



Near-surface Disposal Facilities on Land for Solid Radioactive Wastes

Guidance on Requirements for Authorisation
February 2009

ENVIRONMENT AGENCY
NORTHERN IRELAND ENVIRONMENT AGENCY
SCOTTISH ENVIRONMENT PROTECTION AGENCY

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1. Preface

1.1 About the environment agencies and this guidance

- 1.1.1 The Environment Agency, the Scottish Environment Protection Agency (SEPA) and the Northern Ireland Environment Agency (NIEA) are responsible for regulating the disposal of radioactive waste in England and Wales, in Scotland, 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.
- 1.1.2 The Radioactive Substances Act 1993 (RSA 93; HMSO 1993) gives us legal powers and duties to authorise the disposal of radioactive waste in the UK. When we grant authorisations, we include limitations and conditions to protect people and the environment from the hazards posed by radioactive waste.
- 1.1.3 Subject to the outcome of a UK Government review, RSA 93 may be replaced in England and Wales, possibly by 2010, by new regulations. The new regulations would include provisions broadly similar to those of RSA 93 but are likely to be implemented under the Environmental Permitting Programme which adopts a common framework for environmental permitting across different regulatory regimes. This guidance uses the term 'authorisation', the applicable term under RSA 93. The equivalent term would be 'permit' under the new regulations.
- 1.1.4 This guidance is intended principally for the developers or operators of proposed or existing near-surface facilities for the disposal of radioactive waste. It explains the requirements that we expect a developer or operator to fulfil when they apply to us for an authorisation to develop or operate such a facility. The guidance sets out our radiological protection requirements and explains our regulatory process that leads to a decision on whether to authorise radioactive waste disposal. We also describe the environmental safety case we would expect from the developer/operator of a disposal facility.
- 1.1.5 We have jointly published this guidance, so that it applies throughout the United Kingdom.
- 1.1.6 We may supplement this guidance from time to time in the light of legislative change or other developments.

1.2 Plain English

- 1.2.1 Our main audience, the developers and operators of near-surface disposal facilities, is a specialist one. We need to make our requirements as clear and unambiguous as possible for them. This guidance therefore contains a large number of specialist terms that have a precise meaning. We recognise that this may make the document less accessible to a wider audience, but we have tried to overcome this difficulty as far as possible. In particular, we have provided an introductory section to each chapter, so that everyone can understand what the chapter is about. We have also included an extensive glossary of significant specialist terms.

1.3 History of this guidance

- 1.3.1 In 1984, the government departments then responsible for regulating radioactive waste disposal under the Radioactive Substances Act published a document, *Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Principles for the Protection of the Human Environment* (Department of the

Environment *et al.* 1984). This document considered issues of planning policy and regulation as well as radioactive waste policy and regulation.

- 1.3.2 By 1997, the environment agencies had been made responsible for authorising the disposal of radioactive waste. In that year we published a further document, *Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Guidance on Requirements for Authorisation* (Environment Agency *et al.* 1997). This guidance focused on regulation of the disposal of low and intermediate level solid radioactive waste to specialised facilities on land. In this regard, it replaced the 1984 document. The guidance did not cover policy or planning matters because government departments and devolved administrations are responsible for these matters.
- 1.3.3 For near-surface disposal facilities, this guidance supersedes the 1997 guidance.
- 1.3.4 We shall consider any application to us for an authorisation to dispose of solid radioactive waste to a near-surface facility on its merits. We shall take into account our powers and duties, this guidance and any representations at the time of the application made by consultees, other interested parties and members of the public.
- 1.3.5 During autumn 2006, we produced a draft specification for the new guidance. We discussed our proposals at workshops with government bodies and a range of interested parties. Subsequently we developed the draft guidance in detail, and held further workshops on our emerging proposals in 2007. We consulted formally on fully-developed draft guidance during summer 2008, and took account of the many responses we received before publishing this final version of the guidance. Reports of the workshops, and a summary of how we dealt with the responses to the consultation, are available from us on request.

1.4 Other related developments

Environmental Permitting Programme (England and Wales)

- 1.4.1 The Environmental Permitting Programme (EPP) is a joint initiative between the Department for Environment, Food and Rural Affairs (Defra), the Department for Energy and Climate Change (DECC) and the Welsh Assembly Government (WAG). EPP aims to reduce administrative burdens on industry and regulators without compromising environmental and human health standards. It seeks to streamline and integrate permitting regimes into one single system and has already been successfully adopted for two major pollution control regimes.
- 1.4.2 Defra, DECC and WAG are reviewing whether to incorporate radioactive substances regulation into EPP. Depending on the review's outcome, new regulations applicable to England and Wales might be produced, possibly by 2010, to replace and modernise the existing legal provisions under RSA 93. EPP would clarify and update the procedures for issuing permits and monitoring compliance, whilst providing the same high standard of protection for people and the environment as achieved under RSA 93.

ICRP Recommendations

- 1.4.3 In 2007 the International Commission on Radiological Protection (ICRP) issued its latest recommendations in ICRP Publication 103 (ICRP 2007). These recommendations supersede those set out in ICRP Publication 60 (ICRP 1991). ICRP 103 makes small adjustments both to the definition of the dose/risk relationship and to the numerical values it recommends. Consequently, there is a

slight reduction in the risk per unit dose that ICRP recommends. The dose/risk relationship specified in this guidance is consistent with the ICRP 103 recommendations.

- 1.4.4 The UK's Health Protection Agency (HPA) has published advice on the recommendations in ICRP 103 (HPA 2009a).

HPA advice on solid radioactive waste disposal

- 1.4.5 HPA has revised its advice on solid radioactive waste disposal (HPA 2009b). HPA has a statutory function to provide radiological protection advice in the UK; it is not a regulator. We, the environment agencies, regulate disposals of radioactive waste.
- 1.4.6 HPA's document and our documents serve different purposes and have different scopes, although there is some common content. Annex I to this guidance explains the background to and reasons for the interpretation of HPA's advice chosen by the environment agencies (but does not form part of our guidance).

2. Summary

- 2.1.1 Radioactive waste is created on nuclear licensed sites and also on non-nuclear premises such as hospitals, universities and various industrial premises. There are nuclear sites in England, Scotland and Wales, but not in Northern Ireland. However, non-nuclear premises that create radioactive waste are located throughout the UK.
- 2.1.2 Solid radioactive waste is stored at nuclear licensed sites and non-nuclear premises; much of it will in due course be disposed of at facilities on land. The types of disposal facilities that are used depend on the properties of the waste including the level of radioactivity it contains. Solid radioactive waste needs to be disposed of in specialised facilities, except when the waste has a very low level of radioactivity.
- 2.1.3 The UK has a rigorous and robust framework for regulating radioactive waste. On nuclear licensed sites, the Health and Safety Executive (HSE) regulates all aspects of radioactive waste management, except disposal, and consults with the environment agencies on these aspects. The environment agencies are responsible for regulating the disposal of radioactive waste.
- 2.1.4 The environment agencies attach limits and conditions to the authorisations for the accumulation and disposal of radioactive waste that we grant under RSA 93. These limits and conditions are binding on operators and provide the means by which we shall regulate the development and operation of any near-surface disposal facility for radioactive waste. In setting limits and conditions, we shall take into account the developer/operator's responses to the principles and requirements in this guidance.
- 2.1.5 The developers and operators of near-surface facilities for solid radioactive waste disposal have to demonstrate that their facilities will properly protect people and the environment. They will need to show that their approach to developing the facilities and the location, design, construction, operation and closure of the facilities will meet a series of principles and requirements. This guidance sets out these principles and requirements, and describes how we shall interpret them. It also provides information about the associated framework of legislation, government policy and international obligations.
- 2.1.6 Although our guidance is non-mandatory, we use the term "requirements" in this document to emphasise items that are particularly important from our perspective as regulators and our strong expectation that a developer/operator will need to meet them.
- 2.1.7 We include a requirement that the developer/operator of a disposal facility should produce an *environmental safety case*. This should show how the facility meets the requirements set out in this guidance, and show that people and the environment are protected from the hazards associated with disposals to the facility.
- 2.1.8 This guidance replaces earlier regulatory guidance issued in 1997. Since then the Nuclear Decommissioning Authority (NDA) has been set up to decommission and clean up a large number of nuclear sites, some of them many decades old. The work of the NDA will create large amounts of solid radioactive waste that will need to be disposed of in near-surface facilities. By providing up-to-date regulatory guidance we can help make sure development and operation of near-surface disposal facilities is done properly.
- 2.1.9 We aim to apply this guidance in a transparent, accountable, consistent and proportionate way. We shall work closely with other regulators, in particular the

HSE and the Department for Transport (DfT), to ensure that regulation is effective and efficient, and that public confidence in the regulatory system is maintained.

3. Introduction

3.1 Background

- 3.1.1 The Radioactive Substances Act 1993 (RSA 93) provides the legal framework for controlling the management of radioactive wastes in a way that protects the public and the environment. RSA 93 imposes requirements for registering the use of radioactive materials and for authorising the accumulation or disposal of radioactive wastes.
- 3.1.2 Responsibility for granting registrations and authorisations rests in England and Wales with the Environment Agency, in Scotland with the Scottish Environment Protection Agency (SEPA) and in Northern Ireland with the Northern Ireland Environment Agency (NIEA). For simplicity, we have used the terms "the environment agencies" and "we" throughout this document when we refer to these organisations collectively.

3.2 Purpose and nature of this guidance

- 3.2.1 This guidance applies to existing and proposed land-based disposal facilities that have, or require, an authorisation issued by one of the environment agencies under RSA 93, and are classed as near-surface facilities.
- 3.2.2 This guidance sets out the framework within which we regulate near-surface disposal facilities, and our intended regulatory approach. We are directing it mainly at the developers and operators of these facilities. The guidance is also for our own regulatory staff, to help ensure systematic and consistent regulation. We expect that the guidance will help other interested parties to understand our regulatory powers and duties concerning near-surface disposal facilities; our approach to regulating these facilities; and the standards we shall apply.
- 3.2.3 The guidance focuses on five principles for solid radioactive waste disposal and fourteen more specific requirements which, if fulfilled proportionately to the hazard presented by the waste, should ensure that the principles are properly applied. The relationship between the principles and the requirements is illustrated in Figure 3.1. We shall consider each application to develop or operate a near-surface disposal facility on its merits, taking into account the responses to any consultation that we carry out.
- 3.2.4 Although our guidance is non-mandatory, we use the term "requirements" in this document to emphasise items that are particularly important from our perspective as regulators and our strong expectation that a developer/operator will need to meet them.
- 3.2.5 This guidance describes the overall framework of legislation, government policy and international obligations relevant to solid radioactive waste management. It also provides a more specific summary of the main legal provisions under which we shall regulate a near-surface disposal facility.
- 3.2.6 Near-surface disposal facilities may operate for several decades. Over this period of time, we shall need to update the present guidance to reflect, for example, changes in government policy or legislation. Changes may also be necessary to take account of experience in the UK and overseas, or because better ways of meeting our requirements emerge.
- 3.2.7 This is simplified guidance based on complex and changing policy and legislation. It does not constitute legal advice or provide a complete statement of all the

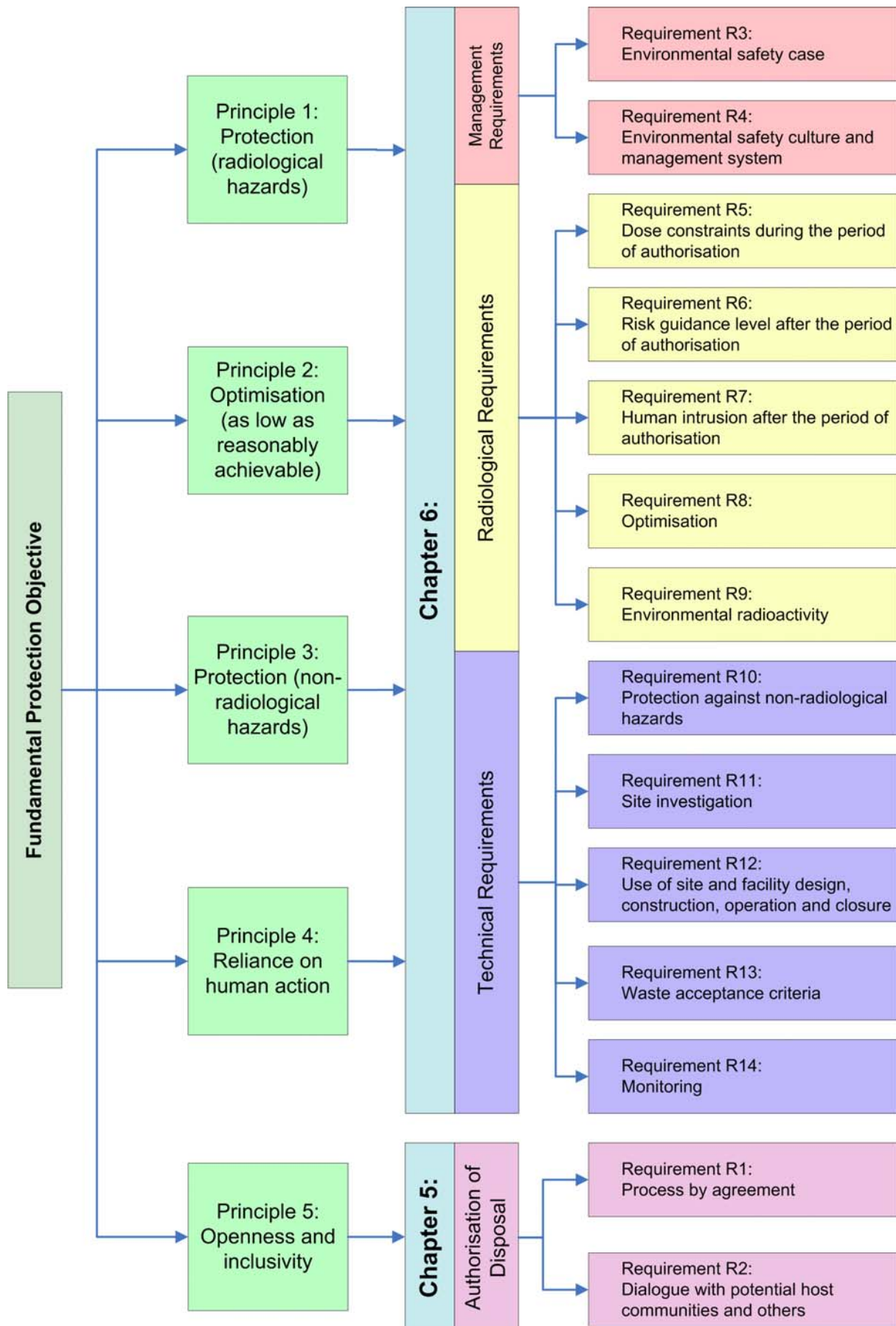
legislation that may be relevant. It provides a broad overview as at the date of publication and shall not constrain the environment agencies' regulatory independence at any future time.

3.3 Near-surface disposal facilities

- 3.3.1 For the purpose of this guidance, near-surface disposal facilities are those located at the surface of the ground, or at depths down to several tens of metres below the surface. Near-surface facilities may use the geology (rock structure) to provide an environmental safety function, but some may rely solely on engineered barriers. They could include facilities constructed under the seabed but accessed from land. Near-surface disposal facilities may use existing structures if an acceptable environmental safety case can be made.

3.4 Radioactive waste suitable for disposal in near-surface facilities

- 3.4.1 Types of solid radioactive waste that might be suitable for disposal in near-surface facilities include very low level waste (VLLW), low level waste (LLW), and shorter-lived or less radiotoxic intermediate level waste (ILW). We do not envisage that near-surface facilities would be suitable for the disposal of high level waste (HLW), spent nuclear fuel or nuclear materials such as plutonium.
- 3.4.2 Some solid radioactive waste that might be suitable for disposal in a near-surface facility may also present a non-radiological hazard. Examples of non-radiological hazards include chemical toxicity and biological hazards. Non-radiological hazards will need to be taken into account in the location and design of the facility; the environmental safety case will need to show that the environment and members of the public are adequately protected from such hazards.
- 3.4.3 The decision to grant an authorisation for a facility to dispose of a certain type of radioactive waste depends on whether an acceptable environmental safety case can be made.

Figure 3.1 Relationship between principles and requirements in this guidance.

3.5 Applying this guidance

Proportionate approach and related considerations

- 3.5.1 We shall aim to apply this guidance in a transparent, accountable, consistent and proportionate way. The guidance sets out principles and requirements. We have established the requirements by reference to the principles; our intention is that demonstration of conformity with the requirements should be sufficient to establish conformity with the principles.
- 3.5.2 We shall expect the developer/operator of a near-surface disposal facility to show in the environmental safety case that the facility meets each requirement. Whether the waste accepted for disposal at the facility presents a low or a high hazard, the developer/operator should always address the requirements in this guidance in a technically sound way.
- 3.5.3 For disposal facilities where the radiological hazard of the waste is low, a developer/operator may be able to demonstrate through a relatively simple approach that the requirements have been met, whereas a more complex approach may be needed for disposal facilities where the radiological hazard of the waste is higher. In other words, we shall expect the developer/operator to adopt an approach to each requirement that is proportionate to the level of hazard presented by the inventory of waste for disposal in the facility. In this paragraph, 'hazard' includes both the radiological hazard the waste presents and any non-radiological hazard it may also present.

New facilities

- 3.5.4 This guidance applies to new, near-surface facilities operating solely for the disposal of solid radioactive waste. Such facilities include those limited to the disposal of waste where the radiological hazard is very low, for example dedicated facilities for large volumes of VLLW. This guidance may also be used for co-disposal of solid radioactive wastes with conventional waste if no alternative approach is available or if an alternative approach does not provide sufficient assurance that people and the environment are adequately protected.
- 3.5.5 From time to time we may issue further general guidance or guidance specific to particular types of near-surface disposal facility. This new guidance may supplement or replace the present guidance. We recommend that the developer of a new facility enters into discussion with us at an early stage to clarify this position.

Existing facilities

- 3.5.6 This guidance applies to disposal facilities currently receiving waste where the operator holds an RSA 93 authorisation. It potentially applies to disposal facilities that have been closed, but where a relevant RSA 93 authorisation is still held. If there are doubts at any time about the applicability of this guidance to a particular facility the operator should seek clarification from us.
- 3.5.7 If an existing facility (as described above) is significantly deficient in relation to any of the requirements set out in Chapters 5 and 6, we shall expect the holder of the RSA 93 authorisation to propose improvements; we may well include these proposals as conditions in the authorisation.

- 3.5.8 Most of the requirements are not specified in absolute terms, but allow some exercise of judgement. Requirement R9, concerning optimisation, entails judgement to find the best way forward by balancing many different considerations. We envisage that the “optimum solution” for an existing facility will be significantly different from the optimum solution for a new facility. Nevertheless, the holder of the RSA 93 authorisation will still need to show that all the requirements are met.
- 3.5.9 This guidance does not apply to closed disposal facilities where no relevant RSA 93 authorisation is still held.

Low volume very low level waste

- 3.5.10 This guidance does not apply to the disposal of low volume very low level waste (LV VLLW), as defined in the March 2007 ‘*Policy for the Long Term Management of Solid Low Level Radioactive Waste in the United Kingdom*’ (Defra et al. 2007). The environment agencies will be publishing separate guidance on what constitutes LV VLLW, and the conditions that apply to its disposal.

Geological disposal facilities

- 3.5.11 This guidance does not apply to geological disposal facilities. The Environment Agency and the Northern Ireland Environment Agency have issued separate guidance on geological disposal facilities for England, Wales and Northern Ireland (Environment Agency and Northern Ireland Environment Agency, 2009).

Storage facilities

- 3.5.12 This guidance applies only to facilities for the disposal of waste and not to facilities for the storage of waste. In this context, ‘disposal’ means placing waste in a facility without intent to retrieve it later. A developer may choose to design a waste disposal facility in a way that makes it easier to retrieve waste; however, if the intention from the outset is to retrieve waste at a later date, the facility is a waste ‘storage’ facility. This distinction is important for the following reasons:
- The relevant environment agency is the regulator for all disposals of radioactive waste, and for the storage of radioactive waste in facilities other than those on a nuclear licensed site. If a radioactive waste storage facility is on a nuclear licensed site, then the HSE’s Nuclear Installations Inspectorate (HSE/NII) is the regulator. HSE/NII consults the relevant environment agency on its regulatory requirements for storage on nuclear sites.
 - The operator of a radioactive waste storage facility must demonstrate that waste stored there will be managed appropriately. As well as the controls required to ensure the waste is safely contained during the period of storage, the management arrangements must also address when and how the waste will eventually be retrieved from the storage facility.

3.6 Monitoring and retrievability

Monitoring

- 3.6.1 We draw a distinction between monitoring for technical reasons in support of the environmental safety case and monitoring for public reassurance. Our requirements regarding monitoring for technical reasons are discussed under Requirement R15 in Chapter 6. This guidance does not require monitoring for public reassurance. We require that any arrangements for public reassurance monitoring should not damage the environmental safety case for the facility, for

example, by providing routes through which significant amounts of radioactivity might reach people.

Retrievability

- 3.6.2 This guidance considers placing waste in a disposal facility as 'disposal', even though later actions, such as backfilling or capping to close the facility, may be needed to establish the environmental safety case fully. After it has been emplaced, the waste can still be retrieved, but this tends to become more difficult as time goes by, as further actions are taken and as closure approaches. Even after the facility has been closed, it is still possible in principle to retrieve the waste. However, this guidance does not require the waste to be retrievable after the act of disposal i.e. emplacement of the waste.
- 3.6.3 If a developer/operator makes provisions for retrievability, these should not unacceptably affect the environmental safety case. For example, a developer/operator might propose to keep a facility open that would otherwise be ready for closure, solely to maintain the option to retrieve waste emplaced in the facility. In such circumstances, the environmental safety case would need to demonstrate that processes such as degradation of waste packages would not unacceptably affect the safety of people or the environment. Such a demonstration would need to consider the effect of remaining open on the environmental safety case both for the period before the delayed closure and for the post-closure period.

3.7 Contents of this document

- 3.7.1 The remainder of this document consists of three main Parts. Parts 1 and 2 contain six further chapters outlining the technical detail and context of our guidance. Part 3 contains a list of references and a glossary of terms. This document also includes two annexes that deal with the relationship between this guidance and the advice on solid radioactive waste disposal issued by the Health Protection Agency.

Part 1: Our Guidance

Chapter 4 – Principles for solid radioactive waste disposal

- 3.7.2 Here, we set out the fundamental protection objective for solid radioactive waste disposal that forms the basis of this guidance, and five principles that are consistent with internationally agreed advice and recommendations.

Chapter 5 – Authorisation of disposal

- 3.7.3 In this chapter we describe how we expect a developer of a near-surface disposal facility to communicate with us, with people living near a potential site, and with others early on when selecting a site. We cover the type of agreement we would expect a developer to have with us so we can give advice on environmental matters at an early stage when a site is being selected.
- 3.7.4 Also we describe the authorisation process that is required after a site has been selected and before disposal of solid radioactive waste can begin.
- 3.7.5 We describe our role in the land-use planning process. We also describe the methods that we might use to help discussions with people living near a potential site, other interested parties and the public.

Chapter 6 – Management, radiological and technical requirements

- 3.7.6 In this chapter we describe the management requirements that the developer/operator of a near-surface disposal facility should fulfil. We also set out the radiological and technical requirements that the use of the site and the design, construction, operation and closure of the facility should meet.

Chapter 7 – Environmental safety case

- 3.7.7 This chapter gives guidance on how to prepare and what to include in an environmental safety case. A developer needs to provide an environmental safety case as part of proposals to develop a disposal facility for solid radioactive waste. The operator of a disposal facility for solid radioactive waste should already have in place a properly updated environmental safety case. The environmental safety case needs to demonstrate that members of the public and the environment are adequately protected, both when the waste is disposed of and in the future.

Part 2: Context – Policy, Legislation and International Obligations

Chapter 8 – Policy and legislative framework

- 3.7.8 This chapter gives an overview of the UK's obligations under international treaties and other influences on the policies of the UK Government and devolved administrations for managing radioactive waste. We give an overview of those policies and the broader background to regulating the disposal of solid radioactive waste. We summarise the legislation that we and HSE use to ensure that radioactive waste is disposed of safely and securely. We touch on planning issues, strategic environmental assessment and environmental impact assessment, and outline the regulatory regime for the transport of radioactive waste.

Chapter 9 – The legislation we enforce

- 3.7.9 This chapter describes the legal framework under which we shall regulate a disposal facility for solid radioactive waste. It is not intended as a comprehensive review but as a broad summary of our legal powers and duties relevant to this task.

Part 3: References, Glossary and Acronyms

Section 10 References

- 3.7.10 Section 10 provides a list of key references.

Section 11 Glossary and acronyms

- 3.7.11 This section provides a glossary of terms and a list of acronyms used in the document. It explains the specialist terms used in this guidance for solid radioactive waste disposal. Further explanation of terms that are used more general in the context of radioactive waste and radiological protection can be found in the safety glossary on the website of the International Atomic Energy Agency, and in publications by the Health Protection Agency and other specialist radiological protection bodies such as the International Commission on Radiological Protection.. Some more general technical terms will be explained in a general technical dictionary.

Annexes I and II

- 3.7.12 Annexes I and II do not themselves form part of the guidance, but help to put the guidance in context. Annex I explains the relationship between our guidance and

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 the HPA which clarifies the process by which HPA advice has been incorporated into this guidance to ensure the application of high standards of radiological protection for solid waste disposal.

Part 1: Our Guidance

4. Principles for solid radioactive waste disposal

4.1 Introduction

- 4.1.1 This chapter sets out the fundamental protection objective for the disposal of solid radioactive waste on land that forms the basis of this guidance. It also sets out five principles, consistent with internationally accepted standards and recommendations, that the developer/operator of a disposal facility and the environment agencies should follow. We have chosen the fundamental protection objective and the principles as far as possible to be of an enduring nature. For each principle we provide additional explanatory text and identify its basis in international publications by ICRP and IAEA. The principles also draw on advice provided by HPA (HPA 2009a, 2009b).
- 4.1.2 The principles do not refer to the ICRP principle on the justification of practices, because radioactive waste management operations, including the disposal of solid radioactive waste, are considered to be part of the practice giving rise to the waste, which will itself have been subject to justification considerations.
- 4.1.3 The fundamental protection objective (Section 4.2) and three of the five principles, namely Principle 1 (Section 4.3), Principle 2 (Section 4.4) and Principle 3 (Section 4.5), relate to outcomes in the future after a disposal facility has been closed. These describe aims that are key to protecting people and the environment. Measures taken today cannot guarantee a particular outcome in the future and so whether sufficient measures have been taken to meet these aims is inherently a matter of judgement.
- 4.1.4 The remaining two principles, namely Principle 4 (Section 4.6) and Principle 5 (Section 4.7) relate to measures that the developer/operator and the relevant environment agency should take at various stages before a disposal facility is closed. At the time of facility closure, we can judge whether they have been followed.
- 4.1.5 The principles in this chapter lead on to the requirements in Chapters 5 and 6. The requirements are deliberately more specific than the principles, so that the developer/operator of a disposal facility can provide evidence that they have been met. We can then judge whether this evidence is good enough.
- 4.1.6 The environment agencies' expect that the developer/operator of a disposal facility should meet the requirements of Chapters 5 and 6 in a manner proportionate to the hazard of the waste disposed of.
- 4.1.7 The principles recognise that decisions are based on the understanding and information available at the time the decisions are taken, and according to standards and accepted practices at that time.
- 4.1.8 The Environment Agency has issued Environmental Principles for Radioactive Substances Regulation (REPs) (Environment Agency 2008a), applicable to England and Wales – see footnote.¹

¹ The principles contained in the Environment Agency's REPs provide the underlying basis for the technical assessments and judgements that Environment Agency staff make when regulating radioactive substances. This regulatory guidance for facilities for the disposal of solid radioactive waste is technical guidance relating to a specific type of facility, to support the consistent application by the Environment Agency's regulators of the principles contained in the REPs. The fundamental

4.2 Fundamental protection objective

4.2.1 **The fundamental protection objective is to ensure that all disposals of solid radioactive waste to facilities on land are made in a way that protects the health and interests of people and the integrity of the environment, at the time of disposal and in the future, inspires public confidence and takes account of costs.**

4.2.2 The environment agencies must, subject to other powers and duties, contribute towards achieving sustainable development, in accordance with guidance from Government. Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs. Government's sustainable development guidance (see Chapter 8) expands this basic concept into a series of general guiding principles with which this guidance aims to be consistent.

4.2.3 The environment agencies recognise the need for public confidence in the development and operation of a disposal facility. The developer/operator and we, as environmental regulators, all have important parts to play in inspiring public confidence.

4.3 Principle 1: Level of protection against radiological hazards at the time of disposal and in the future

4.3.1 **Solid radioactive waste shall be disposed of in such a way that the level of protection provided to people and the environment against the radiological hazards of the waste both at the time of disposal and in the future is consistent with the national standard at the time of disposal.**

4.3.2 This principle is consistent with the concept of intergenerational equity, including the availability of a clean environment to future generations. We can only judge what constitutes a clean environment according to present-day standards.

4.3.3 Radiological risks are not confined within national borders and may remain for a long time. When working out how to control radiation risks, the consequences, both now and in the future, of current actions have to be taken into account. In particular:

- safety standards not only apply locally, but also far from radioactive waste facilities and activities;
- where future generations could be affected, they are afforded the same level of protection as that applied at the time of disposal, without needing to take significant protective actions.

4.3.4 Measures are needed not only to protect people but also to protect the environment. The aim is to maintain biological diversity, conserve species, and protect the health and status of natural habitats and communities of living organisms. For non-human species the general intent is to protect ecosystems against radiation exposure that would have adverse consequences for a population as a whole, as distinct from protecting individual members of the population.

protection objective and the principles contained in this chapter are consistent with the Environment Agency's REPs.

- 4.3.5 Where a standard of protection is numerical, the developer/operator of the disposal facility will need to carry out quantitative assessments to show conformity with it. In accordance with Chapter 6, numerical standards of protection to people are provided during the period of authorisation by the dose constraints and after the period of authorisation primarily by the risk guidance level.
- 4.3.6 Standards are continually being reviewed and protection standards may change with greater scientific understanding of the effects of radiation on human health and the environment. Such changes might lead to future revisions to this guidance.
- 4.3.7 ICRP provides recommendations and guidance on radiation protection (see paras 8.2.23 to 8.2.25). This principle relates to *the principle of optimisation of protection* taken from ICRP's recommendations (ICRP 2007). The ICRP principle includes the statement that: "In order to avoid severely inequitable outcomes of this optimisation procedure, there should be restrictions on the doses or risks to individuals from a particular source (dose or risk reference levels and constraints)." As discussed in Annex I, the environment agencies have chosen to apply a risk guidance level rather than a risk constraint.
- 4.3.8 The environment agencies regard the advice from the International Atomic Energy Agency (IAEA) as a statement of good practice (see paras 8.2.20 to 8.2.22). This principle relates to *Principle 6: Limitation of risks to individuals* taken from the IAEA's principles (IAEA 2006). The IAEA principle states that: "Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm." It also relates to *IAEA Principle 7: Protection of present and future generations* (IAEA 2006). The IAEA principle states that: "People and the environment, present and future, must be protected against radiation risks."

