental concentrations of radionuclides in biota and environmental media arising from outflows from the geosphere. The temporal and spatial distribution can be based on that employed to determine human exposures. These are interim endpoints that may have to be varied in light of separate work in progress on environmental risk assessment.

Assessment philosophy (concerning use of cautious or more realistic assumptions)

- Assume cautious but realistic assumptions in critical group assumptions for dose and risk calculations for comparison with individual risk criterion, but be prepared to discuss issues as in BIOMASS [1999a].
- Assume realistic assumptions for collective doses, and also calculate the dose in dose bands in different time periods and spatial locations, and individual dose rate. The nature of these dose bands will depend on the area extent and timing of the releases from the geosphere.

Repository type

- SFR repository for the low and medium level waste.
- Deep repository for HLW.

Site context

- Forsmark for SFR.
- Deep repository, site independent but Swedish territory.

Source term

- Assume outflow includes all radionuclides assessed in the geosphere model, but allow for short-lived daughters that may have been neglected in the geosphere modelling.
- Assume outflow boundary is the interface between the geosphere and biosphere models. This is a key area for interaction between geosphere and biosphere components of the PA.
- Assume wide range of radionuclides, unless specific advice provided from rest of PA. Wide range to include: C-14, Cl-36, Ni-59, Se-79, Nb-94, Tc-99, I-129, Cs-135, Np-237 and daughters, Pu-239 and daughters, Pu-240 and daughters and Pu-242 and daughters. Emphasis on different radionuclides may arise for SFR and HLW.

Geosphere-biosphere interface

- Unless advice provided from rest of PA, assumptions have to be made about gaseous, erosive and groundwater releases. Potential receiving environments are near-surface aquifers, wells into deep or near-surface aquifers, fresh and marine surface water bodies, surface soils and sediments, and bogs. Linked to source term issues, this is a key area for interaction between geosphere and biosphere components of the PA.
- Note that for a deep repository there may be no expected outflow for undisturbed performance within 1,000 years, which may make things easier.

Time-frame

- Emphasis is on the first 1,000 years. From 1,000 to 10,000 years, less emphasis is to be placed on the quantitative results. Allow that the biosphere model results may be applied to releases for longer than 10,000 years; however, the results may be interpreted differently.

Societal Assumptions

- Assume at least one calculation case in which the conditions are the same as those at the time of licence application. Alternatives should be considered to allow for environmental change as may occur over the time-frame of interest and be consistent with the other PA assumptions, e.g. the effect on groundwater flow as a result of landrise and the consequent affect on apparent sea level. A procedure for justifying management of environmental change within the biosphere part of a PA has been drafted and reviewed internationally [BIOMASS, 1998c].

Assuming that the above suggestions for assessment context are adopted, then it follows that biosphere modelling would need to be extended compared with former assessments along the following broad lines:

- To allow for assessment of a wider range of exposure groups.
- To allow for assessment of collective doses in different dose bands, time periods and spatial locations.
- To include closer integration of geosphere and biosphere aspects of the modelling at the geosphere-biosphere interfaces.
- To include evaluation of doses and dose consequences to non-humans biota.

These extensions would apply to assessments produced by SKB and to SSI's ability to review these assessments.

7.3 Implications for Biosphere Model Development

7.3.1 INTERACTION WITH THE REST OF THE PA

The requirement to consider different geosphere-biosphere interfaces arises because it is well understood (see for example, Pinedo et al [1999]) that dilution at the interface can have a big effect on dose estimates, and that the level of dilution can be largely influenced by the type of interface. This places a requirement on the geosphere part of the modelling to be carefully interfaced with the biosphere model. This is more than a matter of mathematical model boundary conditions, e.g. on groundwater flow; it also concerns the assumptions for overall evolution of the system. For example, if the geosphere modelling has taken account of climate change or sea-level change, it may appear odd if the biosphere model has not, e.g. because constant biosphere conditions have been adopted.

Such conceptual and mathematical modelling interfacing can best be handled by not separating geosphere and biosphere modelling, nor indeed near field modelling. This approach has been proposed and illustrated to SSI in Maul et al [1999], which allows time dependent changes in all parts of the system, including temporal evolution of how contaminant releases in groundwater may, for example, be discharged into the marine environment and later into a terrestrial environment as the Baltic Sea level drops. Such time dependent models do not have to be detailed; they can at least be used to take account of basic changes in the system that it could appear strange to ignore.

A well abstraction interface may or may not be included as a disturbance of the system. Either way, it represents a kind of short cut for release to the biosphere. Dilution in the groundwater or aquifer system before or as abstraction takes place is sometimes considered as a geosphere modelling issue and sometimes a biosphere modelling issue. BIOMASS [1999b] discusses the issues involved and the approach in Maul et al [1999] takes due account.

7.3.2 BIOSPHERE MODEL STRUCTURE

Individual doses and risks

The range of risk within the exposure group(s) suggested by SSI is 100. For undisturbed systems, where the probability of exposure is assumed to be unity, this means assuming larger initial dilution than in some previous assessments, since either a range of about 10 was assumed as per ICRP, or results showed that for a range of 100 then the group could be so large that it would appear to contradict any attempt to identify the individual dose representative of the group most at risk. For example, a small community obtaining all its water from a single most contaminated source may have a very narrow dose range because their doses are dominated by a single pathway associated with their water use and the particular radionuclides in the water. To achieve a range of 100 in the dose (and hence risk, assuming this is for undisturbed release) would require that the single source is mixed with a larger volume of water to achieve the range of 100. Such an assumption would not sit comfortably with the approach taken to critical group dose assessment for present day releases. It gets worse if the facility you are assessing is leaking now (present day assessment) and will continue to leak for a long time (long-term assessment). Nevertheless, the long-term aspect of repository assessment does make a difference. The point should be to provide as clear as possible justification for the model assumptions, and this in turn should be based on very clear objectives for the assessment and very clear understanding of the protection objectives.

In any event, it is not possible to choose in advance the parameters for the model such that the resulting dose distribution for the exposed group is necessarily within some specific range. One approach to solving this problem is to determine the size of model compartments not on the basis of achieving the required level of dilution such that the group exposed to those compartments has a dose range of 100, but to do so on the basis of physical adequacy of assumed instantaneous mixing within each compartment. Then carry out calculations of doses associated with unit exposure via each pathway in each part of the system, e.g. consumption of 1 kg of fish, and then use a variety of alternative assumptions to see how such unit exposures could reasonably be combined to determine the distribution of exposures. This avoids having to rely on a priori assumptions about what you expect to be critical in the assessment. A posteriori evaluation of the unit results allows more implications to be investigated.

Collective doses

The same type of conceptual and mathematical model can be used as for individual dose assessment. However, different temporal and spatial scales need to be considered, including spatial scales further from the point of release from the biosphere.

The models probably do not need to be very detailed to obtain a reasonable measure of the collective impact; for example, local drinking water consumption and use of water for irrigation may be shown to dominate total collective exposure for terrestrial releases; if realistic assumptions are used, then nearly all of this dose would be delivered at an individual dose rate less than 0.01 mSv. This can be demonstrated from examination of results of the application of models developed within the European Community [NRPB-CEA, 1979; and Smith and Lawson, 1994] and applied in assessments [Smith et al, 1987, Smith et al [1988]. (The novel thing would be to use the results intelligently.)

For marine releases, a higher proportion of collective dose arises from wider regional dispersion in the sea and fishing. Again see many EC reports on routine discharges, but Lawson and Smith [1984] for examples related specifically to solid waste disposal.

A few radionuclides, notably H-3, C-14, Kr-85 and I-129 can be very widely dispersed before they decay to insignificant levels, however that is defined. In these cases, global circulation models are required. Such models are described in Smith [1983] although a number of variants

have been produced since. Such models are relatively robust in terms of the implied long-term average individual dose rates to humans because of the knowledge of global average atmospheric mixing rates, the carbon and water cycles and studies of iodine distribution related to goitre etc; the only big uncertainty is the assumption about the number of people. Different assumptions can be made and then judgements made on the significance of the results arising. Cl-36 is a further radionuclide for which a global circulation might be required, because of its half-life and mobility. Such a model has not been developed to the author's knowledge, but no literature search has been made.

The above references provide examples of how to structure the collective dose models. Such structures can readily be incorporated into the modelling approach described in Maul et al [1999].

Environmental concentrations

The same modelling structures are likely to be very relevant for environmental concentrations as for other end points. In general, the concentrations (as would be determined according to Maul et al [1999]) are required in order to calculate the other end points. It may be the case that different temporal and spatial averaging is of interest. Also, some specific media may be of interest to environmental health protection that would not be considered for the other end points. However, they remain to be identified according to development of the environmental health protection criteria under development.

7.3.3 DATA AVAILABILITY

Sufficient radio-ecology data are generally available for some of the important radioelements, e.g. Cs, Sr, but lacking for others, e.g. Np, especially as regards the long-term behaviour and chemical form affecting the potential for accumulation in soils and sediments and hence the scope for bio-accumulation. New information is constantly coming from monitoring of previous releases to the marine and terrestrial environments. C-14 is especially difficult, but even in this case there is relevant work in progress.

Physical data to describe the biosphere systems are also generally available from work on routine releases; here the question is the justification of current system data to the long-term assessment. Use of current day analogues in other places for future conditions at the site in question is suggested. Work on Reference Biospheres within the IAEA's BIOMASS project is potentially relevant.

7.3.4 TREATMENT OF UNCERTAINTIES

Numerical methods for dealing with parameter uncertainty (e.g. Monte Carlo technique is commonly used, but SSI has investigated fuzzy sets for biosphere modelling, as reported in SSI News) are just one part of the solution. Such uncertainty analysis capability is built into Maul et al [1999]. Whatever approach is used, it is intensive in terms of effort required to provide relevant input data and to interpret the results.

Choice of particular parameter values in biosphere models for PA has rarely involved much more than selection from previous databases, mostly collated for other purposes. Of special relevance to parameter value justification is the protocol developed in BIOMASS [1999c]. This is based on ideas developed within IPSN, but with input and review from many BIOMASS participants.

A more intransigent uncertainty concerns the uncertainty at the conceptual model level arising because of uncertainties about human behaviour and the consequent effects on the evolution of

the human and natural environment. Use of a range of example reference biospheres, and the technique for developing them to specific assessment situations, are reported in detail within Working Documents produced within the IAEA's BIOMASS project, copies of which are all with SSI. Such a range of example reference biospheres has been developed with the intention of not relying on a single biosphere assumption. The aim is to explore the real dose and risk distribution (real within the context of the alternative reference biosphere assumptions for the system being assessed) and then to be able to discuss the results.

8 Conclusion

This report provides a commentary on the Swedish Radiation Protection Institutes Regulations and related guidance for final management of Spent Nuclear Fuel and Nuclear Waste. A number of issues are discussed concerning implications for performance assessment in relation to international and other national regulations and guidance. Provisional suggestions for dealing with these issues are provided leading to a proposal for the context for an assessment designed to meet SSI's regulatory requirements. This in turn is used to identify some implications for biosphere model development. These could be applicable to SFR and proposals for High Level Waste disposal. The suggestions made here are consistent with the assessment model structure and illustrations provided to SSI and reported in separate documents produced within the same work programme [Maul et al, 1999].

9 References

BIOMASS (1998a). Alternative Assessment Contexts: Implications for the Development of Reference Biospheres and Biosphere Modelling, BIOMASS Theme 1, Working Document No 2, International Atomic Energy Agency, IAEA Working Material, Vienna.

BIOMASS (1998b). Long-term Releases from Solid Waste Disposal Facilities: The Reference Biosphere Concept, BIOMASS Theme 1, Working Document No 1, International Atomic Energy Agency, IAEA Working Material, Vienna.

BIOMASS (1998c). Biosphere System Identification and Justification. BIOMASS Theme 1, Task Group 4 draft report for comment, Version 4, IAEA Working Material, Vienna.

BIOMASS (1999a). Guidance on the Definition of Critical and Other Hypothetical Exposed Groups for Solid Radioactive Waste Disposal, BIOMASS Theme 1, May 1999 Final Draft Working Document No. 3, International Atomic Energy Agency, IAEA Working Material, Vienna.

BIOMASS (1999b). Example Reference Biosphere 1: Drinking Water Well. BIOMASS Theme 1, Final Draft Working Document No 5. IAEA Working Material, Vienna.

Channel J K and Neill R H (1998). Individual Radiation Doses from Transuranic Wate Brought to the Surface by Human Intrusion at the WIPP. Environmental Evaluation Group EGG66, New Meico.

Charles D and McEwen T J (1991). Radiological Consequences of Drilling Intrusion into a Deep Repository for High Level Waste. Report for SSI, I2446-1.

Charles D and Smith G M (1991). Conversion of Releases from the Geosphere to Estimates of Individual Doses to Man. SKI Technical Report 91:14, Stockholm.

Clarke R H (1999). ICRP Main Commission Meeting, October 1998. Note in: Radiological Protection Bulletin No 209, National Radiological Protection Board, Chilton.

CTBYMS (1995). Report of the Committee on Technical Bases for Yucca Mountain Standards. National Academy Press, Washington DC.

Davis J P and Klos R (1988). Assessment of the Radiological Impact of Disposal of Solid Radioactive Waste at Drigg. National Radiological Protection Board, NRPB-M148.

EA et al (1997). Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Guidance on Requirements for Authorisation. Environment Agency, Scottish Environment Protection Agency and Department of the Environment for Northern Ireland.

Finnish Radiation and Nuclear Safety Authority (1998). General Regulations for the Safety of the Disposal of Spent Nuclear Fuel into Bedrock. Unofficial translation, June 1998.

IAEA (1995). The Principles of Radioactive Waste Management. International Atomic Energy Agency, IAEA Safety Series No. 111-F, Vienna.

ICRP (1985). Radiation Protection Principles for the Disposal of Solid Radioactive Waste. International Commission on Radiological Protection, ICRP Publication 46. Pergamon.

ICRP (1997). Radiological Protection Policy for the Disposal of Radioactive Waste. International Commission on Radiological Protection, ICRP Publication 77. Pergamon.

ICRP (1999). Committee 4. Task Group on Radiation Protection Recommendations as Applied to the Disposal of Long-lived Solid Radioactive Waste. Version TG4 6 & 9, 1999-02-24.

