

Response to Consultation Comments

March 2009



Geological Disposal Facilities on Land for Solid Radioactive Wastes

Guidance on Requirements for Authorisation



**GEOLOGICAL DISPOSAL FACILITIES ON LAND FOR
SOLID RADIOACTIVE WASTES:**

**GUIDANCE ON REQUIREMENTS FOR
AUTHORISATION**

Response to Consultation Comments

**ENVIRONMENT AGENCY
NORTHERN IRELAND ENVIRONMENT AGENCY**

20 March 2009

Contents

1.	Introduction	1
2.	The consultation process	2
2.1	Preparatory workshops.....	2
2.2	Consultation draft	2
2.3	Consultation workshop	3
2.4	Comments received.....	4
2.5	Document Revision	4
3.	Comments and Responses	8
3.1	Comment categories	8
3.2	General comments	9
3.3	Responses to Q1 – Clarity.....	12
3.4	Responses to Q2 – Relationship to HPA.....	14
3.5	Comments on Chapters 1–3.....	14
3.6	Responses to Q3 – Principles	17
3.7	Responses to Q4 – General comments on Requirements	22
3.8	Comments on <i>Requirements 1–3 (Chapter 5)</i>	23
3.9	Comments on Requirement R4 – Environmental Safety Case	25
3.10	Comments on Requirement R5 – Environmental safety culture and management system	26
3.11	Comments on Requirement R6 – Dose constraints	27
3.12	Responses to Q5 – Risk guidance level.....	28
3.13	Responses to Q6 – Risk assessment.....	30
3.14	Responses to Q10 – Human intrusion (geological disposal).....	32
3.15	Responses to Q8 – Optimisation.....	34
3.16	Comments on Requirement R10 – Environmental radioactivity	36
3.17	Comments on Technical Requirements – R11 to R15	37
3.18	Comments on Chapter 7 – Environmental safety case	39
3.19	Comments on Chapters 8 and 9 – Context	41
3.20	Responses to Q7 – Supplementary guidance	42
3.21	Responses to Q9 – Combined safety cases	44
4.	List of Responding Organisations	46

1. Introduction

- 1.1.1 The Environment Agency and the Northern Ireland Environment Agency (NIEA) are responsible for regulating the disposal of radioactive waste in England and Wales, and in Northern Ireland, respectively. For simplicity, we have used the terms "the environment agencies" and "we" throughout this document when we refer to these organisations collectively. Together, the environment agencies have published *Geological Disposal Facilities on Land For Solid Radioactive Wastes: Guidance On Requirements For Authorisation*.
- 1.1.2 This new guidance is the result of a programme of review and revision of earlier guidance, *Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Guidance on Requirements for Authorisation* (GRA), which is more than ten years old. We revised the guidance in the light of our experience of using it and in the light of broader developments both in the UK and internationally.
- 1.1.3 During our revision of the guidance we consulted stakeholders through a series of workshops. We also issued a draft of the guidance for public consultation. This document, which we have tried to keep reasonably concise and readable, presents our responses to the comments received during this consultation. We are very pleased that many organisations and some individuals responded. We are grateful to all those who took the time and trouble to read, consider and comment on our draft guidance. Their comments have helped us improve it and make it clearer.
- 1.1.4 Following this Introduction, Section 2 summarises the consultation process, Section 3 summarises the comments received and our responses to them, and Section 4 lists the stakeholders who responded to the consultation.

2. The consultation process

2.1 Preparatory workshops

2.1.1 During our programme to review and revise our guidance, we held two preparatory workshops for stakeholders.

2.1.2 A workshop held in Manchester on 21 June 2007 had the following objectives:

- To present and obtain feedback on the scope of the literature to be considered in developing revised versions of the GRA;
- To obtain views on safety principles for the revised versions of the GRA, based on a comparison of safety principles from the existing GRA with updated principles from the International Atomic Energy Agency (IAEA) and from elsewhere;
- To identify stakeholder engagement issues relevant to both short-term and long-term planning and development of radioactive waste disposal facilities.

2.1.3 A workshop held in Manchester on 28 November 2007 had the following objectives:

- To show key elements of the project to participants and, in particular, to seek answers to the following questions:
 - Does the revised guidance as it is emerging meet participants' expectations?
 - Are there issues that the environment agencies should address ahead of the forthcoming public consultation?
- To seek participants' views in the following areas:
 - Comments on the structure of the guidance;
 - Areas that would benefit from detailed review outside the workshop.

2.1.4 At both workshops, there were presentations on the status of our programme, followed by group discussions on key topics. Issues raised at the workshops were recorded in reports that were distributed to participants. The reports are available on request. We considered the issues raised as we developed our guidance, but have not prepared formal responses.

2.2 Consultation draft

2.2.1 On 15 May 2008 we released a draft of our guidance for consultation. We invited comments from individuals and organisations on any aspect of the draft, and also asked some specific questions (Table 2.1). The consultation was open until 1 September 2008.

Table 2.1: Questions posed in the consultation draft.

No.	Question	Text Reference (Where Applicable)
1	Is the document sufficiently clear to a non-technical reader? If not, what improvements would you suggest?	N/A
2	Is the relationship between the environment agencies' regulatory guidance documents and HPA's advice on solid radioactive waste disposal clear enough in the documents? If not, how might it be made clearer?	Section 1.8
3	Are the principles set out in the guidance clear, sensible and complete with respect to the disposal of solid radioactive waste to land? If not, what changes and/or additions would you suggest?	Chapter 4
4	Are the requirements set out in the guidance clear and sensible and do they sufficiently cover all the areas that need to be addressed in the disposal of solid radioactive waste to land? If not, what changes and/or additions would you suggest?	Chapter 5 & Chapter 6
5	The environment agencies are proposing a risk guidance level of 10^{-6} per year (i.e. 1 in a million per year) after the period of authorisation. Does this provide a sufficient and appropriate standard of protection? Is the term 'risk guidance level' sufficiently clear and unambiguous? If not, what would you suggest?	Section 6.3.8
6	Do you agree with the proposed approach for assessing risks and comparing them with the risk guidance level? If not, what approach would you suggest?	Section 6.3.13–6.3.27
7	Would additional supplementary guidance be useful? If so, in what areas and when should it be issued?	N/A
8	Do you agree with the approach to optimisation set out in the document? If not, what alternative approach would you suggest?	Section 6.3.42–6.3.53
9	Should the environmental safety case required by the environment agencies be combined with the nuclear safety case required by the Nuclear Installations Inspectorate? What are your reasons for the view you express?	Section 7.1.3
10	Do you agree with the proposed approach to dealing with human intrusion into deep geological disposal facilities? If not, what approach would you suggest?	Section 6.3.28–6.3.41

2.3 Consultation workshop

2.3.1 During the consultation on our draft guidance, we held a workshop for stakeholders. The objectives of the workshop, held in Manchester on 10 July 2008, were:

- To provide participants with an overview of the intent and content of the draft guidance;
- To provide a forum for the discussion of key topics;

- To inform the environment agencies' consideration of these topics when evaluating consultation responses.

2.3.2 The workshop included presentations and discussion of the draft guidance, followed by group discussions on a set of detailed topics:

- Group A – Stepwise approach to authorisation/stakeholder engagement.
- Group B – Approach to the use of risk.
- Group C – Approach adopted for human intrusion.
- Group D – Approach adopted for optimisation.
- Group E – Practicality of implementation.

2.3.3 The results of the group discussions were reported back to the workshop and were included in a report that was distributed to participants. The report is available on request.

2.3.4 Although we advised participants that they should not rely on the workshop as a means of passing on comments on the consultation draft, we have considered the issues raised at the workshop during our revision of the guidance and have included the workshop comments in our responses in Section 3 of this report.

2.4 Comments received

2.4.1 We received comments on the draft guidance from twenty-three organisations and from seven people responding as individuals. A list of the respondents is presented in Section 4 of this report.

2.4.2 We received over one hundred pages of comments in total, ranging from philosophical considerations on the setting of goals and objectives to very detailed editorial corrections.

2.4.3 At the same time as this consultation, the Environment Agency, the Scottish Environment Protection Agency and the NIEA also consulted on the guidance entitled *Near-Surface Disposal Facilities on Land For Solid Radioactive Wastes: Guidance On Requirements For Authorisation*. Some respondents said that they were responding to both consultations. Where comments we received in response to the consultation for near-surface disposal facilities seemed relevant to geological facilities, we took them into account in revising our guidance for geological facilities.

2.4.4 We have considered all the comments received on the consultation draft and at the consultation workshop. We have also reviewed the guidance to make sure it is consistent and clear. Because we received a large number of comments, we decided that in order to respond in a reasonably concise and readable manner we should group together comments on similar issues. We have set out our responses to these grouped comments in Section 3.

2.5 Document Revision

2.5.1 This section summarises the most important changes that we have made to each chapter in producing the final version of our guidance. We have also made many smaller changes that are not mentioned in our summary.

Chapter 1 – Preface

- 2.5.2 In the consultation draft, this chapter introduced the consultation. It has now been completely rewritten as a preface to our final guidance, summarising its history and relationship to other related developments.

Chapter 2 – Summary

- 2.5.3 Only minor modifications have been made here to clarify the role of the environment agencies.

Chapter 3 – Introduction

- 2.5.4 We have made minor changes to clarify the application of the guidance and to reflect changes elsewhere in the guidance.

Chapter 4 – Principles for solid radioactive waste disposal

- 2.5.5 We have extensively revised this chapter following our own review of responses to the consultation. We have combined *Principles 1 and 3* from the consultation draft into a revised *Principle 1 – Level of protection against radiological hazards at the time of disposal and in the future*. We have also revised the wording of the Fundamental Protection Objective, the other principles and the explanatory text. These changes aim to clarify the status of the Fundamental Protection Objective and of the principles, and to explain how they will be satisfied through our requirements.

Chapter 5 – Authorisation of disposal

- 2.5.6 This chapter describes the authorisation process; it contains significant changes to the consultation draft. The consultation draft was published before the Managing Radioactive Waste Safely (MRWS) White Paper was published in June 2008. We have aligned our guidance with the MRWS White Paper and have also discussed the possibility that regulation of radioactive substances in England and Wales could come within the scope of the Environmental Permitting Regulations (EPR). Parts of the authorisation process are discussed twice in this chapter, once for regulation under the EPR and again for a process by agreement leading into regulation under the Radioactive Substances Act 1993 (RSA 93). New diagrams are included illustrating how our regulatory process relates to the MRWS process, regulation by the Nuclear Installations Inspectorate of the Health and Safety Executive and the land-use planning process.