4.4 Principle 2: Optimisation (as low as reasonably achievable)

- 4.4.1 **Solid radioactive waste shall be disposed of in such a way that the radiological risks to individual members of the public and the population as a whole shall be as low as reasonably achievable under the circumstances prevailing at the time of disposal, taking into account economic and societal factors and the need to manage radiological risks to other living organisms and any non-radiological hazards.**
- 4.4.2 This principle applies specifically to radiological risks to people in every situation where radiation could cause damage or harm. 'Optimisation' (keeping risks as low as reasonably achievable) applies only to radiological risks to people. Other living organisms must also be protected from radiological hazards but there is no optimisation requirement. Protection of people and other living organisms from non-radiological hazards must also comply with applicable legislation and take relevant guidance into account.
- 4.4.3 Optimisation is a continuing, forward-looking and iterative process aimed at maximising the margin of benefit over harm. It takes into account both technical and socio-economic factors, and requires qualitative as well as quantitative judgements. It involves continually questioning whether everything reasonable has been done to reduce risks. In every organisation concerned, it requires commitment at all levels, together with adequate procedures and resources.
- 4.4.4 Optimisation decisions balance the detriment or harm associated with the radiological risk, together with other benefits and detriments (economic, human, societal, political, etc.) associated with disposing of the radioactive waste, both at the time the decisions are taken and in the future, and the resources available for protecting people and the environment. Optimisation decisions are constrained by

the circumstances prevailing at the time. Optimisation needs to be viewed as part of a bigger picture, recognising that there will be competing claims for limited funds, and that there is no completely risk free way of managing radioactive waste. The result of optimisation provides a radiological risk at a suitably low level, but not necessarily the option with the lowest possible radiological risk. The dose constraints and risk guidance level under Principle 1 are aimed at ensuring that the radiological risk is at a suitably low level.

- 4.4.5 Careful attention needs to be paid to optimisation in a way that is proportionate to the radiological hazard. Where the radiological hazard of the waste is low, only limited effort will be required to reach an optimised radiological risk; conversely, for disposal facilities where the radiological hazard of the waste is high, considerable effort will be required to reach an optimised radiological risk. For a given radiological hazard, there is no point on the scale of reducing radiological risk at which optimisation can be stopped, but there are diminishing returns as the risk is progressively driven lower. Optimisation needs to be embedded in the developer/operator's organisational culture so that it is regular practice to explore possible alternative options and to make the best choice among them.
- 4.4.6 If the disposal facility is on a nuclear licensed site, the nuclear safety regulator, HSE/NII, is responsible for regulating radiological risks to workers at the facility, and to members of the public in abnormal situations or accidents. Treatment and packaging of the waste prior to disposal is also likely to give rise to some radiation exposure to the workers involved. These classes of radiological risk are subject to optimisation considerations and must be taken into account in overall optimisation.
- 4.4.7 'Optimisation' means judgements have to be made about the relative significance of various issues, including:
- the number of people (workers and the public) and other environmental targets that may be exposed to radiological risk;
 - the chance they could be exposed to radiation, where exposure is not certain to happen;
 - the magnitude and distribution in time and space of radiation doses that they will or could receive;
 - nuclear security and safeguards requirements;
 - issues similar to those above, but relating to non-radiological hazards;
 - economic, societal and environmental factors;
 - uncertainties in any of the above.
- 4.4.8 Optimisation should be considered at all stages in the lifecycle of the disposal facility, including use of the site and facility design, construction, operation and eventual closure. These stages and the environment agencies' role at each of them are described in Chapter 5.
- 4.4.9 Optimisation needs to balance risks and other factors while the facility is operating, during any period of active institutional control, and after institutional control is withdrawn but whilst there is still a significant radiological hazard. Different people within the developer/operator organisation may have responsibility for these different periods. Good communication among them is needed to ensure that overall optimisation is achieved for the whole lifetime of the facility.

- 4.4.10 The environment agencies will consider optimisation processes, procedures and judgements as well as specific outcomes. There should be good communication between the developer/operator of the disposal facility and the relevant environment agency. A co-ordinated approach among regulators will also be needed to ensure that optimisation across different regulatory regimes is effective.
- 4.4.11 This principle relates to *the principles of optimisation of protection and application of dose limits* taken from ICRP recommendations (ICRP 2007). The ICRP principle states that: “the likelihood of incurring exposures, the number of people exposed and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors.”
- 4.4.12 It also relates to *Principle 5: Optimization of protection* taken from the IAEA’s principles (IAEA 2006). The IAEA principle states that: “Protection must be optimized to provide the highest level of safety that can reasonably be achieved.”

4.5 Principle 3: Level of protection against non-radiological hazards at the time of disposal and in the future

- 4.5.1 **Solid radioactive waste shall be disposed of in such a way that the level of protection provided to people and the environment against any non-radiological hazards of the waste both at the time of disposal and in the future is consistent with that provided by the national standard at the time of disposal for wastes that present a non-radiological but not a radiological hazard.**
- 4.5.2 This principle recognises that there may be non-radiological hazards associated with the disposal of solid radioactive waste, and that there needs to be an appropriate level of protection from these hazards. There are national standards for the disposal of wastes that present a non-radiological but not a radiological hazard. This principle does not require these standards necessarily to be applied, but requires a level of protection to be provided against these hazards that is consistent with the level of protection that would be provided if the standards were applied.
- 4.5.3 For example, radioactive wastes may contain residues of substances such as uranium and plutonium. These are heavy metals and as such are chemically toxic as well as being radioactive. Such wastes would present both a radiological and a non-radiological hazard. Non-radioactive wastes containing residues of heavy metals such as mercury and lead, which present a non-radiological but not a radiological hazard, would be consigned to a specialised disposal facility for hazardous waste, which must meet the national standards for such a facility. This principle does not ask for the specified national standards for non-radiological hazards to be applied, but asks for non-radiological hazards such as chemical toxicity to be taken into account when radioactive waste is disposed of. Any suitable means can be used to protect against the non-radiological hazards, providing the protection against these hazards is as great as it would be if the wastes were not radioactive.

4.6 Principle 4: Reliance on human action

- 4.6.1 **Solid radioactive waste shall be disposed of in such a way that unreasonable reliance on human action to protect the public and the environment against radiological and any non-radiological hazards is avoided both at the time of disposal and in the future.**
- 4.6.2 During the operational period of a solid waste disposal facility, protection of the public and the environment is provided both through passive measures, i.e.

measures that do not depend on human intervention or on any active engineered system, and through active measures that rely on people. Protection is confirmed by monitoring, which also relies on people. It is good engineering practice for protection to be provided during this period as far as reasonably practicable through passive measures. This will help to reduce the risks during the operational period. As progress is made towards closure of the facility, we expect engineered features conducive to long-term environmental safety to be completed progressively. We expect a progressive and planned shift from partial reliance on active measures and monitoring towards reliance on passive measures only. After the end of the authorisation period, the environmental safety case will need to rely entirely on passive measures, i.e. to avoid any reliance on human action.

- 4.6.3 If the disposal facility is on a nuclear licensed site, the nuclear safety regulator, HSE/NII, will also have an interest in passive measures for the important potential contribution they can make to limiting radiological risks to workers and to members of the public in abnormal situations or accidents. In general, the interests of HSE/NII and the environment agencies in favour of passive measures are likely to be complementary and mutually supportive. There needs to be effective joint working of regulators, to resolve any potential issues that might arise.
- 4.6.4 In the developer/operator organisation, relying too much on people to take action to forestall or resolve environmental safety issues may lead to problems, for example:
- i. if proper procedures and/or training are lacking;
 - ii. if action needs to be taken more quickly than would be practicable in the circumstances;
 - iii. if sufficient numbers of the right people are unavailable.
- 4.6.5 Where very long timescales are involved, there may not be people available to take action for various reasons, for instance:
- records may have been lost;
 - society may have other priorities;
 - society may have broken down or have changed beyond recognition;
 - technical understanding may have been lost.
- 4.6.6 For these reasons, it is widely regarded as unreasonable to rely on people to take action for more than a few hundred years at most to control risks from a disposal facility for solid radioactive waste. It is not likely that we would accept an environmental safety case if it relied on human action for longer than this. Nevertheless, measures to promote the long-term care and management of a disposal facility and its site are an important topic that needs to be discussed in the environmental safety case (see Chapter 7). The meaning of 'unreasonable reliance' is a matter for judgement by the developer/operator of a disposal facility and the relevant environment agency within this broad guidance.

4.7 Principle 5: Openness and inclusivity

- 4.7.1 **For any disposal of solid radioactive waste, the relevant environment agency shall:**

- **establish ways of informing interested parties and the public about regulatory goals, processes and issues;**
- **consult in an open and inclusive way.**

4.7.2 This principle sets out how we shall carry out our work and deal with disposals of solid radioactive waste. We shall seek to:

- Explain the basis for our regulatory decisions;
- Explain how we reach our judgements about the significance of uncertainties; and
- Provide an audit trail of regulatory decision-making.

4.7.3 We recognise that consulting in an open and inclusive way requires considerable perceptiveness and sensitivity on our part. We aim to ensure that everyone likely to be significantly affected by a proposal and those who reasonably feel that they should be consulted will be given the opportunity of commenting on it.

4.7.4 To be successful, the developer/operator of the disposal facility and other organisations will also need to work in a way that is consistent with our approach. For example, we shall expect the developer/operator to consult with and involve their own interested groups.

4.7.5 We shall carry out our role in a proportionate way. For example, we shall involve stakeholders in considering disposals to a facility but not necessarily consult separately about every individual disposal of waste.

4.7.6 This principle relates to *Principle 2: Role of government* taken from the IAEA's principles (IAEA 2006). The supporting text to the IAEA principle states that:

“The regulatory body must:

- have adequate legal authority, technical and managerial competence, and human and financial resources to fulfil its responsibilities;
- be effectively independent of the licensee and of any other body, so that it is free from any undue pressure from interested parties;
- set up appropriate means of informing parties in the vicinity, the public and other interested parties, and the information media about the safety aspects (including health and environmental aspects) of facilities and activities and about regulatory processes;
- consult parties in the vicinity, the public and other interested parties, as appropriate, in an open and inclusive process.”

5. Authorisation of disposal

5.1 Introduction

- 5.1.1 This chapter describes how we expect a developer of a near-surface disposal facility to communicate early in the development process with us, the potential host community and others.
- 5.1.2 We describe the type of agreement we expect a developer to have with us so we can give advice on environmental matters at an early stage when a site is being selected.
- 5.1.3 This guidance does not cover the process of selecting a site. But our early involvement with the developer would help to identify potential environmental safety issues before there is a significant investment of time and money.
- 5.1.4 After a site for developing a disposal facility has been selected and before disposal of solid radioactive waste can start, the developer/operator will need an authorisation. We describe the regulatory process.
- 5.1.5 We describe our role in the land-use planning process. We also describe the methods that we could use to help discussions with potential host communities, other interested parties and the public.

5.2 Early dialogue with the environment agencies

- 5.2.1 The process of selecting a site is outside the scope of this guidance, because we have no regulatory remit. However, we would expect dialogue between us and the developer to begin early.
- 5.2.2 Starting a process for selecting a site will generally involve the developer committing a significant amount of resources in both time and money. We consider that entering into a process by agreement should be part of a developer's risk management strategy.

Requirement R1: Process by agreement

- 5.2.3 **The developer should follow a process by agreement for developing a disposal facility for solid radioactive waste.**
- 5.2.4 Under Section 37 of the Environment Act (TSO 1995), the environment agencies in Great Britain can enter into an agreement with a developer to provide advice and assistance, and they can charge for that service. We would expect a developer to enter into an agreement with us after a decision to start a process to select a site for a disposal facility for solid radioactive waste or, before a developer plans a site investigation programme for a disposal facility at a specific location. The process by voluntary agreement is described in Section 5.4.
- 5.2.5 We consider that early dialogue would provide significant benefits for both the developer and us. Although we cannot provide regulatory certainty, dialogue would help to ensure sufficient attention is focused on regulatory requirements in the early stages of developing a near-surface disposal facility. For example, we could comment on the potential suitability of a possible site or sites and give early advice on possible environmental concerns so that a developer could develop a strategy for addressing them before proceeding with an application under RSA 93 or equivalent legislation.

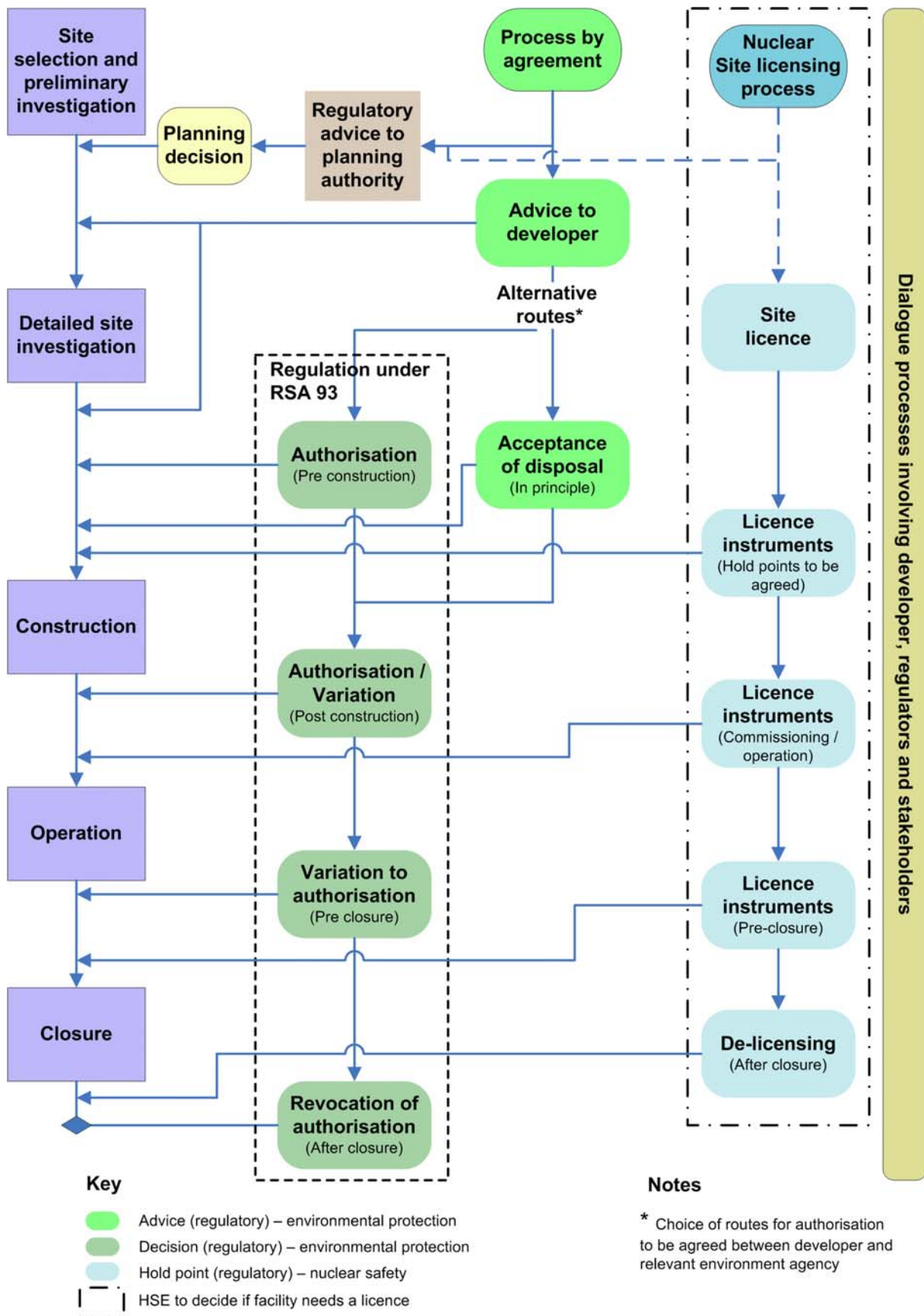
- 5.2.6 Early dialogue with us could also offer benefits to a developer under the land-use planning process. The developer of a disposal facility for solid radioactive waste will need to produce an environmental statement as part of the environmental impact assessment (EIA) process (see Section 8.5). The planning authority is required to consult us and we shall give our views on the developer's environmental statement. Early dialogue would help this process by increasing our knowledge and understanding of the developer's proposals so that we can make informed comments to the planning authority.
- 5.2.7 Another advantage of early dialogue is that we could publish our advice and comments on the developer's work. This would allow open discussion of the regulator's views with stakeholders such as potential host communities, other interested parties and the public (see Section 5.6), to help wider understanding of environmental regulation of a radioactive waste disposal facility.

5.3 Authorisation process

- 5.3.1 An operator must hold an authorisation under RSA 93 before any disposal of radioactive waste. The developer/operator must apply for authorisation. We shall determine the application and may grant or refuse it. If we grant the authorisation, we shall decide what limits and conditions to include. We shall also consult widely on our decisions on authorisation of proposed waste disposals.
- 5.3.2 The indicative regulatory process that might be applied to a near-surface disposal facility is shown in Figure 5.1. This includes a period of 'process by agreement'. This would continue until the developer decided to submit an application for authorisation under RSA 93 (or equivalent legislation) to allow radioactive waste disposal operations to start. A developer might decide to submit an application for an authorisation before construction if there was sufficient confidence that an environmental safety case could be made.
- 5.3.3 After submission of an application, there would be regulatory control under RSA 93 (see Section 5.5).

5.4 Process by agreement

- 5.4.1 A process by agreement aims to reassure both the developer and the regulator that a facility can be built at the selected site that will meet the principles and requirements of this guidance. An indicative process by agreement is shown in Figure 5.1. We would provide advice to the developer before the start of a formal regulatory process. A process by agreement would help to make sure that dialogue between us and the developer is constructive and runs smoothly. It would also provide a basis for discussions with the planning authority (see Section 5.6), the potential host community and other stakeholders (see Section 5.7).
- 5.4.2 A process by agreement would also allow dialogue between us and the developer about the form of a future application and the developer's forward programme for making an application.



- 5.4.3 Under a process by agreement, we would agree with the developer what submissions should be made to us and when they should be delivered; these would generally be at points in the developer's programme where decisions to invest substantial amounts of time and resources are required. At agreed points in the developer's programme, the most up to date environmental safety case would be submitted to us for review. For example, the developer might provide an environmental safety case before the start of a site investigation programme and an updated version of the environmental safety case before construction of the facility.
- 5.4.4 We would also expect the developer to provide a forward work programme which we would review. This would identify the proposed work during the next development phase including discussion of how any regulatory issues are to be addressed.
- 5.4.5 Between the agreed regulatory review points, our intention would be to maintain our awareness and knowledge of the developer's work so that we are in an informed position when we come to review major submissions.
- 5.4.6 The level of detail in the environmental safety case should reflect, for example, the stage of development of the facility, what is known and understood about the selected site, the proposed radioactive waste inventory for disposal and what decision has to be made at the time.
- 5.4.7 The environmental safety case will provide an important part of the technical input needed to inform the developer's decisions as the development programme proceeds. Chapters 6 and 7 give further guidance on the environmental safety case.
- 5.4.8 At some stage the developer will need to submit a formal application to us for an authorisation. The point at which the developer chooses to submit this application will be a matter for the developer to decide in discussion with us; but no emplacement of radioactive waste will be allowed prior to the granting of an RSA 93 authorisation.

5.5 Authorisation during facility operation and subsequently

- 5.5.1 Before any radioactive waste can be placed in a disposal facility, a developer/operator must hold an authorisation under RSA 93 (or equivalent legislation) and will need to submit an application for such an authorisation. In support of that application, we shall require the developer/operator to provide an environmental safety case (see Requirement R4).
- 5.5.2 The indicative regulatory process for developing a near-surface disposal facility is shown in Figure 5.1. This shows a period of process by agreement leading to an application for authorisation and the subsequent regulatory process up to withdrawal of the authorisation.
- 5.5.3 The authorisation will include limits and conditions, to make sure that members of the public and the environment are protected to a standard consistent with legal requirements and this guidance. The limits and conditions will take account of the assumptions in the environmental safety case and we might wish to impose, for example, inventory limits or allowable activity concentrations for specified radionuclides. We might also place conditions on how the facility can be operated.

- 5.5.4 During the operational phase of the facility, we shall periodically review the authorisation. We shall expect to agree the timing and scope of reviews with the operator. To support an authorisation review, we shall expect the operator to submit an updated environmental safety case that includes, for example:
- knowledge gained during construction and operation of the facility;
 - new understanding gained from on-going site characterisation work;
 - results of continuing research and development studies;
 - experience from similar facilities in other countries
 - technological advances in the characterisation, conditioning and packaging of radioactive waste.
- 5.5.5 When we receive an updated environmental safety case, we shall review the authorisation and determine the need to revise limits and conditions.
- 5.5.6 When waste emplacement ends, the operator will need to submit a post-operational environmental safety case to show that the facility can be closed in a way that allows the principles and requirements of this guidance to be met. The environmental safety case will need to address, for example, the operator's engineering approach to closing the facility and how this contributes to long-term environmental safety. Subject to the outcome of regulatory review, we could grant a variation to the authorisation to allow closure of the facility to proceed.
- 5.5.7 To support a request for revocation of the authorisation, the operator will need to submit a final environmental safety case to demonstrate that the facility meets the principles and requirements of this guidance. This might be submitted some time after closure of the facility if there is a period of active institutional control. Subject to the outcome of regulatory review, we could revoke the authorisation and release the facility from regulatory control.
- 5.5.8 The developer of a near-surface disposal facility might require a Nuclear Site Licence under NIA 65 from HSE. The potential links between the environmental regulatory process and the HSE process are illustrated in Figure 5.1. The decision on whether a Nuclear Site Licence is required would be made by HSE. Where such a licence is required the regulators would work together to ensure that their two processes are efficient and complementary.

5.6 The environment agencies and the land-use planning process

- 5.6.1 Planning permission will be needed when developing a near-surface disposal facility (see Section 8.6). A process by agreement (see Section 5.4) would make dialogue easier between us and the planning authority. From the earliest stages of developing a facility, the planning authority would be able to seek the regulator's views on environmental issues.
- 5.6.2 We cannot anticipate in this guidance a planning authority's requirements on when planning permission might be needed. In Figure 5.1, we provide an indication of how the link between the planning process and the regulatory processes might work in practice. At points where the developer seeks planning permission, we would provide advice to the planning authority based on a review of the developer's environmental statement (see 5.6.3) and, where available, a developing environmental safety case.

- 5.6.3 As noted in Section 8.5, the planning authority is required to consult us under the regulations that require an environmental impact assessment to be carried out before a disposal facility for solid radioactive waste can be developed. In this role, we would support the planning authorities by providing our views on a developer's environmental statement. This could include giving evidence to a planning inquiry into the proposed development.

5.7 Dialogue with local communities and others

Requirement R2: Dialogue with local communities and others

- 5.7.1 **The developer should engage in dialogue with the planning authority, local community, other interested parties and the general public on its developing environmental safety case.**
- 5.7.2 Generally, we expect the developer to engage widely in discussion of its developing environmental safety case. We recognise that we also need to be involved at an early stage, in particular, to explain the regulatory process and our requirements. The planning authority and local community are also likely to have an important role in discussions. Flexible approaches for engaging in discussions will be required that adapt to meet a community's needs and expectations.
- 5.7.3 This guidance applies to a range of near-surface facilities. The developer will need to consider, in discussion with the relevant local authorities, how to define "local community" for any specific proposal, taking into account the nature, size and location of the proposed facility.
- 5.7.4 In Figure 5.1, dialogue processes involving the developer, regulators and stakeholders including the local community and other interested parties are shown as continuing processes from an early stage of site selection up to and including the decision to revoke the authorisation after closure. For clarity, these are shown as a single component of the overall process, but we recognise this is a simplification and that a coordinated approach to discussions will be required.
- 5.7.5 Both the developer and the regulator should aim to work together to make sure that discussions with the planning authority and local community are open, inclusive and constructive. Technical, social or economic issues that might affect development of a disposal facility should be discussed openly with explanations of what the operator or regulator is doing to deal with these issues. Local communities and others should also be able to challenge the views of the developer and/or regulator on technical and other issues.
- 5.7.6 Working within a process by agreement, we would aim for a continuing dialogue with the planning authority and the local community, other interested parties and the public about the developer's environmental safety case. Before each major development, we shall actively seek the views of local communities and others. We might use local workshops or 'surgeries' for discussions between community members and our staff. We shall ensure that such processes do not compromise our regulatory independence but complement the consultation requirements under legislation such as RSA 93.
- 5.7.7 We shall make information widely available on the present and future environmental safety of the facility, subject to considerations such as national security. We shall also provide information about our regulatory goals and processes and explain what we can and cannot do.

6. Management, radiological and technical requirements

6.1 Introduction

- 6.1.1 This chapter sets out the management requirements that the developer/operator of a near-surface disposal facility for solid radioactive waste should meet. It also sets out the radiological and technical requirements that the use of the site and the design, construction, operation and closure of the facility should meet. We explain some of the major implications of each requirement in the text that follows the statement of the requirement.
- 6.1.2 The requirements in each category below – management, radiological and technical – are equally important. In particular, to meet the radiological and technical requirements it is very important that the organisation responsible for fulfilling them is properly managed and led.
- 6.1.3 The developer/operator needs to meet each requirement in this chapter in a manner proportionate to the level of hazard the waste presents. Demonstrating conformity with one requirement does not reduce the need to demonstrate conformity with each of the others. We shall expect the developer/operator to provide information under each requirement. Information provided under one requirement may be relevant to judging conformity with another requirement. For example, information provided under Requirement R7, Human Intrusion, may be relevant to judging conformity with Requirement R8, Optimisation.
- 6.1.4 As stated in Chapter 4 (para. 4.1.7), decisions are based on the understanding and information available at the time the decisions are taken, and according to standards and accepted practices at that time. This applies to decisions regarding whether the requirements set out in this chapter are met. However, as also stated in Chapter 4 (para. 4.3.6), standards are continually being reviewed and may change. Such changes might lead to future revisions to this guidance.

6.2 Management requirements

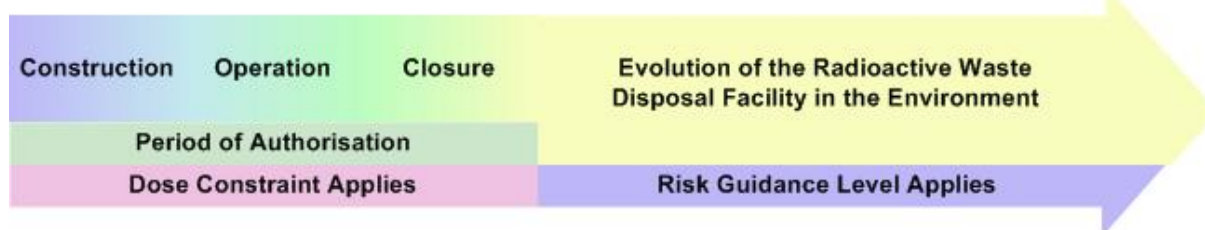
Requirement R3: Environmental safety case

- 6.2.1 **An application under RSA 93 relating to a proposed disposal of solid radioactive waste should be supported by an environmental safety case.**
- 6.2.2 An environmental safety case is a set of claims concerning the environmental safety of disposals of solid radioactive waste, substantiated by a structured collection of arguments and evidence. It should demonstrate that the health of members of the public and the integrity of the environment are adequately protected. It will be provided by the developer/operator of the disposal facility and should be designed to demonstrate consistency with the principles set out in Chapter 4 of this guidance and that the management, radiological and technical requirements set out in this chapter (Chapter 6) are met. Further guidance on the content of the environmental safety case is provided in Chapter 7.
- 6.2.3 We shall expect the developer/operator of a near-surface disposal facility to show in the environmental safety case that the facility meets each requirement set out in this chapter. Whether the waste disposed of to the facility presents a low or a high hazard, the developer/operator should always address the requirements in a technically sound way. For disposal facilities where the hazard presented by the waste is low, a developer/operator may be able to demonstrate through a relatively simple approach that the requirements have been met, whereas a more complex approach may be needed for disposal facilities where the hazard presented by the

waste is higher. In other words, we shall expect the developer/operator to adopt an approach to each requirement that is proportionate to the level of hazard the eventual inventory of waste in the facility will present. In this paragraph, 'hazard' includes both the radiological hazard the waste presents and any non-radiological hazard it may also present.

- 6.2.4 Figure 6.1 provides a timeline showing when in the environmental safety case the dose constraint under Requirement R5 applies and when the risk guidance level under Requirement R6 applies.

Figure 6.1 Periods of applicability for the dose constraint and the risk guidance level.



Requirement R4: Environmental safety culture and management system

- 6.2.5 **The developer/operator of a disposal facility for solid radioactive waste should foster and nurture a positive environmental safety culture at all times and should have a management system, organisational structure and resources sufficient to provide the following functions: (a) planning and control of work; (b) the application of sound science and good engineering practice; (c) provision of information; (d) documentation and record-keeping; (e) quality management.**
- 6.2.6 We shall expect the developer/operator of a disposal facility to foster and nurture a positive environmental safety culture, i.e. appropriate individual and collective attitudes and behaviours, and require its suppliers to do the same. This culture needs to be reflected in and reinforced by the management system that the developer/operator adopts.
- 6.2.7 The developer/operator's management system should be such as to ensure that sufficient protection is provided to people and the environment against the radiological and non-radiological hazards of the waste both at the time of disposal and in the future. In other words, the management system should reflect a proportionate approach.
- 6.2.8 The organisation needs to demonstrate to us that it is fully capable of assuring environmental safety by implementing a management system that includes effective leadership, proper arrangements for policy and decision making, a suitable range of competencies, provision of sufficient resources, a commitment to continuous learning and proper arrangements for succession planning and knowledge management. The management system should be progressively adapted to provide suitable corporate governance of the organisation over the whole lifecycle of the project, i.e. from the early stages of site investigation onwards until the eventual closure of the disposal facility and any subsequent period of active institutional control.
- 6.2.9 The written management arrangements supporting the management system should show how, with an appropriate environmental safety culture, environmental safety is directed and controlled. They should also show how the management system is

maintained in a living state through regular review, progressive updating and implementation of the management arrangements.

Organisational structure

- 6.2.10 The structure of the developer/operator organisation should be appropriate for its needs including, in particular, its responsibilities for environmental safety. The structure should reflect current and foreseeable operations and should show how key responsibilities are allocated. A new organisation should plan for and establish a structure based on a set of organisational structure principles that are linked to the activities it intends to perform. For an established organisation the structure should remain a 'live' issue, so that it continues to match the business needs and maintains clarity about responsibilities.

Leadership

- 6.2.11 The Board, directors and managers of the developer/operator organisation should provide strong leadership to achieve and sustain high standards of environmental safety. They should also provide reassurance that the organisation can be trusted to dispose of radioactive waste in an environmentally safe way. In particular, environmental safety messages must be seen to come from the top of the organisation and be embedded throughout its management levels.