Lawson G and Smith G M (1984). BIOS: A Model to Predict Radionuclide Transfer and Doses to Man Following Releases from Geological Repositories for Radioactive Wastes. NRPB-R169 (EUR-9755 EN).

Maul P R, Watkins B M and Venter A (1999). Work in Support of Assessments for Solid Radioactive Waste Disposal: Biosphere Modelling and Related Amber Case Files.

NEA (1997). Compilation of National Regulations on the Disposal of Long-Lived Radioactive Waste, and other papers presented at a workshop on Regulating the Safety of Radioactive Waste Disposal, Cordoba, January 1997.

NRPB-CEA (1979). Methodology for Evaluating the Radiological Consequences of Radioactive Effluents Released in Normal Operations.

Persson L (1988). Chemical Risks from Nuclear Waste Repositories. SSI-rapport 88-16, Stockholm.

Pinedo P, Cancio D, Simon I, Aguero, A and Carboneras P (1999). The Geosphere-Biosphere Interface in Performance Assessment of HLW Disposal. Proceedings of the International Symposium on Radioactive Waste Disposal: Health and Environmental Criteria and Standards, Stockholm Environment Institute.

Radiation Protection and Nuclear Safety Authorities in Denmark, Finland, Iceland, Norway and Sweden (1986). Application in the Nordic Countries of International Radioactive Waste Recommendations.

Radiation Protection and Nuclear Safety Authorities in Denmark, Finland, Iceland, Norway and Sweden (1989). Disposal of High Level Radioactive Waste, Consideration of Some Basic Criteria: A Consultative Document.

Radiation Protection and Nuclear Safety Authorities in Denmark, Finland, Iceland, Norway and Sweden (1993). Disposal of High Level Radioactive Waste, Consideration of Some Basic Criteria.

SKI (1997). Premises for Regulations concerning Safety in connection with the Final Disposal of Spent Nuclear Fuel, etc. SKI Memorandum 97017, Stockholm.

Smith G M and Kessler J (1999). Defining and Justifying Assumptions for Exposure Groups in HLW Repository Performance Assessment. Proc. Int. Symp. on Radioactive Waste Disposal, Stockholm, Sept 1998.

Smith G M, Charles D, Robinson P C and Downing R A (1990). A review of Various Aspects of the Safety Assessment of the SFR Facility for Disposal of Low and Intermediate Level Radioactive Waste. Report prepared for the Swedish Nuclear Power Inspectorate. Intera-ECL I2137-1, version 2.

Smith G M and Hodgkinson D P (1988). Briefing Document on Alternative Criteria for Disposal of Radioactive Waste in Deep Geological Repositories. Report prepared for the Swedish Nuclear Power Inspectorate. Intera-ECL I1802-3.

Smith G M, Fearn H S, Delow C E, Lawson G and Davis J P (1987). Calculations of the Radiological Impact of Disposal of Unit Activity of Selected Radionuclides. National Radiological Protection Board. NRPB-R205.

Smith G M (1983). Models and Results for the Global Circulation of Tritium, Krypton-85, Carbon-14 and Iodine-129. National Radiological Protection Board. ADM-1(83).

SSI (1988). English Translation of Three Documents. SSI Report 88:21, Stockholm.

SSI (1995). The Swedish Radiation Protection Institute's Criteria for Disposal of Spent Nuclear Fuel. SSI Report 95:35, Stockholm.

SSI (1998a). The Swedish Radiation Protection Institute's Regulations concerning the Protection of Human Health and the Environment in connection with Final Management of Spent Nuclear Fuel and Nuclear Waste, 28 September 1998, Stockholm.

SSI (1998b). The Swedish Radiation Protection Institute's Regulations concerning the Final Management of Spent Nuclear Fuel and Nuclear Waste, draft Background and Comments, 23 November 1998, Stockholm.

SSI (1999). Health, Environment and Nuclear Waste. SSI's Regulations and Comments. SSI Report 99:22, Stockholm.

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A Methodology for Review of a Post-Closure Radiological Performance Assessment

1 Introduction

The Swedish Radiation Protection Institute (SSI) has key responsibilities for regulatory developments, assessment methodologies and modelling capabilities to ensure the safety of humans and the environment in relation to the disposal of radioactive waste. It is understood that SKB (formerly the Swedish Nuclear Fuel Supply Co, SKBF) will soon submit a performance assessment (PA) for the continued operation of the SFR disposal site for low and intermediate level radioactive wastes. For this reason, the SSI wants to develop a PA Review Methodology in preparation for the examination of such a PA. SSI's responsibility for scrutiny of the SKB PA is shared with the Swedish Nuclear Power Inspectorate (SKI).

This report has been prepared by QuantiSci Ltd as an input to the development of SSI's PA Review Methodology. The background to the SFR site and the previous SFR PA is summarised in Section 2. Implications for PA requirements in the light of recent regulatory developments within Sweden are provided in Section 3. Proposed components of a PA Review Methodology are outlined in Section 4 whilst related issues are discussed in Section 5. Conclusions are presented in Section 6; references are provided in Section 7.

2 Background to the Original SFR Authorisation Process

SFR is a repository for low- and intermediate-level wastes (LLW and ILW) that arise from the Swedish nuclear power programme. In addition, some other wastes generated by research and other uses are also disposed of to SFR. The disposal site is located at Forsmark nuclear power plant, about 150 kilometres north of Stockholm. The repository consists of a surface facility plus a sub-seabed underground facility (approximately 50 m deep) accessed via 1 km long tunnels. The underground disposal area consists of a number of rock vaults (for various types of low activity ILW) and a silo (for ILW). The latter contains most of the radioactivity.

2.1 The Original Licensing Process

The original licensing process took nearly 10 years. SKB submitted an application to construct and operate the repository in 1982. An operating permit with conditions was issued in early 1988 and permission to operate was given later in 1988 following submission of the final safety analysis report (FSAR). However, SKB had to provide additional reporting to SSI and SKI in late 1989 and 1990 on the long-term safety of the silo. Finally an in-depth safety assessment was submitted to SKI and SSI in August 1991. The basis of the evaluation of the submission was given in SKI/SSI [1994]. Permission for full operation was granted in 1992 although some conditions were still attached to the licence. A new version of the FSAR was submitted in 1993 (however, this version is not available in English).

One of the conditions of the operating licence is that a PA has to be submitted to SSI and SKI every 10 years. The next PA is due to be submitted by no later than the year 2000.

In the FSAR for SFR-1, biosphere safety case calculations were undertaken for two main scenarios. The first, associated with current day conditions, were for radionuclide releases in groundwater discharging to the marine environment of the Baltic Sea (called the Salt Water Period). Rapid transport through the geosphere was assumed. The second scenario considered a change in sea level due to land rise so that after 2,500 years the environment above the repository was considered to become terrestrial rather than marine (the Inland Period). The main assessment for this second scenario was for direct discharge of contaminated groundwater to a freshwater lake. Additional supporting calculations were provided for other potential biosphere receptors such as rivers, sediments and peat bogs as well as for a dried out lake receptor. Use of contaminated groundwater obtained from wells sunk either into the groundwater plume or directly into the SFR facility was investigated under human intrusion activity scenarios.

2.2 Objectives of the Original FSAR Licensing Review

The basis of the evaluation of the original FSAR review by SSI and SKI [SKI and SSI, 1994] was that:

- management of the spent fuel and nuclear wastes should ensure accidents and serious incidents are prevented or limited if they should occur;

- final disposal should be carried out to prevent or limit leakage of radioactive substances in accordance with the applicable criteria.

Secondary principles related to biosphere aspects of the FSAR were that:

- scenarios for the development of the repository and its surrounding should be analysed and investigated to an adequate extent;
- different kinds of uncertainties should be considered in a suitable way when formulating scenarios and making calculations.

With respect to the regulatory responsibilities of SSI, this meant determining the potential effect of any movement of radionuclides from the repository to the biosphere and the subsequent effect on man and the environment. SKB was required to demonstrate that sufficient information had been provided and suitable analyses had been carried out to support calculations of estimated doses to individuals in the near and distant future and that collective doses were within the limits set in the regulations. According to SKI/SSI [1994] the assumption used was that plants and animals are protected as individual species (not necessarily individuals within a species) if humans are protected. As discussed in Section 3, the regulatory criteria have recently changed and therefore the basis and objectives of the forthcoming SSI review of SKB's application to continue operation of SFR will have to take these regulatory changes into consideration. This aspect is more fully discussed in Smith [2000] and summarised in Section 3.

2.3 Issues Raised at Original FSAR Review

In 1994, four of the key issues that formed the basis of requests by SSI and SKI for further information from SKB were:

1. Gas formation due to corrosion of some of the engineered barrier components and the potential consequences (e.g. water displacement, crack formation).
2. The processes leading to complex formation and the consequences.
3. The rate and timing of land rise for the inland period scenario.
4. A better demonstration that consistent and logical scenario analysis had been used to support the PA.

It will be important to ensure that these issues are covered adequately in the application for reauthorisation. Issues that are likely to be of particular concern to SSI in the forthcoming licensing application are discussed in Section 5.

3 Regulatory Aspects and Implications for Performance Assessments

The starting point for any review procedure is the regulatory background against which an application will be judged. In this section a brief overview of the relevant criteria is given as a background to the proposed Review Methodology that follows in Section 4. Since the original SFR licensing procedure, radiation protection regulations have changed in Sweden. Such changes have implications for the requirement of PA calculations for the biosphere and hence how to review the submission. Smith [2000] has provided information on the new regulations and the implications for PA requirements. The following is a summary from that document in order to set the overall quantitative criteria against which the SFR re-authorisation application will need to be reviewed:

- the appropriate end points for assessing radiological safety during the post-closure period are: annual individual risks from expected releases, collective doses from outflows in the first 1,000 years integrated over the first 10,000 years, and radiological impacts on the environment and ecosystems;
- there should be a demonstration that optimisation and the ALARA (As Low As Reasonably Achievable) principles have been taken into account;
- although it is a requirement that quantitative assessments should be provided only for the first 1,000 year period, there should also be a demonstration of impacts after 1,000 years.

Smith [2000] has provided additional suggested inputs to an Assessment Context (see below) for a biosphere assessment based on the SSI regulations (and draft commentary on those regulations) and an understanding of recommendations from other international (e.g., IAEA BIOMASS) and national programmes. Following feedback from SSI on Smith [2000], a fuller checklist may be provided here.

4 A Proposed Review Methodology

The regulatory assessment of a licensing application for the continued operation of a waste repository is a very complex process. In order to judge the acceptability and validity of the applicant's safety case and to probe the submission in an informed manner, it is important that both SSI and SKI have an independent assessment capability of their own. However, it is necessary to bear in mind that SSI's and SKI's independent PA methods do not have to meet the same requirements, nor do they have to be as extensive as those developed by SKB as they will have been developed with different objectives. The applicant, SKB, has to demonstrate compliance with all appropriate regulatory criteria, whereas the regulators' methods should form an integral part of the overall review procedure and do not have to be capable of making the safety case for the applicant. For this reason SSI's and SKI's PA tools do not have to be complete, as is the requirement for SKB. Indeed, there are positive advantages in different modelling approaches being employed from those of the applicant. The key objective of the SSI and SKI modelling approaches is to be able to probe the uncertainties inherent in SKB's PA in order to test the robustness of the application.

The regulatory responsibilities of SSI and SKI are different. It is envisaged that SSI will focus on the biosphere aspects of the safety case whilst SKI will develop more of a capability with respect to the engineered barrier system and the hydrogeological understanding of the site. Nevertheless it will be important for SSI and SKI to liaise in the run up period to the licensing review in order to share information and to ensure that all important aspects of the expected submission by SKB are covered. The proposed Review Methodology which is outlined in the following sub-sections concentrates on SSI's perspective and hence on biosphere aspects and does not deal with the liaison between the regulators since this is a matter for internal policy.

It is considered that the overall objectives of the Review Methodology for the PA are to:

- determine whether SFR-1 still fulfils the requirements for safety and radiation protection in the light of the new regulatory criteria;
- investigate whether operational limitations are still appropriate;
- reveal any important gaps in SKB's safety case;
- ensure that SSI's capabilities are developed and tested in order to fulfil the regulatory responsibilities.

To meet the above objectives, it is suggested that there should be a number of key components of the Review Methodology. Each of these components is outlined in Figure 1 and explained in more detail in the following sub-sections. The horizontal line in Figure 1 divides activities that are recommended to take place before and after the submission of formal documentation by SKB. It is understood that SKB will deliver a number of pre-submission documents from the spring of 1999. These documents should form the basis of the pre-submission activities shown above the horizontal line on Figure 1. Once formal documentation of the PA application has been submitted to the regulators, Review Methodology activities shown below the horizontal line should begin.

It is proposed that the overall Review Methodology should be composed of two main types of activity. The first (shown on the left side of Figure 1) revolves around actual review of the submitted documentation. The second main activity is concerned with developing an appropriate

independent biosphere modelling capability (see Figure 1 and Sub-section 4.6). Fuller details of the development of the modelling capability are given in Egan [1999] and Maul et al [1999]. The first task of the Review Methodology is to set up the two teams, or at least to have documented those SSI staff and approved individuals or organisations from which the members of the two teams can be drawn. It is desirable that the document review team is separate from the team that develops the independent biosphere modelling capability. This would ensure that the calculations performed using the SSI capability really are independent from those in the SKB submission. However, limitations on staff time and budgetary constraints may prevent complete separation of the modelling and document review processes so if members of the two teams are drawn from the same departments within SSI or the same contractor organisations a system of 'Chinese Walls' could be used.

4.1 Document Review Procedure

Members of the document review team can be members of SSI staff or other external organisations approved by SSI. The basis for the choice of the team members should be documented. It is recommended that review team activities should be co-ordinated by one nominated person who has clearly defined responsibilities for the review process and for requesting further information from SKB.

The document review team should have responsibility for undertaking the following key components of the Review Methodology:

- assessment context;
- QA issues;
- traceability aspect;
- initial document review;
- detailed technical review.

Each of these components is described below.