Chapter 6 – Management, radiological and technical requirements

- 2.5.7 This chapter includes most of the requirements we set out, and all have been re-numbered to take account of the changes to *Chapter 5*.
- 2.5.8 We have extended the explanatory text describing the requirement for an environmental safety case (in addition to the changes in *Chapter 7* described below). The environmental safety case requires the dose constraint and the risk guidance level to be considered, and we have added a diagram to show the periods over which these requirements apply.
- 2.5.9 We have made some changes to the explanatory text for the requirement addressing the environmental safety culture and management system. In particular, we have added material relating to resources and competences.

- 2.5.10 The Health Protection Agency (HPA) has recommended a value for the dose constraint for a new disposal facility for radioactive waste which is lower than those we (as directed by Government) currently use in our regulatory decisions. We have therefore made the requirement addressing the dose constraint more general by not specifying dose constraint values in the statement of the requirement itself. We have included both the current dose constraint values and HPA's recommended value in the explanatory text.
- 2.5.11 We have given more information on the origin of the value we have set as the risk guidance level, and we have re-ordered some of the material in the explanatory text for this requirement. We have also explained how we expect risks from different facilities to be combined.
- 2.5.12 We have included an exchange of letters with HPA as *Annex II* to our guidance. HPA's letter notes some differences between HPA's advice and our guidance, but concludes that the overall level of protection provided by our guidance should in practice be the same as that intended by HPA's advice, because both HPA's advice and our guidance specify a requirement to optimise.
- 2.5.13 Given the uncertainty of future human actions, it may not be possible to substantiate the effectiveness of practical measures aimed at reducing the likelihood or consequences of human intrusion. We have included an expectation that such measures should nevertheless be adopted.
- 2.5.14 Under the requirement on optimisation, we have included a discussion of collective dose. We have also corrected the requirement and the explanatory text to make clear that the specific requirement for radiological risks to be as low as reasonably achievable only applies to people and not to the environment. We still expect the developer and operator of a facility to take steps to protect other species against radiological risks.
- 2.5.15 We have included references to research studies and regulatory guidance that can be considered in assessments of radiological effects on the environment.
- 2.5.16 We have revised the explanatory text for the requirement on protection from non-radiological hazards. We have noted that the demonstration of protection may be straightforward because of the design of the facility.
- 2.5.17 We have made no major changes to the requirements on site investigation, the use of the site, etc., and waste acceptance criteria.
- 2.5.18 In the explanatory text for the requirement on monitoring, we have made it clear that we expect the monitoring programme to set out the levels of specific contaminants that will trigger action. We also expect action plans for responding if these levels are reached.

Chapter 7 – Environmental safety case

- 2.5.19 We have made a number of detailed revisions to clarify our expectations for the environmental safety case, but have made no major changes.

Chapter 8 – Policy and legislative framework

- 2.5.20 We have made some additions and changes to reflect new information available since we prepared the consultation draft. A new section covers the MRWS White Paper, which was published after the consultation version of this guidance. Other new and revised sections cover the draft revised UK strategy for radioactive

discharges (OSPAR), land-use planning, the Water Framework Directive and Groundwater Directive, flood risk management and Best Available Techniques (BAT). We have added information about the Environment Agency's Radioactive Substances Regulation Environmental Principles and the relationship in England and Wales between them and the new guidance on disposal facilities for solid radioactive waste. A new section on radiological protection advice describes the role of the Department of Health and HPA.

Chapter 9 – The legislation we enforce

- 2.5.21 We have made a few additions and changes to clarify our roles and responsibilities. These include clarifying our duty to undertake assessments of a site's conservation objectives under the Conservation (Natural Habitats &c.) Regulations 1994. We have changed the text to refer to 'nuclear licensed sites' but have kept the term 'non-nuclear premises' for sites of lower radiological risk.

Chapter 11 – Glossary and acronyms

- 2.5.22 We have linked the definitions of 'disposal', 'geological disposal' and 'geological disposal facility' to stress that we shall regard the time of emplacement (i.e. the time the waste is placed in the facility) as the time of disposal, even if the facility is closed many years later. We have also made a number of changes to the glossary, in some cases linked to changes to the text of the guidance, to improve clarity.

Annexes I and II

- 2.5.23 We have added two annexes which are not part of the guidance but help to put the guidance into context. *Annex I* explains how our guidance relates to HPA's *Advice on the Radiological Protection Objectives for the Land-based Disposal of Solid Radioactive Wastes*. *Annex II* contains an exchange of letters between the environment agencies and HPA which clarifies the process by which HPA advice has been incorporated into this guidance to ensure that high standards of radiological protection are applied.

3. Comments and Responses

3.1 Comment categories

- 3.1.1 As discussed in Section 2.4, we received a large number of detailed comments through the consultation process, including those made at the consultation workshop. We have decided to categorise and group together the comments to provide a framework for our responses, based on the part of the guidance to which the comments apply.
- 3.1.2 The consultation version of the guidance included a set of questions (Section 2.2), and we have also used these to group the responses. However, because several questions are wide-ranging and some of the associated comments are quite specific, we have added several more categories linked to specific sections in the guidance or to specific requirements. The full list of categories is presented in Table 3.1.

Table 3.1: Categorisation of consultation comments and responses.

Comment Category
General comments
Responses to Q1 – Clarity
Responses to Q2 – Relationship to HPA
Comments on Sections 1–3
Responses to Q3 – Principles
Responses to Q4 – General comments on Requirements
Comments on Requirements 1–3 (Section 5)
Comments on Requirement R4 – Environmental Safety Case
Comments on Requirement R5 – Environmental safety culture and management system
Comments on Requirement R6 – Dose constraints
Responses to Q5 – Risk guidance level
Responses to Q6 – Risk assessment (Requirement R7)
Responses to Q10 – Human intrusion (Requirement R8)
Responses to Q8 – Optimisation (Requirement R9)
Comments on Requirement R10 – Environmental radioactivity
Comments on Technical Requirements – R11 to R15
Comments on Section 7 – Environmental safety case
Comments on Section 8 to 9 – Context
Responses to Q7 – Supplementary guidance
Responses to Q9 – Combined safety cases

3.1.3 Within each of the categories listed in Table 3.1, we grouped the comments into themes. In the following sections we summarise each of these themes and describe how the issue has been addressed in the final guidance. We also list, as numbered references, the organisations and individuals who commented on a particular issue or theme. The key to the references can be found in Section 4.

3.2 General comments

3.2.1 This section summarises general comments on the consultation draft of our guidance.

Broad support and agreement

Many respondents said that they broadly supported the revised guidance and agreed with most of the changes, even if they had detailed comments on some issues.

6, 9, 11, 14, 16, 22, 28

We are encouraged by the level of support for the draft guidance and hope that the final guidance will also be widely supported.

Opposed to disposal / nuclear policy

Some respondents said they opposed the policies on geological disposal of radioactive waste and on nuclear energy.

10, 18, 26, 30

We note these comments and are aware of people's concerns. Geological disposal is, however, government policy and we regulate activities that are consistent with it. We shall assess any application for or variation of an authorisation on its individual merits.

Utility of assessment and/or authorisation

Some respondents felt that the guidance, and any related authorisation of radioactive waste disposal, was based on a misleading assumption about the extent to which risk assessments can provide confidence about long-term safety.

2, 7, 19, 24

We consider that it is possible to use qualitative and quantitative assessments of the future behaviour of the disposal system to gain a reasonable understanding of how the system might evolve and the associated risks. We do not seek predictions of what will actually happen as this is not possible. In coming to a judgement about whether to grant an authorisation we consider that it is important to look at qualitative as well as quantitative information and to address extreme scenarios. We have made some changes to clarify the points raised but have not changed the basis of the guidance.

Definition of disposal / retrievability

Several respondents commented on the definition of 'disposal' and the role of retrievability in any proposal for geological disposal. This was also raised at the consultation workshop.

6, 10, 14, 26, 31

We have clarified the differences between disposal and storage, and why it is important to make the distinction. We have also revised the description of retrievability and closure, and explained why any provisions for retrieval will be

examined closely for unacceptable effects on the safety of people or the environment.

Definition of deep disposal

Two respondents asked us to make clear what was meant by ‘deep disposal’ in terms of actual depths. This was also raised at the consultation workshop.

2, 28, 31

A key feature of geological disposal is that the host rock (geology) provides an environmental safety function and the effectiveness of this function may depend upon the nature of the host rock. An appropriate depth for a disposal facility is likely to differ from one location to another and our guidance cannot anticipate the nature of the geology that the developer of a facility will select. We therefore have not indicated particular depths.

Alignment with MRWS White Paper

Several respondents noted the need to align the guidance with the MRWS White Paper in terms of the stages of the process and terminology. This was also raised at the consultation workshop.

2, 6, 12, 14, 25, 28, 31

The MRWS White Paper was published during the consultation period on our draft guidance. We have now made our guidance consistent with the MRWS White Paper in terms of the terminology used and stages of the process.

Two versions of the guidance

Two respondents questioned whether two versions of the guidance were necessary and felt that the relatively small differences between them could lead to confusion. Other respondents agreed with having two versions.

3, 21

There are a number of reasons for maintaining two versions of the guidance. The guidance on geological disposal has been closely integrated with the process described in the White Paper *Managing Radioactive Waste Safely (MRWS)*, which was published during the consultation period. The MRWS process does not apply to near-surface disposal facilities. Also the guidance for near-surface disposal is intended to cover a wide range of facilities that might be used for this type of disposal.

Audience

Some respondents felt that, although the guidance seems suitable for the developer and operator of a geological facility for the disposal of radioactive waste, other readers would benefit from clearer language or more definitions of technical terms.

1, 2, 4, 28

We have clarified the text in places to explain some topics further. The guidance is aimed at the developer and operator and it is important that the guidance remains as precise as possible in explaining our requirements to them.

Scope (including level of prescription)

One respondent thought that the guidance was too detailed and that not all the information on legislation was required. The level of prescription in the guidance was also discussed at the consultation workshop and some participants asked

whether less ambiguity (i.e. greater prescription) in the guidance would strengthen the environment agencies' independent role.

21, 31

Part 1 of the guidance sets out our principles and requirements and our expectations of an environmental safety case. Part 2 provides information and sets our guidance in context. We do not think that Part 2 detracts from the guidance in Part 1.

We have amended Part 1 to make our expectations clearer, providing guidance on how the developer and operator of a geological disposal facility will need to address each of the requirements we specify. It is the responsibility of the developer and operator to decide how to meet the requirements. If they consider that parts of our guidance are not relevant or are too detailed for their particular circumstances, then we may not insist that they follow the guidance fully, as long as they provide satisfactory reasons in their environmental safety case.

It is by stressing the responsibilities of the developer and operator that we maintain our independence. We would not wish to provide guidance that was so detailed and prescriptive that we were effectively pre-judging many issues. We want to carry out an independent review of an environmental safety case that is based on actual designs and site characteristics.

Different levels of detail / document structure

Some respondents thought that the different levels of detail for different requirements were confusing, particularly when we said that all requirements were of equal importance.