Capable and forward-looking organisation

- 6.2.12 The developer/operator's organisation should be capable and forward-looking so as to secure and maintain the environmental safety of the disposal system for the whole of the lifecycle of the disposal facility. Roles, responsibilities, accountabilities and performance standards for environmental safety at all levels should be clear and not conflict with other business roles, responsibilities, accountabilities and objectives.

Resources and competences

- 6.2.13 The management system should enable the organisation to develop and maintain the resources and competences needed to ensure environmental safety. Competence may be defined as 'the ability to put skills and knowledge into practice in order to perform a job in an effective and efficient manner to an established standard'. Training will be needed to acquire and support the necessary competences. The written management arrangements should show how the organisation achieves and maintains a trained, qualified and experienced workforce that matches the need.
- 6.2.14 The organisation may need to use contract resource to complement its in-house capability but we shall want to see that it has recognised the implications of this for its ability to remain in control in the short and longer term. The organisation needs to be a capable operator in its own right and able to oversee and manage the work where it uses contractors. Achieving a suitable balance between employee and contractor numbers should take these aspects into account through a resource plan. The organisation will also need a sufficient capability to ensure that goods and services from its suppliers are of a fit and proper standard to meet the requirements of the relevant RSA 93 authorisation and the environmental safety case.
- 6.2.15 Under the management system, the developer/operator of the disposal facility will need to maintain relevant competences over the lifetime of the facility, including any period of authorisation after closure. The environment agency responsible for

regulating the disposal facility will also need to maintain its competencies over the same period.

Policy and decision making

- 6.2.16 The policies of the organisation and decisions at all levels that affect environmental safety should be rational, objective, transparent and prudent. All relevant considerations need to be taken into account whenever a policy is established or decision is made. New policies and decisions need to relate properly to, and build on, policies already established and decisions already made. Rigorous questioning of all factual material presented and assumptions made should be part of policy and decision making throughout the organisation. Policy and decision making implies choice: whenever a policy is established or a decision is taken, the reasons for the choice made need to be recorded. The reasons recorded should include the other choices considered and reasons why they were rejected.

Learning

- 6.2.17 Lessons should be learned from internal and external sources to assure continuous improvement in all aspects that affect environmental safety. A learning organisation should challenge established understanding and practice by reflecting on experience to identify and understand the reasons for differences between actual and intended outcomes. The organisation should seek to learn from external sources, including other industries, both in this country and abroad, analysing and acting on the lessons learned.
- 6.2.18 Learning should take place throughout the organisation. Staff at all levels should be encouraged to report any actual or potential problems and to make suggestions to avoid or overcome these problems and to achieve improvements generally.
- 6.2.19 Lessons learned should be embedded through a structured system that is rigorously applied. Reviews should be carried out to confirm that the changes have been made and that they have brought about the desired improvements.

Succession planning and knowledge management

- 6.2.20 The organisation will need to identify all the key areas in which it requires competency and to develop a strategy for succession planning and knowledge management in all these areas. The capabilities and competencies of the organisation must never be dependent on the understanding and skills of too limited a number of people in any such area. Furthermore, the lifecycle of a disposal facility is in many instances likely to be very much longer than the period of time for which an individual could reasonably be expected to stay in post. Successor staff will need to be provided with the understanding and skills enabling them to run the organisation in a capable and competent manner and to interpret the information recorded by their predecessors correctly.

Management system functions

- 6.2.21 The management system of the developer/operator will only fulfil its functions up to the end of the period of authorisation. If the functions are not carried out properly, however, environmental safety could be affected both during and after the period of authorisation. Where appropriate, the approaches used to fulfil these functions should be based on principles derived from national and international standards.

Work supporting the environmental safety case

- 6.2.22 The management system needs to be effective in all work that supports the environmental safety case. This covers most of the things that the developer/operator does and includes, at least: investigating the site; designing and constructing the facility; emplacing the waste; closing the facility; and putting in place any arrangements for active institutional control. It also includes work to document these activities and to provide the environmental safety case.
- 6.2.23 The management system also needs to be effective in work that supports the environmental safety case specifically during the period of authorisation. This includes demonstrating compliance with the operational limits and conditions that will be included in the authorisation under RSA 93 held by the facility operator. We shall expect the operator, through the management system, to monitor and assess radioactive discharges from the facility and levels of radioactivity in the environment, to conduct prospective and retrospective dose assessments and to report accordingly.

Planning and control of work

- 6.2.24 All work that supports the environmental safety case needs to be properly planned and controlled. Any changes need to be made within a well-defined change control procedure, described in the written management arrangements, that assures quality and includes decision-making, doing the work and recording what has been done.
- 6.2.25 Planning considerations need to include protection against, and mitigation of the effects of, human error and unplanned events during construction, operation and closure (for example accidental flooding), where the environmental safety case might be affected.

Applying sound science and good engineering practice

- 6.2.26 All work that supports the environmental safety case needs to apply sound science. The developer/operator needs to be able to make informed judgements about the quality of the science being applied and to make sure that timely scientific investigations are carried out to remedy any deficiencies in understanding of especial relevance to the particular disposal facility. The developer/operator also needs to maintain awareness of scientific developments, both within and outside the UK, that may have a bearing on the environmental safety case for the facility.
- 6.2.27 All work that supports the environmental safety case needs to follow good engineering practice, for reasons of both quality management and optimisation. This will usually mean applying tried and tested methods, except where the technology used in the construction and operation of a disposal facility is at the leading edge of engineering practice.
- 6.2.28 In such instances, a judgement will need to be made as to whether the benefits of using a novel technology instead of a tried and tested method are sufficient to outweigh any uncertainties about the outcome of using it. Before the decision is made to use a novel technology, we shall expect the developer/operator to have carried out trials to demonstrate that any such uncertainties are kept to a minimum.

Passive safety

- 6.2.29 After the end of the period of authorisation, the environmental safety case will need to rely entirely on features of the disposal system that do not depend on human intervention or on any engineered system requiring the operation of electrical

circuits or mechanical moving parts. This is sometimes known as 'passive safety'. It will mean reliance on a combination of engineered measures that can contribute to passive safety (recognising the lifetime for which such features can be expected to remain effective) and natural features and processes.

- 6.2.30 During the period of authorisation, it is good engineering practice for the developer/operator of the disposal facility to aim for passive safety as far as reasonably practicable, but some active engineered systems and/or human actions will be necessary for much or all of this period. Passive safety will help to reduce the risks during this period.
- 6.2.31 Passive safety is not a precise term. In general, engineered measures that depend for their effectiveness on structural integrity are likely to be less durable than those that depend only on their physical and chemical properties. However, all engineered measures will degrade with time and this should be recognised in any environmental safety case.
- 6.2.32 Relevant natural features and processes include: the rate, volume and direction of groundwater flow; the chemistry of the groundwater and geological materials; and the physical distance that radionuclides must travel between the waste and the accessible environment.
- 6.2.33 Engineered measures that can contribute to passive safety include:
- Immobilising the radioactive material. This can be achieved by putting it into a solid form that is essentially insoluble and resistant both to temperature changes and to chemical and biological breakdown and attack.
 - Making the waste form and its container stable physically and chemically and resistant to any form of degradation.
 - Providing a local environment that optimises the lifetime of waste containers. This can be promoted, for example, by restricting water inflow into the disposal facility and by creating a chemical environment surrounding the waste containers that inhibits corrosion.
 - Using a multi-barrier approach to provide containment. Egress of radionuclides from the disposal facility can be delayed by the chemical environment surrounding the waste containers and by engineered physical barriers.

Providing information

- 6.2.34 The developer/operator will be responsible for all information necessary to support the environmental safety case, and will need to provide it to us in a timely way within an agreed documentation structure so that its relevance to the environmental safety case is clear. The information is likely to include:
- plans and programmes;
 - results from research and development programmes;
 - data from tests and investigations on the natural parts of the system, together with the interpretation which follows;
 - proposals for facility design and development;

- waste inventories and characteristics (including the requirements that will be imposed for acceptance of waste for disposal);
- details of modelling and assessment methodologies used;
- the results of design, modelling and assessment studies;
- any reviews carried out, including peer reviews.

Technical information will need to be submitted in an agreed form that allows us to understand fully the arguments put forward in the environmental safety case and to carry out our own environmental safety assessments to support our judgements.

- 6.2.35 At stages during the development and operation of a disposal facility, we may request or require the developer/operator to gather information to confirm or refine the environmental safety case, or we may gather our own information, to assist in our review of the environmental safety case. This should enable us to develop a progressively increasing understanding of the performance characteristics of the disposal facility and a growing appreciation of the robustness of the environmental safety case.
- 6.2.36 Information the developer/operator supplies to us as part of an application to dispose of solid radioactive waste will be made public except where there are national security restrictions or where, exceptionally, the information can be demonstrated as having a commercial value that would be adversely affected by publication.

Documentation and record-keeping

- 6.2.37 The developer/operator will need to set up and maintain a comprehensive system for recording information on all aspects of the project affecting the environmental safety case. The information to be recorded should include: decisions taken and the reasons for them, data and results from the site investigation and characterisation programme; design documents, drawings and engineering details of the facility as constructed; records of waste form and characterisation; records of waste emplacements and their location in the facility; other operational information; details of facility closure; and results of monitoring and assessment at all stages of the project. Duplicates of the records will need to be kept at diverse locations and in durable form. During the period of authorisation, the records will be needed by the organisation exercising control and, potentially, by the regulators. We shall expect the operator to make arrangements at the end of the period of authorisation for the records to be included in the public archive.

Quality management

- 6.2.38 The quality management arrangements should be regularly audited internally and from time to time by an external auditor registered by the International Register of Certificated Auditors. As the environmental regulators, we may also audit the arrangements.
- 6.2.39 Quality management arrangements that allow all types of information to be traced back to their source are particularly important. We shall require access to the original data and shall want to know how they were gathered, so that we can examine the provenance and interpretation of the data.

Peer review

- 6.2.40 Where appropriate for some technical work, peer review should be used to supplement other approaches to quality management, because these other approaches cannot, in general, identify lapses or weaknesses in technical quality. Peer review involves independent specialists in a particular technical field examining work performed by specialists in the same field. The rigour with which peer review is carried out needs to be proportionate to the significance of the work being reviewed to the environmental safety case. The peer review process must not be inappropriately curtailed. 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. The relevant environment agency will expect to see the comments made by peer reviewers and the responses to those comments, and will take them into account in its regulatory judgements. Peer review is important both to quality management and to the application of sound science and good engineering practice.

6.3 Radiological requirements

Requirement R5: Dose constraints during the period of authorisation

- 6.3.1 **During the period of authorisation of a disposal facility for solid radioactive waste, the effective dose from the facility to a representative member of the critical group should not exceed a source-related dose constraint and a site-related dose constraint (see paras 6.3.2 and 6.3.3 below).**
- 6.3.2 The UK Government and Devolved Administrations have directed the environment agencies to have regard to the following maximum doses to individuals which may result from a defined source, for use at the planning stage in radiation protection:
- 0.3 mSv per year from any source from which radioactive discharges are made; or
 - 0.5 mSv per year from the discharges from any single site. (See paras 8.2.5 and 8.2.6.)
- 6.3.3 For the operational and active institutional control phases, HPA has recommended that a dose constraint of 0.15 mSv (annual dose) should apply to exposure to the public from a new disposal facility for radioactive waste (HPA 2009a). The developer/operator of a disposal facility may wish to take into account HPA's recommendation as well as the direction from the UK Government and Devolved Administrations.
- 6.3.4 The dose constraints place upper bounds on optimisation of the facility that apply during the period of authorisation. For comparison with the source-related dose constraint, the assessment of effective dose should take into account both direct radiation from the facility and radiation from current discharges from the facility. For comparison with the site-related dose constraint, the assessment of effective dose should take into account radiation from current discharges from the facility, together with radiation from current discharges from any other sources at the same site. The site-related dose constraint applies to the aggregate exposure from a number of sources with contiguous boundaries at a single location, i.e. the sources may be in the same site (including tenants) or on adjoining sites (e.g. A and B nuclear power stations). It applies irrespective of whether different sources on the site are operated by the same or different organisations.

6.3.5 The period of authorisation of a disposal facility includes the period of time while disposals are taking place and any period afterwards while the site is under active institutional control. The facility developer/operator will hold an authorisation under RSA 93 issued by us, which will include limits on operational discharges. Throughout this time, we shall expect the developer/operator to have a management system in place that provides a level of control proportionate to the hazard. During the period of authorisation our regulatory approach regarding current radioactive discharges will be the same as for any other authorised facility. We shall expect the developer/operator, in accordance with the authorisation to:

- monitor and assess radioactive discharges from the facility and levels of radioactivity in the environment;
- have plans for action if monitoring suggests an unexpected release from the facility;
- put into action remediation plans if any adverse anomalies are identified as a consequence of monitoring;
- carry out dose assessments based on the levels of radioactive discharge permitted by the authorisation (prospective assessments) and assessments based on the levels of radioactivity measured in the environment (retrospective assessments);
- report this information to us.

6.3.6 Chapter 8 explains the origin of these dose constraints and their legal status.

Active institutional control

6.3.7 If the developer/operator claims for the purposes of the environmental safety case that during the period of authorisation there will be a time after closure when the facility is under active institutional control, the developer/operator will need to show that the controls proposed for this time are sufficient to support the claim and that the arrangements for applying the controls can be relied on to be implemented as planned. A claim for active institutional control will need to be supported by detailed forward planning of organisational arrangements and a suitable demonstration of funding arrangements.

6.3.8 Organisational arrangements would need to provide for continued management, staffing and site security. A claim of active institutional control for a period of time is expected to include provisions for site surveillance with scope for remedial work if needed, a programme of environmental monitoring, control of land use and arrangements for the preservation of records. It will need to be supported by evidence that these provisions can be relied on to remain effective throughout the claimed period of time. Because of the major social changes that may take place over long periods of time, it is unlikely that the environment agencies would accept a claim for active institutional control lasting longer than 300 years after the end of waste emplacement.

6.3.9 For any time after closure of the facility where the developer/operator does not claim, or we do not accept, that there will be active institutional control, our regulatory approach will be to apply a risk guidance level (see Requirement R6 below) and, for human intrusion, a dose guidance level (see Requirement R7 below).

Requirement R6: Risk guidance level after the period of authorisation

- 6.3.10 **After the period of authorisation, the assessed radiological risk from a disposal facility to a person representative of those at greatest risk should be consistent with a risk guidance level of 10^{-6} per year (i.e. 1 in a million per year).**
- 6.3.11 We use the term “risk guidance level” (see Glossary) in this guidance to describe the assessment standard for natural evolution of the system (not including human intrusion), because it indicates the standard of environmental safety we are looking for, but does not suggest that there is an absolute requirement for this level to be met. “Risk guidance level” in this guidance means the same as “risk target” in the previous guidance (Environment Agency *et al.* 1997). “A person representative of those at greatest risk” in this guidance means the same as “a representative member of the potentially exposed group at greatest risk” in the previous guidance (Environment Agency *et al.* 1997). The value of 10^{-6} per year is consistent with advice given in the HSE publication “Reducing Risks, Protecting People” (HSE 2001). The HSE publication identifies this value as “a very low level of risk” which should be used as a guideline for the boundary above which people are prepared to tolerate risks in order to secure the benefits from the activities giving rise to the risks and below which risks are broadly accepted by society because they are generally regarded as insignificant.
- 6.3.12 The risk guidance level does not apply to human intrusion after the period of authorisation, for which see Requirement R7 below.
- 6.3.13 The assessed radiological risk associated with a potential exposure situation corresponds to the product of the estimated effective dose that could be received, the estimated probability (as a quantified uncertainty – see below) that this dose will be received and the estimated probability that detriment would occur as a consequence to the person exposed (see para. 6.3.15 below). For comparison with the risk guidance level, assessed risks must be summed over all situations that could give rise to exposure of the same person to radiation.
- 6.3.14 For situations in which only stochastic effects of radiation exposure need to be considered (i.e. when the estimated annual effective dose is less than 100 mSv and the estimated equivalent dose to each tissue is below the relevant threshold for deterministic effects), a risk coefficient of 0.06 per Sv should be used. This corresponds to recommendations set out in HPA’s advice on the disposal of solid radioactive waste (HPA 2009b).
- 6.3.15 For annual effective doses below 100 mSv, HPA recommends the use of the *detriment-adjusted risk* coefficient and that a rounded value of 0.06 per Sv be used for waste management assessments. HPA notes that *detriment* is a concept used to quantify the harmful health effects of radiation exposure in different parts of the body. It includes the weighted probability of attributable non-fatal cancers and the length of life lost as well as the probability of attributable fatal cancers and the weighted probability of severe heritable effects in all subsequent generations (the latter is represented by the risk factor for the next two generations).
- 6.3.16 HPA advises that the definition of risk used to calculate the detriment-adjusted risk coefficient quoted above is not applicable to deterministic doses and therefore it is inappropriate to combine risks of stochastic effects with risks of deterministic effects. HPA recommends that, for simplicity, if the estimated effective dose received over the period of a year or less is greater than 100 mSv it should not be combined with the probability of receiving the dose to give an estimated risk but they should be presented separately.

- 6.3.17 Making use of the risk coefficient of 0.06 per Sv, a dose can be calculated that gives rise to a risk of 10^{-6} per year. This calculated dose is around 20 microSv/year and represents the situation where the dose has been received, that is to say the probability of receiving the dose is one. For situations where the probability of receiving a dose is less than one, doses could be greater than 20 microSv/year while still maintaining consistency with the risk guidance level and, for situations where the probability is very much less than one, doses could be very much greater than 20 microSv/year.

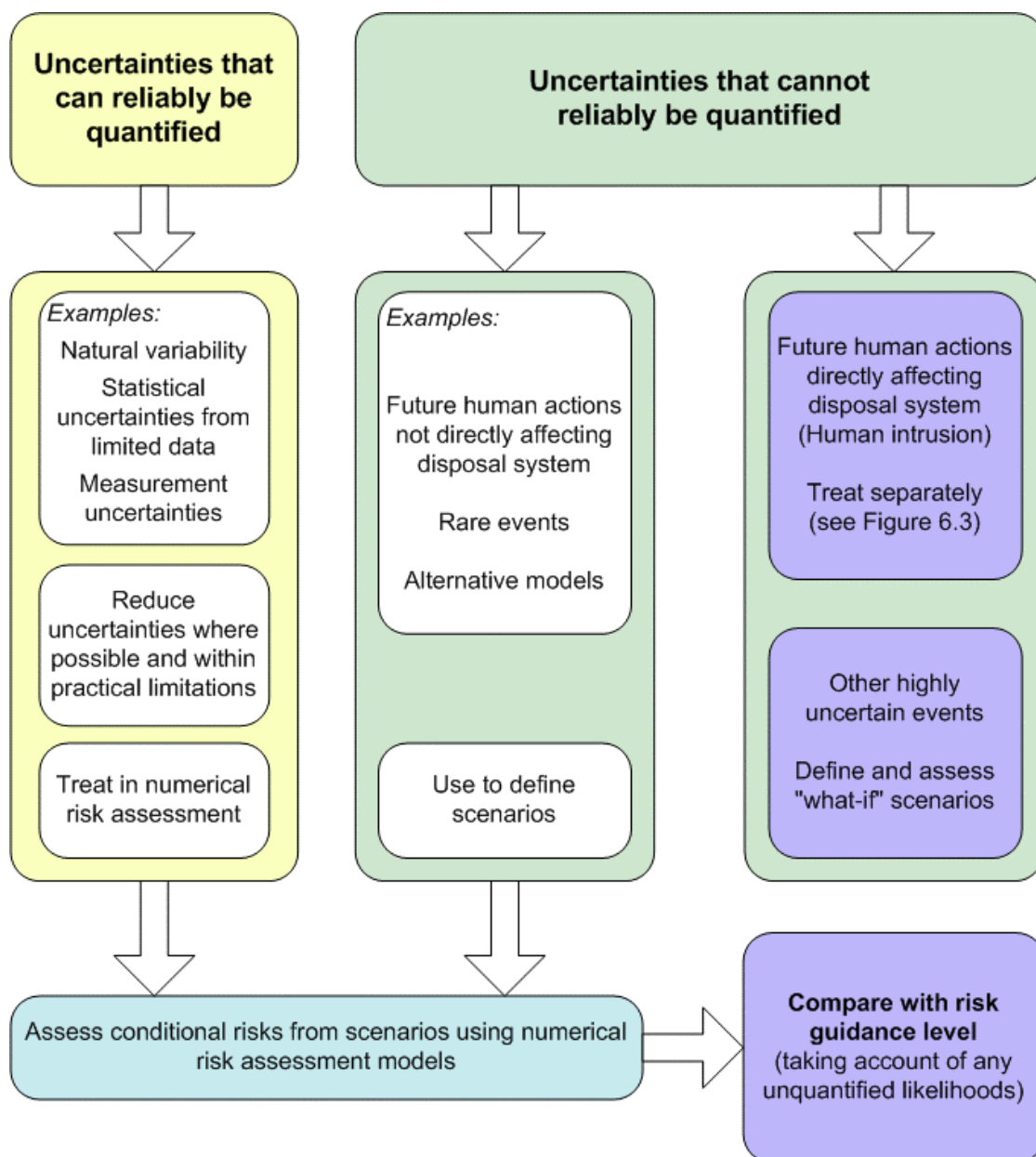
Risk assessment

- 6.3.18 Risk assessment aimed at showing consistency with the risk guidance level helps to inform the developer/operator about how models and research should be directed and developed, by highlighting which model components dominate risk and to which parameters risk is sensitive. It also has the important role of informing our regulatory decision making.
- 6.3.19 We have chosen a cautiously low value for our risk guidance level. It is not necessary when expressing the aggregate risk for comparison with the risk guidance level to include an additional conservative bias. The expectation (mean) value of risk is an example of a measure that does not include such a bias, but other measures could also be devised that might be more suitable in particular circumstances. We shall expect the developer/operator to demonstrate that the measure chosen is reasonable. Information about the sensitivity of the chosen measure to important parameter values should also be presented.
- 6.3.20 We shall not expect the complexity or sophistication of a risk assessment to be disproportionate to the radiological hazard presented by the waste. For some of the lower-hazard facilities to which this guidance applies, the developer/operator may be able to avoid using complex models in the risk assessment by making simple conservative assumptions.
- 6.3.21 In setting up a risk assessment, in general the developer/operator should aim for data and assumptions that represent realistic or best estimates of the system behaviour. However, where the data do not support this approach or where the assessment can usefully be simplified, the developer/operator may choose some data and assumptions to be conservative as long as the requirements are still shown to be met.
- 6.3.22 In cases where the hazard presented by the waste warrants a detailed assessment of risks, we shall expect a probability distribution of dose to be one of the outputs from each risk assessment that the developer/operator undertakes. The probability distribution will cover the range of possible doses that a person representative of each potentially exposed group may receive and will provide the probability that this person receives any given dose. The probability distribution will vary with time into the future. Various different probability distributions of dose could give the same aggregate risk, and hence could be equal in terms of acceptability against the risk guidance level.

Uncertainties

- 6.3.23 After the period of authorisation, the evolution of the disposal system (i.e. the disposal facility in its geological setting) becomes increasingly uncertain with time. An important distinction can be made between two types of uncertainties: those that can reliably be quantified and those that cannot.

- 6.3.24 This section and the accompanying Figure 6.2 are limited in the scope of the uncertainties they address, but they illustrate an approach to the treatment of uncertainties that is more widely applicable. Chapter 7 extends the discussion to include, for example, modelling uncertainties. Whatever the origin and nature of an uncertainty, the same basic issue arises as to whether the uncertainty can reliably be quantified. If an uncertainty is quantified without a reliable basis, it will devalue a numerical risk assessment into which it is introduced and it therefore needs to be dealt with by other means.
- 6.3.25 An uncertainty cannot reliably be quantified if, for example, it is not possible to acquire relevant data, or if acquiring enough data to evaluate it statistically could only be done at disproportionate cost. Important examples of uncertainties that cannot reliably be quantified (i.e. that are effectively unquantifiable) include those associated with future human actions and with certain rare events for which the data available historically do not provide an adequate basis for statistical evaluation. An example of such a rare event might be a severe earthquake at a particular location in a region of generally low seismicity.
- 6.3.26 We expect that quantifiable uncertainties will be considered within a numerical risk assessment developed as part of an environmental safety case (see Chapter 7). Unquantifiable uncertainties will also need to be taken into account in developing the case, but should be kept apart from the quantifiable uncertainties and given separate consideration. Taking into account unquantifiable uncertainties will inevitably involve judgement. Identifying significant unquantifiable uncertainties is a necessary first step, since judgements about them cannot be made until this is done. The judgements should then be based on 'balance of likelihood' rather than on 'beyond reasonable doubt', so that outcomes are not unduly influenced by remote possibilities.
- 6.3.27 One way of exploring unquantifiable uncertainties about future events is through the use of separate risk assessments for each set of possible events. Each set of events, or scenario, is assigned a nominal probability of one and a risk assessment that accounts for the remaining, quantifiable, uncertainties is carried out. There may be several risk assessments because there may be several scenarios. The resulting calculated risks are compared to the risk guidance level, bearing in mind how likely it might be that the assumptions made in setting up the scenarios would correspond to circumstances arising in practice.
- 6.3.28 Some scenarios will involve future events so uncertain that it may not be appropriate to undertake numerical risk assessments for comparison with the risk guidance level, as this could distort the overall picture of risks. These scenarios might include a range of "what-if" scenarios. Such scenarios may affect whether or not the environmental safety case overall is judged acceptable and the environment agencies will need to consider them one by one. Specific guidance on human actions that affect the disposal system is given under Requirement R7 below.
- 6.3.29 Figure 6.2 illustrates the approach to uncertainties described above.

Figure 6.2 Approach to the treatment of uncertainties

Exposed groups

- 6.3.30 Risk assessments will need to consider different groups of people that could be at risk of exposure (potentially exposed groups) in order to identify a person representative of those people at greatest risk at a given time. There is a range of possible doses that each group might receive and, for each dose, an assessed probability of their receiving that dose.
- 6.3.31 The developer/operator will need to substantiate the choice of potentially exposed groups as being reasonable and suited to the particular circumstances. The location and characteristics of the groups considered should be based on the assessed releases of radioactivity and on assumptions about changing environmental conditions. The habits and behaviour assumed for people in potentially exposed groups should be based on present and past habits and behaviour that have been observed and that are judged relevant. Metabolic characteristics similar to those of present-day populations should be assumed. The other parameters used to characterise a representative member of a potentially

exposed group should be generic enough to give confidence that the assessment of risk will apply to a range of possible future populations.

Combining risks from different facilities

- 6.3.32 If two or more separate disposal facilities present significant risks to the same potentially exposed groups, consideration will need to be given to the combined risks to relevant exposure groups. An unacceptably large total for the assessed risks from different disposal facilities affecting the same exposure group at the same time could indicate an unacceptably large assessed risk from one or more of the facilities taken individually. This would require attention from the developer/operator and ourselves. We would not accept an approach in which the assessed risks from multiple different modules of the same disposal facility were put forward individually in order to show that each module, taken alone, presented a risk consistent with the risk guidance level.

Regulators' considerations

- 6.3.33 When considering an application for authorisation of a disposal facility, we shall use all the information put forward in the environmental safety case to inform our decision. We shall make a judgement about whether the degree of consistency that the developer/operator is able to demonstrate with the risk guidance level is good enough. This judgement will take account of the uncertainties that have been included in the risk assessment as well as information from the developer/operator on the uncertainties that have not been included in the risk assessment.
- 6.3.34 We are likely to be satisfied with a risk assessment if we judge that: (a) it is unlikely to be presenting an optimistic picture; (b) the consistency with the risk guidance level is good enough; and (c) the probability distributions of dose presented for different future times show that larger doses are, in broad terms, matched by correspondingly smaller probabilities.
- 6.3.35 If we judge that there is a significant discrepancy between the results of a risk assessment and the risk guidance level, or if the probability distribution of dose at some future time causes us concern, we shall need additional assurance from other information presented in the environmental safety case to satisfy us that an appropriate level of environmental safety is assured.

Requirement R7: Human intrusion after the period of authorisation

- 6.3.36 **The developer/operator of a near-surface disposal facility should assess the potential consequences of human intrusion into the facility after the period of authorisation on the basis that it is likely to occur. The developer/operator should, however, consider and implement any practical measures that might reduce the chance of its happening. The assessed effective dose to any person during and after the assumed intrusion should not exceed a dose guidance level in the range of around 3 mSv/year to around 20 mSv/year. Values towards the lower end of this range are applicable to assessed exposures continuing over a period of years (prolonged exposures), while values towards the upper end of the range are applicable to assessed exposures that are only short term (transitory exposures).**
- 6.3.37 We do not envisage that the developer/operator will be able to substantiate that human intrusion into a near-surface disposal facility is unlikely to occur after the period of authorisation. Wastes in such a facility are potentially vulnerable to disturbance by relatively commonplace human actions.

- 6.3.38 The standard against which human intrusion into a near-surface disposal facility should be assessed is specified in terms of dose, not risk. Because the likelihood of human intrusion cannot reliably be assessed in terms of a numerical value of probability, dose is in effect being used as a surrogate for risk when considering intrusion into such a facility. We use the term *dose guidance level* (see Glossary) in this guidance to describe the assessment standard, because it indicates the standard of environmental safety we are looking for, but does not suggest that there is an absolute requirement for this level to be met. The range of around 3 mSv/year to around 20 mSv/year that we specify for our dose guidance level is the same as the advice issued by the HPA in their publication on the disposal of solid radioactive waste (HPA 2009b).
- 6.3.39 The developer/operator needs to assess potential exposures of possible intruders to the radiological dose that might arise from a range of possible exposure scenarios. These scenarios should consider the exposures that arise from the potential exposures from the inventory of waste to be disposed of including any gaseous emissions from the waste such as radon; this should not include exposures to naturally occurring radon. Due to the large uncertainties associated with exposures to radon the developer should present these both aggregated with other exposures and individually.
- 6.3.40 The developer/operator will need to show that dose thresholds for severe deterministic injury to individual body tissues are unlikely to be exceeded as a result of human intrusion into a near-surface disposal facility (see also 6.3.16 above). Severe deterministic injury means injury that is directly attributable to the radiation exposure, that is irreversible in nature and that severely impairs health and/or the quality of life of that individual, for example, lung morbidity and early death.

Applicability of dose guidance level

- 6.3.41 Human intrusion may be regarded as falling into three classes: (i) intrusion with full knowledge of the existence, location, nature and contents of the disposal facility; (ii) intrusion without prior knowledge of the disposal facility; and (iii) intrusion with knowledge of the existence of underground workings but without understanding what they contain. We do not expect the developer/operator to consider the first of these classes because we take the view that a society that preserves full knowledge of the disposal facility will be capable itself of exercising proper control over any intrusions into the disposal system. We expect the developer/operator to consider the second and third of these classes. Examples of the second class would be exploratory drilling for mineral resources because the local geology appears promising and excavation during future development of the site. An example of the third class would be an archaeological investigation carried out without knowing about or understanding radioactivity, but recognising that there has been human activity at the site in the past.
- 6.3.42 We regard the following as events for which our dose guidance level of around 3 mSv/year to around 20 mSv/year is the standard that applies after the period of authorisation:
- human intrusion directly into a disposal facility;
 - other human actions that damage barriers or degrade their functions, such as removing material from a disposal facility cap. Barriers considered to be affected by these human actions may be engineered, natural or a combination of both.