4.1.1 COMPONENT 1: ASSESSMENT CONTEXT

Under the auspices of the International Atomic Energy Agency (IAEA) there is an international collaborative project to develop a Reference Biosphere methodology for use in solid radioactive waste disposal assessments [IAEA, 1996; 1998a]. As part of this project, it is recommended that a context for the assessment should be clearly specified. The Assessment Context answers fundamental questions about the PA, namely:

- What are you trying to assess?
- Why are you trying to assess it?

In a quantitative assessment these questions become:

- What are you trying to calculate?
- Why are you trying to calculate it?

In order to answer these two questions, IAEA [1998b] recommends that information should be provided on eight key Assessment Context components. These components are:

- purpose of the assessment;
- endpoints of the assessment;
- assessment philosophy;
- repository system;
- site context;
- source terms and geosphere-biosphere interface;
- timeframes;
- societal assumptions.

It is recommended that SSI should develop an Assessment Context for its own biosphere assessment based on the recent regulatory requirements. As shown in Figure 1, this document would form the basis for the development independent modelling activities. It would also provide useful input for what the Document Review Team might expect from SKB's Assessment Context in terms of the interpretation of the regulatory criteria for PAs for solid radioactive waste disposals. A commentary on the type of information that should be included and different alternatives for each of these eight components is provided in BIOMASS [1998b].

SSI should also expect SKB to provide an Assessment Context either for the whole PA or for the biosphere part of the PA. If the Assessment Context is given for individual parts of the system, then there should be no inconsistencies with other parts of the PA (such as the near-field and far-field modelling), or with the overall PA. The provision of such information in a top level document sets the scene for the whole PA and gives the regulators and the reviewers of the assessment the baseline for auditing and evaluating the safety case.

The members of the Document Review team that reviews SKB's PA should ask whether the Assessment Context:

- is clearly documented;
- is consistent with the regulatory requirements;
- provides sufficient information on each of the Assessment Context components outlined above;
- is consistent with other parts of the PA.

4.1.2 COMPONENT 2: QA ISSUES

Quality assurance (QA) is an important aspect that can help to provide confidence and documentary evidence that a PA has been conducted in a satisfactory manner. QA principles can be demonstrated throughout a PA programme but they are especially important when the PA is to be submitted to the regulators for the actual licensing of a repository.

The four main functional aspects of a PA can be considered to be:

1. Data input.
2. Models to describe and assess the various parts of the disposal system, including the conceptual and mathematical models for each of the main parts of the system (in this case the biosphere).
3. The computer codes used to run the mathematical models using the data inputs.
4. The data output or endpoints obtained from code runs, sensitivity analyses, probabilistic calculations or manual calculations.

In the examination of SKB's PA submission, SSI should be satisfied that each of these functional aspects has been designed, planned and executed with the level of QA appropriate for the task and its importance in contributing to the demonstration of safety and regulatory compliance. Maul et al [1998] have provided information to SKI on various QA standards that can be used in PAs and they also provided guidance on the application of the standards in performance assessments.

A checklist of QA related questions/issues that should be addressed in the review of the SKB documentation is given below.

Questions/ Issues	**Answer with Document Location**	**Comments**
Has an international QA standard been used?		
What standard?		
Has a QA plan for the PA been provided?		
Is the QA plan adequate?		
Is the PA organisational structure clear with key responsibilities defined?		
Have key decisions and assumptions been documented and justified?		
Is documentation of the development of the conceptual models satisfactory?		
Have model changes and associated reasons for change been documented?		
Is there adequate documentation concerning the design and approval of the computer codes?		
Is there satisfactory documentation for the testing and validation of the codes?		
Have code changes been documented and justified satisfactorily and is there evidence of version control?		
Is there adequate evidence that output from the code runs has been checked?		
Have ancillary calculations been used to support code input or output? Is the information provided adequate to fully understand what has been done?		
Has the data selection process been documented and justified?		
What methods have been used to extrapolate from site-specific data to data used in the models and codes? Are the methods suitable?		
Have key input data been checked for accuracy and appropriateness?		
Has expert judgement been used?		
Have the qualifications of the experts been documented and approved?		
Is there evidence that documents have been reviewed and output from PA tasks checked and approved?		
Is there evidence of document version control?		

4.1.3 COMPONENT 3: TRACEABILITY ASPECTS

Linked to the requirement for an appropriate level of QA in a PA development programme, there is also the need to demonstrate that all key aspects of the representation of the disposal system have been documented in a transparent and traceable manner. Guidance from the Nuclear Energy Agency (NEA) states that there should be clear, traceable documentation of the assessment process and the scientific principles underlying the assessment [NEA, 1990; 1991]. As noted elsewhere in this report, the IAEA BIOMASS Theme 1 programme is concerned with developing a traceable and justifiable methodology for developing reference or assessment biospheres. This may not be the only suitable methodology and SKB may have applied a different methodology, but the underlying principles should be similar to those being exercised in BIOMASS. An example of a specific methodology devised for recording key decisions, assumptions and omissions during development of an assessment capability (developed for potential use in the UK prior to the BIOMASS programme) is given in Grindrod [1993].

With respect to the biosphere system and its representation, SSI must be satisfied that:

- all the biosphere models and data used in the PA safety calculations adequately represent the disposal system and the environment;
- all the important scenarios for future development of the system have been considered and documented in a traceable manner;
- the decisions, assumptions and omissions used as a basis for developing the conceptual and mathematical models have been justified and documented in a traceable and repeatable manner;
- there is traceable documentation to show that the models and data have been used correctly and the results from calculations interpreted correctly;
- there is adequate documentation of where expert judgements have been used and the basis for the judgements.

Questions concerning the traceability of the biosphere representation, modelling assumptions and use of data should be asked at the stage both of the initial document review and particularly during the detailed technical audit (see Sub-sections 4.4 and 4.5 and Figure 1).

4.1.4 COMPONENT 4: INITIAL DOCUMENT REVIEW

The document review team should undertake both an initial and a detailed technical audit of the applicant's submission (see also Sub-section 4.5). The purpose of the initial document review is to assess if SKB have:

- addressed the main regulatory criteria;
- provided adequate analyses of the key technical issues together with associated uncertainties.

If it is considered that SKB have provided insufficient information on any of the key aspects of the PA, then SSI should request further information at this early stage in the PA review process. For this component of the Review Methodology, the review team members should have expertise and knowledge of each of the main biosphere issues, including:

- biosphere systems and associated data;
- climate and environment change (if this is included in the PA requirements);
- biosphere modelling and geosphere-biosphere interface issues.

The Document Review team will also form an opinion about aspects of the SKB documentation such as: the Assessment Context; QA issues and traceability aspects during this initial review stage as outlined above.

A 'check list' of regulatory criteria that need to be addressed by SKB should be produced as a fundamental basis for any consideration of the submission. A summary list of the regulatory requirements is given in Section 3. If an initial review of the submitted documentation shows that one or more of the regulatory requirements has/have not been addressed then a request should go back to the applicant for more information. Similarly, if any aspect of the PA does not match the stated Assessment Context (see Sub-Section 4.1) then SKB should be asked to provide clarification. A judgement may have to be taken as to whether it is appropriate to continue with the next stages of the PA review procedure or whether the omission is so fundamental that a response from the applicant is required before proceeding further.

A second part of the document review is a check that the overall basis of the PA biosphere calculations has been satisfactorily documented and that all necessary supporting documentation is available. Again, any omissions or inadequate documentation should result in a request for further information. The documentation should provide information on:

- the geosphere-biosphere interface assumptions;
- the basis for the scenarios to be analysed;
- the basis for the selection of critical and other exposure groups for which dose calculations are made;
- the development of the biosphere models;
- analyses of calculations (from main code runs and additional supporting calculations) that demonstrate that continued operation of the site is safe from a human and environmental perspective.

It should be possible to make comparisons between the information provided by the applicant and what SSI has documented in their own biosphere model development and understanding of radionuclide transport impacts in the surface environment. Such comparisons can be used to identify key technical areas that require particular attention in the subsequent detailed technical reviews.

4.1.5 COMPONENT 5: DETAILED TECHNICAL REVIEW

The detailed technical audit of the submission is bound to be a complex task involving many different technical disciplines. It is important therefore that prior to a detailed technical review audit of the applicant's documentation, a review guidance document should be issued to the review team members. The team should be briefed as to objectives, scope and timescales for the technical audit procedure. The guidance document should be available at least in draft form prior to the submission, but may need to be amended in the light of the format of the documents received and the details of the PA included in actual licensing application. The review guidance document should include:

- brief descriptions of the scope and purpose of the document(s) to be reviewed;
- information on how the review is to be divided up and undertaken by review team members;
- a list of key technical issues to be given priority in the detailed audit (partly derived from the independent biosphere modelling and calculations undertaken by SSI);
- check lists to be used to identify the completeness of the assessment approach and results in each main technical area.

By the time the licence application has been submitted, a detailed list of biosphere features, events and processes (FEP list) will have been developed for use by SSI [Egan et al, 1999]. The FEP list will also have formed the basis for the independent biosphere model development and calculations [Maul et al, 1999]. The SSI Biosphere FEP list should be used as a basis for mapping the FEPs included in SKB's scenario development and biosphere modelling. Further information should be requested from SKB in the event of any of the following:

- information is unavailable to determine what decisions or assumptions were used as the basis for any of the key biosphere scenarios that have been modelled;
- the applicant's documentation shows that a potentially significant feature, or event or process has been omitted;
- significant modelling and/or data decisions have been taken where alternative approaches are clearly possible and where the alternatives have not been satisfactorily ruled out by the applicant;
- adequate justification for the modelling assumptions and data used has not been provided;
- the technical audit has raised doubts about the correctness or accuracy of the biosphere PA calculations (if necessary, the SSI biosphere modelling team could be asked to undertake parallel calculations for comparison).

The detailed topic specific checklists and the final review procedure guidance document would need to be prepared following SKB's formal submission and development of SSI's independent biosphere modelling capability. However, draft checklists could be prepared if SKB's pre-submission documentation is sufficiently detailed.

4.2 Component 6: Independent Biosphere Modelling

As noted above, without an independent assessment capability it would be very difficult for SSI to judge the acceptability of SKB's biosphere calculations, particularly the validity of the use of any of the expert judgements used for important modelling decisions. The development of independent biosphere model and calculations has the following advantages:

- the experience gained places SSI in a much better position to be able to identify shortcomings in the re-authorisation application;
- public confidence in a decision on the application will be greater if safety has been assessed using different methodologies with consistent conclusions;
- selected aspects of SKB's PA can be examined in detail using relevant components of the independent model(s).

The independent PA calculations do not have to be 'complete' in the way that those of SKB have to be. However, the development of an independent biosphere model (or models) leads to a much greater understanding of the site and the potential consequences of any radionuclides released to the environment. Although models should have been developed independently, data used for model calculations may be the same site-specific data as that provided by the applicant in appropriate documents.

A reference document should be produced which gives details of the SSI biosphere modelling capability. Important issues should be described adequately and the reasons for modelling decisions should be documented in order to provide a good audit trail. In the same way of course, SSI will expect to see the same from SKB. Important issues include:

- identifying, justifying and describing the biosphere systems which form the basis of the model development;
- setting the principles by which critical or other exposure groups will be identified and for whom dose calculations will be performed;
- methods used to develop the conceptual and mathematical models;
- information on the code(s) used to set up the mathematical models;
- analyses of calculations performed.

SSI have been participating in the IAEA BIOMASS Theme 1 programme and relevant documents which give further information and guidance on the methodologies recommended for establishing such a clearly traceable audit trail include IAEA [1998 a, b] and BIOMASS [1998 a, b, c, d, e; 1999].

A further important issue is the treatment of the geosphere-biosphere interface. This is discussed in Maul et al [1999].

4.3 Component 7: Summary Documentation

At the end of the review methodology, SSI will have the following information:

1. SKB's PA submission for re-authorisation of SFR.
2. The results of the initial document review plus information on the QA and traceability of SKB's PA development process.
3. The results of the detailed technical audits.
4. Documented results of SSI independent biosphere calculations.
5. Any further information from SKB requested under activities associated with 2), 3) or 4).
6. Information on any important, but unresolved issues.

Information from all these six aspects should be set out in a summary document. Information from the perspective of SKI's scrutiny of the submission should also be summarised. The document would thus bring together information on the regulatory criteria and methods used by both the proponent and the regulators to test if these criteria have been met. This information would therefore provide the basis on which the regulatory decision will be made (Figure 1). An example of such a document from the original authorisation process is SKI/SSI [1994].