2, 25, 28

It is important that the developer or operator addresses all the requirements set out in the guidance. However, this does not mean that the same amount of information or detail is required for all parts of the environmental safety case. We have amended the text in response to some of the comments and to make our expectations clearer, but some requirements will need more detail than others.

Role of stakeholders

More information on the scope of consultation with stakeholders and communities was requested, together with information on how community views could affect an application for disposal under RSA 93.

4, 28

We have explained more clearly our expectations on dialogue with local communities and others (*Requirement R2* in the final guidance). The details of how the dialogue processes with the local community will take place will vary from site to site. These should take into account the needs of the potential host community including the relationship with any Community Siting Partnership. To allow for flexibility according to particular circumstances, we have decided not to specify these processes in more detail in this guidance.

Planning issues

One respondent suggested including more references to documents on sustainable development and to regional as well as national planning guidance. This respondent also called for more complete referencing, including web links.

4

We have revised the section describing the planning framework (*Section 8.6*) to reflect recent changes, but this is not intended to be a detailed guide to planning or sustainable development.

Where information is available solely on the web we have provided current web links. We have provided sufficient bibliographic information for readers to find references easily.

Authorisation process

Several respondents asked questions about the regulatory process and the time-line for meeting the requirements set out in the guidance. This was also raised at the consultation workshop.

2, 4, 25, 28

We have added new material to *Chapter 5 – Authorisation of disposal*, describing the regulatory process and illustrating the time-line for authorisation.

Relationship to other regulations / guidance

Several respondents wanted more cross-referencing to other regulatory regimes and requirements, along with advice on environmental planning and reference to HPA. This issue was also raised at the consultation workshop.

2, 6, 28, 31

We have made clear how our regulatory process relates to the planning process and to our involvement with HSE/NII at a nuclear licensed site (*Chapter 5 – Authorisation of disposal*). We have also made small changes to *Chapter 9 – The legislation we enforce*. A new annex (*Annex I*) sets out the relationship between our guidance and HPA's advice.

Need to develop skills

One respondent noted the need to address the skills requirement associated with a geological disposal programme.

9

We agree that it is important that personnel with the necessary skills are available. We have noted under *Requirement R4 – Environmental safety culture and management system* that the developer and operator of the disposal facility, together with the environment agency concerned, will need to maintain relevant competences over the lifetime of the facility, including any period of authorisation after closure.

3.3 Responses to Q1 – Clarity

- 3.3.1 This section summarises responses to Question 1: Is the document sufficiently clear to a non-technical reader? If not, what improvements would you suggest?

Clearly presented

Several respondents noted that the guidance is presented in a way that a non-specialist could understand.

3, 8, 14, 20, 27

We are encouraged by the level of support and hope that the final guidance will also be widely supported.

More on dose and risk, including examples

Some respondents felt that more non-technical explanations of risk, including examples from everyday activities, would widen the audience for the guidance.

11, 12, 31

We have tried to make the guidance accessible to as wide an audience as possible while recognising that the document is aimed at the needs of the developer and operator in developing an environmental safety case. We are considering the development of a separate lay person's guide to accompany the guidance.

Relationship to other regulations / guidance

Two respondents noted that the Environment Agency's proposed Radioactive Substances Regulation Environmental Principles appear to fulfil similar functions to the guidance. They thought that the links between the new guidance and other guidance being consulted on should be made clear.

16, 17

We have added information about the Environment Agency's Radioactive Substances Regulation Environmental Principles and the relationship in England and Wales between them and the new guidance on disposal facilities for solid radioactive waste.

Improve glossary

Two respondents commented that a reasonable balance had been achieved in making the guidance accessible and useful for different audiences but suggested that more terms could be defined in the glossary to help the non-technical reader.

4, 15

We have added more terms to the glossary. Definitions of terms not in the glossary can be found in general reference sources.

Clear but unattainable / unreasonable

Two respondents expressed the view that, although the guidance was clearly written, its goals were not attainable.

24, 26

The overall goal of our guidance is to ensure protection of people and the environment. In pursuit of this goal, we have established a set of Principles (which are in part aspirational because they relate to the future) and a set of Requirements against which conformity can be judged.

Vagueness / lack of clarity and precision

One respondent was concerned that terms used in the guidance were vague and that precise definitions should be used in describing the requirements.

2

We have tried to use precise terms where these are appropriate, but it is inevitable that judgement will be needed in assessing proposals for disposal facilities. It is therefore appropriate that requirements have some flexibility and that the guidance is not unreasonably prescriptive.

Too technical

One respondent thought that, although the guidance needed to be technically specific, it was written in too technical a manner.

6

We have clarified the text to explain some topics further. The principal audience for the guidance is the developer and operator of a geological disposal facility and it is important that the guidance remains as precise as possible in explaining our requirements. We are considering the development of a separate lay person's guide to accompany the guidance.

3.4 Responses to Q2 – Relationship to HPA

- 3.4.1 This section summarises responses to Question 2: Is the relationship between the environment agencies' regulatory guidance documents and HPA's advice on solid radioactive waste disposal clear enough in the documents? If not, how might it be made clearer?

Sufficiently clear

A number of respondents thought that the links between the guidance and HPA's advice were clear enough.

3, 8, 20

We have noted their comments but have decided to develop the discussion of the links between our guidance and HPA's advice and have now included it as an annex (*Annex I*) that does not form part of the guidance itself.

More explanation required

Several respondents thought that the relationship between the guidance and HPA's advice was not well explained and not particularly clear.

2, 4, 11, 15, 17

We have added *Annex I* which sets out the relationship between our guidance and HPA's advice.

Need for commonality

Some respondents felt the environment agencies and HPA should work more closely together to ensure that there was consistent use of terms such as 'risk' and 'dose' and that these should be applied in a similar way.

6, 10, 12, 14, 16, 26, 27

We have worked closely with HPA in developing *Annex I* that sets out the relationship between our guidance and HPA's advice. Where possible, we have ensured consistency. Some differences remain because we have different roles, as *Annex I* explains.

3.5 Comments on Chapters 1–3

- 3.5.1 This section summarises comments on *Chapters 1–3* of the consultation draft.

Reasons for guidance

Two respondents noted that no specific justification for the new guidance had been presented, only a history of developments.

26, 28

We have revised *Chapter 1* in the final guidance. Although we include a brief history of our guidance and identify other related developments, we do not imply that this is the justification for the new guidance. However, by providing up-to-date regulatory guidance on geological disposal, we can help make sure that a geological facility for the disposal of higher activity radioactive wastes is developed properly.

Retrievability and facility closure

Three respondents asked about retrievability, the relationship of disposal to storage, phased disposal and how closure is defined.

11, 25, 26

We have clarified the differences between disposal and storage and why it is important to make the distinction. We have also revised the description of retrievability and closure and explained that any provisions for retrieval or proposals to delay closure of the facility will need to be examined closely for any unacceptable effects on the safety of people or the environment.

Role of regulators

Two respondents thought that the guidance on the role of the regulators in consultation was too vague.

26, 28

These chapters are intended to give an overview of the communication process and other activities and not to define our statutory role or other details.

Our role is discussed in more detail in *Chapter 5 – Authorisation of disposal*.

Implications of inventory

Several respondents asked about the specific disposal issues relating to plutonium and spent fuel.

1, 11, 26

We consider that the guidance is broad enough to encompass the current status of these materials. We might need to review the guidance if these materials are declared as wastes in the future.

Monitoring

One respondent suggested there should be no distinction between monitoring for technical reasons and monitoring for public reassurance.

26

We consider that there is a distinction between monitoring intended to provide data to ensure that the facility is operating within the parameters set out in the environmental safety case and monitoring for public reassurance. We anticipate that all arrangements for monitoring, whether for technical reasons or public reassurance, will be set out in the developer and operator's monitoring plan. We shall expect to see this plan as part of the supporting information for the environmental safety case. When we grant an authorisation we shall set appropriate conditions regarding monitoring of the facility.

Types of facility

One respondent noted that storage was an inevitable part of a disposal strategy lasting decades and that the guidance should acknowledge this.

28

For the purposes of our guidance, disposal takes place when waste is emplaced in the facility with no intention of later retrieval, even if other activities such as backfilling and closure are deferred for some time after emplacement. If the operator stores waste before emplacement, such storage would be subject to regulation by HSE/NII (assuming that the facility is on a nuclear licensed site).

State of knowledge

One respondent thought that the guidance should be more explicit about assumptions made within the current state of knowledge.

26

We have made clear that assumptions can only be made on the basis of the current state of knowledge, and that we shall make regulatory judgements on this basis. We have also made clear that it is important that the developer and operator of a geological disposal facility undertakes appropriate research and development and incorporates the results of this work into future assessments and environmental safety cases.

In general, however, we consider that the current knowledge base is sufficient for us to write the guidance. The developer of a disposal facility must satisfy us that the knowledge base at the time of a submission is sufficient to support an environmental safety case acceptable at that time.

Relationship to other regulations / guidance

One respondent noted that there are other guidance developments and consultations taking place and that the final version of this guidance should be consistent with them.

11

We have mentioned other developments relevant to our guidance and have taken into account new policy and advice where it is available.

Utility of assessment and/or authorisation

One respondent questioned whether any assessment or associated authorisation could demonstrate 'proper protection'.

26

We use 'proper protection' to mean protection that meets our principles and requirements, and we consider that this is clear from the context. We consider that it is possible to make assumptions and calculations about the future behaviour of the disposal system which will provide a reasonable understanding of how the system might evolve and the associated risks. We do not ask for predictions of what will actually happen as this is not possible.

Consistency

One respondent noted that the guidance should be consistent with the assumptions necessary to make a satisfactory environmental safety case.

12

We have removed reference to possible timescales and the role of geology and engineering, so that the developer and operator can develop an environmental safety case based on their selected disposal concept.

3.6 Responses to Q3 – Principles

- 3.6.1 This section summarises responses to Question 3: Are the principles set out in the guidance clear, sensible and complete with respect to the disposal of solid radioactive waste to land? If not, what changes and/or additions would you suggest?

Clear, sensible and complete

Several respondents thought that the principles were clear, sensible and complete.

3, 6, 8, 12

We are encouraged by the level of support and hope that the final guidance will also be widely supported.

Avoid ‘safeguards’

One respondent suggested that ‘protects’ was a better word to use than ‘safeguards’ because of the special meaning attached to the latter in the nuclear context.

12

We recognise the special meaning attached to ‘safeguards’ in relation to nuclear materials and now use the term only in this context.

Scope and status of Principle 6

Several respondents commented on *Principle 6*, relating to the responsibilities of the environment agencies, and questioned whether this was appropriate as a principle.