- 6.3.43 Beyond the region where these kinds of event might happen, the risk guidance level of Requirement R6 is the standard that applies to future human actions. The risk guidance level applies where radionuclides have spread beyond barriers and are subject to mechanisms of dilution, including where these parts of the disposal system have been disturbed by human action. An example of a future human action to which the risk guidance level applies is the sinking of a well into an aquifer contaminated by radionuclides from a disposal facility.
- 6.3.44 Where barriers that provide environmental safety functions are natural, rather than engineered, they may have a considerable spatial extent. In this case, we would discuss with the developer/operator how far from the disposal facility itself it is reasonable to apply the dose guidance level rather than the risk guidance level, recognising that the circumstances in every case may be different. The value of invoking barriers that are natural in origin and their associated environmental safety functions needs to be weighed against the undesirability of invoking the dose guidance level over a wide area.

Measures to reduce the likelihood of human intrusion

- 6.3.45 The developer/operator should consider, and implement, any practical measures that might reduce the likelihood of human intrusion. We encourage such measures where they are likely to be beneficial. We may not accept that an absolute claim can be made in the environmental safety case for their effectiveness, particularly over the timescales relevant to long-lived wastes, but it may still be useful to invoke them in contributory, qualitative arguments included in the environmental safety case. We recognise that it is not easy to judge the benefits of these measures and that some measures, such as providing a marker at the surface, might have the opposite of the intended effect. We also recognise that there are practical limits to what can be done. In particular, it is important that any measures intended to reduce the likelihood of human intrusion do not compromise the environmental safety performance of the disposal system if human intrusion does not occur. We shall expect the developer/operator to consider measures to reduce the likelihood of human intrusion as part of option studies under Requirement R8, Optimisation. Implementation of any measures intended to reduce the likelihood of human intrusion is subject to our agreement to those measures.
- 6.3.46 For many wastes considered suitable for near-surface disposal, human intrusion after the period of authorisation is likely to result in doses well below the dose guidance level. In such cases, we are unlikely to insist on any but the simplest measures for reducing the likelihood of intrusion.

Assessing the consequences of human intrusion on people and the environment

- 6.3.47 The timing, type and extent of human intrusion into a near-surface disposal facility are so uncertain that they need to be explored through one or more 'what-if' scenarios, separate from the scenarios representing evolution of the disposal system undisturbed by human intrusion that are considered under Requirement R6 Risk Guidance Level.
- 6.3.48 Human intrusion scenarios should be based on human actions that use technology and practices similar to those that currently take place, or that have historically taken place, in similar geological and geographical settings anywhere in the world. The assumed habits and behaviour of people should be based on present and past human habits and behaviour that have been observed and are judged relevant. Scenarios should include all human actions associated with any material removed from the facility, including considering what is then done with this material. The number of people involved in actions associated with intrusion should be assessed,

and may be assumed to be similar to the typical number involved in similar actions now or historically. Similarly, the number of people who might be exposed as a result of occupying the site or neighbourhood after the intrusion should also be assessed. These numbers will be important in assessing radiological impact for optimisation purposes (see para. 6.3.51 below). The developer/operator will need to substantiate each scenario considered as being reasonable and suited to the particular circumstances.

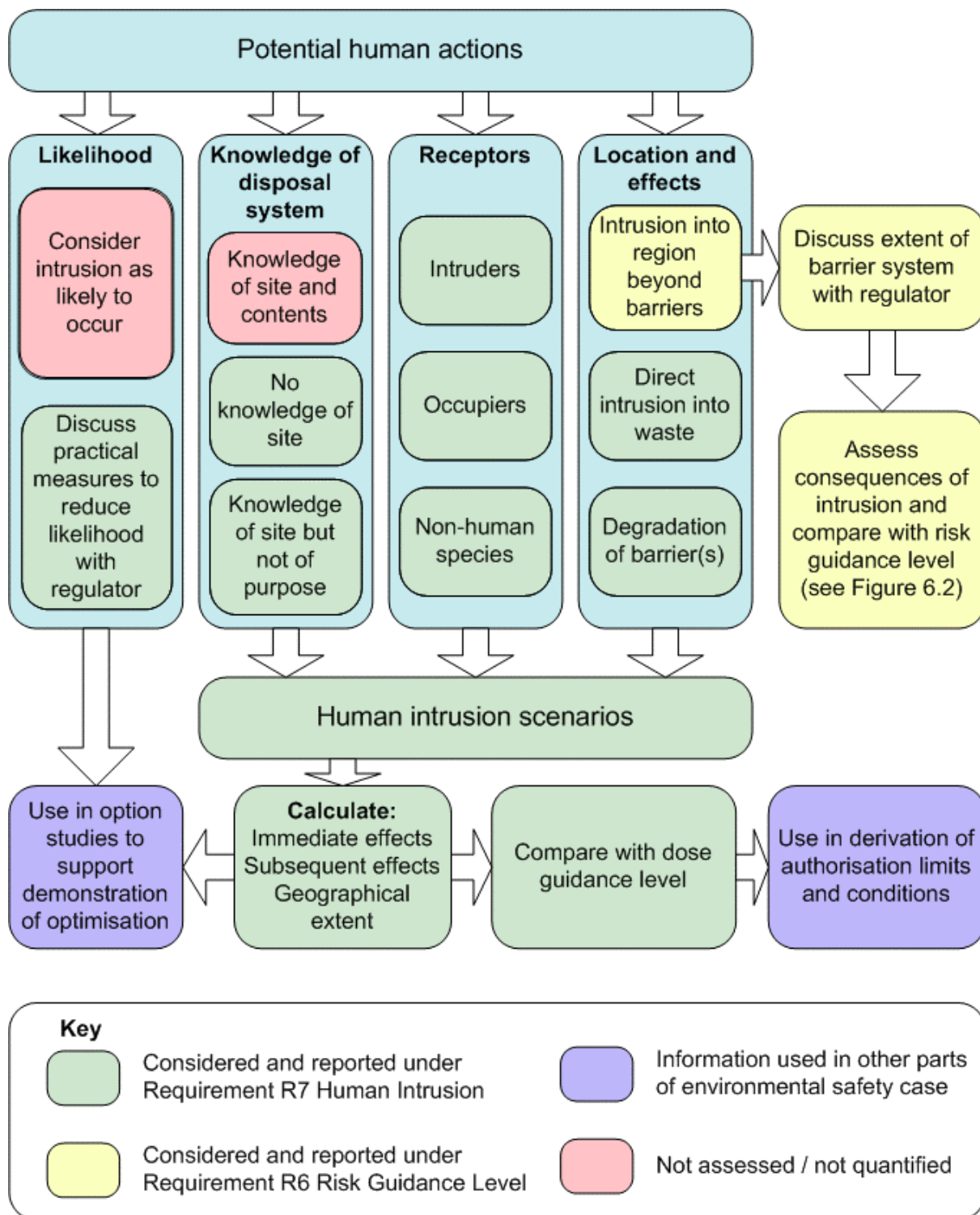
- 6.3.49 The developer/operator should present assessments of radiation doses to individuals representative both of those undertaking the intrusion and those who might occupy the site or the neighbourhood afterwards. The assessments presented should also explore the consequences of intrusion in a wider geographical sense and on the long-term behaviour of the disposal system. The assessments should take into account all radionuclides that may be present in the waste and all decay products making a significant contribution to dose. They should also take into account inhomogeneities in the waste.
- 6.3.50 The developer/operator should present assessments of the radiation doses received by non-human organisms as a result of human intrusion into the facility and demonstrate that these are not at a level liable to cause significant harm to populations of such organisms (see also Requirement R9 below).
- 6.3.51 We shall expect the developer/operator to use the results from the human intrusion scenarios above as part of option studies under Requirement R8, Optimisation. The aim will be to reduce the radiological impacts resulting from human intrusion, subject to balancing all the other considerations relevant to optimisation.
- 6.3.52 For wastes with a significant content of long-lived radionuclides, potential doses around the dose guidance level may be possible for human intrusion scenarios in which significant amounts of waste are disturbed. The results of these scenarios are likely to be important in deriving facility-specific authorisation limits and conditions, such as inventory limits and allowable activity concentrations for specified radionuclides. We shall expect the developer/operator to propose such limits and support these proposals with suitable arguments.
- 6.3.53 Figure 6.3 illustrates the approach described above to human intrusion after the period of authorisation.

Adoption of practical measures and claims in the environmental safety case

- 6.3.54 Because of the uncertainties surrounding human intrusion and other unpredictable and disruptive events, a difference may arise between what would seem on balance to be desirable practical measures to reduce the likelihood or consequences of disruption and what can reasonably be claimed in the environmental safety case. Such a difference might arise, for example, in arrangements for institutional control in the very long term (which are desirable but cannot be claimed as effective), or in barrier design (where the long-term effectiveness of measures, such as increasing the thickness of a cap, cannot be quantified). In such cases, we may expect or require the developer/operator to adopt practical measures that go beyond what we accept as a substantiated claim in the environmental safety case.

Intrusion by non-human species

- 6.3.55 We shall expect the developer/operator to show that intrusion by non-human species, including plant species (for example tree roots), is not a significant issue.

Figure 6.3 Approach to the treatment of human intrusion after the period of authorisation.**Requirement R8: Optimisation**

- 6.3.56 The choice of waste acceptance criteria, how the selected site is used and the design, construction, operation, closure and post-closure management of the disposal facility should ensure that radiological risks to members of the public, both during the period of authorisation and afterwards, are as low as reasonably achievable (ALARA), taking into account economic and societal factors.

- 6.3.57 The process of optimising a disposal facility requires the continuous attention of the developer/operator from the design stage through to the end of the period of authorisation. Our optimisation requirement is that radiological risks to members of the public are ALARA during the period of authorisation and afterwards. Radiological risk during the period of authorisation is reduced by reducing exposure to radiation, which, in turn, may be reduced by reducing radioactive discharges. Radiological risks after the period of authorisation are reduced either by reducing potential exposure, or by reducing the probability of that exposure being received. HSE and other regulators will have their own optimisation requirements as well.
- 6.3.58 Optimisation is about finding the best way forward where many different considerations need to be balanced. Relevant considerations include, for example, economic and societal factors, and the requirement to manage any non-radiological hazards (see Requirement R10 below). Although reducing radiological risk is important, it should not be given a weight out of proportion to other considerations. In other words, the best way forward is not necessarily the one that offers the lowest radiological risk.
- 6.3.59 To succeed, optimisation requires good communication, both within the developer/operator's own organisation and with supplier organisations, as well as with the regulators and the local community.
- 6.3.60 In finding the best way forward, the developer/operator should carry out options studies, where there are choices to be made among significantly different alternatives. They should present the results to us and make them publicly available. The studies will inform the developer's decisions.
- 6.3.61 In the past, we have issued guidance on optimisation (Environment Agency & SEPA 2004; SNIFFER 2005). This guidance is mainly directed at different kinds of facilities during steady-state operation. Optimisation of a disposal facility is not concerned with steady-state operation, but with a changing and evolving state, both during the period of authorisation and afterwards. Whilst previous guidance on optimisation contains much material relevant to disposal facilities, it does not apply directly to them.
- 6.3.62 The development of a disposal facility from the design stage through to the end of the period of authorisation may be seen as the successive implementation of a series of decisions made by the developer/operator. Each decision may be relevant to optimising the facility and so optimisation needs to be considered at each decision-making stage. Once a decision has been implemented, it forms part of the framework within which further decisions, and the optimisation considerations that go with them, must be made. Even when a decision has apparently been made, it continues to represent an uncertainty before it has been implemented, because the decision still might not be implemented or might be implemented in a way different from that envisaged. For example, until a disposal facility has actually been closed at a given time one cannot be sure that it will be closed at that time. The end of the period of authorisation is the end of decision-making by the developer/operator.
- 6.3.63 The optimisation of a disposal facility is optimisation in the presence of uncertainties that would not exist, or would not exist to the same extent, for other types of facility. These uncertainties include decisions not yet implemented and how the disposal system might evolve after closure of the facility.
- 6.3.64 The main optimisation task in the presence of uncertainties is to make sure that an acceptable situation will result, not only in likely future circumstances, but also in circumstances that are possible but unlikely. Acceptability can be measured in

terms of radiation dose or risk, but it will often be unnecessary to go as far as calculating these quantities to recognise a situation as unacceptable. We shall judge acceptability in a proportionate way taking account of the circumstances concerned.

- 6.3.65 Once this main optimisation task has been fulfilled, optimisation follows the more usual path of finding the best way forward for each set of circumstances. At this stage, the developer/operator should focus mainly on the likely circumstances. Unlikely circumstances should not have undue influence on design, construction or operation.
- 6.3.66 We prefer a simple approach to optimisation to a more complex one, where either would deliver an adequate outcome. If the developer/operator uses a numerical approach to compare options, they should recognise that the size of the population at risk is a relevant issue as well as the magnitude of individual risks. This may involve carefully considering the distribution of risks. A blunt tool such as overall collective effective dose is unlikely to be useful (for further discussion, see paras 6.3.68-69 below).
- 6.3.67 At each decision-making stage, we shall expect the developer/operator to provide a written record that they have properly considered optimisation. We shall also expect, as part of the environmental safety case, a historical record of the decisions the developer/operator has taken and implemented, and the optimisation considerations that related to those decisions when they were taken.

Collective dose

- 6.3.68 On the use of collective dose for optimising, ICRP states (ICRP 2006): "When the exposures occur over large populations, large geographical areas, and long periods of time, the total collective dose (i.e. the summation of all individual exposures in time and space) is not a useful tool for decision aiding because it may aggregate information excessively and could be misleading for selecting protective actions." ICRP also states that collective dose is not intended as a tool for epidemiologic risk assessment, and it is inappropriate to use it in risk projections. In particular the calculation of the number of cancer deaths based on collective doses from trivial individual doses should be avoided. HPA states (HPA 2009b) that it concurs with this view for assessments of solid waste disposal.
- 6.3.69 HPA states that, in situations where collective doses are useful, the ICRP document advises on a move away from collective doses to 'group' doses, thus taking earlier guidance on disaggregation a step further. Essentially ICRP recommends that, in broad terms, the concept of collective dose is retained but within the context of a 'dose matrix'. However, as a report by the HPA and the Centre d'études sur l'évaluation de la protection dans le domaine nucléaire (CEPN, France) (Smith *et al* 2007) found, there is little to be gained from the 'dose matrix' approach for times far into the future. Collective doses and 'group' doses should only be calculated for times where they can be a useful discriminator between the different waste management options. This is likely to be of the order of several hundred years post closure but the exact length of time will be dependent on the waste disposed of and type of facility. However it is not advisable to consider the very long term collective dose to members of the public in view of the large uncertainties. These uncertainties effectively make any comparison meaningless.

Requirement R9: Environmental radioactivity

- 6.3.70 **The developer/operator should carry out an assessment to investigate the radiological effects of a disposal facility on the accessible environment both**

during the period of authorisation and afterwards with a view to showing that all aspects of the accessible environment are adequately protected.

- 6.3.71 Discharges and migration of radionuclides from a disposal facility might have a detrimental effect on the accessible environment, through effects on non-human species or more general environmental effects such as damaging habitat quality. This requirement aims to ensure that all aspects of the accessible environment are protected.
- 6.3.72 People are protected from the radiological effects of a disposal facility through application of the dose constraints (Requirement R5), the risk guidance level (Requirement R6), the approach to human intrusion (Requirement R7) and the optimisation requirement (Requirement R8). Although there is no specific evidence that there might be a threat to populations of non-human species from the authorised release of radioactive substances if people are protected, there may be times when there are no people near a disposal facility. Environmental damage might also occur to areas and habitats that are not extensively exploited by people. Furthermore, there is a specific need to be able to demonstrate that non-human species are protected under legislation related to conservation, for example that derived from the EC Habitats Directive (EC 1992).
- 6.3.73 There are currently (February 2009) no internationally established criteria for determining radiological protection of the environment. A number of research studies and regulatory guidance documents have proposed criteria (e.g. Andersson *et al.* 2008; Copplestone *et al.* 2001), and there are ongoing studies to update and expand the scientific basis for such criteria.
- 6.3.74 In the absence of specific criteria, we expect the developer/operator to carry out an assessment and to draw conclusions about the effects of a disposal facility on the accessible environment using the best available information at the time of the assessment. The developer/operator should provide this assessment as an integral part of the environmental safety case for the facility and should update it as new information becomes available and when other parts of the case are updated. We expect the extent and complexity of the assessment to be proportionate to the radiological hazard presented by the waste in the facility.
- 6.3.75 The assessment of effects on the accessible environment should include an assessment of effects after human intrusion, making the same human intrusion assumptions as when assessing the effects on people.

6.4 Technical requirements

Requirement R10: Protection against non-radiological hazards

- 6.4.1 **The developer/operator of a disposal facility for solid radioactive waste should demonstrate that the disposal system provides adequate protection against non-radiological hazards.**
- 6.4.2 Some waste disposed of at a facility receiving radioactive waste may be potentially harmful wholly or partly because of its non-radioactive properties. There are nationally acceptable standards for disposing of hazardous waste. However, these standards may not be suitable to apply directly to waste that presents both radiological and non-radiological hazards. Accordingly, these standards need not necessarily be applied, but a level of protection should be provided against the non-radiological hazards that is no less stringent than would be provided if the standards were applied. This could be achieved by ensuring that materials posing non-radiological hazards are contained within the facility over timescales at least as

long as those provided for by the barriers at a site for disposal of non-radiological hazardous wastes.

- 6.4.3 For some wastes disposed of, the non-radiological hazards may be greater or more persistent than the radiological hazards. Non-radiological hazards may be to people or to the environment or to both. They may constitute properties of the waste as initially disposed of, or may result from subsequent physical or chemical changes to the waste, or from chemical or biochemical action on it. Non-radiological hazards may be presented by a wide range of substances and in diverse ways. Examples of hazardous substances include asbestos, poisonous inorganic chemicals such as heavy metals and their compounds, poisonous organic chemicals such as cyanides, and gases such as methane (generated by biochemical action), that are flammable and/or contribute to climate change. Environmental safety case arguments focused on radiological hazards may not be applicable to non-radiological hazards.
- 6.4.4 As stated in paragraph 4.4.2 under Principle 2, 'optimisation' (keeping risks as low as reasonably achievable) only applies to radiological risks. However, adequate protection against non-radiological hazards needs to be maintained when optimising for radiological risks.
- 6.4.5 The environmental safety case will need to demonstrate that adequate protection against non-radiological hazards is achieved, using methods and approaches suited to the nature and proportionate to the magnitude of these hazards and suited to the characteristics of the disposal system.

Requirement R11: Site investigation

- 6.4.6 **The developer/operator of a disposal facility for solid radioactive waste should carry out a programme of site investigation and site characterisation to provide information for the environmental safety case and to support facility design and construction.**

General

- 6.4.7 The length, complexity and detail of the site investigation need to be appropriate for the information requirements of the environmental safety case which, in turn, should be proportionate to the hazard presented by the waste to be disposed of. The developer/operator should establish a proportionate approach to site investigation that uses some or all of the results from site characterisation, modelling studies, design and construction to guide investigations. The site investigation should be presented as part of a structured programme that provides the requisite information for the environmental safety case.
- 6.4.8 The developer/operator will need to show that the geological environment is characterised, understood and can be analysed to the extent necessary to support the environmental safety case. This will involve considering, for example, the lithology, the stratigraphy, the geochemistry, the local and regional hydrogeology, and the resource potential of the area. Where appropriate, the developer/operator will also need to assess the potential for, and effects of, dynamic processes that are significant to the environmental safety case.
- 6.4.9 The developer/operator will need to show that the biosphere is characterised, understood and capable of analysis to the extent necessary to support the environmental safety case. This may involve consideration of, for example, topography, soils, surface water systems, flora and fauna distributions and human settlement patterns and activities. The investigation and characterisation of the

biosphere should be sufficiently comprehensive to support calculations of dose during the period of authorisation and should be proportionate to the assumptions made in the environmental safety case for calculating risks after the period of authorisation.

- 6.4.10 The developer/operator should show that the geological, hydrogeological and other characteristics of the region and the site under present and reasonably foreseeable future conditions will allow the environmental safety case for the facility to be made. This demonstration should include considering features and properties of the site related to the release and transport of radionuclides in the gas phase.
- 6.4.11 The developer/operator should identify the presence of any actually or potentially valuable resources near the site and make an assessment of the extent to which the site and its surroundings might be disturbed as a result. The developer/operator will need to consider the implications for the integrity of the disposal system (see Requirement R7).
- 6.4.12 Knowledge of the site characteristics is expected to increase progressively through the site investigation and the facility development phases. We shall be proportionate in our assessment of the adequacy of the site characterisation information presented in the context of an evolving environmental safety case.

Site characterisation

- 6.4.13 Before carrying out any intrusive geological investigations, the developer/operator should assess the extent to which these might disturb the site and any implications this might have for the environmental safety case.
- 6.4.14 Site characterisation should involve investigating specific properties of the site and its surroundings in sufficient detail to support the environmental safety case and may include the following:
- Local and regional borehole investigations.
 - Characterisation of soil layers and quaternary deposits.
 - Characterisation of surface waters and sediments.
 - Characterisation of surface and sub-surface flora, fauna and ecosystems.
 - Development of regional and local geological, geotechnical, hydrogeological and geochemical understanding.
 - Description of the environmental baseline prior to facility construction activities.

For near-surface facilities that are constructed underground (caverns), the developer/operator may need to consider including a phase of underground investigation within the body of the host rock for the proposed disposal facility.

- 6.4.15 Depending on the hazard presented by the waste to be disposed of, the developer may need to adopt an iterative approach to facility design and development of the environmental safety case as results are progressively obtained from the site characterisation activities. This will include a growing understanding of the capability of the proposed facility in terms of the types and quantities of waste it will be able to receive. As the environmental safety case is developed, it will help to guide what further site characterisation activities are needed.

Requirement R12: Use of site and facility design, construction, operation and closure

- 6.4.16 **The developer/operator of a disposal facility for solid radioactive waste should make sure that the site is used and the facility is designed, constructed, operated and capable of closure so as to avoid unacceptable effects on the performance of the disposal system.**
- 6.4.17 The developer/operator's approach to the use of the site and to facility design, construction, operation and closure should be proportionate to the hazard presented by the waste that the facility is intended to receive.
- 6.4.18 The developer/operator should demonstrate that the proposed location of the facility within the site is large enough to accommodate the categories and quantities of waste to be disposed of, whilst being far enough away from geological media of less suitable characteristics.
- 6.4.19 The developer/operator should show that the methods of construction of the facility are consistent with the claims made in the environmental safety case, in that they do not unduly disturb the geological environment and that any containment properties of the geology that are to be relied on are not adversely affected.
- 6.4.20 The developer/operator should show that the conditions in each section of the disposal facility, as disturbed by construction, are suitable for the types and quantities of waste that it is proposed to dispose of in that section. Where backfilling is used, the developer/operator should show that methods and materials have been chosen that are compatible with the waste form and the geological setting, and that provide an overall system performance consistent with the claims made in the environmental safety case.
- 6.4.21 In design and construction, the developer/operator will need to take into account a number of effects that may arise from properties of the waste, including:
- gas generation through microbial, chemical, or radiolytic action, or as a result of radioactive decay;
 - heat generation through microbial or chemical action, or as a result of radioactive decay;
 - criticality through concentration of fissile nuclides (we expect that, for near-surface facilities, this may be dealt with by a simple analysis).

These topics will also need to be considered in the environmental safety case.

- 6.4.22 Gas generation within the disposal facility can lead to gas movement through and around the facility. This may affect the rate at which, and the paths by which, radionuclides migrate from the facility. Considerations will need to include any venting of gases, both those presenting a radiological hazard and those presenting other hazards such as explosions or asphyxiation, to the atmosphere that may occur and any implications this may have for people and the environment.
- 6.4.23 The developer/operator should make plans for corrective action to deal with foreseeable geological or geotechnical problems which might arise during construction, operation or closure.
- 6.4.24 Although we shall regard disposal of a consignment of waste as taking place at the time when the consignment is emplaced in the facility, we shall not consider the

disposal process complete until all the requirements of the environmental safety case have been met. At the design stage and periodically during the lifetime of the facility, the developer/operator should demonstrate that it is able satisfactorily to close the disposal facility and, where relevant, seal any preferential pathways that will or may be introduced as a result of the siting, construction and operation of the disposal facility.

- 6.4.25 Before authorising the disposal of any waste in a facility, we shall need to be satisfied that the developer/operator has reasonable arrangements in place to fund the closure of the facility, the subsequent maintenance of any necessary controls and the eventual completion of disposal by removing all controls from the site.

Requirement R13: Waste acceptance criteria

- 6.4.26 **The developer/operator of a disposal facility for solid radioactive waste should establish waste acceptance criteria consistent with the assumptions made in the environmental safety case and with the requirements for transport and handling, and demonstrate that these can be applied during operations at the facility.**
- 6.4.27 Waste characterisation, treatment and packaging are the responsibility of the consignor of the radioactive waste to the disposal facility, but it is the responsibility of the developer/operator of the facility to make sure that the waste accepted for disposal is consistent with the environmental safety case and the requirements at the facility for transport and handling. The developer/operator of the facility needs to establish waste acceptance criteria that can fulfil this second responsibility, and to demonstrate that there are procedures in place to make sure that these criteria are met before waste is emplaced in the facility.
- 6.4.28 The factors that affect the performance of the waste before and after disposal, and that need to be covered by the acceptance criteria, include the radionuclide content, the chemical and physical form and durability, the susceptibility to microbial action, the thermal and radiation stability, and the mechanical stability.
- 6.4.29 The waste acceptance criteria should include requirements that ensure as far as reasonably practicable that all waste accepted for disposal is passively safe. The chemical and physical form of the waste should limit detrimental chemical or microbial interactions, and should restrict the release of radionuclides into the disposal environment, in accordance with the assumptions of the environmental safety case. The radiation and heat resistance of the waste form should be in accordance with the assumptions of the environmental safety case. The waste package should have sufficient mechanical stability to withstand the conditions of transport and handling, and to meet any assumptions regarding structural integrity made in the case. We shall also expect the developer/operator to demonstrate that the possibility of a local accumulation of fissile material, such as to produce a neutron chain reaction, will not arise.
- 6.4.30 The developer/operator of the facility will need to make sure that the radionuclide content and composition, including the fissile content, of waste consignments received for disposal are sufficiently well characterised to comply with the conditions of the authorisation under RSA 93.

Requirement R14: Monitoring

- 6.4.31 **In support of the environmental safety case, the developer/operator of a disposal facility for solid radioactive waste should carry out a programme to**

monitor for changes caused by construction, operation and closure of the facility.

- 6.4.32 The developer/operator should establish a reasoned and proportionate approach to a programme for monitoring the site and facility. This monitoring will provide data during the period of authorisation to ensure that the facility is operating within the parameters set out in the environmental safety case. However, the monitoring must not itself compromise the environmental safety of the facility.
- 6.4.33 In order to provide a baseline for monitoring at later stages, the developer/operator will need to carry out monitoring during the investigation and pre-construction stages. The same measurements may form part of the site investigation programme (see Requirement R11 above). They should include measurements of pre-existing radioactivity in appropriate media, together with geological, physical and chemical parameters which are relevant to environmental safety and which might change as a result of construction and waste emplacement (for example groundwater properties such as pressures, flows and chemical composition).
- 6.4.34 During the period of authorisation, radiological monitoring and assessment will be needed to provide evidence of compliance with authorised discharge limits and assurance of radiological protection of members of the public. In addition, during the construction stage and the period of authorisation, the developer/operator will need to monitor non-radiological parameters to confirm understanding of the effects that construction, operation and closure of the facility have on the characteristics of the site. In particular, the developer/operator will need to demonstrate that the changes in, and evolution of, the parameters monitored are consistent with the environmental safety case.
- 6.4.35 We shall need to be satisfied that the developer/operator has carried out appropriate investigation and monitoring during the construction stage and period of authorisation to establish: the characteristics of the site; the behaviour of the disposal system; and the extent of disturbance caused by intrusive site investigation procedures and by construction, operation and closure of the facility.
- 6.4.36 The monitoring programme will also need clearly to set out the levels of specific contaminants that will trigger action. It should include an action plan to deal with possible contamination from the facility and an approach to confirming any apparently positive results to avoid inappropriate action being taken in the event of a false positive observation.
- 6.4.37 In accordance with Principle 4, that unreasonable reliance shall not be placed on human action to protect people and the environment, assurance of environmental safety must not depend on monitoring or surveillance after the declared end of the period of authorisation. Subsequent monitoring that the developer/operator may wish to include is not ruled out, provided it does not produce an unacceptable effect on the environmental safety case.

7. Environmental safety case (Requirement R3)

7.1 Introduction

- 7.1.1 We expect a developer to provide an environmental safety case as part of a proposal to develop a disposal facility for solid radioactive waste. The operator of such a facility needs to have an environmental safety case, properly updated, already in place. The environmental safety case will demonstrate that members of the public and the environment are adequately protected, both at the time of disposal and in the future. This chapter gives guidance on how to establish and maintain an environmental safety case and on what it should contain.
- 7.1.2 The developer/operator of a near-surface disposal facility should provide an environmental safety case that responds to the guidance set out in this chapter in a manner proportionate to the radiological hazard presented by the waste. A simple environmental safety case may be adequate for a facility accepting only waste with very low concentrations of radioactivity, whereas a more complex environmental safety case may be needed for a facility accepting higher concentrations of radioactivity. Similarly, an environmental safety case for a facility with stringent limits on the quantity of long-lived radionuclides in the waste it accepts may not need to look as far into the future as an environmental safety case for a facility where the limits on long-lived radionuclides are less stringent.
- 7.1.3 A near-surface disposal facility may or may not be on a nuclear licensed site, depending on the particular circumstances. If the disposal facility is on a nuclear licensed site, the developer/operator will also need to provide a nuclear safety case for the facility that meets the requirements of HSE/NII. The nuclear safety case will have different objectives from the environmental safety case. It will be required for the period of time while the site is subject to a nuclear site licence and will deal with worker radiation safety in normal operation and the avoidance and mitigation of faults and accidents that could lead to the radiation exposure of workers and the public. The arguments presented in the two separate safety cases will need to be compatible. The nuclear safety case is not discussed further in this guidance.

7.2 General guidance

What should the environmental safety case demonstrate?