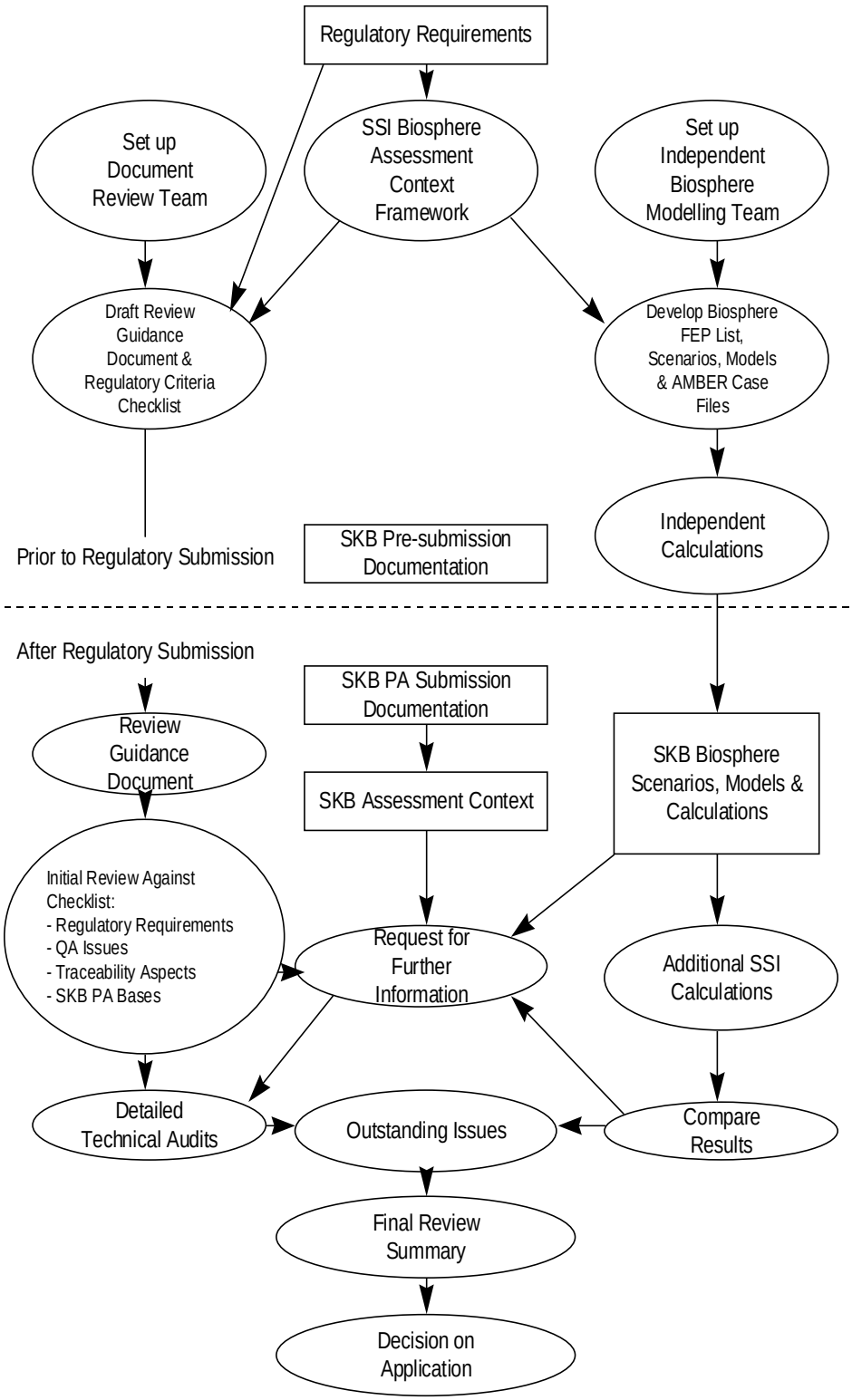

Figure 1
Overview of Suggested SSI Review Methodology.

5 Special Issues of Concern

A number of particular issues, either raised in the previous PA, or of special concern need to be borne in mind during a regulatory review of a licensing application. For example, issues may be raised due to the changes in the regulatory context for the new PA. These changes may mean that approaches used in the original PA, and which have been re-used in the new submission, are no longer consistent with the new regulations. It will be important to check for any inconsistencies. In particular, there is now a requirement to consider impacts not just to humans, but also to other, non-human, species. SKB should demonstrate how this issue has been addressed.

As noted in Section 2.3, in 1994 SSI and SKI required clarification from SKB for a number of points. The regulators will need to be satisfied that such issues have been adequately addressed in the new PA.

One issue of concern is the rate and timing of land rise. In the original PA application, SKB calculated that the so-called Inland Period would occur after 2,500 years. However, information suggests that the rate of land rise is faster than originally calculated and that the Inland Period could begin after 1,000 years [SKB and SSI, 1994]. The consequences of the different land rise rates on calculated environmental impacts need to be assessed.

Another related issue is how to model the transition period between the Salt Water Period and the Inland Period. A key consideration is the geosphere-biosphere boundary and how this should be represented in models developed by SKB and independently by SSI. In addition, the question of whether to include other time-dependent processes in the biosphere model should be addressed and if so how.

The boundary conditions and associated assumptions for the near-field, geosphere and the biosphere models need to be clearly specified. Such assumptions have impacts on how the models are set up and the required data to run the models.

Furthermore, many biosphere processes are time dependent but to model such processes requires a different approach from that used to model individual scenarios or snapshots of the biosphere and environmental change. SSI need to be satisfied that the approach used by SKB is well justified and is adequate to meet the regulatory requirements.

In the original PA, most attention was given to a groundwater release type. However, corrosion of metal components in the wastes and engineered barriers and the volatile nature of some of the inventory radionuclides could result in the generation of radioactive gases. The implications of a gas release (e.g. C-14, H-3, Cl-36, Se-79 and I-129) to the biosphere during the Inland Period should be addressed either in the main part of the PA or in additional calculations.

Other issues may become evident either during the development of SSI's independent modelling capability or during any stage of the review of SKB's submission. Such issues should be noted and followed through with the appropriate people from the relevant organisations.

6 Discussion

The proposed review methodology presented above is designed in the context of a formal submission by SKB for the re-licensing of the SFR disposal facility. The overall review process is divided into those activities that should precede and those that should follow the formal submission. Prior to the formal submission, SSI will have to consider any interim documentation supplied by the applicant. In this situation, the full procedure will not be appropriate, but some of the key features can be exercised in the production of draft guidance to the review and model development teams.

Key features of the suggested methodology are:

- the use of two teams of experts; the first for reviewing the documents submitted by SKB and the second to develop an independent biosphere modelling capability to probe the applicant's PA biosphere calculations;
- general and detailed examination of the submissions assisted by review guidance documents and relevant checklists;
- the production of a summary document to clarify the key issues on which the regulatory decision is made.

7 References

BIOMASS (1999). Guidance on the Definition of Exposure Groups for Solid Radioactive Waste Disposal. BIOMASS Theme 1: Draft WD3 (IAEA Working Material).

BIOMASS (1998a). Guidance for the Application of Data to Assessment Models. BIOMASS Theme 1: Draft Task Group 2 Working Document (IAEA Working Material).

BIOMASS (1998b). Revised Set of Example Assessment Contexts. BIOMASS Theme 1: Task Group 3, Note 1, Version 1.0 (IAEA Working Material).

BIOMASS (1998c). Biosphere System Identification and Justification. BIOMASS Theme 1: Task Group 4 Report, Version 4.0 (IAEA Working Material).

BIOMASS (1998d). Biosphere System Descriptions. BIOMASS Theme 1: Task Group 5 Report, Version 2.1 (IAEA Working Material).

BIOMASS (1998e). BIOMASS Reference Biosphere Examples 1A and 1B. Task Group 6 Report, Version 2.1 (IAEA Working Material).

Egan M J (1999). Work in Support of Biosphere Assessments for Solid Radioactive Waste Disposal: Biosphere FEP List. QuantiSci Report to SSI. Report No. SSI-6181A-3, V 1.0.

Grindrod P (1993). Uncertainty and Bias Audit. Report No. TR-Z1-12. Available from the UK Environment Agency, London.

IAEA (1996). Themes for a new co-ordinated research programme on environmental model testing and improvement. Theme 1: Radioactive Waste Disposal. Theme 2: Environmental Releases. Theme 3: Biosphere Processes. International Programmed on Biosphere Modelling and assessment Methods (BIOMASS), International Atomic Energy Agency, Vienna.

IAEA (1998a). Long-term Releases from Solid Waste Disposal Facilities: The Reference Biosphere Concept. BIOMASS Theme 1, Working Document No. 1.

IAEA (1998b). Alternative assessment contexts: Implications for development of Reference Biospheres and biosphere modelling. BIOMASS Theme 1, Working Document No 2. IAEA Working Material.

Maul P R (1994). HMIP Assessment of Nirex Proposals Performance Assessment Project (Phase 2). A review procedure for post-closure performance assessments of LLW and ILW repositories. Report No. TR-Z2-14.

Maul P R, Watkins B M, Salter P and Mcleod R (1998). Quality Assurance in Performance Assessments. Report No. SKI-6068A-1, Version 1.

Maul P R, Watkins B M, Egan M J and Penfold J S (1999). Work in Support of Biosphere Assessments for Solid Radioactive Waste Disposal: Biosphere Modelling and Related AMBER Case Files. QuantiSci Report to SSI. Report No. SSI-6181A-4.

NEA (1990). Disposal of High-Level Radioactive Waste: Radiation and Safety Criteria. Proc. of NEA Workshop, Nuclear Energy Agency, OECD, Paris, France.

NEA (1991) Disposal of Radioactive Waste: Review of Safety assessment Methods. Nuclear Energy Agency, OECD, Paris, France.

SKI/SSI (1994). Evaluation of SKB's in-depth safety assessment of SFR-1. SKI Report 94:30, SSI Report 94-19.

Smith G M (2000). Work in Support of Biosphere Assessments for Solid Radioactive Waste Disposal: Requirements for Performance Assessments Based on Swedish Regulations and Criteria. QuantiSci Report to SSI. Report No. SSI-6181A-1, V 1.0.

M. EGAN, M. LOOSE, G.M. SMITH (1999)
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Development of Criteria for Radiological Protection of the Environment

1 Introduction

1.1 Background

The most recent statement of ICRP policy relating to disposal of radioactive waste [ICRP, 1998] identifies 'safeguarding the environment' as one of the goals of waste management. However, this policy has been developed exclusively from fundamental policy on public exposure; indeed, it has to be borne in mind that ICRP's remit is confined to the protection of man. Hence their primary concern in identifying environmental protection as a specific objective is to ensure that human health is safeguarded through adequate protection of the different environmental resources that may in some way be exploited by human communities.

In current regulatory practice, concerns for protection of the environment from the potential adverse effects of radiation exposure have typically been addressed through reliance on the assumption that protection of humans to the required standard will result in adequate protection of non-human organisms and hence, by implication, the environment as a whole. For example, the latest formal guidance from the UK regulatory agencies on requirements for authorisation of solid radioactive waste disposal [Environment Agency et al., 1997] specifically excludes consideration of non-human biota on this basis.

Thus, quantitative criteria used to determine the regulatory requirements for radiological protection (including radioactive waste disposal) are typically focused on limiting the effects on those humans who are assessed to be at greatest risk of exposure, whenever this might occur. In certain regulatory contexts, criteria related to radiological impacts at a group, or population, level (based on collective dose) have also been developed, with the aim of demonstrating that protection has been optimised. Although interest grows in dealing explicitly with non-human impacts [Smith, 2000], the focus has generally remained on human health protection.

Concern for protection of the environment from the potential radiological impacts of radioactive waste disposal is not a new issue. Studies of the effects of radiation on fauna and flora have been undertaken for many years, and the available information is regularly reviewed and summarised (see, for example [NCRP, 1991; Pentreath, 1996; UNSCEAR, 1996]). More recently, the UK Environment Agency commissioned an extensive review of relevant research [Woodhead, 1998]. Indeed, it may be noted that the conclusions of this latter review effectively contradict the justification given by Environment Agency et al. [1997] for excluding consideration of effects on non-human biota from regulatory guidance.

Statements of basic radiological safety principles (such as those relating to the management of radioactive wastes) have occasionally highlighted the significance of environmental protection issues. For example, the IAEA's fundamental safety principles in relation to radioactive waste management [IAEA, 1995] include several statements that have implications, either directly or indirectly, for environmental protection. In particular, Principle 2 states 'radioactive waste shall be managed in such as way as to provide an acceptable level of environmental protection'. The associated commentary notes that exposure of non-human organisms should be taken into consideration. Unfortunately, such statements have not, to date, been supported by guidance (formal or informal) on how the principles are to be applied in practice.

However, this situation is changing. A number of countries, including the USA [1993] and Canada [1997], are moving in the direction of the use of quantitative standards for radiological pro-

tection of the environment. The Swedish Radiation Protection Institute (SSI) is also currently investigating how a suitable regulatory framework can be developed. They and other organisations have recognised a need for more explicit consideration of the radiological protection of non-human organisms and environmental systems in regulatory practice [Amiro et al., 1996; SSI, 1998]. Through this project, QuantiSci is providing support to assist in the development of a suitable regulatory framework, with particular emphasis on the long-term impacts of radioactive waste disposal, and consistent with the principles outlined by SSI [1998] and IAEA [1995].

Several factors have contributed to the current perceived need for a broader basis to govern radiological protection of the environment. First, there is an increasing recognition of the imbalance of present approaches in the light of fundamental principles for sustainable development, such as those embodied in the Rio Convention [UNCED, 1992]. This has provided support to various stakeholders, including influential NGOs, in articulating a straightforward desire for more explicit recognition of environmental issues in the decision-making process. In this light, the assumption that '… the standard of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk' [ICRP, 1991] is seen as technically inadequate because the desired level of protection is not specified and compliance with environmental protection objectives cannot therefore be demonstrated [IAEA, 1998].

Second, the premise that adequate protection of non-human organisms is secured through satisfactory protection of the most exposed human individual itself incorporates caveats that are not always recognised in practice. In particular, although modelling studies have concluded that the assumption is likely to be reasonable in many circumstances [IAEA, 1992], the conclusion does not necessarily hold for disposal of radioactive wastes in locations remote from man [Pentreath, 1996]. The Russian Federation is, for example, developing criteria for the protection of arctic ecosystems [Sazykina and Kryshev, 1999].

Hence, although some safety assessments for radioactive waste disposal may have demonstrated adequate safety from the current regulatory perspective, through using a range of safety indicators, wider audiences have not always been persuaded that all the relevant environmental issues have been addressed.

1.2 Document Overview

The aim of this report is to provide research input to the development of radiological protection framework for the environment, for use in Sweden. This is achieved through a review of various approaches used in other fields, demonstrating how environmental protection concerns are currently being addressed in various different contexts. In particular, the report includes:

- a reflection on basic premises underlying an environmental protection framework (Section 2);
- a review of concepts, techniques and standards used across a broad spectrum of industries to address environmental protection in relation to hazardous releases and emissions from a non-radiological standpoint (Section 3);
- a summary of the way in which environmental protection is currently addressed in existing national regulations and regulatory guidance for solid radioactive waste (Section 4).

Finally, in Section 5 of the report, we identify some of the main features and requirements that we consider appropriate in the formulation of a formal system of radiological protection for the environment. Here, we note that Pentreath [1999] has recently outlined some initial ideas for the structure of such a system, suggesting how it might be developed, consistent with current radiological protection approaches used for man. The recommendations we present here are perhaps

not as comprehensive as those identified by Pentreath; however, we believe that – in approaching the issue from a slightly different standpoint – we have arrived at broadly consistent conclusions.

2 Basic Premises

In addressing radiological protection requirements for public health, Pigford [1999] has recently underlined the essential requirement that regulatory standards should be developed consistently from a given set of principles and ethical goals. The same will also be true in relation to the development of a system for radiological protection of the environment; such a system has to be developed from a clear set of objectives and principles.