12, 16, 26

We have kept this principle (now *Principle 5 – Openness and inclusivity*), with some changes to the wording. We consider that it is appropriate to have principles that govern the way in which all aspects of the authorisation of radioactive waste disposal facilities are conducted. *Principles 1–4* in our final guidance and the associated requirements determine the work undertaken by the developer and operator. *Principle 5* determines how we should work.

Determining cost-effectiveness

One respondent felt that it was not the role of the regulator to judge cost-effectiveness.

25

Although we have an obligation to take account of economic considerations, we have amended the text concerning cost-effectiveness to make our role clear.

Similarity of Principles 1 and 3

Several respondents noted that *Principles 1 and 3* appeared to be very similar and asked whether they could be combined.

11, 12, 17

We agree. We have combined these principles into a revised *Principle 1 – Level of protection against radiological hazards at the time of disposal and in the future*.

State of knowledge

One respondent thought the principles were not achievable given the current state of knowledge.

26

We recognise that it is not possible to set criteria against which all of the principles can be assessed – they are partly aspirational. This is why we have established a set of requirements against which conformity can be judged. We consider that it is possible to assess the future behaviour of the disposal system to gain a reasonable understanding of how the system might change and the associated risks. If we consider that the state of knowledge at the time the environmental safety case is submitted is insufficient to allow the environmental safety case to be made, we shall require the developer and operator to undertake appropriate research before we authorise further development.

Determining / defining what is ‘adequate’

One respondent asked for clarification of what the term ‘adequate protection’ meant in relation to *Principle 1*.

26

We no longer use the term ‘adequate’ in the principle.

Clarify ‘risks will vary’ and associated text

One respondent asked for clarification of the phrase ‘risks will vary’ and associated text relating to *Principle 1*.

15

We have revised this part of the explanatory text for *Principle 1*.

Applicability of the Fundamental Safety Objective

Some respondents thought that the Fundamental Safety Objective was poorly worded and that the criteria that would be applied were unclear.

4, 18

We have revised the wording of the Fundamental Protection Objective to make it clearer. We accept that it is not possible to set criteria against which the Fundamental Protection Objective can be judged – it is aspirational. This is why we have established a set of principles (which are partly aspirational because they relate to the future) and a set of requirements against which conformity can be judged.

Principle 4 unclear (text and application)

One respondent felt that the guidance was not clear on what was required for non-radiological hazards under this principle.

1

We have changed the wording of this principle (now *Principle 3 – Level of protection against non-radiological hazards at the time of disposal and in the future*), and also the explanatory text, to make clear what is required.

Clarify scope of Principle 2 (Optimisation) and mechanism by which it should be applied / assessed

Two respondents thought that more information was needed on how different considerations could be balanced and the point at which reducing the risk is not worth the cost involved.

12, 14

We have revised the explanatory text for *Principle 2 – Optimisation (as low as reasonably achievable)* to set out more clearly what we mean by optimisation. We also note that optimisation will always need to be considered. It is the responsibility of the developer and operator to do this. The details of how this is done, including the relative weights applied to different factors in reaching a decision, will be site-specific. We consider that optimisation should be addressed further on a site-specific basis, rather than in this generic guidance.

Status of ICRP and IAEA principles

One respondent proposed that the IAEA and ICRP principles and requirements should be stated up front with the resultant regulatory requirements derived from them. Another respondent questioned whether IAEA and ICRP were unbiased sources of advice and principles.

25, 26

We think it is important to acknowledge the relationship between our guidance and documents published by international organisations. This helps provide confidence that our guidance is comprehensive and consistent at a fundamental level with international views and guidance. However, our own guidance is independent of these sources.

Clarify ‘commanding confidence’

One respondent noted that it would be difficult to measure or assess whether disposal commands confidence.

18

We agree and have changed the phrase accordingly.

Applicability of principles

One respondent asked whether the principles should be applied proportionately rather than equally as implied in the guidance.

2

It is the requirements that we have developed in support of the principles that can be applied proportionately (rather than the principles themselves, which are partly aspirational). Applying the requirements in a proportionate manner will help to ensure that the principles are properly addressed.

Terminology – consistency with other sections, sufficient explanation, confusing use of range of terms / concepts

Two respondents noted that terminology was not always consistent between sections and that more entries in the glossary would help readers.

11, 18

We have made changes throughout our guidance to make clear what is required and to be consistent between sections. We have also added some terms to the glossary.

Inclusion of economic factors

Two respondents thought that economic factors should not play a role in determining what measures are implemented.

26, 27

We have a statutory obligation to consider economic factors in our regulatory activities – for example, under section 4(1) of the Environment Act 1995 in England, Wales and Scotland.

Clarify applicability over life-cycle, including site selection.

Two respondents felt that more information about the authorisation process over the life-cycle of a facility would be useful and also asked how optimisation would be applied to site selection.

11, 20

We recognise that site selection is an important stage in the development of a disposal facility, but RSA 93 does not give us regulatory control until a developer submits an application for an authorisation. This would normally happen when a site had been identified and site characterisation had started. We shall nevertheless want to engage with the developer at an early stage, in a process by agreement. This will allow us to provide advice on the developer's plans, including site selection issues, when asked.

We shall also provide advice to the planning authority on any application for planning permission, based on the developer's environmental statement and any available environmental safety case. This is likely to be before an application for an authorisation and may cover site selection issues. In terms of optimisation, we would always expect the developer and operator to consider options and make decisions using the best available information. We recognise that social and economic factors, as well as technical ones, may have a major influence on site selection.

In *Figures 5.4 and 5.5*, we provide a timeline for an indicative process from the start of intrusive site investigation to closure of a facility and surrender of an environmental permit or revocation of an authorisation.

Need for criteria

One respondent noted that there are no criteria against which it can be determined whether a principle has been met.

18

We recognise that there are no criteria against which some of the principles can be assessed. This is why we have developed the requirements. We consider that meeting the requirements will provide a significant degree of confidence that the principles, and the fundamental protection objective, are met.

Clarify relationship between principles and requirements

One respondent felt that the diagram gave a misleading impression about the relationship between the principles and the requirements.

11

Figure 3.1 shows that *Requirements R3 to R14* (grouped into management, radiological and technical requirements) are all presented in *Chapter 6* and that they all relate to the first four principles. Similarly, *Requirements R1 and R2* are presented in *Chapter 5* and relate to the final principle. We hope that this helps to clarify the relationship between the principles and requirements.

Maintaining expertise

One respondent suggested that the need to maintain expertise should be included under *Principle 6*.

11

We agree that it is important to maintain expertise but we do not think that this should be singled out to be included under the principle. We have noted under *Requirement R4 – Environmental safety culture and management system* that the developer and operator of the disposal facility, together with the environment agency concerned, will need to maintain relevant competences over the lifetime of the facility, including any period of authorisation after closure.

Potential change in standards

One respondent thought that the guidance should state more clearly that the protection standards applied might change in the future as scientific understanding increases.

11

We agree and have clarified this text accordingly.

Clarify Principle 5

One respondent suggested clarifying *Principle 5* by separately addressing the approaches to be taken at the time of disposal and in the future.

12

We have revised the explanatory text for this principle (now *Principle 4 – Reliance on human action*) to make clear that it applies mainly to the period after closure and that, during operations, some reliance on human action and active safety systems is expected.

Phased disposal

One respondent thought that the guidance was inconsistent with the concept of phased disposal.

26

We do not understand what aspect of our guidance is inconsistent with the concept of phased disposal. If phased disposal forms part of the developer and operator's strategy, then it must be documented in the environmental safety case, even if details of future plans and phases are not yet fully decided. We shall base our regulatory decisions, including any authorisation conditions, on the developer's overall strategy, not just on the early phases of disposal.

Role of regulators and assessment process

Several respondents questioned whether the environment agencies were in a position to decide what was acceptable to future generations and whether it was appropriate to issue guidance based on an assumption that a facility could meet the principles.

10, 18, 26, 29

We have revised the wording of *Principle 1 – Level of protection against radiological hazards at the time of disposal and in the future* to avoid any implication that we know what would be acceptable in the future – our guidance is based on current standards.

We recognise that it is not possible to set criteria against which all the principles can be assessed – they are partly aspirational. This is why we have established a set of requirements against which conformity can be judged. We consider that it is possible to make assumptions and calculations about the future behaviour of the disposal system which will provide a reasonable understanding of how the system might evolve and the associated risks. It is therefore appropriate that we issue this guidance.

3.7 Responses to Q4 – General comments on Requirements

3.7.1 This section summarises general responses to Question 4: Are the requirements set out in the guidance clear and sensible and do they sufficiently cover all the areas that need to be addressed in the disposal of solid radioactive waste to land? If not, what changes and/or additions would you suggest?

3.7.2 Comments on specific requirements are presented in the following sections.

Reasonable

One respondent thought the requirements were reasonable and did not identify any additional requirements.

8

We welcome this support.

Reasonable, but different level of detail confusing and detailed information needed to meet requirements not always clear

Several respondents considered the requirements to be reasonable, but the differing amount of detail was confusing and it was not always clear what information was needed to meet the requirements.

2, 4, 11, 15, 17, 31

It is important that the developer and operator satisfies all the requirements set out in the guidance, although this need not mean that the same amount of information or detail is required for all parts of the environmental safety case. We have amended the text under certain requirements in response to some of the comments received to make our expectations clearer, but some requirements will always need more detail than others.

Develop a clear time-line – Clarify what is meant by ‘developing’ a facility / when authorisation ends, etc. / when different criteria apply

Two respondents wanted a clearer explanation of when the requirements needed to be met during the life-cycle of a facility and at various stages of the authorisation process.

4, 31

The way in which the developer and operator interacts with us, and the stages at which environmental safety cases might be submitted, are now discussed in detail in *Chapter 5 – Authorisation of disposal*. We have illustrated the various stages of the authorisation process on a time-line.

Clarify the engagement / consultation processes and responsibilities

Two respondents asked for clarification of the anticipated engagement and consultation processes and who would have responsibility for them.

6, 16

We have explained more clearly our expectations on dialogue with local communities and others (*Requirement R2* in the final guidance). The details of how the dialogue processes with the local community will take place will vary from site to site. These should take into account the needs of the potential host community including the relationship with any Community Siting Partnership. To allow for flexibility according to particular circumstances, we have decided not to specify these processes in more detail in this guidance.

Degree of uncertainty and how can this be assessed / meeting requirements demonstrated

Several respondents noted that there were very large uncertainties involved in the transport of radionuclides through the environment and questioned how meeting the requirements could be demonstrated in the presence of these uncertainties. This issue was also raised at the consultation workshop.

23, 26, 27, 31

We agree that there are uncertainties in many aspects of an assessment of the future behaviour of a disposal system, including the transport of radionuclides from the facility through the environment. Our guidance explains what we would expect the developer and operator to do to address these uncertainties. The environmental safety case will need to identify uncertainties and explain how they are managed. We shall take account of the significance of uncertainties when we make our regulatory decisions.