- 7.2.1 The environmental safety case should demonstrate a clear understanding of the disposal facility in its geological setting (“the disposal system”) as it evolves. The environmental safety case should be designed to demonstrate consistency with the principles set out in Chapter 4 of this guidance and that the management, radiological and technical requirements set out in Chapter 6 are met. The principles and requirements provide for protection of members of the public and the environment from radiological and non-radiological hazards, both during the period of authorisation and subsequently. The environmental safety case needs to show how the various components of the disposal system contribute to meeting the requirements.
- 7.2.2 The environmental safety case should include an environmental safety strategy supported by detailed arguments to demonstrate environmental safety. The environmental safety strategy should present a top level description of the fundamental approach taken to demonstrate the environmental safety of the disposal system. It should include a clear outline of the key environmental safety arguments and say how the major lines of reasoning and underpinning evidence support these arguments. The strategy should explain, for example, how the

chosen site, design for passive safety and multiple barriers each contribute to environmental safety.

- 7.2.3 The environmental safety case should demonstrate, using a structure based on clear linkages, how the environmental safety strategy is supported by the detailed arguments and how the arguments are supported by evidence, analysis and assessment. Internal consistency within the environmental safety case needs to be established and maintained.
- 7.2.4 The environmental safety case should explain how uncertainties have been considered and will be managed in the future and demonstrate that there can be confidence in the environmental safety case notwithstanding the uncertainties that remain. It should also demonstrate that potential biases and their effects on the environmental safety case have been identified and eliminated or minimised.
- 7.2.5 Everything significant that is claimed or assumed in the environmental safety case should be supported by evidence that is adequate in content and is of appropriate type or types, detail and robustness.

What should the environmental safety case include?

- 7.2.6 The environmental safety case should describe all aspects that may affect environmental safety, including the geology, hydrogeology and surface environment of the site, the characteristics of the waste (including any waste treatment and conditioning before disposal), the design of the facility and the techniques used to construct, operate and close it.
- 7.2.7 To an extent appropriate to the radiological hazard presented by the waste, the environmental safety case should make use of multiple lines of reasoning based on a variety of evidence, leading to complementary environmental safety arguments. The evidence may be both qualitative and quantitative, supported where appropriate by robust numerical analyses. The reasoning and assumptions should be clear and the evidence supporting them traceable.
- 7.2.8 The environmental safety case should include quantitative environmental safety assessments for both the period of authorisation and afterwards. These assessments will need to extend into the future until the radiological risks have peaked or until the uncertainties have become so great that quantitative assessments cease to be meaningful. They should show how radionuclides might be expected to move from the wastes through the immediate physical and chemical environment of the disposal facility and through the surrounding geological formations into and through the environment. After the period of authorisation and while any significant hazard remains, the environmental safety case should explore the consequences not only of the expected evolution of the disposal system, but also of less likely evolutions and events. For some facilities with only a small residual hazard at this stage, the risks may be so low that the case can be very simple.
- 7.2.9 The environmental safety case should describe the developer/operator's arguments for having confidence in the case including, for example, reference to:
 - the quality and robustness of the quantitative safety assessment and consideration of uncertainty;
 - the quality, robustness and relevance of the other arguments and evidence presented;

- the developer/operator's environmental safety culture and the breadth and depth of expertise and experience of individuals involved in activities supporting the environmental safety case;
- the main features of the developer/operator's management system, such as planning and control of work, the use of sound science and good engineering practice, record-keeping, quality management and peer review (see Requirement R5).

What should the environmental safety case achieve?

- 7.2.10 The environmental safety case should describe and substantiate the level of protection provided by the disposal system both during the period of authorisation and in the long term. It should be sufficiently comprehensive and robust to provide adequate confidence in the environmental safety of the disposal system bearing in mind the radiological hazard presented by the waste. It should avoid complexity disproportionate to technical understanding and the availability of data. Peer review will be important to help assure quality. The developer/operator should be alert to possible future changes to standards and to basic data, and should make the environmental safety case as robust as reasonably practicable in this respect.

How will the environment agencies consider the environmental safety case?

- 7.2.11 We shall consider the environmental safety case against the principles and requirements of this guidance. Quantitative assessments are likely to be important to our consideration, but regulatory acceptance of the case will ultimately be based on judgement. The quantitative and qualitative assessments provided in the environmental safety case will aid the judgements we make. In judging whether to accept the environmental safety case, we shall take into account the step that has been reached in the development of the disposal facility and the regulatory decisions we are being asked to make at that step.

Updating the environmental safety case

- 7.2.12 The developer/operator will be responsible for providing and updating the environmental safety case at each step during the development of a disposal facility and at suitable intervals during the period of authorisation. The environmental safety case, including quantitative environmental safety assessments, will need at each step to be sufficiently detailed and comprehensive for the regulatory decisions it is intended to inform and support. While the disposal facility is being operated and up until the time when it is closed, we shall expect any necessary updates to be provided progressively in a timely manner.
- 7.2.13 Updates to the environmental safety case should reflect growing knowledge about the site and should increasingly reflect the disposal facility as built and wastes as disposed of rather than as anticipated. Updates should also take into account, for example, feedback from regulators and feedback from other relevant facilities, both nationally and internationally, together with developments in environmental safety assessment techniques, in radiological protection and in technical understanding more generally. The eventual aim will be to show that the disposal system as realised in practice will provide proper protection to people and the environment.
- 7.2.14 The developer/operator should consider how the documentation will be structured and updated to promote traceability between steps and transparency. The developer/operator should also maintain a detailed audit trail for changes to the environmental safety case and documentation.

Presenting and preserving the environmental safety case

- 7.2.15 The developer/operator will need to secure and maintain the confidence of local interested parties by presenting the environmental safety case in a way that people will understand. Different styles and levels of documentation are likely to be needed to present the environmental safety case to different audiences, but these should be consistent in referring to the same fundamental arguments.
- 7.2.16 The developer/operator will be responsible throughout the development and period of authorisation of the facility for preserving the environmental safety case documentation and all relevant records and providing access to these by interested parties.

Other uses for the environmental safety case

- 7.2.17 The environmental safety case should be used to help specify a forward programme of improvement work, both to the environmental safety case itself and more broadly. For example, the environmental safety case may be useful in helping to identify improvements to the development and operation of the disposal facility and to the developer/operator's management system. Operational decisions and practices should be consistent with the environmental safety case.
- 7.2.18 The environmental safety case will provide an input to deriving facility-specific regulatory limits and conditions, and should help to underpin the developer/operator's waste acceptance criteria and emplacement requirements. It may also help to guide the monitoring of discharges for compliance with the authorisation, and the environmental monitoring programme for the site and the surrounding area.

7.3 Additional considerations

- 7.3.1 Below, we provide further guidance on aspects we consider are particularly important in preparing an environmental safety case.

Multiple-function environmental safety approach

- 7.3.2 The disposal system will consist of multiple components or barriers. There is a distinction between these components and the environmental safety functions they provide. A given component may contribute to the environmental safety case in a number of ways, and these safety functions may be wholly or partly separate from one another. For example, the host rock may provide a physical barrier and may also have chemical properties that help to retard the migration of radionuclides. There may be circumstances where one of these functions is impaired without the other necessarily being affected.
- 7.3.3 The environmental safety case should include an explanation of, and substantiation for, the environmental safety functions provided by each part of the system. It should also identify which radionuclides each function is relevant to and the expected time period over which the function is effective. The environmental safety case for the period after closure of a disposal facility should not depend unduly on any single function.
- 7.3.4 The developer/operator will need to explore the contribution that each environmental safety function makes to the environmental safety case (for example, by sensitivity analyses). The developer/operator will also need to explore the circumstances where more than one function is impaired.

Multiple lines of reasoning and complementary environmental safety arguments

- 7.3.5 For assessments covering times after the period of authorisation and extending into the very long term, our main environmental safety standard is a risk guidance level (Requirement R6). We shall expect the developer/operator to provide one or more quantitative assessments aimed at calculating risk, which can then be compared to the risk guidance level, as a key part of the environmental safety case for these times. However, quantitative risk assessments – even with appropriate treatment of uncertainties (see below) – are unlikely to be sufficient on their own to establish the environmental safety case for the very long term.
- 7.3.6 Where environmental safety needs to be assured over very long timescales, it is likely this will only be achieved through multiple lines of reasoning based on a variety of evidence, leading to complementary environmental safety arguments. In the overall environmental safety case, these complementary arguments need to be brought together in a structured way.
- 7.3.7 Examples of environmental safety indicators that might be used to strengthen the environmental safety case include radiation dose, radionuclide flux, radionuclide travel times, environmental concentration and radiotoxicity. Where the radiological hazard presented by the waste warrants it, the developer/operator should provide a wide range of information relating to such indicators, for example:
- assessments of radionuclide release characteristics from the waste and from the various barriers that make up the disposal system;
 - assessments of the concentrations in the accessible environment of radionuclides released from the disposal system and comparison of these with naturally occurring levels of radioactivity in the environment;
 - where appropriate, assessment of collective radiological impact (as a measure of how widespread any significant increase in risk may be as a result of radioactivity released into the accessible environment) - however, see paras 6.3.68-69;
 - unifying statements that aim to place in context the different items of information that contribute to assuring environmental safety.

Managing uncertainties

- 7.3.8 Managing uncertainties is a necessary and important part of establishing the environmental safety case, and will need to be addressed each time the environmental safety case is updated. The developer/operator will need to account for uncertainties explicitly, analyse their possible consequences and consider where they may be reduced or their effects lessened or compensated for. Uncertainties themselves are not obstacles to establishing the environmental safety case, but they do need proper consideration and including in the structure of the environmental safety case as appropriate.
- 7.3.9 Uncertainties arise from diverse sources and have a number of different characteristics. They are caused, for example, by natural variability, practical limitations on sampling relevant processes and data, alternative interpretations of data, and natural events and future human behaviour that may affect radionuclide release, transport and exposure pathways. How significant they are depends on the effect they could have on the arguments used in the environmental safety case.

- 7.3.10 The developer/operator will need to demonstrate that the environmental safety case, for both the period of authorisation and afterwards, takes adequate account of all uncertainties that have a significant effect on the environmental safety case. This will mean establishing and maintaining:
- a register of significant uncertainties;
 - a clear forward strategy for managing each significant uncertainty, based on considering, for example, whether the uncertainty can be avoided, mitigated or reduced, and how reliably it can be quantified.
- 7.3.11 The developer/operator should provide explanations for interested parties of the significance of uncertainties important to the environmental safety case, by presenting these explanations in a way that people will understand. This material could form part of the environmental safety strategy (see para. 7.2.2 above). The relevant environment agency will provide its own view on the developer/operator's statements.
- 7.3.12 As explained under Requirement R6, an important distinction can be made between two types of uncertainties: those that can reliably be quantified and those that cannot. Natural variability and statistical inexactness belong to the first type (capable of being assessed statistically), while problems of data relevance, lack of understanding of processes, and uncertainty about future human behaviour belong to the second type. Uncertainties of the second type are no less real and important than those of the first type and both types need to be taken into account in the environmental safety case.
- 7.3.13 The two extreme types of uncertainties described above may be considered to lie at the opposite ends of a range. When dealing in practice with a particular uncertainty for which only limited data exist, it may be necessary to regard it as including both a quantifiable and an unquantifiable component in order to take it properly into account in the environmental safety case. Expert judgement (see paras 7.3.29-30 below) may often play a significant part in developing approaches to handling such uncertainties.
- 7.3.14 The developer/operator should follow radiological protection advice generally accepted at the time of use for the assessment of dose and risk (e.g. dosimetric data and the applicable risk coefficient). Uncertainties in these areas are common to all radiological assessments and are normally left implicit. There is, therefore, no special reason to include them explicitly in assessments supporting the environmental safety case for a disposal system.
- 7.3.15 Some uncertainties may be quantified and applied to parameter values used in quantitative environmental safety assessments. There are established methods for carrying out these calculations, and the environmental safety case should make clear which uncertainties have been addressed in this way.
- 7.3.16 Some uncertainties may be managed by making simplifying deterministic assumptions based on reasoned arguments. Because processes that take place in a natural environment are liable to be highly complex, some simplifications in environmental safety assessments are likely to be unavoidable. As part of the environmental safety case, the developer/operator needs to show that any simplifications adopted either have an insignificant effect on the outcome of the assessment, or have a conservative effect (i.e. do not lead to impacts being underestimated).

- 7.3.17 It may be inappropriate to quantify some uncertainties because relevant and reliable data are not available. If these uncertainties are important to the environmental safety case, they may be treated by a series of risk assessments, in each case making deterministic assumptions and exploring the effects of varying these. Important examples include qualitatively different sequences of events that could occur in the future (for example different evolutions of climate or landscape), and different conceptual models (for a part of the disposal system) that are each consistent with the data available but that produce different projections of future environmental performance (see also para.7.3.25).
- 7.3.18 In some circumstances, where few or no relevant data can be gathered, a 'stylised' approach may be adopted, in which arbitrary assumptions are made that are plausible and internally consistent but tend to err on the side of conservatism. The evolution of the biosphere and human intrusion provide examples of where it may be appropriate to use a stylised approach. Stylised approaches may be suitable where neither the choice of site nor the design of the disposal facility would greatly affect the uncertainties concerned. If a stylised approach is used for modelling part of a disposal system (for example for the biosphere), the developer/operator needs to take care that the use of this approach does not distort the modelling of the rest of the system such that important properties of other parts of the system are obscured in the overall model.
- 7.3.19 Because many uncertainties in the environmental safety case for times after the end of the period of authorisation cannot reliably be quantified, the results of quantitative environmental safety assessments in the form of calculated risks can only be regarded as broad indicators of environmental safety. This is one reason why the environmental safety case needs to be based on multiple lines of reasoning and on a variety of evidence, leading to complementary environmental safety arguments.
- 7.3.20 Uncertainties are not confined entirely to times after the period of authorisation. The design, construction, operation and closure of a disposal facility all contain their own uncertainties. These are caused, for example, by data not yet gathered, work not yet carried out and decisions not yet taken. These uncertainties can affect the environmental safety case for both the period of authorisation and afterwards, and need to be managed alongside all other uncertainties. These types of uncertainties, however, are resolved as the disposal facility develops. The environmental safety case will need to be updated as these uncertainties are resolved, taking into account, for example, data on the facility as built, in place of data assumed in the design.

Modelling studies and confidence-building

- 7.3.21 Modelling studies are likely to make up an important part of the quantitative environmental safety assessment. They may also contribute to or support complementary arguments based on alternative lines of reasoning. As well as the results of the studies, the developer/operator will need to provide details of the models and methodologies used including any assumptions.
- 7.3.22 The general aim of modelling studies will be to help in understanding the characteristics and behaviour of the overall disposal system and its component parts. However, in order to contribute usefully to the environmental safety case, each specific set of modelling studies will need to have more specific defined and documented objectives:
- modelling objectives should take account of the decisions that the results are intended to support;

- the selected approach should be driven mainly by the modelling objectives, and not by the availability of models or software or by considering what models or software were used previously (unless there is an overriding need for consistency);
- modelling objectives should be defined in terms of what can be accomplished with the available data. Complex models should not be developed if there is not enough data to support them;
- the objectives should be reviewed throughout the modelling process.

In cases where there are likely to be extensive modelling studies, we encourage the developer/operator to consider discussing the modelling objectives at an early stage with the relevant environment agency.

- 7.3.23 The developer/operator will need to carry out a systematic programme of work to build confidence in the modelling. This will include interpreting raw data and developing and testing conceptual, mathematical and computational models. The process of building confidence in a model for its intended purpose is iterative and progressive. Because of the long timescales to which the models used to support the environmental safety case may need to be applied, it will rarely be possible to have meaningful direct validation by comparing model outputs with observations. The measures adopted in a confidence-building programme should include:
- systematic approaches to model building and consideration of alternative models;
 - iteration between model building, quantitative assessments and data collection;
 - good communication between modellers (including those developing and using models), suppliers of data (including those planning research or data collection and those actually making observations) and those using modelling results;
 - continuing peer review of model development;
 - rigorous quality assurance of all modelling activities and associated data handling, including controls over changes to models and data and a detailed audit trail.
- 7.3.24 Models and associated parameter values should, to the extent possible at the time of the assessment, be site-specific. The use of generic or default data instead of site-specific data will need to be supported by considering the effect that this has on the environmental safety case: in general the use of such data should be shown not to lead to an underestimation of impacts. Using generic models and parameter values may be more acceptable in the early stages of development of a facility or where the radiological hazard associated with the waste is particularly low.
- 7.3.25 In some areas, for example seismic survey data, there may be a number of alternative credible interpretations of the data. Therefore, no one conceptual model of the system can be regarded as uniquely valid. This is a further uncertainty, and considering only one preferred conceptual model could significantly underestimate the actual overall uncertainty. We shall expect the developer/operator to show that the environmental safety case is not unduly sensitive to alternative interpretations or conceptual models.

- 7.3.26 Area by area, the developer/operator will need to judge when it will be sensible to end the programme of building confidence in the modelling. The developer/operator will need to provide us with the basis for these judgements.
- 7.3.27 Computational models need to be used in an appropriate manner. In particular, the input parameters will have ranges of values outside which the results from a model cannot be relied on. The developer/operator needs to provide a statement of these ranges, together with appropriate evidence.
- 7.3.28 We recognise that models used to support the environmental safety case will often be used to provide projections over time periods far exceeding any period for which the models have been tested against observations. Modelling projections of this nature cannot be regarded as predictions, but as assessments provided to support judgements about environmental safety. Quantitative modelling projections should not be made for times so far into the future that uncertainties make the modelling results lose any meaning.

Use of expert judgement

- 7.3.29 Expert judgement is essential in gathering and interpreting evidence and applying it to construct and use the qualitative and quantitative models that will support the environmental safety case. Much expert judgement is held in common and is fundamental to standard approaches. As far as possible, the developer/operator should use standard approaches to establish the environmental safety case, thus relying on this kind of expert judgement.
- 7.3.30 There are likely to be parts of the environmental safety case, however, where expert judgement that is not held in common will be used to complement or interpret evidence or to compensate for data gaps. Such judgement may be made in an informal fashion or may be elicited using more formal structured procedures, as appropriate to the situation. Where this type of expert judgement is used, the developer/operator should, to an extent proportionate to the significance of the judgements to the environmental safety case:
- explain the choice of experts and method of elicitation;
 - document explicitly expert judgements that have been made and the reasons given by experts to support their judgements;
 - take and document reasonable steps to identify and eliminate or minimise any biases resulting from the use of expert judgement and/or the elicitation methods adopted.

Fissile material

- 7.3.31 We do not expect significant amounts of fissile material to be disposed of to near-surface facilities. The environmental safety case should consider the issue of a criticality event, although we recognise that a simple analysis should be sufficient to demonstrate that such an event will not occur.

Climate change

- 7.3.32 The environmental safety case needs to take into account the potential for climate change. Possible climate change may be induced by natural processes, or by human actions affecting natural processes. There is considerable uncertainty regarding the rate, amount and even the direction of possible climate change over different timescales. So, the developer/operator will need to consider a range of

possibilities. The potential consequences of climate change include changes in rainfall patterns (which can affect watercourses and aquifers), changes in sea level, increased rates of erosion including coastal erosion, glacial cycling and glacio-tectonic movements.

Human intrusion

- 7.3.33 We shall expect the developer/operator to consider human intrusion as part of the environmental safety case in accordance with Requirement R7 (see Chapter 6). Because of the obvious uncertainty of trying to predict what people might do in the future, this is likely to involve using stylised calculations as discussed above (see para. 7.3.18).

Optimisation

- 7.3.34 We shall expect the developer/operator to demonstrate in the environmental safety case that optimisation considerations have been applied in all relevant decisions and at all relevant steps. Relevant steps include the choice of waste acceptance criteria, how the selected site is used and the design, construction, operation, closure and post-closure management of the disposal facility (see Requirement R8).

Environmental radioactivity

- 7.3.35 We shall expect the developer/operator to consider environmental radioactivity as part of the environmental safety case in accordance with Requirement R9.

Protection against non-radiological hazards

- 7.3.36 Radioactive wastes disposed of at a near-surface facility may present non-radiological hazards as well as a radiological hazard. In accordance with Requirement R10, the environmental safety case will need to demonstrate that an adequate standard of protection is reached for any non-radiological hazards.

Part 2: Context – Policy, Legislation and International Obligations

8. Policy and legislative framework

8.1 Introduction

- 8.1.1 This chapter describes the UK's obligations under international treaties and other influences on UK policy for managing radioactive waste. It also gives an overview of UK Government policy and the background to regulating the disposal of solid radioactive waste.
- 8.1.2 We summarise the legislation implemented by the environment agencies and the Health and Safety Executive to make sure radioactive waste is disposed of safely and securely.
- 8.1.3 The chapter summarises the planning regime covering the development of disposal facilities and highlights changes to the planning system for England. It also highlights the role of strategic environmental assessment (SEA) for plans and programmes and environmental impact assessment (EIA) for projects.
- 8.1.4 This chapter is intended to give an indication of the regulatory processes that could apply to development of a disposal facility for solid radioactive waste. Policy and legislation will change over time and the information presented can only be a snapshot at the time this guidance was produced. Developers are encouraged to make early contact with regulators or take independent advice to gain an understanding of applicable policy and legislation.
- 8.1.5 The structure of this chapter is shown in Figure 8.1, which indicates broadly how policy and regulatory requirements are linked. Regulation by the environment agencies often proceeds in parallel with regulation by other public bodies (such as HSE). In this guidance, we focus on environmental regulation while providing summary information on other regulatory activities and on policy. In Section 8.12 (not shown in Figure 8.1), we provide a summary of the regulation of disposal facilities for solid radioactive waste.

Figure 8.1 Structure of the policy and legislative framework chapter.

Section	Activity	Responsible Organisation	
8.2	International treaties and conventions	European Commission, IAEA, Ospar Commission	Policy
8.3	UK national policy	UK Government and devolved administrations	
8.4	Strategic environmental assessment	Public bodies	Guidance / Statutory requirements
8.5	Environmental impact assessment	Developer/operator	
8.6	Land-use planning	Planning authorities	
8.7	Environmental regulation	Environment agencies	
8.8	Environment agencies' advice and guidance	Environment agencies	
8.9	Radiological protection advice	Health Protection Agency	
8.10	Health, safety and security regulation	Health and Safety Executive	
8.11	Radioactive material transport regulation	Department of Transport and Health and Safety Executive	

8.2 International background

- 8.2.1 Certain international treaty obligations affect radioactive waste management policy in the UK, including obligations from the European Union (EU), the OSPAR Convention and under the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management. Policy in the UK also takes account of outputs from the International Atomic Energy Agency (IAEA) and the International Commission on Radiological Protection (ICRP). We outline below all these influences on policy in the UK.

European legislation

- 8.2.2 The Euratom Treaty establishing the European Atomic Energy Community was signed in 1957 (EU 1957) and covers activities involving radioactive substances. The European Court of Justice has ruled that the Euratom Treaty does not apply to defence activities – however, national legislation applies to those activities.
- 8.2.3 Under Article 37 of the Treaty, Member States have to give the European Commission sufficient information about any plans to dispose of radioactive waste (to air, land or water) to allow the Commission to decide whether the plans could cause radioactive contamination of the water, soil or airspace of another Member State. This information must be provided before the competent authority of the Member State concerned authorises the disposal of the waste.
- 8.2.4 Also, under Article 33 of the Euratom Treaty, Member States have to implement appropriate provisions to ensure compliance with the basic standards established under Article 31. In order to meet this requirement, basic standards for protection of workers and the public have been set out in various directives since 1959. The most recent is Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (the Basic Safety Standards (BSS) Directive (EC 1996)).
- 8.2.5 Parts of the BSS Directive have been implemented in the UK through the Radioactive Substances (Basic Safety Standards) (England and Wales) Direction 2000 (DETR 2000), the Radioactive Substances (Basic Safety Standards) (Scotland) Direction 2000 (Scottish Executive 2000) and the Radioactive Substances (Basic Safety Standards) Regulations (Northern Ireland) 2003 (TSO 2003a). The environment agencies comply with these requirements through our role in regulating radioactive waste disposal under RSA 93. As part of our role, we have to make sure that:
- all exposures to ionising radiation of any member of the public and of the population as a whole resulting from the disposal of radioactive waste are kept as low as reasonably achievable (ALARA), economic and social factors being taken into account; and
 - the sum of the doses resulting from the exposure of any member of the public to ionising radiation should not exceed an effective dose limit of 1 millisievert (mSv) in a year. In special circumstances, a higher effective dose may be authorised in a single year, provided that the average over five consecutive years does not exceed 1 mSv per year.
- 8.2.6 The environment agencies must have regard to the following maximum doses to individuals which may result from a defined source, for use at the planning stage in radiation protection:
- 0.3 mSv per year from any source from which radioactive discharges are made; or
 - 0.5 mSv per year from the discharges from any single site.

OSPAR Convention

- 8.2.7 The 1992 OSPAR Convention guides international cooperation on protecting the marine environment of the North-East Atlantic. The OSPAR Radioactive Substances Strategy (OSPAR 2003) seeks progressive and substantial reductions

of discharges, emissions and losses of radioactive substances. The Strategy applies only to discharges to the marine environment. By 2020, it aims to achieve concentrations near to natural background levels in the marine environment for naturally occurring radioactive substances and close to zero for releases of artificial radioactive substances. Natural background levels are the levels of naturally occurring radioactive substances found in the marine environment without any releases from human activities.

8.2.8 In 2002, Defra and the devolved administrations published the '*UK strategy for radioactive discharges 2001–2020*' (Defra 2002a), which sets out how the UK will implement the OSPAR Radioactive Substances Strategy. The UK strategy is being revised (see para. 8.2.10). The UK strategy does not set individual site limits for radioactive discharges, but rather provides a strategic framework for reducing radioactive discharges from UK installations over the next 20 years. Its aims are:

- '- progressive and substantial reduction of radioactive discharges and discharge limits, to achieve the strategy targets for sectors such as nuclear fuel production and uranium enrichment, nuclear energy production, spent fuel reprocessing and defence;
- progressive reduction of human exposure to ionising radiation arising from radioactive discharges, as a consequence of reductions in discharges, such that a representative member of a critical group of the general public will be exposed to an estimated mean dose of no more than 0.02 mSv a year from liquid radioactive discharges to the marine environment made from 2020 onwards;
- progressive reduction of concentrations of radionuclides in the marine environment resulting from radioactive discharges, such that by 2020 they add close to zero to historic levels.'

8.2.9 The terms 'close to zero' and 'historic levels' are not defined in the OSPAR Strategy. The OSPAR Commission, which manages work under the Convention, is aiming to develop agreed definitions.

8.2.10 In June 2008, Defra and the devolved administrations published for consultation a revised draft UK strategy for radioactive discharges that describes how the UK will continue to implement its commitments under the OSPAR Convention (Defra *et al.* 2008). The revised strategy builds on the UK strategy published in 2002 and expands its scope to include aerial, as well as liquid discharges, from decommissioning as well as operational activities, and from the non-nuclear sector (for example, hospitals, universities and research laboratories) as well as the nuclear industry.

8.2.11 The objectives of the revised draft UK strategy are:

- to implement the UK's obligations, rigorously and transparently, in respect of the OSPAR Radioactive Substances Strategy intermediate objective for 2020;
- to provide a clear statement of Government policy and a strategic framework for discharge reductions, sector by sector, to inform decision making by industry and regulators

8.2.12 The expected outcomes of the revised draft UK strategy are:

- progressive and substantial reductions in radioactive discharges

- progressive reductions in concentrations of radionuclides in the marine environment resulting from radioactive discharges, such that by 2020 they add close to zero to historic levels;
- progressive reductions in human exposures to ionising radiation resulting from radioactive discharges, as a result of planned reductions in discharges.

8.2.13 The revised draft UK strategy sets out the radiological, environmental and other principles that the regulatory bodies will apply when setting discharge authorisations. It does not set individual site limits for radioactive discharges, but it does set targets at the sectoral level which it expects to be achieved by 2020 and by 2030 and a strategic framework for addressing radioactive discharges over the next 20 years. Discharges from five nuclear sectors are considered in the strategy: nuclear fuel production and uranium enrichment, nuclear energy production, spent fuel reprocessing, research facilities and defence facilities. Discharges from the non-nuclear sectors are also discussed.

8.2.14 In setting discharge limits, it is proposed that the application of Best Available Techniques (BAT) will replace the use of Best Practicable Means (BPM) in England and Wales although BPM will continue to be used in Scotland and Northern Ireland (see Section 8.8).

Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management

8.2.15 The UK has ratified the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (Joint Convention; IAEA 1997), sponsored by the IAEA.

8.2.16 The Joint Convention applies to spent fuel and radioactive waste from civilian nuclear reactors and applications. The Joint Convention also applies to planned and controlled releases into the environment of liquid or gaseous radioactive materials from regulated nuclear facilities.

8.2.17 One of the objectives of the Joint Convention is:

‘to ensure that during all stages of spent fuel and radioactive waste management there are effective defences against potential hazards so that individuals, society and the environment are protected from harmful effects of ionising radiation, now and in the future, in such a way that the needs and aspirations of the present generation are met without compromising the ability of future generations to meet their needs and aspirations.’

8.2.18 This objective fits with our duty to contribute to sustainable development. It is also central to the aims and objectives of this guidance.

8.2.19 Also under the Joint Convention, the UK must:

- establish and maintain a legislative and regulatory framework to govern the safety of spent fuel and radioactive waste management;
- ensure that the design and construction of a radioactive waste management facility provide for suitable measures to limit possible radiological impacts on individuals, society and the environment, including those from discharges or uncontrolled releases;

- take the appropriate steps to ensure that at all stages of radioactive waste management individuals, society and the environment are adequately protected against radiological and other hazards.

International Atomic Energy Agency

8.2.20 The IAEA has published advice on the legal and governmental responsibilities for the safety of nuclear facilities, the safe use of sources of ionising radiation, radiation protection, managing radioactive waste and transporting radioactive material safely (IAEA 2000). The environment agencies regard the IAEA's advice as a statement of good practice.

8.2.21 The IAEA's advice sets out the responsibilities and functions of regulatory bodies involved in nuclear, radiation, radioactive and transport safety. The IAEA has identified that:

'In fulfilling its statutory obligations, the regulatory body shall:

- a. establish, promote or adopt regulations and guides upon which its regulatory actions are based;
- b. review and assess submissions on safety from the operators both prior to authorisation and periodically during operation as required;
- c. provide for issuing, amending, suspending or revoking authorisations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified):
 - the facilities, activities or inventories of sources covered by the authorisation;
 - the requirements for notifying the regulatory body of any modifications to safety related aspects;
 - the obligations of the operator in respect of its facility, equipment, radiation source(s) and personnel;
 - any limits on operation and use (such as dose or discharge limits, action levels or limits on the duration of the authorisation);
 - conditioning criteria for radioactive waste processing for existing or foreseen waste management facilities;
 - any additional separate authorisations that the operator is required to obtain from the regulatory body;
 - the requirements for incident reporting;
 - the reports that the operator is required to make to the regulatory body;
 - the records that the operator is required to retain and the time periods for which they must be retained; and
 - the emergency preparedness arrangements.
- d. carry out regulatory inspections;
- e. ensure that corrective actions are taken if unsafe or potentially unsafe conditions are detected; and

- f. take the necessary enforcement action in the event of violations of safety requirements.'