The authors of this report profess no formal ethical or philosophical expertise from which to develop a necessary set of fundamental values and goals. Nevertheless, before giving detailed consideration to the practical concepts, performance measures and assessment approaches that have been used elsewhere in different contexts, it is useful to reflect on what is signified by the key words 'environment' and 'protection'. This is not simply a question of technical definition; whether or not the assumptions are made explicit, such basic premises will inevitably underlie any criteria used in regulatory or other performance measures.

2.1 Environmental Ethics

A general discussion of the ethical basis for environmental protection policy is beyond the scope of this report. Nevertheless, as is clear from the quotations that preface this report, the earliest written texts recognise a tension between the exploitation of the environment to support human life and a parallel responsibility of stewardship. Science alone is insufficient to provide an interpretation of general propositions such as sustainability and the precautionary principle (see Section 3.1). Decisions over the potential release of pollutants to the environment raise questions of values that cannot be answered simply by referring to the scientific evidence.

For example, an anthropocentric environmental ethic may use measures of detriment that relate principally to the 'value' of environmental resources as perceived by human society. Consideration of the tolerability of releases of pollutants therefore tends to be restricted to the extent to which impacts on the environment may somehow affect human measures of quality of life. Hence, for example, the loss of rainforest or coral reef is deemed undesirable because of the value that we attach to the organic richness, ecological complexity and systemic coherence of such habitats [Schönfeld, 1995]. Similarly, the loss of endangered species and priority habitats is considered undesirable because of the importance society assigns to biodiversity.

This, in turn, implies the use of environmental protection objectives that draw on considerations of limits to the assimilative capacity of the environment before effects are observed at the system, or population scale. Indeed, as a general rule, standard ecotoxicological practice is to focus concern on populations and communities and their ability to reproduce themselves, rather than on the deaths of, or harm to, individuals [RCEP, 1998].

By contrast, a 'deep green' ethic submits that environmental degradation is undesirable in general, rather than simply to the extent to which it impacts on human interests and sensibilities. This concept of an 'intrinsic value' in nature invokes broader considerations of the 'interests' and well-being of non-human beings, to the level of individual organisms. Moreover, because ecological integrity can be considered as a 'goal state' of an ecosystem, such integrity is, in itself, a positive value.

A clear dividing line needs to be drawn between analysis of the scientific evidence and the ethical and social considerations that are necessarily part of policy decisions [RCEP, 1998]. For example, the adoption of cautious discharge limits because of scientific uncertainty regarding

environmental detriment is necessarily distinct from a value-based judgment to minimise all traces of contamination by human activity. It is perhaps interesting to note that, in some areas, (see e.g., [OSPAR, 1998]) policy is tending to become shaped as strongly by the latter consideration as the former. However, it is not obvious that such policy developments take due account of either the environmental risks inherent in 'favoured' alternatives (e.g. indefinite storage/containment rather than final disposal), or the wider ethical implications of ceasing waste producing activities altogether.

2.2 The Environment

SSI's regulations on protection of human health and the environment related to radioactive waste disposal [SSI, 1998] require that 'biological effects of ionising radiation in habitats and ecosystems shall be described'.

Strictly, the *biological* effects of ionising radiation can only be realised in the biotic components of ecosystems. Non-biological effects of radiation may occur in non-living constituents of ecosystems, but the inherent quality of such media will only be affected in situations where significant neutron irradiation may be involved. This is very unlikely to be the case in situations relevant to radioactive waste disposal.

Nevertheless, it is possible to conceive of situations in which impacts on abiotic media (soils, sediments, air and water) may indirectly arise if plants, animals or other organisms are affected [IAEA, 1998]. In such circumstances, the overall impacts on the ecosystem can encompass both biological and non-biological effects. Conversely, it is the migration and accumulation of radionuclides within abiotic media that potentially provides the contaminated environment within which biological organisms may be exposed.

Because of such interactions, the overall 'target' of concern in environmental protection is typically taken to include both the living and non-living components of the biosphere. Both the components themselves, and the way in which they are organised and function together, are therefore covered by the goal of environmental protection.

Swedish regulations [SSI, 1998] also suggest that analysis should be based on 'available knowledge on the ecosystems concerned'. Clearly, for a particular industrial practice with a limited operational lifetime, the neighbouring, present-day environment represents the predominant concern. On the other hand, even where limited information is available (for example in the context of the long-term impact of solid waste disposal), lack of knowledge should not be permitted to justify a potentially inappropriate practice. It is acknowledged that descriptions of the biosphere adopted for the purpose of long-term radiological assessments can, at best, provide only a representative indicator of the radiological impact of future releases [BIOMASS, 1998]. However, such indicators, when integrated with understanding arising from assessments of the behaviour of the disposal system as a whole, can provide an input to decisions regarding the acceptability of long-term system performance. This is equally as true for measures of the potential impact on the environment itself as it is for human health impacts.

As such, the indicators must be sufficiently representative to provide a suitable degree of assurance, consistent with the overall objectives of the performance assessment. In the development and application of criteria relevant for long timescales, it is therefore important to consider the extent to which identified indicators of radiological impact should be specific to the present-day situation local to a particular site. Nevertheless, it is pertinent to note, that the use of quantitative measures of impact as a basis for decision-making in relation to timescales of many thousands of years is unknown outside the field of radioactive waste management, even though other environmental hazards may be similarly persistent.

2.3 Protection

In understanding what is intended by protection, the fundamental question to be addressed is: Protection from what? Broadly speaking, the goal must be protection of the environment from 'harm', where the definition of harm provides the instrument for expressing ethical values (see Section 2.1).

It has been noted (see, for example [Webb, 1999] and [Pentreath, 1999]) that many effects have been studied in experimental work concerned with the effects of radiation of organisms other than man. These include:

- chromosome mutation frequency;
- effects on immune systems;
- physiological changes;
- effects on fertility and fecundity;
- life span shortening;
- community diversity reduction.

Protection of the environment, in the context of SSI's regulations [SSI, 1998] is explicitly identified with upholding biodiversity and the sustainable use of biological resources. As suggested above, the quantitative interpretation of these objectives ultimately demands scientific and political, social and ethical judgments. Indeed, if the basis on which goals are established is unclear or inconsistent there may be confusion when specific targets are attached.

Here, it is interesting to note that SSI's regulations also stress that the description of radiological effects should give particular emphasis to 'the existence of genetically distinctive populations'. The implication of this is that value is here attached to the overall viability of the community, with special concern for its most vulnerable components. By demonstrating a lack of detrimental effects to the viability of particular susceptible 'indicator species', there should be no harmful effects on the community as a whole, or an ecosystem in general [IAEA, 1998].

Clearly, there is no single, obvious answer to the problem of defining what is understood by 'environmental protection'. Without such a definition, however, it is difficult to have a clear basis for the development of criteria to achieve such a goal. Proper definition of these goals should therefore be considered fundamental to a coherent framework for radiological protection of the environment.

3 Standards for Environmental Protection

Environmental standards used in environmental protection regulation take many different forms; they differ in their stringency, in their force (e.g. as mandatory requirements or simply as guidance), and in their stability. The review presented here is not intended to be exhaustive, but an attempt has been made to characterise the main forms that environmental standards can take. Overall guidance in developing the review has come from recent reports by the UK Royal Commission on Environmental Pollution [RCEP, 1998] and the Institute for European Environmental Policy [Haigh, 1996]. Where appropriate, reference has been made to specific guidance on individual topics.

The discussion separates those quality standards that relate to environmental pathways (e.g. air, water and land, emissions standards) and those that relate to process and management performance (IPC, BPEO, EMAS, etc.). First, however, in recognition of the fact that the general scope of environmental protection has widened significantly in the last decade following various international initiatives, attention is focused certain basic principles. In particular, since the 1992 Rio declaration [UNCED, 1992], the sustainable development paradigm has been generally adopted as the foundation from which environmental protection standards should be derived.

3.1 Sustainable Development

The Brundtland Report [WCED, 1987] defined sustainable development as:

> '… a process of change in which the exploitation of resources, the direction of investments, the orientation of technological development, and institutional change are all in harmony and enhance both current and future potential to meet human needs and aspirations.'

The basic aim embodied in the concept has been summarised as ensuring that the demands of the present generations do not compromise the ability of future generations to meet their own needs. It is therefore seen as necessary to protect the environment in order to safeguard the future well being of man.

Concern for the future impacts of today's decisions has led a strong link in international policy and law-making between sustainable development and the precautionary principle [UNCED, 1992; UNECE, 1990]. In essence, this requires that: (a) measures should anticipate, prevent and address the causes of environmental degradation; and (b) where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures.

Despite – or perhaps because of – the general validity of these principles, they necessarily involve questions about values, relating to the interpretation of terms such as 'development', 'serious or irreversible', and 'full scientific certainty'. Clearly, there is a need to adopt a rational response to uncertainties in scientific evidence, but practical expressions of that response invoke questions of beliefs, attitudes and values that are rooted in culture, economics and politics. Its apparent ability to mean 'all things to all men' has meant that sustainable development has come to be seen and used largely as a political tool, rather than a guide to practical decision-making.

One approach to addressing the sustainable development paradigm is to use the 'capacity' of the environment as a planning tool, identifying thresholds to the changes that can be endured before something valuable and irretrievable is lost. However, there are real practical problems to be addressed in attempting to quantify environmental capacity without resorting to crude cost-benefit tools. Moreover, a distinction needs to be drawn between the practical application of such an approach in the context of spatial planning and for pollution control.

On the one hand, the idea of a 'space' within which development is permitted to occur may help to frame siting decisions under conditions of environmental sensitivity or scarcity. This has found some support in the context of general controls on land use [CPRE, 1993]. By contrast, the concept of an 'assimilative capacity' for environmental contamination has fallen into disrepute in some circles. This is partly because of past failures to recognise all potential uses and functions of particular ecosystems, or to anticipate the fate of persistent substances and the possible combined action of chemical mixtures [RCEP, 1998; ENDS, 1998].

Various agencies have attempted to incorporate the sustainable development paradigm and the precautionary principle into environmental standards. Ultimately, however, these have inevitably leaned towards general statements of principle, such as 'ensuring that decisions throughout society are taken with proper regard to their environmental impact' [United Kingdom, 1994], rather than leading directly into quantitative regulatory goals. Nevertheless, within Europe, process standards geared towards integrated pollution prevention and control (see below) have stemmed from attempts to balance sustainable development objectives against present-day practicalities.

3.2 Process and Management Standards

Best practice standards that identify process techniques and management approaches, rather than 'acceptable' environmental concentrations or exposures, play an important role in environmental protection and regulation for many industries. However, not all such approaches are applicable in the context of waste disposal, where the emphasis is developing satisfactory approaches for controlling long-term environmental impacts from a specific, localised source. For example, product life cycle and materials 'use' standards (see, for example, [EC, 1976a; 1992]), relate to the minimisation of overall environmental burden, rather than the direct control of the hazards themselves.

Consideration is nevertheless given here to certain concepts and standards for environmental management that have found broad general application. In particular, the basic concept of integrated pollution control (IPC) or, more widely within Europe, integrated pollution prevention and control (IPPC) is to establish regulatory standards on the control of industrial processes capable of causing significant environmental pollution. Associated with this are appraisal tools and regulatory mechanisms (e.g. BATNEEC and BPEO, see below) aimed at optimising overall environmental performance. In addition, management standards are increasingly being applied to provide assurance that operators are 'fit and proper' to conduct their business with due respect to the environmental impacts of their operations.

3.2.1 BEST AVAILABLE TECHNIQUE NOT ENTAILING EXCESSIVE COST

The aim of applying an integrated approach is to ensure that an overall view is taken on the potential environmental burden where substances from the same process could be released to different media. The European Directive on IPPC [EC, 1996a], which covers a larger number of processes and a wide range of substances, is due to be transposed into national legislation within the European Union by October 1999.

Under existing UK law [United Kingdom, 1990], the operator of a prescribed industrial process is required to prevent the release into any medium of substances prescribed for that medium. Alternatively, where prevention is not practicable using the 'best available techniques not entailing excessive cost' (BATNEEC), such techniques should be used to reduce releases of substances to a minimum and render them harmless. The new Directive uses BAT (best available technique) rather than BATNEEC as the criterion for process standards; however, the definition of 'available' includes consideration of costs and refers to 'implementation … under economically … viable conditions'. In practice, therefore, there may well be little different between the two [RCEP, 1998].

At its heart, BATNEEC (or BAT) is therefore essentially a qualitative process standard, rather than a definitive 'licence to pollute'. Rather than prescribing specific solutions, or acceptable emission levels, the regulator has the scope to exert pressure on the operator continually to improve performance against general objectives. Nevertheless, guidance on best available techniques (together with presumptive limits on emissions, representing the performance that the specified techniques can be expected to achieve) is published by the regulator. Under the IPPC Directive, BREFs (BAT Reference Documents) are to be published by the European Commission every three years. The competent authorities are then responsible for considering the reference documents (alongside relevant EC legislation and international conventions) in decisions for particular sites.

A fundamental aspect of BATNEEC is that it provides for dynamic, rather than static, regulatory control over environmental protection. Irrespective of any limit values on emissions and environmental concentrations contained in any authorisation, the operator remains under a general obligation to use BATNEEC, where the 'best' will change over time as techniques improve. At the same time, in establishing such authorisations, the regulator must take into account practicability considerations, including the extent to which market conditions allow abatement costs to be met by a 'representative' operator.

For these same reasons, however, the concept has somewhat limited utility in the context of long-term impacts of solid waste disposal, except perhaps in some current trends favouring long-term retrievable underground storage rather than final disposal (see e.g. [United Kingdom, 1999]). A permit to close a waste disposal facility is a 'once for all' decision that is not readily amenable to review if new technological solutions become available. Indeed, whereas IPC/IPPC provides a dynamic vehicle for implementing sustainability principles – including waste minimisation – through BATNEEC [UKDoE, 1996], it is much less clear how such principles would apply in regulating waste disposal practices.