Consistency with SAPs

Two respondents noted that parts of the guidance covered issues that are also addressed in HSE/NII's Safety Assessment Principles (SAPs), and that the regulatory requirements should be consistent.

20, 31

Where appropriate, we have used the SAPs in developing our requirements and in the descriptions of our expectations.

3.8 Comments on Requirements 1–3 (Chapter 5)

- 3.8.1 This section summarises comments on *Requirements 1–3* in the consultation draft (requirements on the authorisation of disposal).

Broad agreement

Commenting on *Requirement R2*, one respondent felt that early engagement with the developer and stakeholders and a staged authorisation process would be useful.

3

We agree with the comment and have stressed the importance of early engagement. The way in which the developer and operator interacts with us, and the stages at which environmental safety cases might be submitted, are now discussed in detail in *Chapter 5 – Authorisation of disposal*. *Requirement R2* in the consultation draft has been deleted.

Consistency with MRWS

Respondents noted that the guidance must be consistent with the MRWS White Paper. This issue was also discussed at the consultation workshop.

12, 25, 31

We have extensively revised *Chapter 5* of the guidance to describe how the regulatory process interacts with the development stages set out in the MRWS White Paper. In particular, Figure 5.1 from the consultation draft has been further developed, and Figures 5.2, 5.3, 5.4 and 5.5 now show the relationship between our regulatory processes, the planning system and HSE/NII's licensing of a nuclear site, and MRWS stages. Figures 5.2 and 5.4 assume suitable powers are provided for staged authorisation through legislative change. If such powers are delayed or not available, Figures 5.3 and 5.5 illustrate an alternative process

based on authorisation under RSA 93. We have also changed text to reflect MRWS stages.

Exclusion of site selection

Respondents noted that, although the guidance states that site selection is outside its scope, the environment agencies will be involved in the site selection process. The guidance should reflect this.

2, 14, 25

Although we expect to be consulted about some aspects of site selection, this stage remains outside our regulatory scope. We have extensively revised *Chapter 5 – Authorisation of disposal* to make clear how staged authorisation (under revised legislation) or, if this is delayed or not available, authorisation under RSA 93 relate to the MRWS stages.

Clarification of consultation roles / scope / outcome

Several respondents thought that *Requirement R3* was confusing and did not clearly set out the roles and responsibilities of participants in a consultation.

11, 12, 16, 23, 25, 26, 28, 31

We have explained more clearly our expectations on dialogue with local communities and others (*Requirement R2* in the final guidance). The details of how the dialogue processes with the local community will take place will vary from site to site. These should take into account the needs of the potential host community including the relationship with any Community Siting Partnership. To allow for flexibility according to particular circumstances, we have decided not to specify these processes in more detail in this guidance.

Planning issues

One respondent asked for more explanation of the relationship between the authorisation process and the planning process. This issue was also raised at the consultation workshop.

25, 31

We have made clear that the land-use planning process and environmental regulation are separate decision-making processes.

We shall provide advice to the planning authority on any application for planning permission, based on the developer and operator's environmental statement and any available environmental safety case. It is likely that this will be before any application for an authorisation, although there may be a need for further planning decisions during operations. These interactions are described in more detail in *Chapter 5 – Authorisation of disposal*.

Step-wise process

Several respondents asked for clarification of 'step-wise' and 'staged', and asked how decision points would be determined. This issue was also raised at the consultation workshop.

11, 12, 25, 28, 31

To avoid confusion, we no longer use the term 'step-wise' to describe the way in which authorisation will proceed. In *Chapter 5 – Authorisation of disposal*, we have described an indicative process based initially on a process by agreement covering site investigation, authorisation of a facility and closure. We have also clarified the points in a development programme when we expect a developer might submit an environmental safety case to us for review.

Timing of submissions / authorisation reviews

Several respondents thought that the guidance should explicitly mention reviews and revisions to the authorisation during the operational, closure and post-closure (institutional control) periods. They also wanted authorisation reviews to consider waste packaging and other issues before waste is consigned to a facility. This was also raised at the consultation workshop.

11, 23, 26, 31

We have extensively revised *Chapter 5 – Authorisation of disposal*, to make clear how staged authorisation (under revised legislation) or, if this is delayed or not available, authorisation under RSA 93 relate to the MRWS stages. These stages relate to the development, operation and closure of a disposal facility.

Waste packaging at consigning sites is also subject to scrutiny by the Environment Agency under agreements with HSE/NII. We acknowledge that there are important links between waste packaging, facility design (*Requirement R12 – Use of site and facility design, construction, operation and closure*) and the development of waste acceptance criteria (*Requirement R13 – Waste acceptance criteria*). Nevertheless, it is not appropriate to combine guidance for different facilities. We shall ensure, through our reviews and authorisation conditions, that the developer and operator understands these relationships and takes them properly into account.

Voluntary agreement

Two respondents asked for more information about a voluntary agreement and what responsibilities the environment agencies would have under such an agreement.

2, 12

We have revised the section of the guidance describing the process by agreement (we no longer use the term ‘voluntary’) under *Requirement R1*. It includes a description of the responsibilities of the environment agencies.

3.9 Comments on Requirement R4 – Environmental Safety Case

- 3.9.1 This section summarises comments on *Requirement R4 – Environmental safety case* in the consultation draft.

Expectations

One respondent felt that more clarity was needed on the environment agencies’ expectations for an environmental safety case and how such a case would be evaluated.

12

We have made general changes to the text to make clearer the environment agencies’ expectations both on timing and on content of the environmental safety case.

Utility of assessment and/or authorisation

One respondent questioned whether any assessment or associated authorisation could demonstrate that a demonstration of isolation was supported by arguments and ‘evidence’.

26

The guidance does not call for the demonstration of long-term isolation but does require that all our requirements are met. By meeting the requirements set out in

the guidance, any risks posed by the migration of radionuclides from the facility are minimised. We have removed reference to isolation.

Scope / expectations

At the consultation workshop, a point was raised that the environmental safety case described in the guidance would not cover all activities, and that expectations of what the environmental safety case does provide need to be managed.

31

We have revised *Chapter 7 – Environmental safety case* to clarify our expectations of what should be included.

3.10 Comments on Requirement R5 – Environmental safety culture and management system

- 3.10.1 This section summarises comments on *Requirement R5 – Environmental safety culture and management system* in the consultation draft.

How assessed

One respondent questioned how the environment agencies would measure and evaluate an environmental safety culture.

25

We consider that it is possible to evaluate an environmental safety culture, although we recognise that evaluation requires some exercise of judgement. We already include a similar requirement in our current RSA 93 authorisations.

Peer review

One respondent noted that it may not always be possible to reach agreement with reviewers. Another thought there may be a case for extending peer review to involve key stakeholders.

12, 16, 26

We agree with the first comment and have amended the text accordingly. Peer review is important but total agreement between developer and reviewer is not required. In particular, we do not want to detract from the process by giving the developer an incentive to choose reviewers who are less likely to raise issues with the work.

Regarding the second comment, we have added reference to the possibility of 'peer preview' by key stakeholders where technical work is considered to be of sufficient importance or there is some significant controversy in a particular subject area. Peer preview could involve key stakeholders reviewing and agreeing the terms of reference for a proposed work package or 'joint fact finding' where they review work packages at key stages.

Form of submissions / records

Two respondents requested more information about the required form of submissions from the developer and operator.

1, 2

We have clarified the specific text referred to in this comment.

Possible additions to information required

One respondent asked whether information about choices that were discarded was required.

1

We consider that such information could be important and have amended the text to address this point.

Isolation not feasible

One respondent questioned whether the measures described and the delays achieved by the multi-barriers provided by a geological disposal facility could lead to isolation over the timescales required.

26

There is no way to isolate waste completely; at some time in the future radionuclides will migrate from the facility. It is the calculated risks associated with this migration that are to be considered by the environment agencies.

3.11 Comments on Requirement R6 – Dose constraints

- 3.11.1 This section summarises responses concerning *Requirement R6 – Dose constraints during the period of authorisation* in the consultation draft.

Clarify authorisation period and applicability of this requirement

Two respondents asked about the period over which the dose constraint applies.

11, 25

The authorisation period is defined in the Glossary. We have included a diagram to illustrate the periods over which the dose constraint and the risk guidance level apply.

Discharge strategy is being consulted on and liable to change – consider deleting explicit detail

Two respondents noted that the UK discharges strategy 2006–2030 is subject to consultation and suggested removing material that may need to be revised soon after the guidance was published.

11, 26

We acknowledge that some material in this part of the guidance represents a snapshot in time and will be superseded. We shall consider updating the guidance at an appropriate time in the future. Updated text on the draft revised UK discharges strategy is included in *Chapter 8*.

Length of control period

One respondent questioned whether an institutional control period was consistent with the concept of disposal (removal of burden).

26

Disposal does remove the burden of ongoing management of radioactive waste from future generations after the period of authorisation. The concept of an institutional control period implies that the burden would be limited, rather than that there would be no burden on some future generations.

Contribution of radon

One respondent asked the regulators to clarify their position on natural radon emanating from the host rock.

12

The regulation of naturally occurring radon in a work environment is the responsibility of HSE and is not dealt with in our document. We expect that doses to the public from any discharge of naturally occurring radon into the atmosphere from an excavation would be very small.

Relationship to risk guidance level

One respondent noted that the relationship between the current dose constraint and the future 'risk guidance level' (covering a factor of 15) needs to be more explicitly defined.

24

We have included a discussion on the origins of the 10^{-6} figure based on the HSE recommendation in their publications *Reducing Risk, Protecting People* and *The Tolerability of Risks from Nuclear Power Stations*.

Nature of remediation

One respondent questioned what types of remediation might be required if the dose constraint were to be exceeded.

26

We have added a bullet point asking for suitable plans that would be acted upon if monitoring data showed a potential problem.

3.12 Responses to Q5 – Risk guidance level

- 3.12.1 This section summarises responses to Question 5: The environment agencies are proposing a risk guidance level of 10^{-6} per year (i.e. 1 in a million per year) after the period of authorisation. Does this provide a sufficient and appropriate standard of protection? Is the term 'risk guidance level' sufficiently clear and unambiguous? If not, what would you suggest?

Appropriate / clear

Many respondents thought that the risk guidance level was set at an appropriate value and was adequately explained.

3, 4, 8, 17, 20

We are encouraged by the level of support and hope that the final guidance document will also be widely supported.

Appropriate but further explanation / justification

Several respondents thought the risk guidance level was set at an appropriate value but required further explanation or justification.

2, 12, 14, 15, 31

We have included a discussion on the origins of the 10^{-6} figure based on the HSE recommendation in their publications *Reducing Risk, Protecting People* and *The Tolerability of Risks from Nuclear Power Stations*.