8.2.22 Our guidance is mainly aimed at (a) and (b) and, to some extent, at the more detailed information presented under (c). All these requirements fall within the normal regulatory activities of the environment agencies.

International Commission on Radiological Protection

8.2.23 The ICRP is an independent advisory body that provides recommendations and guidance on radiation protection. ICRP has no formal power to impose its proposals, but most countries adhere closely to its recommendations. In March 2007, ICRP approved a new set of fundamental recommendations on protecting people and the environment against ionising radiation (ICRP 2007). These recommendations update ICRP's previous recommendations from 1990 (ICRP 1991). ICRP has stated that the overall estimate of the risk of various kinds of harmful effects after exposure to radiation remains fundamentally the same as in the 1990 recommendations (ICRP 2007).

8.2.24 In the UK, HPA advises the Government on whether the recommendations of ICRP are acceptable and applicable. HPA has published advice on the recommendations in ICRP 103 (HPA 2009a). HPA's main recommendations are that:

- the linear no threshold model remains the basis for setting radiological protection standards and criteria, because it represents the scientific consensus;
- no changes should be made to the dose limits in the UK;
- a maximum dose constraint of 0.15 mSv per year should apply to exposure of the public from any new source

8.2.25 The ICRP recommendations also inform possible changes to the Basic Safety Standards Directive and, consequently, the UK's legislation for implementing the Directive.

8.3 Policy in the UK

8.3.1 Radioactive substances are used throughout the UK, although there are no nuclear licensed sites in Northern Ireland. The environment agencies seek to apply government policy to the extent permitted under the relevant legislation.. In some cases, the policies are identical in the various parts of the UK but, in others, different policies have been adopted.

8.3.2 Developers of disposal facilities for solid radioactive waste should take account of any differences in policy resulting from geographical location. We encourage early contact with the appropriate environment agency to discuss any differences in policy.

UK policy for management of solid low level radioactive waste

8.3.3 In March 2007, the UK Government and devolved administrations published their '*Policy for the Long Term Management of Solid Low Level Radioactive Waste in the United Kingdom*' (Defra *et al.* 2007). The policy statement covers all aspects of generating, managing and regulating solid low level radioactive waste (LLW). The policy identifies the need for this guidance.

- 8.3.4 LLW consists largely of paper, plastics and scrap metal items that have been used in the nuclear industry, hospitals and research establishments. In future, there will also be large volumes of LLW in the form of soil, concrete and steel, as existing nuclear facilities are decommissioned.

Categories of LLW

- 8.3.5 The upper bound of the LLW category is defined by the policy as:

‘radioactive waste having a radioactive content not exceeding four gigabecquerels per tonne (GBq/te) of alpha or 12 GBq/te of beta/gamma activity’.

However, the policy also notes that this definition might change in future if a new national disposal facility were developed with acceptance criteria different from those for the current LLW Repository (LLWR) near Drigg in Cumbria.

- 8.3.6 Although RSA 93 does not specifically provide for setting clearance levels, the lower bound of LLW is defined for certain naturally occurring radionuclides by Schedule 1 of RSA 93. The Radioactive Substances (Substances of Low Activity) Exemption Order 1986 (HMSO 1986) specifies a level of exemption from regulatory control of 0.4 Bq/g (0.0004 GBq/te) for wastes that are substantially insoluble in water.

- 8.3.7 Two subcategories at the lower end of the LLW spectrum, high volume very low level waste (HV-VLLW) and low volume very low level waste (LV-VLLW), are also defined. These subcategories have implications for the disposal routes that may be suitable for this type of waste.

- 8.3.8 HV-VLLW is expressed in terms of a mass concentration and is defined as:

‘Radioactive waste with maximum concentrations of four megabecquerels per tonne (MBq/te) of total activity which can be disposed of to specified landfill sites. For waste containing hydrogen-3 (tritium), the concentration limit for tritium is 40 MBq/te. Controls on disposal of this material, after removal from the premises where the wastes arose, will be necessary in a manner specified by the environmental regulators.’

- 8.3.9 LV-VLLW on the other hand is expressed in terms of a volume based concentration and is defined in terms of its activity as:

‘Radioactive waste which can be safely disposed of to an unspecified destination with municipal, commercial or industrial waste (‘dustbin’ disposal), each 0.1m³ of waste containing less than 400 kilobecquerels (kBq) of total activity or single items containing less than 40 kBq of total activity. For wastes containing carbon-14 or hydrogen-3 (tritium):

- in each 0.1 m³, the activity limit is 4,000 kBq for carbon-14 and hydrogen-3 (tritium) taken together;
- for any single item, the activity limit is 400 kBq for carbon-14 and hydrogen-3 (tritium) taken together. Controls on disposal of this material, after removal from the premises where the wastes arose, are not necessary.’

- 8.3.10 The 2007 LLW (Defra *et al.* 2007) policy allows "Controlled burial" of LLW and HV-VLLW at specified landfill sites, provided that this meets regulatory requirements.

Radioactive waste suitable for “Controlled burial” is defined in terms of activity volume concentration limits, activity limits per article, radionuclide half-lives, and the way in which the waste is disposed of at a receiving landfill.

- 8.3.11 Two radiological criteria are identified in the LLW policy document for protection of the public and the environment:

- ‘ - **For the period of operation of disposal sites for LLW**, the effective dose to a representative member of the critical group should not exceed the single source-related dose constraint of 0.3 millisieverts (mSv) per year (the average annual dose from background radiation within the UK is 2.6 mSv per year), and shall be reduced below this level to the extent practicable through the use of the Best Practicable Means (BPM) principle to ensure that doses to people are ‘as low as reasonably achievable’ (ALARA), economic and social factors being taken into account. This dose constraint also applies to the period following cessation of operations, during which the site would remain under management control, and when monitoring would be undertaken.
- **Following final disposal** and post-closure monitoring, and once management control of the waste has been withdrawn, the assessed radiological risk of fatal cancer or severe hereditary defect from the facility to a representative member of the potentially exposed group at greatest risk should be consistent with a risk target of 10^{-6} per year (i.e. one in a million per year).’

- 8.3.12 The end point for LLW that remains following the application of the waste management hierarchy should be disposal to an appropriately engineered facility, either below or above ground. The use of centralised facilities, such as the LLWR or any similar future facility, may be appropriate for disposal of much LLW. Other options employing the ‘proximity principle’ (that is, if other considerations allow, the waste should be disposed of close to where it is created) are possible depending on the intrinsic hazard of the LLW for disposal. The developer would need to consider whether an adequate standard of environmental and operational safety could be achieved without transporting the waste.

Sustainable development

- 8.3.13 The UK Government and devolved administrations are committed to sustainable development. In 2005, the Government published ‘*Securing the Future – The UK Government Sustainable Development Strategy*’ (Defra 2005) and the Sustainable Development Framework: ‘*One Future: Different Paths*’ (Defra *et al.* 2005). These provide the strategy and framework in which the environment agencies must operate. We contribute to sustainable development, largely by enforcing legislation aimed at protecting the environment. Authorisations issued under RSA 93 and environmental permits for non-radioactive discharges provide some of the ways in which we carry out this role.

Justification

- 8.3.14 Justification is one of the principles of radiological protection established by the ICRP. ‘Justification’ means that ‘any decision that alters the radiation exposure situation should do more good than harm’ (ICRP 2007).
- 8.3.15 The Justification of Practices Involving Ionising Radiation Regulations 2004 (TSO 2004a) implements this aspect of the BSS Directive. Under these Regulations, the

UK Government and devolved administrations make all justification decisions. These policy decisions are required before any regulatory action can proceed.

- 8.3.16 Defra's guidance (in conjunction with the devolved administrations) on application and administration of the Regulations makes clear that ICRP emphasises that radioactive waste management and disposal operations are an integral part of the practice generating the waste and that it is wrong to regard them as a free-standing practice that requires its own justification (Defra 2007).

8.4 Strategic environmental assessment

- 8.4.1 Under the EC Directive on the assessment of the effects of certain plans and programmes on the environment (EC 2001), certain public sector plans and programmes that are likely to have significant effects on the environment must have a strategic environmental assessment (SEA) when they are being prepared. This is to make sure that these effects are taken into account fully before the plan or programme is adopted.
- 8.4.2 The environment agencies are statutory consultees for all plans and programmes that require SEA. In England, the Environment Agency takes this role under the Environmental Assessment of Plans and Programmes Regulations 2004 (TSO 2004b). In Scotland, SEPA takes this role under the Environmental Assessment (Scotland) Act 2005 (TSO 2005a). Similar legislation applies in Wales and Northern Ireland.
- 8.4.3 A statutory requirement for SEA will only apply to development of a near-surface disposal facility for solid radioactive waste if a number of regulatory tests are met, which are broadly:
- the plan must be prepared by a public body;
 - it is prepared for certain industrial and ecological sectors (including energy and waste management);
 - it is required by legislative, regulatory or administrative provisions;
 - it sets the framework for future development consent;
 - it is likely to have significant environmental effects.

8.5 Environmental impact assessment

- 8.5.1 EIA identifies the environmental effects (both negative and positive) of development proposals. It aims to prevent, reduce and offset any adverse impacts. The requirement for EIA arises from the EC Directive on the assessment of the effects of certain public and private projects on the environment (EC 1985).
- 8.5.2 EIA is a statutory requirement when developing disposal facilities for solid radioactive waste. In England and Wales, this requirement arises under the Town and Country Planning (Environmental Impact Assessment) (England and Wales) Regulations 1999 (TSO 1999a). In Scotland, the Environmental Impact Assessment (Scotland) Regulations 1999 (TSO 1999b) apply and in Northern Ireland the Planning (Environmental Impact Assessment) Regulations (Northern Ireland) 1999 (TSO 1999c). Under these various Regulations, the environment agencies are statutory consultees to the planning authorities for installations designed solely for final disposal of solid radioactive waste.

8.6 Land-use planning

- 8.6.1 In England and Wales, any proposed facility for disposing of solid radioactive waste will be considered a development under the Town and Country Planning Act 1990 (HMSO 1990) and will need planning permission. In Scotland, planning permission will be required under the Town and Country Planning Act (Scotland) 1997 (TSO 1997a) as modified by the Planning etc. (Scotland) Act 2006 (TSO 2007a). In Northern Ireland, planning permission will be required under the Planning (Northern Ireland) Order 1991 (HMSO 1991a) (as amended by the Planning (Amendment) (Northern Ireland) Order 2003 (TSO 2003b) and the Planning Reform (Northern Ireland) Order 2006 (TSO 2006a)).
- 8.6.2 Currently in Great Britain (England, Scotland and Wales), it is usually one of the local councils, which is the planning authority responsible for considering such an application. In many parts of England, this is the county council for the relevant county or unitary authority and in Scotland it is generally the local authority. In Wales, local councils, which are all unitary authorities, are responsible and in Northern Ireland, the Planning Service has responsibility for planning decisions.
- 8.6.3 Where proposed developments raise questions of national importance or they represent significant departures from the approved structure plan for an area and/or national planning guidance, then intervention by government may occur. In England, an application could be determined by the Secretary of State for Communities and Local Government. In Scotland, it is Scottish Ministers who may call in an application. Similar determination by the relevant minister applies in Wales and Northern Ireland.
- 8.6.4 The environment agencies are statutory consultees to the planning authorities under Regulations requiring EIA. These require EIA for all proposed developments of disposal facilities for solid radioactive waste (see Section 8.5).
- 8.6.5 The planning framework and environmental regulation are separate processes but a developer would need to have planning consent and an authorisation to operate a radioactive waste disposal facility.

Planning developments in England

- 8.6.6 In November 2008, the Planning Act 2008 (TSO 2008) took forward implementation of the UK Government's proposals to streamline the procedure for nationally significant infrastructure projects, as set out in the 2007 White Paper '*Planning for a Sustainable Future*' (TSO 2007b). The Planning Act 2008 introduces a new single consent regime in England and an independent commission to determine applications for nationally significant infrastructure projects.
- 8.6.7 The UK Government will produce national policy statements for different categories of infrastructure. An Independent Planning Commission (IPC), made up of experts from different fields, will then take decisions on individual applications for development consent for nationally significant infrastructure.
- 8.6.8 Determination of planning applications for near-surface disposal facilities is likely to remain with the local planning authority. However, an exception might be an application to develop a new national LLW disposal facility, which may be considered a nationally significant infrastructure project and the application might be determined by an IPC. In England, the Environment Agency will be consulted on major infrastructure projects. For other developments of near-surface disposal

facilities, the environment agencies' will continue to be consulted by the local planning authority under the EIA Regulations.

Wales and Northern Ireland

- 8.6.9 The Planning Act 2008 does not extend the IPC's role to radioactive waste disposal facilities in Wales. The Welsh Assembly Government will continue to consider the issues raised by disposal facilities in the context of the existing statutory consenting regime in Wales (TSO 2008).
- 8.6.10 The Planning Service in Northern Ireland intends to consider the implications of the English planning reforms in the context of any changes envisaged as a result of the Review of Public Administration in Northern Ireland.

Scotland

- 8.6.11 In Scotland, the National Planning Framework (Scottish Executive 2004a) sets out a strategy for Scotland's development. It provides a national context for development plans and planning decisions and helps to inform the wider programmes of government, public agencies and local authorities. The Planning etc. (Scotland) Act 2006 (TSO 2007a) amended the Town and Country Planning (Scotland) Act 1997 (TSO 1997a) to put the Framework on a statutory footing. The legislation places duties on Ministers to prepare the Framework with the objective of contributing to sustainable development and to review it every 5 years.
- 8.6.12 The National Planning Framework 2, 2008 Discussion Draft (Scottish Government 2008a) was published in January 2008 and sets out the development strategy up to 2030. The document will be consulted on prior to being placed before the Scottish Parliament, with final publication expected in the winter of 2008.

8.7 Environmental regulation

Radioactive Substances Act 1993

- 8.7.1 The environment agencies regulate disposal of radioactive waste from premises, including nuclear licensed sites, under RSA 93. The agencies also regulate the keeping and use of radioactive materials and the accumulation of radioactive waste on sites other than nuclear licensed sites. Chapter 9 gives further information about RSA 93.
- 8.7.2 The Environment Agency regulates the disposal of radioactive waste in England and Wales. SEPA carries out this role in Scotland and the Northern Ireland Environment Agency carries out this role in Northern Ireland.
- 8.7.3 RSA 93 does not apply to the Ministry of Defence (MOD). However, in accordance with the Secretary of State for Defence's Policy Statement on Safety, Health and Environmental Protection (MOD 2006), MOD operates to standards and implements management arrangements that are, so far as reasonably practicable, at least as good as those required by the legislation. In addition, the MOD has in place, or is developing, Memoranda of Understanding with each of the environment agencies to help ensure appropriate standards of environmental protection.

Other environmental legislation

- 8.7.4 The environment agencies have other regulatory responsibilities relating to nuclear licensed sites and non-nuclear premises including the following:

- abstracting water (for example, for process use or during construction) may require a licence under the Water Resources Act 1991 (WRA 91; HMSO 1991b) and in Northern Ireland the Water (Northern Ireland) Order 1999 (TSO 1999d);
- discharging aqueous effluent (for example, from cooling or dewatering during construction) requires a consent under WRA 91;
- in Scotland, the above activities would require authorisation under the Water Environment (Controlled Activities) (Scotland) Regulations 2005 (TSO 2005b);
- some 'conventional' plant (for example, combustion plant used as auxiliary boilers and emergency standby power supplies, and incinerators used to dispose of combustible waste) may require a permit under the Environmental Permitting (England and Wales) Regulations 2007 (EPR 07; TSO 2007c) in England and Wales. In Scotland such permits would be issued under the Pollution Prevention and Control Regulations (Scotland) 2000 (PPC 00; TSO 2000a). In Northern Ireland, the Pollution Prevention and Control Regulations (Northern Ireland) 2003 (PPC 03; TSO 2003c) would apply;
- disposing of waste by depositing it on or into land, including excavation materials from construction, may require a permit under PPC 00 or PPC 03. In England and Wales, from April 2008, these permits will be issued under EPR 07;
- protecting conservation sites and biodiversity under the Conservation (Natural Habitats &c.) Regulations 1994 (HMSO 1994) and, in Northern Ireland, the Conservation (Natural Habitats etc.) Regulations (Northern Ireland) 1995 (HMSO 1995a).

8.7.5 The contaminated land regimes (both radioactive and non-radioactive) make provision in relation to certain historical contamination to ensure that it is suitably dealt with.

8.7.6 In the UK, the environment agencies and the Health and Safety Executive together form the competent authorities for the Control of Major Accident Hazards Regulations 1999 (COMAH 99; TSO 1999e) and, in Northern Ireland, the Control of Major Accident Hazards Regulations (Northern Ireland) 2000 (TSO 2000b). On-site storage of certain substances may fall under these regulations.

Water Framework Directive and Groundwater Directive

8.7.7 The Water Framework Directive [WFD] (EC 2000) requires the development and implementation of a strategic framework for the management of the water environment, and establishes a common approach to protecting and setting environmental objectives for groundwaters and surface waters within the European Community.

8.7.8 In Wales and part of England, the WFD is implemented through the Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 (TSO 2003d). In two areas where River Basin Districts include parts of England and Scotland, the Water Environment (Water Framework Directive) (Northumbria River Basin District) Regulations 2003 (TSO 2003e) and the Water Environment (Water Framework Directive) (Solway Tweed River Basin District) Regulations 2004 (TSO 2004c) apply.

- 8.7.9 In Scotland, the WFD is implemented through the Water Environment and Water Services (Scotland) Act 2003 (TSO 2003f) and in Northern Ireland, the Water Environment (Water Framework Directive) Regulations (Northern Ireland) 2003 (TSO 2003g).
- 8.7.10 The WFD sets out general provisions for the protection and conservation of groundwater. It sets objectives for groundwater quality, including an objective to meet "good chemical status" by 2015, an objective on pollution trends, and an objective to prevent or limit the input of pollutants to groundwater. The 2006 Groundwater Directive (EC 2006/118/EC; EC 2006a) clarifies these objectives and sets out specific measures to prevent and control groundwater pollution.
- 8.7.11 Both the WFD and the 2006 Groundwater Directive together make up the complete new groundwater regime. The 2006 Groundwater Directive will operate alongside the 1980 Groundwater Directive (80/68/EEC; EC 1980) ("the 1980 Directive") until December 2013, when the latter will be repealed under Article 22(2) of the WFD. The two Groundwater Directives adopt similar approaches to preventing groundwater pollution but there will need to be adjustments to the existing controls to accommodate the changes brought about by both the WFD and the 2006 Groundwater Directive. Overall the 2006 Groundwater Directive takes a slightly more comprehensive but more risk-based approach to pollution prevention and control than the 1980 Directive.
- 8.7.12 The exclusion for radioactive substances that applied in the 1980 Groundwater Directive does not appear in the 2006 Groundwater Directive (Defra 2008). It is anticipated that new regulations to transpose the 2006 Groundwater Directive into UK law will apply to radioactive substances. The new regulations are expected in 2009 and the environment agencies will need to take these into account when determining applications for authorisation of radioactive waste disposal under RSA 93 (or equivalent legislation).

Flood risk management

- 8.7.13 In England and Wales, the Environment Agency has responsibility for flood risk management and the Environment Agency's permission may be required to change flood management structures. In Northern Ireland, the Rivers Agency within the Department of Agriculture and Rural Development is responsible for flood risk management.

8.8 Environment agencies' advice and guidance

Best Practicable Means

- 8.8.1 A review report describing Best Practicable Means (BPM) and its use in optimising control over radioactive substances was published in 2005 (SNIFFER 2005). The report sets out the regulatory framework for assessing the application of BPM in relation to airborne, liquid and solid radioactive waste. The review considered application of BPM assessment to nuclear licensed sites (both operational and those being decommissioned) and non-nuclear premises (for example, hospitals, universities, industrial premises) for which authorisations under the RSA 93 are granted.
- 8.8.2 The environment agencies view BPM as a way of building more thinking about environmental protection into managing radioactive substances.

Best Practicable Environmental Option

- 8.8.3 The environment agencies have published guidance on how they assess Best Practical Environmental Option (BPEO) studies at nuclear licensed sites (Environment Agency *et al.* 2004).
- 8.8.4 The guidance was developed to provide environment agencies' staff with a framework for assessing BPEO studies submitted by site operators in relation to authorisation under RSA 93. It sets out the main principles of the BPEO process and its role in decision-making. It also addresses issues such as input from stakeholders, uncertainty and costs. BPEO studies can help find ways of disposing of waste that minimise effects on the environment.
- 8.8.5 The BPEO guidance is subject to review in the light of technical developments in radioactive waste management.

Applying BPM and BPEO to disposal facilities for solid radioactive waste

- 8.8.6 The environment agencies will expect a developer to take account of the BPM and BPEO guidance when considering optimisation in developing a disposal facility for solid radioactive waste. The guidance is mainly directed at facilities of various kinds during steady-state operation and there are aspects of optimisation of radioactive waste disposal facilities that are not covered. In Chapter 6, we give further guidance on optimisation.

Best Available Techniques

- 8.8.7 In June 2008, Defra and the Welsh Assembly Government published draft statutory guidance (Defra and WAG 2008) setting out how the Environment Agency should implement the 'UK Strategy for Radioactive Discharges 2006-2030'. The draft Guidance is a strategic high-level document outlining the key responsibilities of the Environment Agency under RSA 93.
- 8.8.8 The main focus of the draft Guidance is the change from Best Practicable Means (BPM) and Best Practicable Environmental Option (BPEO) to Best Available Techniques (BAT). BAT will replace BPM and BPEO in order to deliver a regime that is more consistent with environmental protection regimes in other countries and other regimes in England and Wales. The draft Guidance highlights the importance of the use of BAT in the optimisation of doses and the setting of discharge limits.
- 8.8.9 In June 2008, the Environment Agency published for consultation, 'Assessment Guide No 1 Assessment of Best Available Techniques (BAT)' (Environment Agency 2008b). The Assessment Guide provides guidance to radioactive substances regulators to help them judge whether an operator is using or proposes to use the best available techniques (BAT), as required by its Radioactive Substance Regulation Environmental Principles (REPs, see below). It describes the concept of BAT and the issues to be considered when determining BAT for practices regulated under the Radioactive Substances Act 1993 (RSA93). It does not provide technical guidance or set specific standards.
- 8.8.10 The Scottish Government's statutory guidance to SEPA was published in February 2008 (Scottish Government 2008b). This retains use of BPM and BPEO in setting discharge limits.

Radioactive Substances Regulation Environmental Principles

- 8.8.11 The Environment Agency has developed Radioactive Substances Regulation Environmental Principles (REPs) that are intended to form a consistent and

standardised framework for the technical assessments and judgements that it must make when regulating radioactive substances. The REPs provide technical guidance that helps underpin the decisions that the Environment Agency makes relating to radioactive substances regulation. The REPs require operators to apply Best Available Techniques (BAT).

- 8.8.12 A consultation version of the REPs was published in June 2008 (Environment Agency 2008a) and, subject to consideration of consultation responses, a final version will be published in 2009.
- 8.8.13 The link between the REPs and this guidance is discussed in para. 4.1.8.

8.9 Health, safety and security regulation

Health and Safety at Work etc. Act 1974 and Nuclear Installations Act 1965

- 8.9.1 Under the Health and Safety at Work Act 1974 (HMSO 1974), employers are responsible for ensuring the safety of their workers and the public. In Great Britain, the HSE has responsibilities under the Act for securing the health, safety and welfare of people at work and for protecting others against risks to health or safety in connection with the activities of people at work. In Northern Ireland, the Health and Safety at Work (Northern Ireland) Order 1978 (HMSO 1978) applies.
- 8.9.2 For nuclear installations, employers' responsibilities for health and safety are reinforced by the Nuclear Installations Act 1965 as amended (NIA 65; HMSO 1965). Under NIA 65, a site cannot have nuclear plant on it unless the user has been granted a site licence by HSE. This licensing function is administered by HSE's Nuclear Directorate, which grants a licence with conditions attached. The Nuclear Directorate has published '*Safety Assessment Principles for Nuclear Facilities*' (HSE 2006) that apply to its assessment of safety cases for nuclear facilities (see para. 8.9.9).
- 8.9.3 Nuclear licensed sites are exempt from the requirements under RSA 93 for registration of keeping and use of radioactive materials and authorisation for accumulation of radioactive waste as these activities are regulated by HSE's Nuclear Directorate under NIA 65. However, nuclear licensed sites are not exempt from the requirements under RSA 93 for disposing of radioactive waste. HSE must consult the relevant environment agency about creating, accumulating or disposing of radioactive waste. We have Memoranda of Understanding with HSE to make sure regulatory activities on nuclear licensed sites are effectively co-ordinated.

Nuclear Industries Security Regulations 2003

- 8.9.4 In the UK, civil nuclear operators must have site security plans dealing with the security arrangements to protect nuclear licensed sites and the nuclear material on these sites. The Nuclear Directorate's Office for Civil Nuclear Security (OCNS) within the HSE is the security regulator for the UK's civil nuclear industry. It is responsible for approving security arrangements within the industry and enforcing compliance. OCNS conducts its regulatory activities under the Nuclear Industries Security Regulations 2003 (TSO 2003h).

Nuclear Safeguards Act 2000

- 8.9.5 Nuclear safeguards are measures to verify that states comply with their international obligations not to use nuclear materials (plutonium, uranium and thorium) for nuclear explosives purposes. The Nuclear Safeguards Act 2000 (TSO 2000c) put in place the legal powers and duties needed to enable the UK to fulfil its

obligations under an Additional Protocol to the Nuclear Non-Proliferation Treaty of 1968 (TSO 2005c).

- 8.9.6 The Euratom Treaty also includes requirements to apply safeguards to civilian nuclear activities. The European Court of Justice has ruled that Euratom Directives do not apply to defence activities.
- 8.9.7 The UK Safeguards Office within the Nuclear Directorate of the HSE oversees the application of nuclear safeguards in the UK.

HSE advice and guidance

- 8.9.8 In 2001, HSE published '*Reducing Risk, Protecting People*' (HSE 2001). The document sets out an overall framework for decision taking by HSE to ensure consistency and coherence across the full range of risks falling within the scope of the Health and Safety at Work Act 1974. The framework is a development of the method, which HSE applies to controlling risk at nuclear power stations, published as '*The tolerability of risks from nuclear power stations*' (TSO 1992).
- 8.9.9 HSE has published '*Safety Assessment Principles for Nuclear Facilities*' (SAPs; HSE 2006) that apply to the assessment of safety cases for nuclear facilities. The principles apply to nuclear safety and radioactive waste management. Other conventional hazards are excluded, except where they have a direct effect on nuclear safety or radioactive waste management. The SAPs provide a framework for making consistent regulatory judgements on nuclear safety cases.
- 8.9.10 HSE, the Environment Agency and SEPA have published joint guidance on management of higher activity radioactive waste on nuclear licensed sites (HSE *et al.* 2007). In the guidance, management of radioactive waste means the whole process of managing waste from its generation to (but not including) its disposal. Higher-activity radioactive waste means all radioactive waste other than:
- low-level radioactive waste that will be disposed of promptly at the Low Level Waste Repository near Drigg or to its successor facility; and
 - very low-level radioactive waste that will be disposed of promptly at suitably authorised disposal facilities.
- 8.9.11 Disposal of these low activity radioactive wastes is addressed in the UK Government and devolved administrations' '*Policy for the Long Term Management of Solid Low Level Radioactive Waste in the United Kingdom*' (Defra *et al.* 2007). The policy statement covers all aspects of generating, managing and regulating solid LLW. See Section 8.3 for further information.

8.10 Radiological Protection Advice

- 8.10.1 The Health Protection Agency (HPA) has published its updated advice on radiological protection objectives for the land-based disposal of solid radioactive waste (HPA, 2009b). The new advice will replace that provided previously in 1992 by the National Radiological Protection Board (NRPB) (NRPB 1992). The functions of the National Radiological Protection Board were incorporated into HPA in April 2005 and radiation protection as part of health protection is within the HPA's remit.
- 8.10.2 HPA's advice is intended for the detailed risk assessment of solid radioactive waste disposal facilities at the planning stage. Given the long half-life of some radioactive wastes, an important principle behind the advice is that people in the future should

have the same level of protection as people have today. The primary focus of the proposed advice is therefore on the situation after the facility has closed rather than the operational period when it is receiving waste for disposal.

- 8.10.3 The relationship between the HPA's advice and this guidance is discussed in paras 1.4.4 – 1.4.5 and in Annex 1.
- 8.10.4 HPA's main role is in reducing the dangers to health from infections, chemical and radiation hazards. It provides advice, through the Department of Health, to all government departments and devolved administrations throughout the UK.
- 8.10.5 The Department of Health can seek specialist scientific advice from the HPA when determining applications under RSA 93 relating to nuclear licensed sites in England (see paras 9.2.13 - 9.2.17).

8.11 Radioactive material transport regulation

- 8.11.1 Radioactive waste will be transported to a disposal facility under strict controls and in accordance with national and international regulations applicable to the mode of transport used (i.e. road, rail, or sea). These "modal" regulations are based on the transport regulations issued by the IAEA. The IAEA regulations, first published in 1964, are the primary technical basis for the safe transport of radioactive material and have been subjected to periodic review and update since their introduction. This review and update process will continue, reflecting current experience and technical developments (IAEA 2005). Compliance with these regulations will provide the necessary levels of safety during transport.
- 8.11.2 The international and national modal regulations and the IAEA transport regulations on which they are based are designed to protect persons, property and the environment when radioactive material is transported in the public domain. All activities associated with the transport of the radioactive waste, which will include the performance characteristics and quality of manufacture of the packaging used to contain the waste, are subjected to verification and audit by the DfT. DfT's audit process provides assurance that controls and processes are in place in accordance with the regulations, confirming that the necessary levels of safety during transport are achieved.
- 8.11.3 Some categories of very low activity waste material may be transported unpackaged provided it is shown that such material:
 - meets stringent external contamination and dose rate limits which are prescribed in the modal regulations;
 - will not deteriorate during transport releasing radioactive material into the environment above the prescribed stringent limits.

Transport of radioactive materials within the boundaries of nuclear licensed sites is not regulated by DfT. It is regulated by HSE through a condition in the site licence.

8.12 Regulation of disposal facilities for solid radioactive waste

- 8.12.1 Near-surface disposal facilities for solid radioactive waste will need an authorisation from the relevant environment agency under RSA 93 (or equivalent legislation).
- 8.12.2 There will also be requirements for environmental regulatory processes or consents for other activities, covered in separate guidance, such as waste management,

operation of combustion plant or water abstraction. See Chapter 9 for information on other environmental legislation.