Moreover, BAT and BATNEEC decisions on individual plants are usually (except perhaps in the case of 'greenhouse gas' emissions) taken in isolation, ignoring the marginal contribution to broader regional or even global cumulative impact. For decisions concerning the long-term acceptability of waste disposal, it can be relevant to consider the cumulative effect of many practices, and not just that of a current practice.

3.2.2 BEST PRACTICABLE ENVIRONMENTAL OPTION

Under UK law [United Kingdom, 1990], a duty is imposed to have regard to the 'best practicable environmental option' (BPEO), where local conditions point to more stringent limits on emissions for prescribed IPC processes than would be required under BATNEEC alone. The aim is to identify the 'most sustainable' approach by establishing an optimum distribution of pollutants to the environment, after these have been minimised through BATNEEC [UKDoE, 1996]. Overall, however, the statutory requirement is quite limited in scope, applying only to discharges (rather than the complete lifecycle) regulated under IPC.

Outside the strict requirements of legislation on pollution prevention and control, however, BPEO has become more sophisticated and extended for more general application [RCEP, 1988] as a planning tool. If rigorously and comprehensively applied, a BPEO study can provide the framework for making environmentally responsible, efficient and cost-effective planning decisions in a transparent and auditable manner. It is particularly relevant to consideration of alternative management and/or siting options to meet a defined development objective. In summary, the primary concepts involved in a BPEO assessment can be explained by considering the words of the acronym in reverse order:

Option	Alternative ways of achieving the desired result have to be considered
Environmental	Environmental (and safety) issues have to be considered at an early stage in the decision-making process
Practicable	Options have to be in accordance with current technical knowledge and should not have disproportionately adverse financial or social implications
Best	The best option may change with time; the BPEO should be kept under review

Nevertheless, the BPEO will depend on the technology and commercial arrangements that are available and can thus, in principle, change with time. The appraisal should therefore be both technologically and commercially challenging, so that it is reasonably robust with respect to time.

The use of BPEO to support strategic decision making for radioactive waste is well established [UKDoE, 1986]. Importantly, it is informally accepted that the BPEO approach can provide a practical expression of the fundamental principle of optimisation. Nevertheless, whereas optimisation in a BPEO study can be readily appreciated as a practical common-sense objective, optimisation in the context of radiation protection has a particular intent and interpretation [ICRP, 1998]. This remains an issue of contention, particularly in respect of its practical application to solid waste management (see, e.g., comments in [Clarke, 1999]). Any BPEO study relating to radioactive substances therefore needs to maintain a clear distinction between optimisation according to ICRP principles and the general philosophy underlying BPEO for Integrated Pollution Control.

Moreover, the performance of a BPEO evaluation necessarily involves assessing the alternative management options against defined performance attributes. Where such attributes involve the consideration of ‘environmental protection’, some quantitative measure of the protection afforded against pathway-based environmental quality standards (see Section 3.3) will therefore inevitably be required.

3.2.3 MANAGEMENT STANDARDS

Management standards correspond to the general capability of a company to control the impacts of its operations. Approaches include certification schemes intended to provide assurance that systems and procedures meet a specified standard. The first such standard was British Standard (BS) 7750, published in 1992 (revised 1994), which specified a system aimed to deliver continuous improvement in environmental performance, consistent with a publicly stated policy. The BS 7750 standard has had a strong influence on international developments, and has now been largely superseded by the ISO 14001 standard.

The Eco-Management and Audit Scheme (EMAS) scheme [EC, 1993a] is a voluntary European scheme for industrial sites, designed to provide recognition in situations where positive action has been taken to protect the environment and where continuous performance improvement is

sought. This includes requirements on companies to report publicly at least every three years on their environmental performance.

One of the business performance indicators potentially relevant to EMAS, or other environmental reporting schemes, is that of 'Environmental Burden', originally developed by ICI. This is based on the definition of generic categories of environmental impact that may be related to company activities (such as photochemical ozone, aquatic oxygen demand and hazardous emissions to air). A 'potency factor' is then used to characterise the importance within each of these categories of each type of emission from the processes undertaken by the company. The overall burden for a given period of operation is then given by the sum of these emissions, each weighted by its respective potency factor. Trends in overall 'Environmental Burden' are then used to monitor overall environmental management performance.

As with regulatory control under IPC, schemes such as ISO 14001 and EMAS have rather limited utility in the context of long-term impacts from solid waste disposal. It is nevertheless interesting to note that regulatory standards exist within the UK in relation to the minimum competence of waste management companies to discharge their duties as 'fit and proper' licensees [United Kingdom, 1990; UKDoE, 1994].

3.2.4 LANDFILL DIRECTIVE

Similar provisions in respect of best practice standards are a feature of the long-awaited EC 'Landfill Directive'. However, it seems highly unlikely that this will extend significantly (if at all) the expectations already established by custom and practice in respect of those companies responsible for radioactive waste management and disposal.

According to the October 1998 draft of this Directive [EC, 1998], technical requirements are expressed principally in terms of engineering standards, management procedures and waste acceptance criteria, rather than specific environmental quality indicators. Proposed design standards in the draft Directive are assumed to 'protect soil, groundwater and surface water' (Annex I), but the standards of environmental protection anticipated from the adoption of such norms is not clear. Nevertheless, the primary aim would appear to be consistency with existing EC requirements for protection of groundwater [EC, 1980].

No specific quantitative requirements are established in respect of waste acceptance criteria (Annex II), but it is expected that such standards will take account of the short-, medium- and long-term leaching characteristics of the waste. It is also expected that account will be taken of the surrounding environment (specifically groundwater and surface water) in deriving the criteria. In addition, it is expected that 'environmental risks' will be taken into account in establishing a waste disposal permit, but there is no indication of any quantitative criteria to be used in such assessment, or the timescales that the assessment is expected to address.

Reference is also made in the draft Landfill Directive (Articles 12 and 13) to the potential occurrence of 'significant adverse environmental effects'. It is anticipated that 'trigger levels' will be established, based on 'significant changes' in water quality, with specific values being dependent on the specific hydrogeological conditions (including groundwater quality) in the vicinity of the facility. No specific recommendation is provided, and it seems likely that applicable environmental quality standards will therefore be similar to those adopted with respect to other potential sources of environmental contamination (see below).

3.3 Pathway-based Standards

A fundamental principle of solid radioactive waste disposal is that no management action should be required to ensure long-term safety once institutional controls over the facility have been lifted. Concepts underlying the application of pathway-based environmental standards are therefore perhaps more applicable than process and management standards in the context of developing a regulatory framework for solid radioactive waste disposal. Consideration is given here to environmental quality and emissions standards used to underpin regulatory approaches for a range of industrial processes capable of causing environmental pollution.

3.3.1 BIOLOGICAL STANDARDS

Biological standards take the form of maximum allowable concentrations of substances in human blood or tissue. To date, they have found only limited application in the context of environmental protection, having been applied predominantly in respect of biomarkers for human exposure.

As a general rule, biological standards are not considered as useful basis for regulatory control in themselves. Direct measurements are difficult to make and, by the time an exposure has occurred, it is too late to prevent any effect that may ensue. A mandatory biological standard for lead was contained in a draft Directive proposed by the European Commission in 1975, but was removed prior to its adoption. However, a different situation exists in the field of occupational health, since monitoring can be established as part of working practice and action can be taken to remove a worker from further exposure if a particular standard is exceeded.

3.3.2 EXPOSURE STANDARDS

Exposure standards define acceptable exposures (or doses) at the point of entry into an organism. In European law, standards for human exposure to radiation are prescribed by the Directive on Basic Safety Standards, the latest of which is scheduled for implementation by May 2000 [EC, 1996b]. However, this provides no guidance on radiation exposure standards for organisms other than man.

For chemical substances, recommendations for exposure standards normally take the form of tolerable or acceptable daily intakes (TDIs or ADIs). Recommendations for TDIs are made by the International Programme on Chemical Safety (IPCS), established in 1980 under the auspices of three United Nations organisations: UNEP, ILO and WHO. For many substances, IPCS evaluations do not result in a recommended standard because there is too little evidence. In the case of pesticides, the main internationally recognised bodies are joint committees of WHO and the FAO.

IPCS does not set exposure standards in the context of protection of the natural environment, but they do contribute recommendations for other forms of standard (as discussed below).

3.3.3 ENVIRONMENTAL QUALITY STANDARDS

Environmental standards relating to the ‘quality’ of an environmental medium are sometimes known as ambient standards.

Air

Guidelines for limiting the concentrations of pollutants in air are primarily intended to safeguard human health and well-being, rather than for protection of the environment, per se. For example, toxicologically based values for 19 organic and inorganic air pollutants have been published by

WHO [1987]. Legally-binding limit values (as well as long-term goals) have been set within the European Union for suspended particulates, sulphur dioxide, nitrogen dioxide and lead.

Whereas current legislation is presently confined to protection of human health, the Framework Directive on air quality [EC, 1996c] provides for quality standards to protect the 'environment as a whole'. Under the terms of the framework, 'daughter legislation' will set legally binding limit values, target values and alert thresholds for twelve pollutants and pollutant groups.

Critical loads (estimates of exposure to one or more specified pollutants, below which present knowledge suggests that 'significant harmful effects' on a sensitive component of the environment do not occur) have been proposed as a basis for regulating emissions to air [Nilsson and Grennfelt, 1988]. The United Nations Economic Commission for Europe has used this approach in setting quality standards for air, for a limited number of pollutants, in the context of Long-range Transboundary Air Pollution. For example, proposed limit values for nitrogen dioxide and sulphur dioxide outside urban areas are more stringent than those within such areas, with the aim of affording protection to ecosystems.

Natural Waters

Water quality standards have been designed predominantly to benefit the natural environment, especially species of fish. Fundamental Standards for surface waters supporting freshwater fish were established by EC legislation in 1978 [EC, 1978], and for coastal waters used for production of shellfish in 1979 [EC, 1979].

There has sometimes been a lack of clarity about the purposes that such standards are intended to serve. The preamble of one Directive, relating to the chloralkali industry [EC, 1982] claims that it is intended 'to protect the aquatic environment … against pollution by certain dangerous substances'. However, the biological standard established for fish within this Directive is set as an indicator for protection of human consumers, not the fish themselves or their environment.

An important aspect of many environmental standards relating to water quality is that they are closely related to the use, or intended use, of the water. The regulator therefore has substantial discretion about what use should be regarded as 'appropriate' for a particular stretch of water, now or in the future. Nevertheless, the proposed Framework Directive on water resources [ENDS, 1997a] sets a broad general standard for water quality in the European Union, requiring Member States to protect waters already in good condition and to bring other waters to 'a good ecological state' by 2010. Setting comparable quality standards for groundwater contamination would be a substantially more complex exercise and has not so far been attempted.

Soil

The major groups of environmental quality standards for soil relate primarily to decision-making concerning the redevelopment and remediation of contaminated sites, rather than as regulatory controls on waste disposal. In addition to human exposure and heath effects, soil quality considerations have also included toxicity to plants but not, in general, other forms of damage to the natural environment. However, it is not clear that consistent methodologies have been used to analyse contamination hazards [Visser, 1994].

Even more than in the case of water protection, such quality standards as have been set for soil relate to particular uses of land. Standards established in the Netherlands were originally set on the principle of 'multifunctionality', in order 'to restore the functional properties of the ground for human beings, flora and fauna' [Netherlands, 1994], but this principle was abandoned in 1997 [ENDS, 1997b].

3.3.4 EMISSION STANDARDS

In the context of discharges to water, a framework for eliminating particularly toxic, persistent or bioaccumulative substances was adopted within Europe in 1976 [EC, 1976b]. This has provided as basis for setting emission standards for so-called 'black list' substances. The preferred approach has been to establish emission limits based on particular categories of source, rather than by reference to the impact of a specific source on environmental quality at a given site. However, for less dangerous (or 'grey list') substances, emission standards are determined by reference to water quality objectives.

It has been recognised that the overall polluting effects of toxic wastewater discharges of variable or mixed composition may not be adequately addressed by limits on individual contaminants. The concept of 'Direct Toxicity Assessment' (DTA) has therefore been introduced under the framework of UK legislation [United Kingdom, 1990] with the stated intention that this might ultimately replace numeric concentration limits for certain substances. The principle is that an 'acceptable' toxicity level should be established for the receiving waters, taking account of direct toxicity tests for the particular discharge under consideration (see Section 3.4, below), including those chemicals that are already present in the receiving waters. However, it is recognised that there is substantial uncertainty as to which organisms should be used in the testing procedures – it has therefore been suggested that a limited range of organisms should be used to provide 'surrogates' for other species. To date, the viability of the approach as a regulatory tool remains to be successfully demonstrated; indeed, specific projects attempting to do so have failed.

European legislation is also in place in relation to the protection of groundwater against pollution [EC, 1980]. In the absence of quality standards for groundwater, the use of emission standards is intended to ensure no 'black list' substances are released to groundwater at all. In addition, 'investigation' is required before the release to groundwater (whether direct or indirect) of 'grey list' substances is permitted. These approaches have particular implications for the siting, engineering standards and monitoring requirements applied in the authorisation of solid waste disposal. As a rule, however, the requirements are expressed only in qualitative or semi-quantitative terms, taking account of the 'vulnerability' of groundwater systems, rather than demanding the explicit assessment of environmental impact.

In the context of air pollution, European framework legislation provides for emissions standards to be set covering particular industries or processes [EC, 1984]. However, the dominant element in setting emission standards (to air and other media) for larger or more complex plants in future is likely to be the principle of Best Available Techniques (BAT, see above). Even so, there may still be circumstances where releases based on process standards do not provide sufficient protection, and more stringent limits will then need to be applied to emissions.

3.4.5 ECOTOXICITY AND ECOLOGICAL RISK ASSESSMENT

Detailed procedures have been developed within the European Union for assessing risks associated with new and existing chemical substances [EC, 1993b; 1994]. For existing substances, the aim is to identify any need for better management of risks posed by a substance, requiring new use standards, product standards, emission or process standards.

The standard approach in environmental risk characterisation is to make a comparison, for each environmental compartment, between the predicted environmental concentration (PEC) of a substance and the predicted no effect concentration (PNEC). The assessment considers the environmental properties of the substances into which the original substance may be transformed or degraded.