Avoid any implication of ‘limit’

One respondent, noting that ‘risk guidance level’ was equivalent to ‘risk target’ in the earlier guidance, was concerned at any implication that the risk guidance level would be applied as a limit.

24

It is clear from the text that that the risk guidance level is not a limit. The guidance is framed at a high level and discussion with the developer will help sort out issues of detail. We do not propose to make changes in the light of this comment.

Appropriateness of risk as a measure

One respondent asked what the basis was or the criteria were for the risk guidance level, and questioned whether use of the dose-risk factor was appropriate.

26

The dose-risk factor is based on the best available information that the environment agencies have and is considered fit for purpose. In granting an authorisation, the environment agencies look at the whole case and exercise judgement; the numerical calculations are only one element of the environmental safety case for a facility. We have made the text clearer.

Relationship to HPA advice concerning ICRP recommendations

One respondent was concerned about the use of the dose-risk factor from ICRP 60, noting that HPA would shortly be issuing advice on the application of ICRP 103.

11

We have modified the text to clarify the use of the dose-risk factor and how it is defined.

Acceptability of high doses with a low probability of occurrence

One respondent was concerned about the implications of the phrase ‘larger dose levels might be allowable in some situations if the probability was low enough’. This point was also raised at the consultation workshop.

11, 31

We have revised the text to clarify this point.

Role of conservatism

Two respondents were concerned that the guidance implied that a quantitative comparison of calculated risk with the risk guidance level was uniformly appropriate throughout the period being considered. It would be better to state that the risk guidance level has been set conservatively.

11, 12

We have included text in Section 7 to bring out the point that for periods far into the future the reliance on quantitative assessments becomes less valid and that we shall place more emphasis on qualitative arguments in judging consistency with the risk guidance level.

Comparison with other risks

Two respondents thought that comparisons of the risk guidance level with other risks would be useful.

6, 25

We have tried to make the guidance accessible to as wide an audience as possible but it is important that the guidance addresses the needs of the developer and operator in developing an environmental safety case. Comparisons of the risk guidance level with other risks would not be useful in this context and could detract from the technical guidance. We are considering the development of a separate lay person's guide to accompany the guidance.

3.13 Responses to Q6 – Risk assessment

- 3.13.1 This section summarises responses to Question 6: Do you agree with the proposed approach for assessing risks and comparing them with the risk guidance level? If not, what approach would you suggest? Also responses concerning *Requirement R7 – Risk guidance level after the period of authorisation* in the consultation draft.

Reasonable approach

Several respondents thought the approach to risk assessment described in the guidance was reasonable.

2, 3, 8, 14, 17, 27

We are encouraged by the level of support and hope that the final guidance document will also be widely supported.

Support, but reduce detail / discourse

One respondent thought the overall approach to risk assessment described in the guidance was reasonable but felt that there should be less detail and discourse.

12

We note the comment, but we consider that the issues raised by risk assessment of disposal facilities over long time-scales are worth discussing. We have set out a framework for our expectations of what will need to be addressed in an assessment and this requires the level of detail we have provided.

Separate doses and risks from radon

One respondent thought that the uncertainties in assessing exposures to radon made it necessary to consider these doses and risks separately.

11

We have revised the explanatory text for *Requirement R7 – Human intrusion after the period of authorisation*, in the light of further advice from HPA. We note that, because of the uncertainties in assessing exposures to radon, the developer should present these both aggregated with other exposures and individually.

Worked examples / guidance on models

One respondent suggested that worked examples and guidance on the models used in risk assessment would be of value. This issue was also raised at the consultation workshop.

6, 31

We have tried to make the guidance accessible to as wide an audience as possible but it is important that the guidance addresses the needs of the developer and operator in developing an environmental safety case. Worked

examples and guidance on models used in risk assessment could influence the choices made by the developer and operator and would therefore not be useful in this context. We are considering the development of a separate lay person's guide to accompany the guidance.

Should require additional information on sensitivities

One respondent thought the expectation value was reasonable but felt that additional information on sensitivities should be required.

11

The guidance discusses the role of sensitivity studies in risk assessments.

Role of conservatism

One respondent sought clarification of how we expected that conservatism might be used in risk assessments. This issue was also raised at the consultation workshop.

15, 31

We have modified the text to explain more clearly that the developer and operator may choose to use data and assumptions that are conservative, rather than realistic or best-estimate, if this simplifies the assessment.

Classification of uncertainties

Some respondents wanted the classification of uncertainties as quantifiable or unquantifiable to be made clearer. This issue was also raised at the consultation workshop.

4, 26, 28, 31

We think the term 'quantifiable uncertainties' is reasonable and clearly describes those uncertainties that can be expressed statistically. We have further discussed the classification in the guidance and have explained both quantifiable and unquantifiable uncertainties in the Glossary.

Will need to support judgements and regulatory decisions

One respondent noted that we shall need to support the judgements made in determining whether results from assessments are consistent with the risk guidance level, and also that the developer should clearly explain the significance of the uncertainties. This was also raised at the consultation workshop.

16

We agree and have described the importance of explaining uncertainties and the judgements made on the basis of these uncertainties.

Include population doses

One respondent thought that population doses should be considered, particularly in relation to the siting of facilities. This issue was also raised at the consultation workshop.

20, 31

We have added a section on collective dose under *Requirement R8 – Optimisation*, although we caution against applying too much significance to such measures.

Utility of assessments and/or authorisation

At the consultation workshop, there was discussion of how meaningful risk assessments could be when there are significant uncertainties in much of the data.

26

We consider that it is possible to make assumptions and calculations about the future behaviour of the disposal system in such a way as to gain a reasonable understanding of how the system might evolve and the associated risks. We do not seek predictions of what will actually happen as this is not possible. In coming to a judgement about whether to grant an authorisation, we consider that it is important to look at qualitative as well as quantitative information and to address extreme scenarios. We have made some changes to clarify the points raised but have not changed the basis of the guidance.

PEGs

The consultation workshop discussed the potentially exposed groups (PEGs) to be included in an assessment.

31

The PEGs to be considered in an assessment will need to be identified on a site-specific basis. It is the responsibility of the developer and operator to identify PEGs, on the basis of the type and timing of the release and assumptions about environmental conditions, and to substantiate this selection as reasonable and suited to the circumstances.

Too much emphasis on numerical assessment

At the consultation workshop, the view was expressed that the guidance placed too much emphasis on numerical assessment and not enough on other supporting arguments.

31

We have stressed in many places that calculations of dose and risk are not the only basis for developing an environmental safety case. We set out the need for other supporting arguments in *Chapter 7 – Environmental safety case* and have made a number of revisions here to make our expectations clear.

Role of other performance measures

At the consultation workshop, the view was expressed that the guidance put too much emphasis on dose values and that other performance measures should be required.

31

We acknowledge that other performance measures can be useful in strengthening an environmental safety case. We already require the developer and operator to present information on other measures if the information available warrants it. It is not sensible for our guidance to be more specific as the decisions concerning which measures are appropriate must be determined on a case-by-case basis. Setting criteria for any such performance measures cannot readily be done without reference to dose and may inhibit optimisation.

3.14 Responses to Q10 – Human intrusion (geological disposal)

- 3.14.1 This section summarises responses concerning *Requirement R8 – Human intrusion after the period of authorisation* in the consultation draft, and responses

to Q10: Do you agree with the proposed approach to dealing with human intrusion into deep geological disposal facilities? If not, what approach would you suggest?

Broadly appropriate

Several respondents thought the approach to human intrusion described in the guidance was reasonable. There was also support for this approach at the consultation workshop.

3, 8, 11, 12, 14, 26, 27, 31

We are encouraged by the level of support and hope that the final guidance will also be widely supported.

Clarification of where / when / to whom guidance on intrusion applies

Several respondents thought that more information was needed on the scenarios and activities that should be considered in assessing the consequences of human intrusion.

11, 12, 24, 26, 31

The scenarios and activities that could result in human intrusion and a degradation of environmental safety functions will depend on the site, the geology and the safety functions that contribute to the developer and operator's environmental safety strategy. It is the responsibility of the developer and operator to consider these factors and to identify the scenarios and activities to be considered.

Additional examples / guidance on assumptions and on calculations required

Two respondents sought additional information or examples concerning the calculation of doses from human intrusion. This issue was also discussed at the consultation workshop.

15, 17, 31

We have tried to make the guidance accessible to as wide an audience as possible but it is important that the guidance addresses the needs of the developer and operator in developing an environmental safety case. Additional information or examples of the calculations of doses could influence the choices made by the developer and operator and would therefore not be useful in this context. We are considering the development of a separate lay person's guide to accompany the guidance.

Doses to non-human species

One respondent thought that the same reasoning for not applying absolute standards for doses to humans from intrusion should also apply to doses to non-human species.

11

We agree and our guidance states that the assumptions made for people should also apply to the assessment of environmental impacts after intrusion.

Need for permanent marker / control

Two respondents sought clarification of responsibilities for the site after institutional control and whether there was a requirement for permanent markers. This issue was also discussed at the consultation workshop.

6, 20, 31

There is no requirement for permanent markers. It is the responsibility of the developer and operator to prepare an institutional control plan, in which the advantages and disadvantages of permanent markers should be discussed. We shall judge these plans on their merits.

Developer to make case for unlikely intrusion

Two respondents suggested the developer should be asked to demonstrate that intrusion is unlikely, rather than simply assume that this is the case. This issue was also discussed at the consultation workshop.

11, 16, 31

We agree and we have made clear that we shall expect the developer and operator to substantiate any claim that human intrusion into the disposal facility is unlikely to occur.

Relate to security provisions

One respondent thought that arrangements for controls against intrusion should take account of any controls put in place for security reasons.

2

We agree and our guidance says that arrangements for institutional controls would need to provide for continued management, staffing and site security.

Role in optimisation

The consultation workshop discussed how human intrusion could be considered in optimisation if it was not feasible to estimate its likelihood.

31

We accept that there can be no reliable information about the likelihood of human intrusion into a geological disposal facility. However, we consider that qualitative approaches to optimisation with respect to human intrusion can be applied without knowing the likelihood of human intrusion.

3.15 Responses to Q8 – Optimisation

- 3.15.1 This section summarises responses to Question 8: Do you agree with the approach to optimisation set out in the document? If not, what alternative approach would you suggest? Also responses concerning *Requirement R9 – Optimisation* in the consultation draft.

Sensible approach

Many respondents thought the approach to optimisation set out in the guidance was a sensible one.

3, 4, 8, 11, 12, 14, 17, 20, 31

We are encouraged by the level of support and hope that the final guidance will also be widely supported.

Include non-radiological risks in optimisation

At the consultation workshop, it was questioned why non-radiological risks and the effects of human intrusion were excluded from the requirement concerning optimisation.