- 8.12.3 The relevant environment agency will 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. It might involve a project-based approach overseen by a project manager with expertise in radioactive substances regulation. The project manager would provide the main point of contact for the developer and would be supported by regulators with expertise in other relevant regimes.
- 8.12.4 Near-surface facilities might not necessarily fall within the definition of a nuclear licensed site under NIA 65, but these facilities would need to meet the requirements under the Health and Safety at Work etc. Act 1974 and the Ionising Radiations Regulations 1999 (TSO 1999f). The equivalent legislation in Northern Ireland is the Health and Safety at Work (Northern Ireland) Order 1978 and the Ionising Radiations Regulations (Northern Ireland) 2000 (TSO 2000d). In the future, if a new national LLW disposal facility is developed, it may need a nuclear site licence under NIA 65.
- 8.12.5 If a near-surface disposal facility was developed on an existing nuclear licensed site, it would need to meet to the requirements of the licence issued by HSE under NIA 65.

9. The legislation we enforce

9.1 Introduction

- 9.1.1 This chapter provides a summary of the powers and duties that the environment agencies have under the laws that will be used to regulate a disposal facility for solid radioactive waste. This summary is for information only and a developer/operator should refer to the original text of the legislation.

9.2 Radioactive Substances Act 1993

- 9.2.1 Under RSA 93 the environment agencies are responsible for regulating disposals of radioactive waste from nuclear licensed sites and other premises using radioactive substances across the UK. Under RSA 93, disposals of radioactive waste include discharges into the atmosphere, surface waters and groundwater, disposals to land, and disposals by transfer to another site. In this guidance, we focus on authorisation of land-based disposal facilities for solid radioactive waste.
- 9.2.2 Under Section 13 of RSA 93, an authorisation is required to dispose of radioactive waste. Operators of land-based facilities will need an authorisation to dispose of solid radioactive waste. The environment agencies have the power to grant these authorisations under Section 16 of RSA 93. Section 16 also gives us powers to attach any limitations and conditions we think fit. If operators do not comply with these limitations and conditions, or if they dispose of radioactive waste without an authorisation, they will be committing an offence under Section 32 of RSA 93.
- 9.2.3 We shall include limitations and conditions in authorisations under RSA 93 for dedicated disposal facilities for solid radioactive waste to reflect requirements under other environmental legislation, including European Directives. For example, we shall include conditions that are appropriate to any hazardous non-radioactive properties of the waste to ensure people and the environment are protected both when the waste is disposed of and in the future.
- 9.2.4 Under Section 17 of RSA 93, we can vary or revoke the authorisations we grant at any time. Section 17A of RSA 93 imposes a legal duty on us to periodically review any authorisations we issue and also gives us a power to carry out additional reviews.
- 9.2.5 As regulators, we can:
- decide whether or not to grant new authorisations or variations to existing authorisations. We can also set appropriate limits and conditions in any authorisations we grant to ensure that the public and the environment are properly protected;
 - periodically review authorisations and operators' environmental performance;
 - vary the limits and conditions of authorisations, as appropriate, to ensure that they are up to date and effective;
 - revoke authorisations;
 - carry out announced and unannounced inspections;
 - investigate incidents;

- use our powers of enforcement, including prosecution, if and when we need to;
- carry out waste, effluent and environmental monitoring and assessments of public radiation exposure.

Environment agencies' decision making

9.2.6 We make decisions about:

- applications for new authorisations;
- applications for variations to existing authorisations;
- reviews of existing authorisations;
- variation or revocation of existing authorisations.

9.2.7 When we make these decisions, we take account of many factors including legal and policy matters and constraints, and comments received through public consultation.

9.2.8 For specific reviews or applications we shall provide, where relevant, an explanatory document to help consultation, and a decision document to explain our decisions.

Powers of the Secretary of State

9.2.9 RSA 93 gives certain powers to the Secretary of State:

- Under Section 23 of RSA 93, the Secretary of State has the power to give directions to the relevant environment agency to:
 - o refuse an application for authorisation or for the transfer (fully or in part) or variation of an authorisation;
 - o effect or grant an authorisation, attaching any limitations or conditions that may be specified in the direction, or;
 - o vary an authorisation, or;
 - o grant an application for the transfer (fully or in part) of an authorisation, or;
 - o carry out a review under section 17A, or;
 - o cancel or revoke (or not cancel or revoke) an authorisation.
- Section 24 of RSA 93 gives the Secretary of State the powers to determine certain applications and also to call for a local inquiry into an application to be held.

9.2.10 In England, 'Secretary of State' is interpreted as the Secretary of State for the Environment, Food and Rural Affairs, and, in the case of nuclear licensed sites, also the Secretary of State for Health. In Scotland these powers are vested in 'the Scottish Ministers', and, in the other devolved administrations, the relevant Ministers.

- 9.2.11 The Secretary of State for Health through the Department of Health could seek specialist scientific advice from the HPA when determining applications relating to nuclear licensed sites.
- 9.2.12 The HPA's main role is in reducing the dangers to health from infections, chemical and radiation hazards. It also provides support to, and works in partnership with others who also have health protection responsibilities and advises, through the Department of Health, all government departments and devolved administrations throughout the UK. The functions of the National Radiological Protection Board were incorporated into HPA in April 2005 and radiation protection as part of health protection is within the HPA's remit.

Nuclear licensed sites

- 9.2.13 A near-surface disposal facility for solid radioactive waste in Great Britain may require licensing by HSE under NIA 65. A disposal facility might be located on an existing nuclear licensed site and would need to comply with conditions attached to that site's licence.
- 9.2.14 HSE's Nuclear Directorate is responsible for regulating safety and security at nuclear licensed sites, including accumulation and storage of radioactive waste. The environment agencies authorise disposal of radioactive wastes from nuclear licensed sites under RSA 93.
- 9.2.15 In regulating existing nuclear licensed sites, and as a statutory requirement, HSE and the relevant environment agencies consult one another. In particular, the environment agencies have a duty under RSA 93 to consult HSE in relation to authorisations for premises on nuclear licensed sites. The arrangements are set out in memoranda of understanding, which cover the regulation of nuclear safety and radioactive waste management on nuclear licensed sites and the disposal or discharge of radioactive waste on or from those sites.
- 9.2.16 For any new development where a nuclear site licence is required, the environment agencies will work closely with HSE Nuclear Directorate to ensure that common hold points are agreed with the developer early in the development programme. The aim will be to put an effective and efficient regulatory process in place that reduces duplicate requests for information and data.
- 9.2.17 In Chapter 5, we provide further information about our authorisation process.

Non-nuclear premises

- 9.2.18 If a near-surface facility for solid radioactive waste disposal is not located on a nuclear licensed site then, depending on the radiological hazard presented by the waste, the relevant environment agency may choose to treat the facility as a 'non-nuclear premises'. In this case, the operator of the facility must have an authorisation for disposal of radioactive waste under Section 13 of RSA 93. For a facility accepting waste presenting only a low radiological hazard, the relevant environment agency may choose not to treat the facility as a non-nuclear premises, in which case the consignor of the waste must hold an authorisation for disposal at the facility.
- 9.2.19 For non-nuclear premises, the environment agencies will consult HSE, where appropriate, on health and safety matters.
- 9.2.20 In Chapter 5, we provide further information about our authorisation process.

9.3 Environment Act 1995

- 9.3.1 The Environment Act 1995 (EA 95; TSO 1995) established both the Environment Agency and SEPA.
- 9.3.2 EA 95 does not apply to Northern Ireland, but many of its provisions are reflected in Northern Ireland-specific legislation, including the Waste and Contaminated Land (Northern Ireland) Order 1997 (TSO 1997b). The Chief Inspector for Northern Ireland, as defined in RSA 93, is mainly responsible for those roles the environment agencies carry out in relation to radioactivity.
- 9.3.3 This guidance focuses on the powers and duties of the Environment Agency and SEPA under EA 95 that are relevant to managing radioactive waste. It describes the duties and powers under EA 95 that are common to both regulators, as well as those that are specific to each.

Common duties and powers

- 9.3.4 Under section 37(3) of EA 95 the Environment Agency or SEPA may provide advice and assistance to persons in the United Kingdom. Section 37(7) also allows these environmental agencies to enter into an agreement with such persons to charge a fee for any work done in connection with environmental licences as a result of such a request.
- 9.3.5 Under Section 39 of EA 95 the Environment Agency and SEPA have a general duty to take into account likely costs (including to people and the environment (EA 95 Section 56(1)) and benefits when considering whether and how to exercise their powers. There is no identical general duty in Northern Ireland although the Chief Inspector considers, as good practice, the likely costs and benefits to people and the environment when he decides whether and how to carry out his responsibilities.
- 9.3.6 EA 95 also places conservation duties on the Environment Agency and SEPA and these are summarised in Section 9.5 below.

The Environment Agency

- 9.3.7 Under Section 4 of EA 95, the Environment Agency's main aim is 'in discharging its functions so to protect or enhance the environment, taken as a whole, as to make the contribution towards attaining the objective of achieving sustainable development as described in Ministerial guidance'. This is 'subject to and in accordance with the provisions of [EA 95] or any other enactment and taking into account any likely costs'.
- 9.3.8 In 2002 Defra published Ministerial Guidance that states the Environment Agency's main contribution to sustainable development will be to meet its objectives in a way that takes account (subject to and in accordance with EA 95 and any other enactment) of economic and social considerations (Defra 2002b). The Ministerial Guidance refers to the objective of regulating aerial and liquid radioactive discharges and solid radioactive waste disposal in accordance with statutory duties, statutory guidance and the policies of the UK Government and devolved administrations.
- 9.3.9 We have similar guidance from WAG relating to our role in achieving sustainable development in Wales (WAG 2003).
- 9.3.10 Both the above documents provide guidance to the Environment Agency on such matters as the formulation of approaches that we should take to our work, decisions

about our priorities and our allocation of resources. They are not directly applicable to our individual regulatory decisions.

- 9.3.11 Section 5 of EA 95 sets out the statutory purpose for which the Environment Agency's pollution control powers, including powers under RSA 93, must be exercised, namely 'preventing or minimising, or remedying or mitigating the effects of, pollution of the environment'.
- 9.3.12 Under section 7(1)(c)(iii) of EA 95, the Environment Agency must consider the effect its proposals may have on the economic and social well-being of local communities in rural areas.

Scottish Environment Protection Agency

- 9.3.13 Section 31 of EA 95 makes provision for the Secretary of State to give guidance to SEPA concerning the aims and objectives it is to have in the performance of its functions. Subsequently, this power was devolved to Scottish Ministers. Specifically, EA 95 requires the guidance to address the contribution that SEPA should make to sustainable development in carrying out its duties.
- 9.3.14 Guidance from Scottish Ministers was published in December 2004 and this aims to make sure that sustainable development is embedded in all SEPA's work (Scottish Executive 2004b).
- 9.3.15 Section 32(1)(a) of the Act requires SEPA to have regard, in considering any proposals relating to any of its functions, to the desirability of conserving and enhancing the natural heritage of Scotland. Section 32 (1)(c) gives SEPA a duty to take into account any effect which the proposals would have on the natural heritage of Scotland.
- 9.3.16 Under section 32(1)(d) of EA 95, SEPA must consider the effect its proposals may have on the social and economic needs of local communities, particularly in rural areas.
- 9.3.17 Section 33 of EA 95 sets out the statutory purpose for which SEPA's pollution control powers, including powers under RSA 93, must be exercised, namely 'preventing or minimising, or remedying or mitigating the effects of, pollution of the environment'.

Northern Ireland Environment Agency

- 9.3.18 The provisions under EA 95 on sustainable development do not apply to Northern Ireland but the main themes of the UK strategy have been adopted in a Northern Ireland context (OFMDFM 2006).

9.4 Basic Safety Standards Directive 1996

- 9.4.1 For the environment agencies' functions in relation to RSA 93 authorisations, the Basic Safety Standards Directive 1996 (BSS Directive 96; EC 1996) has been implemented in the UK through Ministerial Directions in England, Wales and Scotland and regulations in Northern Ireland.
- 9.4.2 In England and Wales, the Radioactive Substances (Basic Safety Standards) (England and Wales) Direction 2000 (DETR 2000) applies. In Scotland, the Radioactive Substances (Basic Safety Standards) (Scotland) Direction 2000 (Scottish Executive 2000) applies. In Northern Ireland, the Radioactive

Substances (Basic Safety Standards) Regulations (Northern Ireland) 2003 (TSO 2003a) apply.

- 9.4.3 In regulating radioactive waste disposal under RSA 93, the environment agencies have to make sure, wherever applicable, that: 'all exposures to ionising radiation of any member of the public and of the population as a whole resulting from the disposal of radioactive waste are kept as low as reasonably achievable, economic and social factors being taken into account' (ALARA).
- 9.4.4 Article 7.1 of the BSS Directive 96 (EC 1996) states that: 'dose constraints should be used, where appropriate, within the context of optimisation of radiological protection'. In making sure that exposures from a particular source are ALARA, the environment agencies need to consider two dose criteria:
- 0.3 mSv/year from any single new source. A source is defined as 'a facility, or group of facilities, which can be optimised as an integral whole [that is, considered as one source] in terms of radioactive waste disposals'. The doses to be compared with this source-related dose constraint are only those that can be altered by changes in the operating regime of a controlled source. This source constraint thus includes the radiological impact of current discharges and direct radiation from the source, but excludes the impact of historical discharges. It is intended to guide the process of optimisation relating to the design, construction and operation of the facility.
 - 0.5 mSv/year from the discharges from any single site. This site-related dose constraint applies to the aggregate exposure resulting from discharges from a number of sources with contiguous boundaries at a single location. It includes the radiological impact of current discharges from the entire site, but excludes the impact of direct radiation and historical discharges. It is particularly relevant to complex sites such as those with more than one nuclear power station. The site constraint of 0.5 mSv/year applies irrespective of whether different sources on the site are owned and operated by the same or by different organisations.
- 9.4.5 In general, we regard the source-related and site-related dose constraints as upper bounds to the optimisation of the relevant doses received by members of the public.
- 9.4.6 Each environment agency must make sure (when carrying out its role in relation to radioactive waste disposal under RSA 93) that: 'the sum of the doses resulting from the exposure of any member of the public to ionising radiation should not exceed the dose limits set out in Article 13 of the Directive (subject to the exclusions set out in Article 6(4) [exposures from medical treatment/research])'.
- 9.4.7 Article 13 of the BSS Directive 96 sets an effective dose limit of 1 mSv/year to members of the public from all man-made sources of radioactivity (other than medical exposure). Assessments of dose against this limit should include the effects of past discharges (HMSO 1995b).
- 9.4.8 The environment agencies must also observe the requirements of Articles 15 and 16 (estimation of effective dose and equivalent dose), 45 (estimates of population doses), and 47 (responsibilities of undertakings) of the BSS Directive 96.

9.5 Conservation (Natural Habitats &c.) Regulations 1994

- 9.5.1 The Conservation (Natural Habitats &c.) Regulations 1994 (the Habitats Regulations; HMSO 1994) implement Council Directive 92/43/EEC on 'the conservation of natural habitats and of wild fauna and flora' (the Habitats Directive;

EC 1992). In Northern Ireland, the Directive is implemented through the Conservation (Natural Habitats etc.) Regulations (Northern Ireland) 1995 (HMSO 1995a) which apply similar requirements.

- 9.5.2 The Habitats Directive aims to establish a network of the most important sites in respect of natural habitats and species of wild fauna and flora. It requires measures to be taken to maintain them at favourable conservation status or, where necessary, restore them by taking remedial action.
- 9.5.3 The Habitats Regulations require the environment agencies to be satisfied that the integrity of designated 'European Sites' will not be adversely affected by relevant permissions that they issue. Sites may be designated as European Sites in respect of the habitats of bird species identified by the Birds Directive (EC 1979) on 'the conservation of wild birds' (Special Protection Areas - SPAs), or in respect of habitats and species listed in Annexes I and II of the Habitats Directive (Special Areas of Conservation - SACs). The Habitats Regulations apply to 'candidate' as well as designated SACs.
- 9.5.4 Planning Policy Statement (PPS) 9 on Biodiversity and Geological Conservation (ODPM 2005) for England and the Planning Policy Wales (March 2002) (WAG 2002) state that potential SPAs, SACs in Wales and listed Ramsar sites (wetlands of international importance designated under the Ramsar Convention 1971; Ramsar 1971) should be treated in the same way as European Sites.
- 9.5.5 The environment agencies have a general duty to take into account effects on European Sites when reviewing existing permissions/authorisations (Reg 3(4) of the Habitats Regulations).
- 9.5.6 The environment agencies have a duty under Regulation 48(1) of the Habitats Regulations to undertake an appropriate assessment of the implications for a site's conservation objectives where, for example, a plan or a plan or project is likely to have a significant effect on a European site. The applicant will need to provide information that the relevant environment agency may reasonably require for the purposes of the assessment.

9.6 Other conservation legal requirements

- 9.6.1 Other relevant legislative requirements relating to conservation are:
 - the Environment Agency under section 6(1) and SEPA under Section 34(2)(b) of EA 95 have general conservation duties with respect to water including the conservation of flora and fauna which are dependent on an aquatic environment;
 - under section 7(1)(b) of EA 95, the Environment Agency must have regard to the desirability of conserving and enhancing natural beauty and of conserving flora, fauna and geological or physiographical features of special interest;
 - under section 32(a) of EA 95, SEPA must have regard to the desirability of conserving and enhancing the natural heritage of Scotland;
 - under section 7(1)(c)(i) of EA95 the Environment Agency must have regard to the desirability of protecting and conserving buildings, sites and objects of archaeological, architectural, engineering or historic interest;

- under section 32(b) of EA 95, SEPA must have regard to the desirability of protecting and conserving the buildings, sites and objects of archaeological, architectural, engineering or historic interest;
- under section 7(1)(c)(ii) of EA 95, the environment agencies must take into account any effect the proposals would have on the beauty or amenity of any rural or urban area or any flora, fauna, features, buildings, sites or objects;
- the Environment Agency takes account of any notification and/or consultation responses received under section 8(3) of EA 95 (relating to sites of special interest);
- under section 11A of the National Parks and Access to the Countryside Act 1949 (TSO 1949), the Environment Agency must have regard to the purposes of conserving and enhancing the natural beauty, wildlife and cultural heritage of specified areas and of promoting opportunities for the public to understand and enjoy the special qualities of those areas;
- under section 28G of the Wildlife and Countryside Act 1981 (HMSO 1981), the Environment Agency must take reasonable steps to further conservation and enhancement of the flora, fauna, or geological or physiographical features by reason of which a site is of special scientific interest (SSSI);
- under section 28I of the Wildlife and Countryside Act 1981, the Environment Agency must consult the appropriate statutory conservation body before permitting any operation which is likely to damage any flora, fauna or geological or physiographical feature by reason of which a SSSI is of special interest;
- in discharging its duties under section 6(1), 7 or 8 of EA 95 the Environment Agency must have regard to any code of practice approved under section 9;
- under section 85 of the Countryside and Rights of Way Act 2000 (TSO 2000e), the Environment Agency must have regard to the purpose of conserving and enhancing the natural beauty of relevant Areas of Outstanding Natural Beauty, when carrying out its functions;
- under section 40 of the Natural Environment and Rural Communities Act 2006 (TSO 2006c), the Environment Agency must have regard to the purpose of conserving biodiversity when deciding whether to grant an authorisation (and what conditions to impose). Biodiversity includes, in relation to a living organism or type of habitat, restoring or enhancing a population or habitat.

9.6.2 Similar legal requirements on conservation apply in Northern Ireland.

9.6.3 The Nature Conservation (Scotland) Act 2004 (TSO 2004d) requires SEPA to consult with, and take account of advice from, Scottish Natural Heritage before permitting any activity which might harm a SSSI. This applies in addition to any responsibilities for European Sites, and thus complements the Conservation (Natural Habitats &c.) Regulations 1994 (HMSO 1994).

9.7 Environmental Permitting (England and Wales) Regulations 2007

9.7.1 The Environmental Permitting (England and Wales) Regulations 2007 (EPR 07; TSO 2007b) do not apply to specialised radioactive waste disposal facilities authorised under RSA 93.

9.8 Landfill (Scotland) Regulations 2003

- 9.8.1 The Landfill (Scotland) Regulations 2003 (TSO 2003i) enact the requirements of the Landfill Directive (1999/31/EC; EC 1999). The vehicle for implementing the technical requirements of the Landfill (Scotland) Regulations 2003 is the PPC Regulations. "Waste" is defined in regulation 2 of the PPC Regulations as meaning, unless the context otherwise requires, anything that is waste for the purposes of the Waste Framework Directive and which is not excluded from the scope of that Directive. Radioactive waste is specifically excluded from the scope of the Waste Framework Directive (now codified as Directive 2006/12/EC; EC 2006b), where already covered by other legislation. In Scotland, radioactive waste is covered by other legislation, such as RSA 93.

9.9 Water Environment (Controlled Activities) (Scotland) Regulations 2005

- 9.9.1 The Water Environment (Controlled Activities) (Scotland) Regulations 2005 (CAR; TSO 2005b) apply, in Scotland only, to activities which are likely to have a significant adverse impact on the water environment, including potentially disposals of radioactive waste which result in, or are considered likely to result in, radionuclides being transferred to surface or groundwaters. Such activities cannot be carried out without either an authorisation issued under CAR or a permit deemed by CAR to be a CAR authorisation. CAR deems an RSA 93 authorisation to be a CAR authorisation, and places a legal duty on SEPA to ensure RSA 93 authorisations are consistent with the requirements of the Water Framework Directive (EC 2000) and the Groundwater Directive (EC 1980).
- 9.9.2 The Regulations also provide for protection of human health and the environment from the hazardous (non-radiological) components of any disposal inventory.

9.10 Human Rights Act 1998

- 9.10.1 The Human Rights Act 1998 (HRA 98; TSO 1998) came into force on 2 October 2000, and incorporates the provisions of the European Convention on Human Rights (Council of Europe 1950) into domestic law. It requires public bodies, such as the environment agencies, to act in a way, which is compatible with the 'Convention Rights', which are those Articles of the European Convention on Human Rights that are specified in HRA 98 (section 1, and Schedule 1).
- 9.10.2 The main Convention rights that might be affected by the environment agencies' radioactive substances regulation decisions are the right to life (Article 2), the right to a fair trial (Article 6), the right to respect for private and family life (Article 8) and the right to protection of property (Article 1, First Protocol).
- 9.10.3 Certain Convention rights are absolute. Some Convention rights are limited in explicit and finite circumstances. Other Convention rights are qualified. Interference with a qualified right may be justified if it is in accordance with the law, serves one of the aims set out in the qualification to the relevant Article and is 'necessary' in a democratic society. Interference may be considered 'necessary' if there is a pressing social need and any interference with individual rights is proportionate to the aim pursued. It is recognised that public authorities, such as the environment agencies, often have to strike a balance between the general social and economic needs of the community and the specific interests of individuals.
- 9.10.4 Under HRA 98, each environment agency must consider whether its decisions in respect of authorisations under RSA 93 will result in or fail to prevent any potential or actual breach of a Convention right. If we identify such a breach, we must then

consider whether we have the discretion under national law to act otherwise. A public authority will not be acting unlawfully under HRA 98, if it is required to act in a particular way by some provision of primary legislation. Where we do have discretion and the Convention right at issue is not absolute, we must then consider whether our decision is justified.

Part 3: References, Glossary and Acronyms

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11. Glossary and Acronyms

11.1 Glossary of terms

For terms not listed below, refer to:

1. IAEA Safety Glossary:
http://www-pub.iaea.org/MTCD/publications/PDF/Pub1290_web.pdf
2. Documents available on the Health Protection Agency website, especially the Glossary at
<http://www.hpa.org.uk/radiation/glossary/default.htm>
3. General technical dictionary

Accessible environment

Those parts of the environment in contact with or readily available for use by humans.

Active institutional control

Control of a disposal site for solid radioactive waste by an authority or institution authorised under RSA 93, involving *Monitoring*, surveillance and remedial work as necessary, as well as control of land use.

Allowable activity concentrations

An amount of radioactivity per unit mass or volume of a material acceptable for disposal in accordance with an *Environmental safety case*.

Assessed radiological risk

See *Radiological risk*.

Authorised discharge limit

A limit on the discharge of one or more specified radionuclides to air or water in accordance with an authorisation under RSA 93.

Backfilling

The refilling of the excavated portions of a *Disposal facility* after *Emplacement* of the waste.

Biosphere

That part of the environment normally inhabited by living organisms. In practice, the biosphere is generally taken to include the atmosphere and the Earth's surface, including the soil and surface water bodies, seas and oceans and their sediments. There is no generally accepted definition of the depth below the surface at which soil or sediment ceases to be part of the biosphere, but this might typically be taken to be the depth affected by basic human actions, in particular farming.

Closure

Technical and administrative actions to put a *Disposal facility* in its intended final state after the completion of waste *Emplacement*.

Collective radiological impact

An indicator of the total radiological consequences from a particular source of exposure on a defined population over some period of time.

Conceptual model

A set of qualitative assumptions used to describe a system, or part of a system, in the real world.

Conservative (of assumptions and data)

Selection of cautious assumptions, or worst case data values, for the purposes of modelling.

Consignor (of waste)

An organisation or person that sends waste to a facility for disposal.

Decision point

A point defined in a voluntary agreement where a developer would seek regulatory agreement before proceeding with an activity. This would generally be before decisions by the developer to invest substantial amounts of time and resources.

Deterministic assumption

Fixed assumption, taken to have a probability of 1, made for the purpose of exploring, developing, or establishing the *Environmental safety case*.

Developer (of a disposal facility)

The organisation responsible for developing a *Disposal facility* before waste disposal begins.

Devolved administrations

Collective term for the Scottish Government, Welsh Assembly Government and the Northern Ireland Assembly Government.

Disposal

Disposal is the *Emplacement* of waste in a specialised land disposal facility without intent to retrieve it at a later time; retrieval may be possible but, if intended, the appropriate term is storage. We shall regard the time of emplacement as the time of disposal, even if the facility is eventually closed many years later.

Disposal facility (for solid radioactive waste)

An engineered facility for the *Disposal* of solid radioactive wastes.

Disposal system

All the aspects of the waste, the *Disposal facility* and its surroundings that affect the radiological impact.

Dose guidance level (for human intrusion)

In the context of *Near-surface disposal facilities*, the dose standard against which the radiological consequences of *Human intrusion* are assessed. It indicates the standard of *Environmental safety* expected but does not suggest that there is an absolute requirement for this level to be met.

Emplacement (of waste in a disposal facility)

The placement of a *Waste package* in a designated location for disposal, with no intent to reposition or retrieve it subsequently.

Environmental safety

The safety of people and the environment both at the time of *Disposal* and in the future.

Environmental safety case

The collection of arguments, provided by the developer or operator of a disposal facility, that seeks to demonstrate that the required standard of *Environmental safety* is achieved.

Environmental safety culture

The characteristics and attitudes of organisations and individuals that ensure that the protection of people and the environment receives proper attention.

Environmental safety functions

The various ways in which components of the *Disposal system* may contribute towards *Environmental safety*, e.g. the host rock may provide a physical barrier function and may also have chemical properties that help to retard the migration of radionuclides.

Environmental safety strategy

An approach or course of action designed to achieve and demonstrate *Environmental safety*.

Exempt waste

Radioactive wastes are considered exempt from regulatory control if they fall outside the scope of RSA 93 or there is an extant exemption order.

Expert judgement

Expert judgement is an approach for obtaining and using informed opinions from individuals with particular expertise. Such judgement may be required when the data available require expert interpretation. Structured expert judgement, or expert elicitation, refers to the application of transparent methodological rules to the judgement process.

Exposed group

For a given source, any group of people within which the exposure to radiation is reasonably homogeneous; where the exposure is not certain to occur, the term 'potentially exposed group' is used.

Geological disposal

A long-term management option involving the *Disposal* of radioactive waste in an engineered underground facility, where the geology (rock structure) provides a barrier against escape of radioactivity and where the depth, taken in the particular geological context, substantially protects the waste from disturbances arising at the surface.

Geological disposal facility

A facility that meets the requirements for *Geological disposal*.

Hazard

A property or situation that in certain circumstances could lead to harm.

High level waste (HLW)

Radioactive waste in which the temperature may rise significantly as a result of the radioactivity, so that this factor has to be taken into account in the design of disposal facilities.

Higher activity waste

Radioactive waste having a radioactive content exceeding four gigabecquerels per tonne (GBq/te) of alpha or 12 GBq/te of beta/gamma activity and any radioactive wastes below these thresholds that are unsuitable for near-surface disposal.

Hold point

A point defined in an appropriate regulatory document, beyond which an activity must not proceed without regulatory approval. A hold point would generally be before a decision by the developer to invest substantial amounts of time and resources.

Host rock

The geological medium in which a disposal facility is located.

Human intrusion

Any human action that accesses the waste or that damages a barrier providing an *Environmental safety function* after the *Period of authorisation*.

Intermediate level waste (ILW)

Radioactive waste exceeding the upper activity boundaries for low level waste (LLW) but which does not need heat to be taken into account in the design of disposal facilities.

Inventory limits

Limits and conditions set by the regulators on volumes, radionuclides and/or activity concentrations for waste disposal.

Long-lived radioactive waste

Radioactive waste that will not decay into a lower category (e.g. ILW to LLW, or LLW to exempt waste) before long-term assumptions have to be made about any disposal facility in which it is emplaced. Indicatively, radioactive waste may be regarded as long-lived if it contains significant levels of radionuclides with half-lives greater than 30 years.

Low level waste (LLW)

In Government policy, low level waste is defined as 'radioactive waste having a radioactive content not exceeding four gigabecquerels per tonne (GBq/te) of alpha or 12 GBq/te of beta/gamma activity'. It consists largely of paper, plastics and scrap metal items that have been used in the nuclear industry, hospitals and research establishments. In future, there will also be large volumes of LLW in the form of soil, concrete and steel, as existing nuclear facilities are decommissioned.

Mathematical model

A set of mathematical equations designed to represent a *Conceptual model*.

Model

A representation or description of a system (or part of a system) in the real world, designed to show or explore how the system would behave under specified conditions.

Monitoring

Taking measurements so as to be aware of the state of the *Disposal system* and any changes to that state. This may include measuring levels of radioactivity in samples taken from the environment, and also measuring geological, physical and chemical parameters that are relevant to *Environmental safety* and that might change as a result of construction of the disposal facility, waste *Emplacement* and *Closure*.

Multiple-function environmental safety approach

An approach to *Environmental safety* which relies on multiple *Environmental safety functions*.

Near-surface disposal facilities

Facilities located at the surface of the ground or at depths down to several tens of metres below the surface. Near-surface facilities may use the geology (rock structure) to provide an *environmental safety function*, but some may rely solely on engineered barriers.

Non-nuclear premises

A site authorised by one of the environment agencies to keep and use radioactive materials or dispose of radioactive waste, that is not licensed by the Nuclear Installations Inspectorate (part of HSE). Non-nuclear premises include hospitals, universities and various industrial premises throughout the UK.

Nuclear licensed site

Any site which is the subject of a licence granted by the Nuclear Installations Inspectorate (part of HSE) under the Nuclear Installations Act 1965. Nuclear licensed sites include nuclear power stations, nuclear fuel production and reprocessing sites, sites undertaking storage of and/or research into nuclear materials, and major plant producing radioisotopes.

Nuclear safeguards

Measures under international treaty obligations to verify that civil nuclear materials (plutonium, uranium and thorium) are not diverted to non-civil uses.