Under EC procedures, PNEC values are derived by dividing the relevant LC_{50} value from a standard set of acute toxicity data by a factor of 1,000. By contrast, in the USA, normal practice has been to divide the same figure by a factor of 100 [USEPA, 1996]. However, the EC procedure recognises that less pessimism may be appropriate if additional data are available. It is relevant to note that, although sub-lethal effects (growth rate, reproduction, etc.) are often used as indicators in ecotoxicity testing, the PNEC relevant to regulatory control seems typically to be derived from results for lethality [RCEP, 1998].

The OECD has developed guidelines for ecotoxicity testing. For the aquatic environment, the general approach involves carrying out assessments that address three trophic levels: algae (representing primary photosynthetic producers), *Daphnia* (as primary consumers), and fish (as secondary consumers). It is typically assumed that a PNEC derived from results obtained at all these three levels will protect all aquatic species exposed to the relevant substance via water. There are no officially recognised test methods for sediment-dwelling organisms, even though many substances with high potential for bioaccumulation will also tend to migrate towards sediments.

Test methods for the terrestrial environment are less well developed than for the aquatic environment. The species most commonly used are earthworms; tests using nematodes, slugs, collembola and millipedes have also been developed. Tests of pesticides often use birds (for which OECD guidelines are available) and bees [Brown, 1998].

As a basis for setting standards to protect the natural environment, ecotoxicological tests are beset by various sources and types of uncertainty. The most useful data would be on effects at ecosystem or population level, but such data are seldom available. Instead, extrapolations have to be made, mainly from laboratory test data for single species or individuals. The primary limitations (which also exist in relation to assessing sensitivity to radiological exposure) include:

- laboratory data are invariably based on short-term exposures to high concentrations of a substance, whereas the effects of exposure to lower concentrations over longer periods are invariably more relevant;
- extrapolation from an individual to a population is a highly complex task;
- different species vary considerably in their characteristics: test species are selected on limited criteria and it is questionable whether the sets of test species prescribed for certain regulatory purposes are adequate;
- wildlife is more likely to be exposed to a mixture of substances than to the single substances normally used in testing;
- physical factors (e.g. temperature and water availability) can be important in determining the ecological impact of certain substances.

The standard practice in the UK is to examine all the available data in order to identify the most sensitive species for a particular substance. It is then assumed that, although ecosystem sensitivity is a complex attribute, the sensitivity of the most sensitive species provides a suitable approximation. The protection of this species is therefore assumed to protect the functioning of the system of which it is a part. A similar concept has been adopted in the drafting of proposed IAEA guidelines [IAEA, 1998], whereby a ‘critical species’ would be identified. The assumption is then that, if the critical species were adequately protected, this ‘would provide strong assurance that other species in the community were protected’.

In the Netherlands, the available ecotoxicological data are transformed into a probability distribution, and from this distribution is derived the concentration that is estimated to be hazardous for a specified proportion (usually 5 %) of species. Thus, the implicit aim is to protect a high proportion of species, rather than all species.

Concerning the assessment of radiation risks to the environment, a number of dose assessments and dose assessment methodologies are reported in NRPA [1999]. The brief papers provide few details, but collectively highlight the difficulty of relating a given level of concentration in the environment to a given level of radiation dose to the organisms that live in it, and even greater difficulty relating the dose to a particular level of harm. Sazykina and Kryshev [1999] suggest a combination of primary dose limits for organisms, and secondary limits that take into account multiple stress factors arising from other insults, both natural and anthropogenic. Blytt et al. [1999] discuss the definition and quantification of 'vulnerable areas' based on application of assessment models and GIS data for land use. This approach is described in relation to contamination by radionuclide fallout and nuclear accidents. However, no clear basis for quantifying the basic standards for protection of the environment is provided.

Despite the difficulties involved, determining dose-effect relationships for toxic substances in the natural environment is clearly essential if appropriate quantitative standards are to be established. However, a comprehensive assessment of ecological risk would not only have to be systematic and, as far as possible, quantified, but also distinguish between the use of the environment on a sustainable basis and the destruction of critical 'natural capital'. A recent review of approaches to environmental standard setting [RCEP, 1998] concluded 'no satisfactory way has been devised of measuring risk to the natural environment, even in principle, let alone defining what scale of risk should be regarded as tolerable'.

4 Review of National Regulatory Guidance

4.1 Background

Forty years or so ago, regulatory concern for the potential impacts of radioactive discharges on the environment was very active and important efforts were made to assess such effects (see Woodhead [1998] for some details). Nevertheless, continuing reviews of impacts in the marine and terrestrial environments (e.g. IAEA [1992]) generally appeared to support the advice from ICRP that other species would not be put at risk provided that man was adequately protected.

It can be argued that ICRP (intentionally, since that was their remit) were taking only a limited a view of 'protection', and their advice was consequently not sufficient to inform regulators with wide environmental as well as human health responsibilities. More recent regulatory interest in the issue is understood to have arisen first in Canada during the 1980s, in relation to evaluation of uranium mill tailings facilities many miles from significant human population groups. Providing adequate protection for humans in such areas might nevertheless permit relatively large radionuclide releases, as noted in Section 3. The issue was then taken up in the process of public review of proposals for a deep repository to dispose of spent fuel and high level waste. Canada has since been at the forefront of environmental protection issues for radioactive waste.

Current national regulatory systems for solid radioactive waste disposal can be grouped into three different classes according to the approach taken in relation to environmental protection. They either:

- do not mention it, relying implicitly on ICRP [1991] and its precursors;
- do mention it, but then place explicit reliance on ICRP [1991] and its precursors in order to preclude the issue from further consideration;
- do mention it and specify some particular requirement, but without providing much in the way of guidance on what the regulations mean or how to demonstrate compliance.

It is relevant to note, however, that the need to address potential environmental impacts can arise from wider considerations than the specific regulations relating to radioactive waste management. In particular, the public review of proposals is itself part of a legal process in many countries. Consequently, the need to give explicit attention to environmental impacts might still be regarded as some form of legal requirement, as in the Canadian case, even where the regulations themselves do not incorporate any specific environmental protection requirements.

In some countries, regulators provide guidance to explain their regulations. This guidance is often of a formal nature and is therefore very important in determining the presentation and authorisation of a safety case, but it is again not strictly part of the regulations themselves. Guidance provided by the UK regulatory agencies [Environment Agency et al., 1997] is an example of this, in this case relying on ICRP advice to dismiss the need for explicit evaluation of impacts on non-human biota. It is relevant to note, however, that the Environment Agency is now supporting continuing work on criteria development for environmental protection.

4.2 Current Status – Examples

Bearing in mind the general pace of development in consideration of environmental protection goals, as discussed in Section 3, the regulations in force in some countries could be considered relatively old. These regulations tend not to include any explicit recognition of requirements for environmental protection (e.g. as in the basic safety rule RFS III.2.f from 1991 in France). Nevertheless, even where there has been no recent change to the regulations themselves, questions of environmental protection requirements have been raised. Hence, for example, Raimbault [1997] identified environmental protection as an issue for France, albeit without offering any kind of comprehensive solution.

Other regulations, such as those of the Finnish Radiation and Nuclear Safety Authority [1998], are comparatively recent. In this case, long-term safety is defined as 'taking account of radiation impacts on man and the environment'. Quantitative standards for human protection are provided, applying for at least several thousand years. Beyond then, it is required that 'radiation impacts [should] remain insignificantly low'; however, it is unclear what this means, either in relation to human or environmental protection. A further long-term requirement in the Finnish regulations is that, at their peak, releases should result in radiation impacts no higher than those from natural radioactive substances. This could be argued as intended to provide a measure of environmental protection, but it still leaves many unanswered questions, such as what is meant by 'natural radiation'. (Such issues were discussed in more detail by Smith and Hodgkinson [1989] in a report for SKI.)

In some countries (e.g. in the USA), the regulations for authorisation of solid radioactive waste disposal are currently under formal review. The Yucca Mountain standards are being revised, but it is understood that the regulatory bodies are only just getting around to introducing dose standards for humans, let alone standards for environmental protection.

In other countries (e.g. in Japan), no standards are yet in place for HLW disposal. However, Miyahara et al. [1997] describe developments that show a clear focus on quantitative goals for human health protection. Moreover, it is understood that little, if any, attention has been given to environmental protection in the current safety assessment studies performed by JNC.

A recent NEA workshop [NEA, 1997] was intended to support the identification of key issues in safety assessment and in safety case demonstration. Review of the papers presented at the workshop reveals the occasional mention of environmental protection issues, but no significant recognition of this as a significant issue. For example, in the paper presented by representatives from the Czech Republic (the only former eastern bloc country participating in the workshop), reference was made to the formal requirement for Environmental Impact Assessment of proposals for repository development. However, no details were provided in respect of how potential radiological impacts on the environment might be taken into account.

Ongoing work within a framework of co-operation between the Russian Federation and Nordic country governments suggests that there is little practical experience in Russia on the regulation of environmental protection for radioactive waste disposal (e.g. see Sneve and Snihs [1999]). Nevertheless, the Russian Federation has a federal law on 'ecological expertise' [Federal Assembly of the Russian Federation, 1995], which mirrors the requirements of legislation on Environmental Impact Assessment for major projects within the EU. In the context of repository development for HLW disposal, it is understood that the State Committee for Environment Protection (Goscomecologia) would need to give its overall approval, even though the licensing of operations would be the responsibility of the nuclear regulator, Gosatomnadzor.

Overall, it is concluded that current regulatory frameworks and regulations in different countries offer little to contribute to the development in Sweden of a regulatory basis for environmental protection in relation to radioactive waste disposal.

5 Conclusions and Recommendations

At the outset, it is worth emphasising the outcome of a recent UK review of approaches to environmental standard setting [RCEP, 1998], which noted that 'no satisfactory way has been devised of measuring risk to the natural environment, even in principle, let alone defining what scale of risk should be regarded as tolerable'. A review of available literature shows that this general conclusion applies in particular to the assessment of radiological impacts, both in a regulatory and a technical context. There is clearly no obvious 'path to follow' in establishing a radiological protection framework for the environment, based on approaches used in relation to other sources of pollution. Nevertheless, some basic principles can be found.

5.1 Environmental Protection Goals

It is interesting to note the increasing emphasis (see, for example [EC, 1996a; OSPAR, 1998]) on using Best Available Techniques for pollution prevention, rather than using risk-based environmental standards as the primary criterion for regulatory control. In some respects, this mirrors the existing hierarchy of principles for radiological protection [ICRP, 1991], in which justification and optimisation precede the use of dose limits in the control of radiological exposure. However, in the context of the long-term impacts of waste disposal, it is a fundamental principle that no management action should be required to ensure long-term safety once institutional controls over the facility have been lifted. There remains an institutional belief that long-term monitoring offers some form of solution, but this places its own burden on future generations. Consequently, emphasis on management controls has a relatively limited utility.

It is increasingly the case that concerns related to actual or potential harm to organisms other than man are no longer restricted to threatened, or endangered species [Pentreath, 1999]. Nevertheless, the concepts and standards adopted in relation to non-radioactive hazardous releases and emissions are clearly directed towards protection at a population, rather than an individual, level. On the other hand, there seems to be little information available on which to base quantitative standards for contamination other than by reference to effects observed at the level of individuals. A population in this context is not usually the entire global population, but a group of individuals of a species in a defined location or habitat.

Hence, the underlying ethic commonly associated with environmental protection is based on more than simply a utilitarian view of biodiversity. On the other hand, the overall goals do not typically extend as far as focusing on prevention of harm to any individual organism. For consistency with approaches used elsewhere, therefore, a radiological protection framework for the environment will need to be based on similar objectives.

5.2 Criteria Setting

It is interesting to note the broad consistency between the approach to ecological risk assessment recommended by IAEA [1998] and the practice adopted in relation to other hazardous materials. Thus, the concept of an 'indicator species' is generally accepted in standard procedures for establishing the potential ecotoxicity of chemical substances.

Although site-specific issues are important, and there have been some attempts to bring these into regulatory practice, it is not clear how these can be translated to the timeframes of relevance for post-closure assessment of solid waste disposal facilities. The standard approach is to take account of local sensitivities in a semi-quantitative way, through siting considerations, but not necessarily to evaluate the impact of contaminants on the local environment itself. Instead, the focus is on 'environmental quality', which draws on toxicological understanding to establish criteria for different environmental media. This has shortcomings – principally that it fails to take proper account of the combined effects of different pollutants; hence the concept of 'direct toxicity assessment' (DTA). However, the DTA approach has not yet been shown to be workable in practice.

In so far as current regulatory standards for 'environmental quality' are implicitly based on a defined set of biotic indicators and standard ecotoxicity evaluation methods, it seems that there may be a case for establishing a similar set of 'radiation environment quality' indicators in the context of radiological protection standards. Then, just as an agreed 'reference man' provides the data set for determining reference exposures to compare assessment results with dose targets and constraints, there is a case for defining an agreed set of 'reference organisms' (possibly with associated methods for dose calculation) for which exposures should be determined in different types of environment, based on the calculated concentrations in environmental media.

Each reference organism would need to have a defined 'dose criterion', based on available radiotoxicological data and (probably) taking account of natural exposures. Such an approach would be broadly consistent with regulatory practice elsewhere (i.e. in terms of using available information to define general standards) – however, it would be a step forward in so far as it recognised the possibility (for radiation) of using total exposure as the endpoint, rather than the environmental concentration of individual contaminants. A version of this sort of approach was adopted in the EIS of the Canadian disposal concept for spent nuclear fuel [Zach and Amiro, 1996]. UK Nirex Limited used a somewhat less sophisticated version in (unpublished) assessments performed in 1992.

Such an approach implies that agreed indicator species/data/methods etc., should be determined and agreed 'up front', rather than requiring analysts to justify the particular organisms that they include in their own assessment calculations. This has the advantage of harmonising with approaches used for non-radioactive contaminants - the operator demonstrates compliance according to an agreed set of rules, which represent the results of a collective interpretation of best available information on ecotoxicity. Such an approach would not necessarily preclude investigation of site-specific concerns (e.g. in terms of significant ecological properties), and it does not stop the analyst from attempting to demonstrate that a different approach may be used in his specific situation. However, it does establish a firm foundation on which compliance with the spirit of the legislation can be demonstrated.