31

We agree that it is important that non-radiological risks and the effects of human intrusion should be reduced as much as possible. However, we have a legal duty to ensure that radiological risks to people are as low as reasonably achievable (ALARA), taking account of economic and social factors. If we were to require that other outcomes were optimised, there could be a conflict with this legal duty.

Disagree with inclusion of economic factors

Several respondents expressed a view that optimisation should not take account of economic factors in determining when risks had been reduced to as low as reasonably achievable.

6, 26, 27

We have a legal duty to ensure that radiological risks are as low as reasonably achievable (ALARA) taking account of economic and social factors. We also consider it unreasonable to suppose that the costs of any activity can be ignored when determining whether it is worthwhile undertaking it. We have revised *Principle 2 – Optimisation* and *Requirement R8 – Optimisation*, to make our expectations clearer but have not changed our underlying position.

Timescales to be considered

Several respondents noted that it was important for optimisation to consider the time-scales over which any calculated risks might arise, and the guidance should indicate our expectations more clearly. This issue was also raised at the consultation workshop.

11, 16, 26, 31

We agree that it is important for interpretations and arguments based on calculations of risk to take account of the time-scales over which the risks might arise, and to acknowledge the generally increasing level of uncertainties with time. We have amended the text to make this clear.

More detail on the application of Best Practicable Environmental Option (BPEO) and Best Practicable Means (BPM)

One respondent supported our approach to optimisation but thought that additional guidance should be provided on how processes such as BPEO and BPM should be applied within this approach. This issue was also raised at the consultation workshop.

15, 31

We have made clearer how the concept and terminology of Best Available Techniques (BAT) are superseding BPEO and BPM in England and Wales. We have also stressed that these techniques are intended to be applied to steady-state systems and may not be directly applicable to dynamic systems over the long term. We consider that our guidance on optimisation is sufficient without further reference to BPEO, BPM or BAT.

Alignment with other studies / guidance

One respondent noted that the approach to optimisation in the guidance needs to take account of other guidance on optimisation and the roles of other regulators.

2

In the context of our guidance, optimisation is about reducing radiological risks to people to a level as low as reasonably achievable (ALARA). We are the environmental regulators and decisions by the developer and operator that affect

radiological risks must satisfy us. We shall work in concert with other regulators, particularly with HSE/NII who will have requirements relating to optimisation during operations. It is the responsibility of the developer and operator to develop a disposal facility that will satisfy the requirements of different regulators and to substantiate the decisions made.

Involvement of stakeholders

The importance of social and economic factors in optimisation led one respondent to note that discussion with stakeholders should be part of the process.

16

We agree and our guidance states that, to succeed, optimisation requires good communication, both within the developer's and operator's own organisations and with supplier organisations, as well as with the regulators and the local community.

Methodology for assessing detriment

One respondent suggested that a methodology for assessing and valuing detriment could be an alternative to calculating risk.

24

We assume from the context that the responder has in mind a broader definition of 'detriment' than the radiological protection use discussed under *Requirement R6 – Risk guidance level after the period of authorisation*. Placing a value on detriment would involve expressing both tangible and intangible factors as costs, requiring a valuation of factors such as societal and radiological impacts in monetary terms. It is not apparent why this might be a better approach than calculating risk, but if the developer and operator believes it could help in decision-making there is no reason for it not to be used in support of optimisation.

More detail / clarity

The consultation workshop discussed a number of issues concerning optimisation and concluded that more detail in the guidance and clarification of the environment agencies' expectations would be of value.

31

We have revised the explanatory text for *Principle 2 – Optimisation (as low as reasonably achievable)*, to set out more clearly what we mean by optimisation, and have also revised *Requirement R8 – Optimisation*. It is the responsibility of the developer and operator to undertake optimisation and the details of how this is done, and the relative weights applied to different factors in reaching a decision, will be site-specific.

3.16 Comments on Requirement R10 – Environmental radioactivity

- 3.16.1 This section summarises responses concerning *Requirement R10 – Environmental radioactivity* in the consultation draft.

Clarify scope (individuals, species, etc.) and end-point (flux, concentration, dose)

Two respondents thought that the objective of this requirement to protect individual organisms, species or ecosystems could be clearer.

12, 25

We have reworded this requirement (now *Requirement R9 –Environmental radioactivity*) to make clear that the aim is to show that the accessible environment is adequately protected. As stated in our guidance, there are currently no established criteria for determining environmental protection. It is the responsibility of the developer and operator to carry out assessments and to draw conclusions about the potential effects of a disposal facility on the environment. In general, it is populations of non-human species that might be threatened, but the developer and operator may also need to consider threats to sensitive habitats or individual organisms, or both. We have referred to some recent research on this topic.

Meaning of protection

One respondent questioned whether the application of current standards could be said to provide protection to the public and to the environment.

26

We have revised the wording of our requirements and explanatory text to make clear the purpose of applying current standards.

3.17 Comments on Technical Requirements – R11 to R15

- 3.17.1 This section summarises responses concerning *Requirements R11 to R15* in the consultation draft.

Broad support for requirements

One respondent expressed broad support for the requirements relating to non-radiological hazards and to site investigation.

12

We welcome this support.

Expectations regarding funding

Two respondents asked for more information on our expectations about funding. This issue was also raised at the consultation workshop.

2, 26, 31

Ensuring the funding of a geological facility for the disposal of radioactive waste is a government responsibility. The developer and operator of such a facility needs to agree with government what arrangements are put in place to fund the facility during operation and after closure. We shall assess these arrangements at the time they are proposed and throughout the authorisation period and will judge them against the prevailing conditions.

Fissile material / criticality assessment

Respondents suggested that it would be useful to clarify that the criterion relating to fissile material could be satisfied by showing that criticality, if it occurred, would not have a significant effect on the safety of the repository, rather than by showing criticality to be very unlikely.

12, 24, 26

We acknowledge that our expectations relating to fissile material were not made clear. We did not make clear that it was our intention to accept an assessment that showed that the consequences of any criticality event were not a significant concern. We recognise that, given the types of waste that might be disposed of to a geological facility, it could be difficult to show that a local accumulation of

fissile material has a negligible probability. We have now made clear in the guidance that we would expect an assessment of the consequences even if this probability was small but not negligible.

Expectations on site investigation / align with MRWS White Paper

One respondent noted that it was important for the guidance to use the terminology relating to the stages of site investigation as set out in the MRWS White Paper.

12

We have now made our guidance consistent with the MRWS White Paper in terms of the terminology used and stages of the process.

Role of monitoring

One respondent sought clarification of the fundamental purpose of monitoring discussed under *Requirement R15*.

26

We have made clear that the purpose of the monitoring under this requirement (now *Requirement R14*) is to provide data during the period of authorisation to ensure that the facility is operating within the parameters set out in the environmental safety case.

Clarify requirements relating to gas release

One respondent sought clarification of the requirements relating to gas release under *Requirement R13*.

1

We note the comment but have not changed the explanatory text for this requirement (now *Requirement R12 – Use of site and facility design, construction, operation and closure*). We expect the developer and operator to assess the potential for gas generation within the facility and any consequent effects on radionuclide transport from the facility. It is the responsibility of the developer and operator to ensure that the design of the facility and the waste acceptance criteria protect people and the environment from all hazards, including gas generation and transport.

Clarify setting of WAC

Two respondents thought the guidance should provide more information on waste acceptance criteria (WAC) and how these criteria are established.

12, 26

The purpose of waste acceptance criteria is to ensure that the waste disposed of at a facility, including the packaging of this waste, is consistent with the assumptions made in developing the environmental safety case. Some of these criteria will apply to individual packages to ensure, for example, that they comply with operational requirements and assumptions about long-term behaviour. Packages that did not meet such criteria would probably be rejected. Other criteria, related to information such as the radionuclide inventory, may not lead to rejection of an individual package but would have a cumulative effect if, for example, the disposed inventory approached the radiological capacity for a particular radionuclide.

The details of these criteria cannot be established until there is more specific information about the disposal concept, the types of waste and packages to be disposed of and the arguments used in the environmental safety case. We

cannot anticipate these details and it remains the responsibility of the developer and operator to establish waste acceptance criteria once this information is available. We shall then review the criteria and the procedures for ensuring that they are met.

Standards for non-radiological hazards

Participants at the consultation workshop asked for more information on how non-radiological hazards should be assessed and our expectations for these assessments.

31

We have revised *Requirement R10 – Protection against non-radiological hazards*, to make our expectations clearer. However, it remains the responsibility of the developer and operator to develop a methodology for assessing these hazards and to demonstrate that this requirement is met.

Clarify when / where approaches to sealing and closure are re-examined and assessed

Two respondents asked whether the periodic review of sealing and closure plans would be part of the environmental safety case.

2, 26

The environmental safety case is the principal means through which the developer and operator will communicate their plans for all aspects of the design of the disposal facility. We expect the environmental safety case to be revised periodically throughout the authorisation period (see revisions in *Chapter 5* of our guidance) to incorporate new information and particularly to justify any changes in plans and designs. We do not consider that changes to the guidance are needed specifically to address this issue.

Utility of assessments and/or authorisation

One respondent questioned whether any assessment or associated authorisation could demonstrate that waste would be isolated or contained over the time-scales under consideration.

26

We consider that it is possible to make assumptions and calculations about the future behaviour of the disposal system to gain a reasonable understanding of how the system might evolve and the associated risks. We do not expect the waste to be isolated or contained indefinitely, nor do we ask for predictions of what will actually happen as this is not possible. We highlight why it is important to look at both qualitative and quantitative information and to address extreme scenarios when coming to a judgement about whether a facility is suitable for authorisation. We have clarified the points raised but have not changed the basis of the guidance.

3.18 Comments on Chapter 7 – Environmental safety case

3.18.1 This section summarises responses concerning *Chapter 7* in the consultation draft.

Support for position

One respondent supported the provision of more specific guidance for the environmental safety case than was given in the previous guidance.

12

We welcome this support.

Include role of stylised approach under Requirement R7 as well as in Section 7

One respondent thought the use of stylised approaches to treat certain types of uncertainty should be discussed in *Chapter 6 – Requirements* as well as under the description of the environmental safety case.

12

We consider that Chapter 7 is the right place to discuss stylised approaches. The discussion on uncertainties in the explanatory text for *Requirement R6 – Risk guidance level after the period of authorisation*, shows that we do not expect all uncertainties to be quantified and used explicitly in a risk assessment. Stylised approaches are one of several alternatives and it is appropriate to discuss them in the more general text on the environmental safety case.

Role of HSE/NII in criticality assessments

One respondent asked for clarification of the role of HSE/NII in criticality assessments.