Nuclear safety case

Documentation provided by a nuclear site licensee to demonstrate that the site meets the nuclear safety requirements of the Nuclear Installations Inspectorate (part of HSE).

Nuclear security

Protection of nuclear licensed sites and the nuclear material on them. This includes, for example, physical protection, the roles of security guards and the UK's Civil Nuclear Constabulary, protection of sensitive data and technologies, and the trustworthiness of the individuals with access to them.

Operator (of a disposal facility)

The organisation responsible for operating a disposal facility after waste *Emplacement* has begun. This organisation will need to hold an authorisation under RSA 93.

Optimisation

Optimisation is the principle of ensuring that radiation exposures are as low as reasonably achievable (ALARA) in the given circumstances. Optimisation is a key principle of radiation protection recommended by the International Commission on Radiological Protection (ICRP) and incorporated into UK legislation.

Partnership

An assembly of local interests established to discuss, evaluate and advise on the potential implications of hosting a geological disposal facility. Its key role will be to represent the host community's interests in negotiations with the implementing body.

Passive safety

Not placing reliance on active safety systems and human intervention to ensure safety.

Peer review

A formally documented examination of a technical programme or specific aspect of work by a suitably qualified expert or group of experts who have not been involved in the programme or aspect of work.

Period of authorisation

The period of time while disposals are taking place and any period afterwards while the site is under *Active institutional control*.

Potential exposure (to ionising radiation)

Exposure to ionising radiation that is not certain to occur.

Potentially exposed group

See *Exposed group*.

Probability distribution (of dose)

A distribution of exposures to ionising radiation that expresses the probability that a given exposure or range of exposures will occur.

Proportionate

Being in suitable proportion.

Quantifiable Uncertainties

Uncertainties associated with a parameter for which numerical estimates of possible values can be made. Uncertainties are quantifiable when there are observations, experiments or models available that can give rise to distributions of values. *Expert judgement* may be needed to interpret such distributions in order to estimate a numerical value for the uncertainty associated with a particular use of the parameter.

Radiation stability

The ability of a material to withstand radiation damage.

Radiological capacity of a disposal facility

An inventory of radioactive material that a facility is capable of accepting based on the *Environmental safety case*.

Radiological risk

The probability per unit time that an individual will suffer a serious radiation-induced health effect as a result of the presence of a radiation source, for example, a disposal facility. In this context, a serious radiation-induced health effect is a fatal cancer or a severe hereditary defect. Radiological risk can only be assessed and not measured.

Retrievability

A characteristic of the design of the *Waste package* and/or the *Disposal facility* that facilitates recovery of waste after emplacement.

Risk

A combination of the probability that someone or something valued will be adversely affected by a *Hazard* and the magnitude of the consequences that might arise from that hazard.

Risk assessment

An assessment of *Radiological risk*.

Risk guidance level

A level of *Radiological risk* from a disposal facility which provides a numerical standard for assessing the *Environmental safety* of the facility after the *Period of authorisation*.

Scenario

A postulated or assumed set of conditions and/or events.

Short-lived radioactive waste

Short-lived radioactive waste is waste that will decay into a lower category (e.g. ILW to LLW, or LLW to *Exempt waste*) before long-term assumptions have to be made about any disposal facility in which it is emplaced. Indicatively, radioactive waste may be regarded as short-lived if it does not contain significant levels of radionuclides with half-lives greater than 30 years.

Site

For a disposal facility, the piece of land where the facility is, or is intended to be, located. More generally, the piece of land where one or a number of sources of radioactivity are, or are intended to be, located.

Site characterisation

Surface and sub-surface investigations to determine the suitability of a site for a disposal facility for solid radioactive waste and to gather information about the site to support an *Environmental safety case*.

Site constraint

The site-related dose constraint applies to the aggregate exposure resulting from discharges from a number of sources with contiguous boundaries at a single location. It includes the radiological impact of current discharges from the entire site, but excludes the impact of direct radiation and historical discharges. The site constraint of 0.5 mSv/year applies irrespective of whether different sources on the site are owned and operated by the same or by different organisations.

Spent nuclear fuel

Fuel removed from a nuclear reactor after use.

Staged authorisation

A regulatory process in which a developer of a disposal facility for solid radioactive waste must not proceed beyond predefined *Hold points* without approval of the relevant environment agency.

Stakeholder

People or organisations, having a particular knowledge of, interest in, or be affected by, radioactive waste, examples being the waste producers and owners, waste regulators, non-Governmental organisations concerned with radioactive waste and local communities and authorities.

Step-wise process

A process in which the regulator would agree with the developer a number of *Decision points* (or steps) during development of a disposal facility for solid radioactive waste, beyond which an activity may not proceed without agreement from the regulator.

Storage (of waste)

Placing waste in a suitable facility with the intent to retrieve it at a later date.

Structural integrity

The ability of an engineered structure to function safely and reliably throughout its life.

Stylised approach to demonstrating environmental safety

An approach to constructing part of an *Environmental safety case* (e.g. modelling the biosphere), through making arbitrary assumptions that are either generally reasonable or clearly *Conservative*. Can be used in the absence of specific information.

Thermal stability

The ability of a material to withstand damage caused by heat or changes in temperature.

Uncertainty

Lack of certainty. A state of limited knowledge that precludes an exact or complete description of past, present or future.

Unquantifiable Uncertainties

Uncertainties for which no numerical estimates can reliably be made. Uncertainties are unquantifiable when there are no observations, experiments or models available that can be used to provide numerical estimates. The effect of these uncertainties may be explored by making alternative sets of conjectural assumptions and determining how these affect the outcome of an analysis.

Very low level waste (VLLW)

Waste with very low concentrations of radioactivity.

Voluntarism

An approach in which communities 'express an interest' in participating in the process that would ultimately provide the site for a geological disposal facility. Initially a community would be expressing an interest in finding out more about what hosting such a facility would involve. In the latter stages there would be more detailed discussion of plans and potential impacts.

Waste acceptance criteria

Quantitative and/or qualitative criteria, specified by the operator of a *Disposal facility* and approved by the regulator, for solid radioactive waste to be accepted for disposal.

Waste characterisation

Determination of the physical, chemical and radiological properties of waste.

Waste consignment

Any waste sent by a *Consignor* to a *Disposal facility*.

Waste form

Waste in its physical and chemical form after treatment. The waste form is a component of the *Waste package*.

Waste package

The *Waste form* and any container(s) and internal barriers (e.g. absorbing materials and liner), prepared in accordance with requirements for handling, transport, storage and disposal.

'What-if' scenario

A *Scenario* put forward to explore the consequences of a defined set of assumptions.

11.2 Acronyms

ALARA	As low as reasonably achievable
BAT	Best available techniques
BPEO	Best practicable environmental option
BPM	Best practicable means
BSS	Basic Safety Standards
CAR	Water Environment (Controlled Activities) (Scotland) Regulations 2005
COMAH	Control of Major Accident Hazards
CORWM	Committee on Radioactive Waste Management
Defra	Department for Environment, Food and Rural Affairs
DfT	Department for Transport
EA 95	Environment Act 1995
EIA	Environmental impact assessment
EPP	Environmental Permitting Programme
EPR 07	Environmental Permitting Regulations 2007
EU	European Union
GRA	Guidance on Requirements for Authorisation
HLW	High-level radioactive waste
HPA	Health Protection Agency
HRA 98	Human Rights Act 1998
HSE	Health and Safety Executive
HV-VLLW	High volume, very low level radioactive waste
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
ILW	Intermediate-level radioactive waste
IPC	Infrastructure Planning Commission
LLW	Low-level radioactive waste
LLWR	Low-level Waste Repository
LV-VLLW	Low volume, very low level radioactive waste
MOD	Ministry of Defence
MRWS	Managing Radioactive Waste Safely
NIEA	Northern Ireland Environment Agency
NDA	Nuclear Decommissioning Authority
NIA 65	Nuclear Installations Act 1965
NII	Nuclear Installations Inspectorate
NRPB	National Radiological Protection Board
OCNS	Office for Civil Nuclear Security
PPC	Pollution Prevention and Control

REPs	Environmental Principles for Radioactive Substances Regulation
RSA 93	Radioactive Substances Act 1993
SAC	Special Area of Conservation
SAPs	Safety assessment principles
SEA	Strategic environmental assessment
SEPA	Scottish Environment Protection Agency
SPA	Special Protection Area
SSSI	Site of Special Scientific Interest
WAG	Welsh Assembly Government
WRA 91	Water Resources Act 1991

Annexes

Annex I: Relationship between Environment Agencies' Regulatory Guidance on Near-Surface Radioactive Waste Disposal Facilities and HPA's Advice

A1-1 Introduction

- A1-1.1 The guidance for near-surface radioactive waste disposal facilities provided by the environment agencies in this document is based on radiation protection advice from the UK's Health Protection Agency (HPA). There are some differences between HPA's specific advice for solid radioactive waste disposal facilities (HPA 2009b) and the interpretation set out in our guidance. This annex to our guidance explains the background to and reasons for the interpretation chosen by the environment agencies: it does not form part of our guidance.

A1-2 Roles, Responsibilities and Organisational Approaches

Health Protection Agency

- A1-2.1 HPA's role is to provide an integrated approach to protecting UK public health through the provision of support and advice to the Department of Health, the Devolved Administrations, the National Health Service, local authorities, emergency services and other bodies. On 1 April 2005, HPA was established as a non-departmental public body, incorporating the former National Radiological Protection Board and with radiation protection as part of its health protection remit. HPA provides support to, and works in partnership with others who have health protection responsibilities and advises, through the Department of Health, all government departments and devolved administrations throughout the UK. HPA's Radiation Protection Division carries out HPA's work on ionising and non-ionising radiations. It undertakes research to advance knowledge about protection from the risks of these radiations, provides laboratory and technical services, runs training courses, provides expert information and gives advice in the UK on radiation protection issues.
- A1-2.2 HPA advises on health protection standards to be applied today. It also recommends that, for the protection of the public following the disposal of solid radioactive wastes, individuals and populations who might be alive at any time in the future should be accorded a level of protection at least equivalent to that which is accorded to individuals and populations alive now.

Environment Agencies

- A1-2.3 The environment agencies (the Environment Agency in England and Wales, the Scottish Environment Protection Agency in Scotland, and the Northern Ireland Environment Agency in Northern Ireland) are the leading public bodies for protecting and improving the environment in their respective parts of the UK. There are close links between the environment and people's health.
- A1-2.4 The environment agencies share the same fundamental objective for the protection of human health as HPA. In the aspects we regulate, we impose legal limits and conditions on industry and other undertakings to protect human health and the environment and ensure that these limits and conditions are complied with. Among the undertakings we regulate are those responsible for disposing of radioactive waste. In carrying out our regulatory work we have regard to advice issued by HPA.

- A1-2.5 We issue guidance to the undertakings we regulate, such as the developers/operators of solid radioactive waste disposal facilities. For our guidance to be of value, it must be possible (although it may be challenging) for developers/operators to meet the requirements it contains. Hence, our requirements are so framed that developers/operators can show they have met them.
- A1-2.6 In our guidance for solid radioactive waste disposal facilities, we have decided not to express our requirements in specific engineering terms. This allows developers/operators to put forward innovative approaches that may better protect people and the environment. Instead, we have chosen to express the requirements so that their relationship to our fundamental protection objective and principles is clear and also so that the requirements can be met. The process of deciding whether a given requirement is met will often involve judgement. We shall expect the developer/operator to support their judgements by means of the environmental safety case they submit to us. We shall then take a view as to whether we consider that these judgements are sound.

A1-3 ICRP Recommendations

HPA Position

- A1-3.1 HPA advises UK bodies with responsibility for protection against radiation, including the environment agencies, on the applicability to the UK of recommendations issued by the International Commission on Radiological Protection (ICRP). After a consultation process lasting several years, ICRP has issued new recommendations for a system of radiological protection (ICRP 2007). These recommendations replace the previous recommendations issued in 1991 (ICRP 1991). HPA has issued its advice on the 2007 ICRP recommendations (HPA 2009a).

Environment Agencies' Position

- A1-3.2 In regulating radioactive waste disposal, the environment agencies must follow the requirements of the relevant legislation. Following the publication of the 1991 ICRP recommendations, the European Union (EU) formally adopted *Council Directive 96/29/Euratom Laying Down the Basic Safety Standards for the Health Protection of the General Public and Workers Against the Dangers of Ionizing Radiation* (the 1996 BSS Directive). The 1996 BSS Directive was implemented in the UK, in part and particularly for the environment agencies' functions in regulating the disposal of radioactive waste in the different parts of the UK, by the following instruments:
- The Radioactive Substances (Basic Safety Standards) (England and Wales) Direction 2000
 - The Radioactive Substances (Basic Safety Standards) (Scotland) Direction 2000
 - The Radioactive Substances (Basic Safety Standards) Regulations (Northern Ireland) 2003
- A1-3.3 Each environment agency must continue to regulate in accordance with the above instruments and other relevant legislation unless and until they are amended or revoked. Work is under way within the European Union to update the 1996 BSS Directive but the process of incorporating into European law a revised BSS Directive reflecting the 2007 ICRP recommendations is likely to take several years.

- A1-3.4 Where it is not bound by the 1996 BSS Directive or other legislation, each environment agency will take into account HPA's advice on the 2007 ICRP recommendations. There is no major change in radiation protection standards between the 1991 and the 2007 ICRP recommendations.

A1-4 Interpretation of Key Aspects of HPA Advice on Solid Radioactive Waste Disposal

A1-4.1 Introduction

- A1-4.1.1 Our guidance for near-surface radioactive waste disposal facilities draws on HPA's advice on solid radioactive waste disposal (HPA 2009b) in a number of areas. In some instances it is clear how our guidance derives from HPA's advice, while in other cases the relationship may not be so apparent. This section provides a commentary on how we have taken HPA's advice into account in developing our guidance.

A1-4.2 Requirement R5: Dose constraints during the period of authorisation

- A1-4.2.1 Requirement R5 (para. 6.3.1 in the guidance) provides the dose constraints that the developer/operator of a radioactive waste disposal facility needs to comply with during the period of authorisation.
- A1-4.2.2 HPA recommends that a dose constraint of 0.15 mSv / year should apply to exposure to the public from a new disposal facility for solid radioactive waste for the operational and active institutional control phases.
- A1-4.2.3 Our guidance refers both to the Directions and Regulations issued by Government (see para. A1-3.2), which specify a source-related dose constraint set at 0.3 mSv/year, and to HPA's advice. We emphasise that the dose constraint is an upper bound on optimisation. Our guidance includes a separate requirement (Requirement R8) for the developer/operator to ensure that radiological risks to members of the public are as low as reasonably achievable (ALARA), taking into account economic and societal factors. This optimisation requirement is consistent with HPA's advice.

A1-4.3 Requirement R6: Risk guidance level after the period of authorisation

- A1-4.3.1 Requirement R6 (para. 6.3.10 in the guidance) provides a risk guidance level of 10^{-6} per year (i.e. 1 in a million per year) that the developer/operator of a radioactive waste disposal facility needs to demonstrate consistency with after the period of authorisation. The risk guidance level is applicable to a person representative of those at greatest risk.
- A1-4.3.2 HPA recommends the use of a detriment-adjusted risk coefficient. The estimate of the detriment-adjusted risk coefficient for the whole population is given in the new ICRP recommendations as 0.057 per Sv. HPA recommends that the rounded value of 0.06 per Sv be used for waste management assessments. The environment agencies accept this value and we quote it in our guidance.
- A1-4.3.3 Once active institutional control has ceased, and for all events and processes that lead to exposure of individuals (other than human intrusion directly into a waste disposal facility), HPA recommends that a risk constraint of 1 in 100 000 per year is applied to the exposure of an individual who is representative of the more highly exposed individuals in the population and is applied to the exposure from a single disposal facility. This is intended to apply at the planning stages of a new disposal facility. For an existing disposal facility already containing wastes in closed

modules, the advice is intended to apply at the planning stages of all future disposals at the facility.

- A1-4.3.4 HPA explains that judgement is needed when comparing estimated risks to individuals from a single waste disposal facility with the risk constraint, especially for risks that are estimated to occur at long times in the future. If risks are estimated to be lower than the constraint, it does not mean that the disposal facility is acceptable with no further consideration; the level of protection must also be demonstrated to be optimum by means of an optimisation study. Conversely if the constraint is exceeded, this does not necessarily mean rejection of the safety case for the proposed disposal facility. Further considerations would be required, involving either further evaluation of the safety case, for example re-examination of the uncertainties or the extent of the conservatism used in the estimation of the risk; or further substantiation, for example the safety case being supported by other evidence. HPA also point out that the further into the future the assessment is made, the more uncertain the assessments of doses and risks become and consequently the greater the flexibility in the application of the constraint.
- A1-4.3.5 For regulatory purposes, the environment agencies have chosen a risk guidance level rather than a risk constraint, to guide the developers and operators of waste disposal facilities towards a level of risk that we consider appropriate for the post-closure phase. That is why our risk guidance level is set an order of magnitude lower than HPA's risk constraint. It is neither a limit nor a constraint: it provides the environment agencies' broad expectations for the outcome of risk assessments relating to the post-closure phase.
- A1-4.3.6 We note that the document *Reducing Risks, Protecting People* (HSE, 2001) states that "HSE believes that an individual risk of death of one in a million per annum for both workers and the public corresponds to a very low level of risk and should be used as a guideline for the boundary between the broadly acceptable and tolerable regions." We share this view and relate it to the value at which our risk guidance level is set.
- A1-4.3.7 HPA advises that if there is another disposal facility which might be affected by the same natural process and events as the disposal facility being proposed then consideration should be given to the combined doses and risks to any relevant exposure groups. The environment agencies agree that consideration of combined doses and risks is appropriate. An unacceptably large total for the assessed risks from different disposal facilities affecting the same exposure group at the same time could indicate an unacceptably large assessed risk from one or more of the facilities taken individually. This would require attention from the developer/operator and ourselves. We would not accept an approach in which the assessed risks from multiple different modules of the same disposal facility were put forward individually in order to show that each module, taken alone, presented a risk consistent with the risk guidance level.
- A1-4.3.8 HPA advises that if risks are estimated to be lower than the HPA constraint, it does not mean that the disposal facility is acceptable with no further consideration; the level of protection must also be demonstrated to be optimum by means of an optimisation study. The environment agencies take a similar view and have presented optimisation as a separate requirement, independent of the requirement to show consistency with the risk guidance level.

A1-4.4 Requirement R7: Human intrusion after the period of authorisation

- A1-4.4.1 Requirement R7 (para. 6.3.36 in the guidance) states that the developer/operator of a near-surface disposal facility should assess the potential consequences of

human intrusion into the facility after the period of authorisation on the basis that it is likely to occur, but should also consider and implement any practical measures that might reduce the chance of its happening. The assessed effective dose to any person during and after the assumed intrusion should be consistent with an annual dose guidance level in the range of around 3 mSv to around 20 mSv. Values towards the lower end of this range are applicable to assessed exposures continuing over a period of years (prolonged exposures), while values towards the upper end of the range are applicable to assessed exposures that are only short term (transitory exposures).

- A1-4.4.2 HPA states that, since the likelihood of inadvertent human intrusion is highly uncertain, the emphasis for protection of human health should be on mitigating the consequences of intrusion that could occur after the end of the active institutional control period, i.e. controls should be placed on the doses likely to be received. For this reason HPA recommends dose criteria for inadvertent human intrusion rather than risk criteria. In specifying dose criteria, HPA considered both transitory and prolonged exposures as a result of inadvertent intrusion. To avoid confusion with the terminology in the new ICRP recommendations, and recognising that there are many sources of uncertainty in performing dose calculations, HPA calls these dose criteria for inadvertent intrusion 'guidance levels'.
- A1-4.4.3 The environment agencies accept HPA's advice. We regard it as impossible to put a meaningful number on the likelihood of inadvertent human intrusion after the period of authorisation, since the circumstances in which such intrusion might occur cannot be known. We consider that assessing the doses that the intruders and other people affected by the intrusion might receive in representative situations is the appropriate approach.
- A1-4.4.4 HPA recommends an annual dose guidance range of around 3 mSv to 20 mSv related to the exposure of an individual representative of the more highly exposed individuals in the population following inadvertent intrusion. Values towards the lower end of this range are applicable to assessed exposures continuing over a period of a year or more (prolonged exposures), excluding the contribution from radon. If the radon contribution is included then the appropriate values could be up to a factor of three higher. Values towards the upper end of the range are applicable to assessed exposures that are only short term (transitory exposures), i.e. where the dose is received within one year and none is received in subsequent years (the 20 mSv applies to the total transient dose). An example of a transitory exposure would be the handling of soil specimens taken from the disposal facility.
- A1-4.4.5 The environment agencies accept HPA's advice. Giving a range has the advantage of emphasising that this is a continuum of potential exposures. We accept HPA's point that radon arising from the disposal facility has the potential for making a major contribution to dose, especially for prolonged exposure. We also accept that particular circumstances are likely to be necessary for a substantial radon dose, i.e. prolonged occupancy of a poorly-ventilated enclosure. Our guidance therefore asks for the radon contribution to be assessed separately, so as to ensure that assumptions are explicitly made that are suitable for the proper assessment of radon.
- A1-4.4.6 When determining an application for authorising the disposal of radioactive waste, we shall disregard any contribution from radon that is present naturally in the environment (rather than originating from the radioactive waste). This is consistent with HPA's advice.

A1-4.5 Requirement R8: Optimisation

- A1-4.5.1 Requirement R8 (para. 6.3.56 in the guidance) states that the choice of waste acceptance criteria, how the selected site is used and the design, construction, operation, closure and post-closure management of the disposal facility should ensure that radiological risks to members of the public and to the environment, both during the period of authorisation and afterwards, are as low as reasonably achievable (ALARA), taking into account economic and societal factors.
- A1-4.5.2 HPA advises that optimisation continues to play a key role in radiological protection and should be a continuous, forward-looking, iterative process. The main factors in the optimisation process are: the likelihood of exposures; the number of people exposed; and keeping the magnitude of their individual doses as low as reasonably achievable, taking into account economic and social aspects. It should be remembered that it will be necessary to weigh up short-term factors relating to the design, construction and operational periods, such as costs and occupational doses, against long-term factors such as doses to the public following the closure of the waste disposal facility. Other relevant considerations are the management of non-radiological hazards, potential adverse impacts and the technical feasibility and effectiveness of any mitigating action.
- A1-4.5.3 HPA advises that, as the best waste management option will always be specific to the exposure situation, the waste and the waste disposal facility, it is not relevant to specify a dose level below which optimisation is no longer required. Nevertheless, if the radiological impact is very small then inappropriate levels of effort could be expended on comprehensive and detailed optimisation studies in order to reduce the risk further. It is important that the level of effort expended on reducing the dose or risk is proportionate to the dose or risk associated with the waste management option.
- A1-4.5.4 The environment agencies accept HPA's advice on optimisation as set out above and as more extensively set out in HPA's report (HPA 2009b), e.g. regarding the use of collective dose for optimisation. We have given additional guidance on optimisation under our Requirement R8.

Annex II:
Exchange of Letters Between Environment Agencies & HPA

Dr R. Cox,
Director, Centre for Radiation, Chemical and Environmental Hazards
Health Protection Agency
Chilton
Didcot
Oxon, OX11 0RQ

29 January 2009

Dear Dr Cox,

Relationship between HPA's Advice on the Radiological Protection Objectives for the Land-based Disposal of Solid Radioactive Wastes and the Environment Agencies' Regulatory Guidance on Near-Surface Disposal Facilities for Radioactive Waste

As you know, your staff and ours have been working closely together to ensure consistency between HPA's Advice on the Radiological Protection Objectives for the Land-based Disposal of Solid Radioactive Wastes and the environment agencies' regulatory guidance on near-surface disposal facilities for radioactive waste. Both your document and ours are shortly to be published. The environment agencies' regulatory guidance includes an annex explaining the background to and reasons for the interpretation of HPA's advice chosen by the environment agencies.

We note three particular points, as follows:

1. HPA recommends that a dose constraint of 0.15 mSv/year should apply to exposure to the public from a new disposal facility for solid radioactive waste for the operational and active institutional control phases. The environment agencies' guidance refers both to the Directions and Regulations issued by Government, which specify a source-related dose constraint set at 0.3 mSv/year, and also to HPA's advice that a dose constraint of 0.15 mSv/year should apply. In our regulatory guidance we state that the developer/operator of a disposal facility may wish to take into account HPA's recommendation as well as the direction from the UK Government and Devolved Administrations.

We recognise that a dose constraint is a prospective and source related restriction on the individual dose from a source, which provides a basic level of protection for the most highly exposed individuals from a source and serves as an upper bound on the dose in optimisation of protection for that source. For public exposure, the dose constraint is an upper bound on the annual doses that members of the public should receive from the planned operation of any controlled source. The dose constraint places a restriction on the annual dose to an individual from a particular source in order to ensure that when aggregated with doses from all sources, excluding natural background and medical procedures, the dose limit is not exceeded.

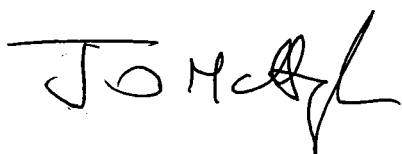
2. Once active institutional control has ceased, and for all events and processes that lead to exposure of individuals (other than human intrusion directly into a waste disposal facility), HPA recommends that a risk constraint of 1 in 100 000 per year is applied at the planning stage of a disposal facility to the exposure of an individual who is representative of the more highly exposed individuals in the population. For regulatory purposes, the environment agencies have chosen a risk guidance level rather than a risk constraint, to guide the developers and operators of waste disposal facilities towards a level of risk that we consider appropriate for the period after active

institutional control. That is why our risk guidance level is set an order of magnitude lower than HPA's risk constraint. It is neither a limit nor a constraint: it provides the environment agencies' broad expectations for the outcome of risk assessments relating to the period after active institutional control.

3. We agree that the principle of optimisation must be applied to all phases of the lifecycle of a disposal facility, including the operational period, any period of active institutional control and the subsequent evolution of the facility in its surroundings. We recognise that the primary aim of the optimisation principle is to minimise the possibility of cancer and heritable effects in people, by keeping doses or risks as low as reasonably achievable, economic and societal factors being taken into account. Our guidance makes the point that the optimisation principle should be applied in an iterative manner throughout the disposal system development process. We consider that the use of our risk guidance level in conjunction with optimisation will provide a suitable level of protection for members of the public.

We should be very grateful, please, if you would indicate whether you are satisfied that the radiological protection guidance contained in the environment agencies' document would, if properly implemented, afford the same level of protection for future generations as that given in the HPA Advice on the Radiological Protection Objectives for the Land-based Disposal of Solid Radioactive Wastes.

Yours sincerely,



Dr J O McHugh

Head of Radioactive
Substances Regulation

Environment Agency



Dr George Hunter

Manager, Radioactive
Substances Policy Unit

Scottish Environment

Protection Agency



Robert Larmour

Principal Pollution Inspector

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10 February 2009

Dear Colleagues

Relationship between HPA's Advice on the Radiological Protection Objectives for the Land-based Disposal of Solid Radioactive Wastes and the Environment Agencies' Regulatory Guidance on Near-Surface Disposal Facilities for Radioactive Waste

Thank you for your letter dated 29 January. I note that the environment agencies have incorporated the majority of the recommendations made in HPA's Advice document on the Radiological Protection Objectives for the Land-based Disposal of Solid Radioactive Wastes. This is explained in Annex 1 of your guidance document.

In summary, HPA staff have looked in detail at the environment agencies' guidance document and its relationship to HPA's advice. HPA is satisfied that if properly implemented the environment agencies' guidance document will in practice afford essentially the same level of protection for future generations as that afforded in HPA's Advice on Radiological Protection Objectives for the Land-based Disposal of Solid Radioactive Wastes. Our detailed comments are provided below.

There are two areas where HPA advice has not been adopted in full in your Regulatory Guidance. These areas are detailed in your letter and also explained in Annex 1 of your guidance document.

The two key areas are 1) the dose constraint for a new disposal facility during the operational and active institutional control phases and 2) the adoption of a risk constraint of 1 in 100 000 per year following the end of active institutional control.

1. Your guidance document refers to HPA's recommended dose constraint of 0.15 mSv y^{-1} for the dose to a member of the public arising from the operational and active institutional control phases given in HPA's advice, and the Directions and Regulations issued by Government which specify a source-related dose constraint of 0.3 mSv y^{-1} . I understand that the environment agencies have to implement the direction issued by Government and the Devolved Administrations. Nevertheless, HPA will continue to advise government that, in the context of solid waste disposal, the dose constraint should be set at 0.15 mSv y^{-1} . This constraint represents the minimum aspiration for protection. I also note your wish to take account of HPA's advice as evidenced in the statement in your guidance document that 'developers/operators may wish to take HPA advice into consideration'. The purpose of a dose constraint is to act as an upper bound on the prospective dose from a proposed facility. However, HPA considers that meeting the dose constraint is not sufficient: doses should be as low as reasonably achievable below the constraint. This is the process known as optimisation.

I note that optimisation below a constraint is also the overriding requirement in your guidance document and this is emphasised in point 3 of your letter. Since the HPA advice and your guidance both seek to keep doses as low as reasonably achievable I am satisfied that the overall level of protection provided by your guidance should in practice be the same as that intended by the HPA advice.

2. Once active institutional control has ceased, and for all events and processes that lead to exposure of individuals (other than human intrusion directly into a waste disposal facility), HPA recommends that a risk constraint of 1 in 100 000 per year is applied to the exposure of an individual who is representative of the more highly exposed individuals in the population. This risk constraint is to be applied at the planning stage of a disposal facility. For regulatory purposes, you have chosen a numerically lower risk guidance level of 1 in 1000 000 per year, with a requirement for optimisation.

Although you have not required the application of HPA's recommended risk constraint directly it is referred to in your document when you specify your risk guidance level. Since the environment agencies' risk guidance level is an order of magnitude below HPA's recommended risk constraint, HPA considers that the combination of applying the environment agencies' risk guidance level and optimisation should lead to broadly the same outcome as applying HPA's recommended risk constraint with optimisation, and HPA considers that the environment agencies' guidance level is consistent with HPA's advice.

The overriding principle in both HPA's advice and your guidance document is optimisation, ie keeping risks as low as reasonably achievable, and this will drive the risks down. HPA define a risk constraint which is to be applied at the design stage. The advice explains that although the constraint is not a limit, especially at long timescales in the future, if it were exceeded then further effort would be needed to demonstrate that the option that gives rise to risks above this value is really the overall optimum option. Even if risks are below the risk constraint, HPA would expect optimisation to be done to keep the risks as low as reasonably achievable.

You have not specified a risk constraint but instead have specified a risk guidance level. This guidance level is not a limit or constraint but an indicator of your broad expectation of the estimated level of risk in a risk assessment of a disposal facility. However, you also require optimisation to be carried out whether the estimated risks are above or below the guidance level.

I am pleased that HPA and the environment agencies have co-operated in setting high standards for radioactive waste disposal.

Yours sincerely



Dr Roger Cox
Director, CRCE



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