5.3 Demonstrating Compliance

Whether or not agreed dosimetric models for defined 'critical species' in different habitats are adopted, an important issue in the context of demonstrating compliance is the basis on which indicative environmental concentrations are calculated. It is well known that, depending on how the 'resource area' exploited by a member of a hypothetical human community (or potential exposed group) is defined; the calculated doses can vary significantly. In the same way, if a future release is assumed to result in a very heterogeneous pattern of contamination (e.g. as a result of localised groundwater release), local exposures to 'resident' organisms may be very high, even if the average over the ecosystem as a whole falls within acceptable limits.

This seems to be an area where collective interpretation of best available information regarding the sensitivity of ecosystems as a whole (rather than simply the exposure of individuals) will be

important. Hence, as well as defining standard 'indicator organisms', dose criteria and exposure calculation methods, it may also be important to define the area over which concentrations should calculated in order to demonstrate environmental protection (which may be very different from that used to demonstrate protection of man). This issue could potentially have important implications for the way in which corresponding performance assessment models are constructed, for example, concerning the surface extent of repository-derived fluxes from the geosphere.

5.4 A Radiological Protection Framework

It has not been the intention of this report to propose an overall framework for radiological protection of the environment. Rather, the aim has been to identify whether or not there is a strong case for following one or other approach as part of such a system.

Recently, Pentreath [1999] has proposed some basic elements of what would be required from a comprehensive system for radiological protection of the environment. These elements were defined through consideration of the desirability of consistency with approaches already used in the context of the ICRP system. The components of this system include:

- a clear set of objectives and principles;
- an agreed set of quantities and units;
- a reference set of dose models for a number of reference fauna and flora;
- reference sets of values by which radiation exposure could be estimated from a knowledge of internal and external sources of radiation;
- basic knowledge of radiation effects that would enable management decisions to be made;
- a means of demonstrating compliance;
- the means of reviewing and revising these basic elements as further understanding develops.

The conclusions and recommendations arising from the present study are not as comprehensive as those identified by Pentreath; however, we believe the specific recommendations identified here to be entirely supportive of such a scheme.

As modifications, we would suggest that reference models, representing the migration and accumulation of radionuclides in the ecosystems of interest as well as biotic exposure, could be developed on a similar basis to 'Reference Biospheres' for human exposure [BIOMASS, 1998]. Translation of those modelling results into impacts on biota (effective doses for animals, etc., and their relationship to population effects) is, we feel, much more problematic. In the short-term, reliance on expert opinion may be necessary to guide the next step, rather than the early prescription of a regulatory approach.

6 References

Amiro B, Avadhanula R, Johansson G, Larsson C-M and Lüning M (eds.) (1996). Protection of the Natural Environment. Proceedings of International Symposium on Ionising Radiation, Stockholm, May 20-24, 1996. Swedish Radiation Protection Institute, Stockholm.

Blytt L D, Steenhuisen F, Borghuis S and Skuterud L (1999). Definition and Quantification of Vulnerable Areas in Northern Norway. In Proceedings of the 4th International Conference on Environmental Radioactivity in the Arctic, Edinburgh, 20-23 September 1999.

BIOMASS (1998). Long-term Releases from Solid Waste Disposal Facilities: The Reference Biosphere Concept, BIOMASS Theme 1, Working Document No.1, International Atomic Energy Agency, Vienna, April 1998.

Brown D (1998). Environmental Risk Assessment and Management of Chemicals. In Hester R E and Harrison R M (eds.) Risk Assessment and Risk Management, Issues in Environmental Science and Technology No.9, Royal Society of Chemistry, Cambridge.

Canada (1997). Nuclear Safety and Control Act. Bill C-23, House of Commons of Canada.

Clarke R H (1999). ICRP Main Commission Meeting, October 1998. Radiological Protection Bulletin, No.209, pp20-23, January/February 1999.

CPRE (1993). Sense and Sustainability. Council for the Protection of Rural England, Publication P087, London, September 1993.

EC (1976a). Council Directive 76/769/EEC relating to Restrictions on the Marketing and Use of Certain Dangerous Substances and Preparations. Official Journal of the European Communities, L262, September 1976.

EC (1976b). Framework Directive 76/462/EEC on the Protection of Groundwater against Pollution caused by Dangerous Substances. Official Journal of the European Communities, L129, May 1996.

EC (1978). Council Directive 78/659/EEC on the Quality of Fresh Waters needing Protection of Improvement in order to Support Fish Life. Official Journal of the European Communities, L222, August 1978.

EC (1979). Council Directive 79/923/EEC on the Quality Required for Shellfish Water. Official Journal of the European Communities, L281, November 1979.

EC (1980). Council Directive 80/68/EEC on the Protection of Groundwater against Pollution caused by Dangerous Substances. Official Journal of the European Communities, L188, January 1980.

EC (1982). Council Directive 82/176/EEC on Limit Values and Quality Objectives for Mercury Discharges by the Chloralkali Electrolysis Industry. Official Journal of the European Communities, L81, March 1982.

EC (1984). Framework Directive 84/360/EEC on Combating Air Pollution from Industrial Plants. Official Journal of the European Communities, L188, July 1984.

EC (1992). Regulation 880/92 on a Community Ecolabel Award Scheme. Official Journal of the European Communities, L99, April 1992.

EC (1993a). Regulation 1836/93 allowing Voluntary Participation by Companies in the Industrial Sector in a Community Eco-Management and Audit Scheme. Official Journal of the European Communities, L168, July 1993.

EC (1993b). Council Directive 93/67/EEC on Risk Assessment for New Notified Substances. Official Journal of the European Communities, L227, September 1993.

EC (1994). Regulation 1488/94 on Risk Assessment for Existing Substances. Official Journal of the European Communities, L161, June 1994.

EC (1996a). Council Directive 96/61/EC concerning Integrated Pollution Prevention and Control. Official Journal of the European Communities, L257, October 1996.

EC (1996b). Council Directive 96/29/EC laying down Basic Safety Standards relating to Ionising Radiation. Official Journal of the European Communities, L159, June 1996.

EC (1996c). Framework Directive 96/62/EC on Ambient Air Quality Assessment and Management. Official Journal of the European Communities, L296, November 1996.

EC (1998). Common Position (EC) No 49/98 with a view to adopting Council Directive 98/…/EC on the Landfill of Waste. Official Journal of the European Communities, C333/15, October 1998.

ENDS (1997a). Lengthy Negotiations Ahead for Directive on Water Resources. Environmental Data Services Report 266, pp41-44, March 1997.

ENDS (1997b). Dutch Policy Retreat on Contaminated Land. Environmental Data Services Report 269, p46, June 1997.

ENDS (1998). A Blast from the Past by the CBI. Environmental Data Services Report 287, Editorial, December 1998.

Environment Agency, Scottish Environment Protection Agency and Department of the Environment for Northern Ireland (1997). Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Guidance on Requirements for Authorisation. HMSO, London.

Federal Assembly of the Russian Federation (1995). Federal Law on Ecological Expertise (English Translation). Adopted by the State Duma on July 19, 1995.

Finnish Radiation and Nuclear Safety Authority (1998). General Regulations for the Safety of the Disposal of Spent Nuclear Fuel into Bedrock (Unofficial translation).

Haigh N (ed) (1996). Manual of Environmental Policy: The EC and Britain. Institute for European Environmental Policy, London.

IAEA (1992). Effects of Ionising Radiation on Plants and Animals at Levels Implied by Current Radiation Protection Standards. IAEA Technical Report Series 332, International Atomic Energy Agency, Vienna.

IAEA (1995). The Principles of Radioactive Waste Management. IAEA Safety Series No. 111-F, International Atomic Energy Agency, Vienna.

IAEA (1998). Protection of the Environment from Ionising Radiation. IAEA Draft Report for Discussion, Draft from the Meeting 7-11 September 1998.

ICRP (1991). Recommendations of the International Commission on Radiological Protection. ICRP Publication 60, Annals of the ICRP, Vol 21, Nos. 1-3.

ICRP (1998). Radiological Protection Policy for the Disposal of Radioactive Waste. ICRP Publication 77, Annals of the ICRP, Vol 27, Supplement 1997.

Miyahara K, Umeki H and Masuda S (1997). Development of the Scientific and Technical Basis for Regulations of Geological Disposal through Generic Assessment. In NEA [1997].

NEA (1997). Regulating the Long-term Safety of Radioactive Waste Disposal. Workshop organised by NEA, held in Córdoba, Spain (Proceedings not published, but papers are available).

Netherlands (1994). Intervention Values for Soil Clean-up. Memorandum issued under the National Environmental Policy Plan for the Netherlands, May 1994.

Nilsson J and Grennfelt P (eds.) (1988). Critical Loads for Sulphur and Nitrogen. Report of a workshop held in Skokloster, Sweden, 19-24 March 1988. Nordic Council of Ministers, Copenhagen.

NCRP (1991). Effects of Ionising Radiation on Aquatic Organisms. NCRP Report 109, NCRP, Bethesda, MD.

NRPA (1999). Environmental Radioactivity in the Arctic. Proceedings of the 4th International Conference, Edinburgh, 20-23 September 1999.

OSPAR (1998). Sintra Statement of the OSPAR Convention for the Protection of the Marine Environment of the North East Atlantic. Ministerial Meeting of the OSPAR Commission, 22-23 July 1998, OSPAR/98/14/1, Annex 45.

Pentreath R J (1996). Effects of Ionising Radiation on Aquatic Organisms and Ecosystems. In Proceedings of International Symposium on Ionising Radiation, Stockholm, May 1996 (Amiro B, et al., (eds.)), Swedish Radiation Protection Institute, Stockholm, pp124-135.

Pentreath R J (1999). A System for Radiological Protection of the Environment: Some Initial Thoughts and Ideas. Journal of Radiological Protection, Vol. 19, No. 2, pp117-128, June 1999.

Pigford T H (1999). Geological Disposal of Radioactive Waste: Ethical and Technical Issues. In Proceedings of the VALDOR International Symposium on Values in Decisions of Risk, Stockholm, 13-17 June 1999 (Andersson K, (ed)), pp113-128.

Raimbault P (1997). Key Points for Safety Assessment of a Deep Disposal Facility in France: Operator Standpoint. In NEA [1997].

RCEP (1988). Twelfth Report of the Royal Commission on Environmental Pollution: Best Practicable Environmental Option. Cm 310, HMSO, London.

RCEP (1998). Twenty-first Report of the Royal Commission on Environmental Pollution: Setting Environmental Standards. Cm 4053, HMSO, London.

Sazykina T G and Kryshev I I (1999). Criteria for Radiation Protection of Arctic Ecosystems. In Proceedings of the 4th International Conference on Environmental Radioactivity in the Arctic, Edinburgh, 20-23 September 1999.

Schönfeld M (1995). Justifying Value in Nature, Electronic Journal of Analytical Philosophy, Editorial, Issue 3, Spring 1995.

http://phil.indiana.edu/ejap/1995.spring/contents.html

Smith G M (2000). Work in Support of Biosphere Assessments for Solid Radioactive Waste Disposal: Requirements for Performance Assessments based on Swedish Regulations and Criteria, QuantiSci Report SSI-6181A-1, Version 2.0.

Smith G M and Hodgkinson D P (1989). Review of Criteria for Radioactive Waste Disposal. Intera Report for SKI.

Sneve M K and Snihs J-O (1999). Report of a Seminar on Radioactive Waste, Oskarshamn, November 1998. Stralevern Rapport No.4, 1999.

SSI, 1998). The Swedish Radiation Protection Institute's Regulations concerning the Protection of Human Health and the Environment in connection with the Final Management of Spent Nuclear Fuel and Nuclear Waste, September 1998.

United Kingdom (1990). Environmental Protection Act 1990.

United Kingdom (1994). Sustainable Development: the UK Strategy. Cm 2426, HMSO, London.

United Kingdom (1999). Management of Nuclear Waste, Report of the House of Lords Select Committee on Science and Technology, 24 March 1999, HMSO, London.

UKDoE (1986). Assessment of Best Practicable Environmental Options (BPEOs) for Management of Low and Intermediate Level Solid Radioactive Wastes. HMSO, London.

UKDoE (1994). Licensing of Waste Management Facilities. Guidance on the Drafting, Supervision and Surrender of Waste Management Licences. Waste Management Paper No.4, Third Edition, HMSO, London.

UKDoE (1996). The Environment Agency and Sustainable Development. Department of the Environment, HMSO, London.

UNCED (1992). Rio Declaration on Environment and Development. United Nations Conference on Environment and Development, Rio de Janeiro, published by the United Nations, New York.

UNECE (1990). Bergen Ministerial Declaration on Sustainable Development in the ECE Region. United Nations Economic Commission for Europe.

UNSCEAR (1996). Effects of Radiation on the Environment. United Nations Scientific Committee on the Effects of Atomic Radiation, Scientific Annex to the 1996 Report to the General Assembly, United Nations, New York.

USA (1993). Radiation Protection of the Public and the Environment. Order 5400.5, US Department of Energy.

USEPA (1996). Proposed Guidelines for Ecological Risk Assessment. EPA/630/R-95/002B, US Environmental Protection Agency, Washington DC.

Visser W J F (1994). Contaminated Land Policies in Some Industrialised Countries. Technical Soil Protection Committee, The Hague.

WCED (1987). Our Common Future. Report of the World Commission on Environment and Development.

Webb G A M (1999). Radiological Protection of the Environment. In Proceedings of the Sixth International Symposium of the UK Society for Radiological Protection, Southport, 14-18 June 1999 (Thorne M, (ed)), pp271-274.

WHO (1987). Air Quality Guidelines for Europe. WHO Regional Publications, European Series No.23. WHO Regional Office for Europe, Copenhagen.

Woodhead D S (1998). The Impact of Radioactive Discharges on Native British Wildlife and the Implications for Environmental Protection. R&D Technical Report P135, UK Environment Agency, Bristol.

Zach R and Amiro B (1996). Development and Application of an Environmental Assessment Methodology. In Proceedings of International Symposium on Ionising Radiation, Stockholm, May 1996 (Amiro B, et al., (eds.)), Swedish Radiation Protection Institute, Stockholm, pp374-383.

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