12

The developer and operator of the disposal facility may be able to demonstrate that the possibility of a local accumulation of fissile material to produce a neutron chain reaction is not a significant concern. It may not be possible to demonstrate this, however, if significant amounts of fissile material are being disposed of at the facility. In such a case, the developer and operator would need to present a criticality assessment. We cannot anticipate the scope of such an assessment in generic guidance. However, we have noted that we might call upon the technical expertise of HSE/NII to help us with reviewing the assessment provided by the developer and operator.

Collective radiological impact

One respondent suggested that examples of what was meant by collective radiological impact would be useful.

11

In our final guidance, we discuss collective dose in the explanatory text for *Requirement R8 – Optimisation*, and have cross-referred to this discussion from the reference to collective radiological impact. There are issues with the use of collective dose in assessments over long time-scales and the developer and operator may select alternative measures of collective radiological impact if these can be substantiated.

Role of environmental safety strategy

One respondent thought that the environmental safety strategy would be a useful place to give a lay explanation of the significance of uncertainties.

16

We agree and have suggested that explanations of the significance of uncertainties that are important to the environmental safety case could be presented as part of the environmental safety strategy in a way that non-experts can understand.

Peer review

One respondent suggested that the discussion on peer review could be strengthened by mentioning methods for resolving differences between experts.

16

We agree that it is important that the peer review process is not inappropriately curtailed. Our guidance notes that there needs to be a clear-cut stage in which the originators of the technical work respond to the reviewers' comments. The process ends only when the organisation that has commissioned the peer review is satisfied that a suitable end point has been reached. It remains the responsibility of the developer and operator to resolve any differences in a way they think is appropriate. We shall expect to see the comments made by peer reviewers and also the responses to those comments, and will take them into account in our regulatory judgements.

Utility of assessments and/or authorisation

One respondent questioned whether any assessment or associated authorisation could demonstrate that it was supported by arguments and 'evidence'.

26

We consider that it is possible to make assumptions and calculations about the future behaviour of the disposal system to gain a reasonable understanding of how the system might evolve and the associated risks. We do not expect the waste to be isolated or contained indefinitely, nor do we ask for predictions of what will actually happen as this is not possible. We highlight why it is important to look at both qualitative and quantitative information and to address extreme scenarios when coming to a judgement about whether a facility is suitable for authorisation. We have clarified the points raised but have not changed the basis of the guidance.

3.19 Comments on Chapters 8 and 9 – Context

- 3.19.1 This section summarises responses concerning *Chapters 8 and 9* in the consultation draft.

Application of BAT

One respondent noted that there needs to be a reasonable practicability test in the application of BAT, namely that disposal is cost-effective.

12

We note that the application of BAT is intended to take into account reasonable practicability.

Planning issues

One respondent thought that the relationship between the guidance and the planning process was not clear.

11

We have made clear that the land-use planning process and environmental regulation are separate decision-making processes.

We shall advise the planning authority on any application for planning permission, based on the developer and operator's environmental statement and any available environmental safety case. These interactions are described in more detail in *Chapter 5 – Authorisation of disposal*.

Role of Department of Health

One respondent noted that the guidance did not mention the statutory role of the Department of Health.

5

We have now described the statutory role of the Department of Health in *Section 8.10 – Radiological Protection Advice*.

Water Framework Directive

One respondent thought we should mention the Water Framework Directive and the enabling legislation.

28

We have included the Water Framework Directive in the discussion of environmental legislation in *Section 8.7*.

Clarify applicability of Landfill Regulations

One respondent asked why the Landfill Regulations did not apply to the disposal of radioactive waste.

12

We have not made any changes in response to this comment. Our guidance is intended to summarise the policies and legislation that could affect a disposal facility, and not to comment on or justify the basis for government decisions.

Environment agencies' approach to enforcing different regulations

One respondent asked how the assessment of issues covered by the guidance will be co-ordinated with the assessment of other issues for which the environment agencies are responsible. This issue was also discussed at the consultation workshop.

12, 31

We have included text in *Chapter 8* to make clear that we shall ensure that the required permits are delivered without imposing unnecessary administrative burdens on a developer. This will require coordination of permitting activities across different regulatory regimes and we shall ensure that our regulation of a facility is consistent between our different areas of responsibility. It is not, however, the role of this guidance to describe our internal processes in detail.

Applicability of European legislation

One respondent wanted us to make clear which provisions of the European legislation mentioned apply to facilities for solid radioactive waste.

11

Chapter 8 gives an overview of the policy and legislative background to our regulatory activities. This includes the influences on UK government policy from international treaties and conventions, including EU Directives. European legislation applies to disposal facilities when transposed into UK legislation and we describe the legislation that we enforce in *Chapter 9*.

3.20 Responses to Q7 – Supplementary guidance

- 3.20.1 This section summarises responses to Question 7: Would additional supplementary guidance be useful? If so, in what areas and when should it be issued?

No further guidance

Several respondents stated that they were not aware of any topics on which further guidance was required.

8, 14, 17

We note this comment and we shall keep the need for further guidance under review.

Optimisation

Several respondents thought that further guidance on optimisation would be useful.

2, 15, 27

We have revised the explanatory text for *Principle 2 – Optimisation (as low as reasonably achievable)*, to set out more clearly what we mean by optimisation, and have also revised *Requirement R8 – Optimisation*. It is the responsibility of the developer and operator to undertake optimisation. The details of how this is done and the relative weights applied to different factors in reaching a decision will depend on the specific site.

Defined methodologies / models for risk estimation

One respondent suggested that further guidance on methodologies and models for risk estimation would be useful.

24

We have tried to make the guidance accessible to as wide an audience as possible, but it is important that the guidance addresses the needs of the developer and operator in developing an environmental safety case. We regard the methodologies and models for risk estimation as matters for the developer and operator to choose and we would not wish to restrict their selection.

Lay guide

One respondent thought that a lay guide to the roles and responsibilities of the environment agencies would be helpful. This topic was also discussed at the consultation workshop.

26, 31

We are considering the development of a separate lay person's guide to accompany the guidance.

Other regulations / guidance

Three respondents thought that further guidance on the expectations of the regulators, including possible changes resulting from bringing regulation of radioactive substances in England and Wales within the scope of the Environmental Permitting Regulations (EPR), would be useful.

6, 12, 20

We have discussed in our final guidance the possibility that regulation of radioactive substances in England and Wales could come within the scope of EPR. Depending on the outcome of a review to decide whether to incorporate the regulation of radioactive substances into EPR, new regulations applicable to England and Wales might be produced, possibly by 2010, to replace and modernise the existing legal provisions under RSA 93. There are no plans at present to replace RSA 93 in Northern Ireland.

Environmental safety case development

Two respondents thought that more guidance on the development of an environmental safety case and our expectations would be useful.

16, 25

We have revised *Chapter 7* to give more guidance on the development of an environmental safety case and to make our expectations clearer.

Develop guidance to be more site-specific as process proceeds

One respondent noted that the guidance was, by necessity, generic and that more specific guidance should be developed for specific geological environments following the initial stages of site selection.

3

We shall consider whether it is appropriate to provide more specific guidance as the MRWS process continues.

More references and links

One respondent requested more references and background material on policies, legislation and reference material.

4

We have revised the sections describing the policy and legislative background and the legislation we enforce, but our guidance is not intended to be a detailed guide to policy and legislation, nor a reference work on waste management or safety assessment. We do not necessarily endorse the methodologies or conclusions of reports from other waste management programmes or research studies and think that references to such reports could be misconstrued.

3.21 Responses to Q9 – Combined safety cases

- 3.21.1 This section summarises responses to Question 9: Should the environmental safety case required by the environment agencies be combined with the nuclear safety case required by the Nuclear Installations Inspectorate? What are your reasons for the view you express?

Combined safety case

Several respondents thought that a combined safety case would ensure compatibility and consistency.

6, 14, 20, 26, 27

After further consideration, we decided that the different objectives of the two safety cases would be best met if they were kept separate but consistent.

Could be useful, but not necessary provided consistent

Several respondents thought that the safety cases should be linked and consistent, but that a combined safety case was not necessary.

2, 8, 11, 15

We decided that the different objectives of the two safety cases would be best met if they were kept separate but consistent.

No. Should be separate, but consistent

Several respondents thought that the safety cases should be separately written for specific purposes. Nevertheless, the safety cases should be consistent.

3, 12, 16, 17

This is the view that we reached. We have therefore mentioned the need for a nuclear safety case, and the need for consistency with the environmental safety case, but have given no further details. We have highlighted the importance of effective joint working between us and HSE/NII.

Information about relationship / commonalities

Two respondents thought that, even if there was not a common safety case, it would be useful to describe the relationships between the standards used and other topics in the different cases.

4, 24

We have referred to publications from HSE, and joint guidance from the environment agencies and HSE, about regulations and guidance for nuclear licensed sites.

4. List of Responding Organisations

- 4.1.1 Table 4.1 lists the organisations that responded to the consultation on our guidance *Geological Disposal Facilities on Land For Solid Radioactive Wastes: Guidance On Requirements For Authorisation*. As noted in Section 2, we have included all responses from the two parallel consultations except where respondents made it clear that they were responding only to the consultation on *Near-Surface Disposal Facilities on Land For Solid Radioactive Wastes: Guidance On Requirements For Authorisation*.
- 4.1.2 The numbers against the organisation in Table 4.1 act as a key to the comments presented in Section 3.
- 4.1.3 We also received comments from seven people responding as individuals. Table 4.1 does not give details of these individuals, but the comments they made can be identified through the cross-reference numbers provided.
- 4.1.4 Comments at the consultation workshop have also been cross-referenced to Section 3.

Table 4.1: List of responders to the consultation.

Organisation	Reference
BAe Systems	1
British Energy	2
British Geological Survey	3
Cumbria County Council	4
Department of Health	5
EA NW REPAC	6
Friends of the Earth	7
Food Standards Agency	8
Geological Society	9
Greenpeace	10
Health Protection Agency	11
Nuclear Decommissioning Authority	12
NI Alliance Party	13
Nuclear Industry Association	14
National Nuclear Laboratory	15
NuLeAF	16
Nuvia	17
Nuclear Waste Advisory Associates (1)	18
Nuclear Waste Advisory Associates (2)	19
Sellafield Ltd	20
Society for Radiological Protection	21

Organisation	Reference
Welsh Assembly Government	22
West Cumbria & North Lakes FoE	23
Individual	24
Individual	25
Individual	26
Individual	27
Individual	28
Individual	29
Individual	30
Consultation Workshop	31



Environment Agency
Rio House
Waterside Drive, Aztec West
Almondsbury, Bristol BS32 4UD
Tel: 0870 8506506
Email: enquiries@environment-agency.gov.uk
www.environment-agency.gov.uk



Northern Ireland Environment Agency
Industrial Pollution and Radiochemical Inspectorate
Klondyke Building
Cromac Avenue
Lower Ormeau Road
Belfast BT7 2JA
Tel: 02890 569299
www.ni-environment.gov.uk