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Title:	Regulators' roles and processes in the implementation of MRWS
Notes:	Updated to include further information on resources and OCNS

1 – Background and Context

1.1 The West Cumbria MRWS Partnership ('the Partnership') exists to *"make recommendations to Allerdale Borough Council, Copeland Borough Council and Cumbria County Council on whether they should participate or not in the geological disposal facility siting process, without commitment to eventually host a facility"*. The Partnership is therefore predominantly concerned with the siting process up to a "Decision to Participate", defined as Stage 3 of the site selection process in the Managing Radioactive Waste Safely (MRWS) White Paper¹.

1.2 The Partnership Steering Group has developed a work programme² derived from the criteria that it will use when making a recommendation on whether to participate further in the MRWS Site Selection process.

1.3 Criterion 1a is that the Partnership should be *"Satisfied that suitable regulatory and planning processes are in place or being developed to protect residents, workforce and the environment"*. The specific task that the Partnership wish to address is having *"Confidence that necessary regulatory bodies and processes exist or are being developed"*. In this respect the Partnership have identified *"Task 1a(i): Understand what regulatory bodies are involved, what their roles are and what regulatory processes they have in place or are developing"*.

1.4 This briefing material has been produced by the environment and safety regulators³ in response to a request from the Partnership's Steering Group for an advance paper covering:

- What regulatory bodies are involved in the implementation of MRWS?
- What are the objectives and roles of each of the regulatory bodies are?
- What regulatory frameworks are in place and/or are being developed?
- When do regulators get involved formally and therefore how they exert influence?
- How can the community and/or Partnership influence these regulatory processes?
- To what extent are the regulators independent? i.e. how is this defined in this context?
- What resources and resource plans are in place and/or are being developed?

1.5 This briefing material focuses on the Environment Agency and Health and Safety Executive whilst providing an overview of the role and responsibilities of the Department for Transport.

1.6 It is noted that this briefing paper and the associated presentation to the Partnership may not be sufficient to fully address this task, and as such that it is likely that follow-up discussions with the Partnership will be required.

¹ *Managing Radioactive Waste Safely: A framework for implementing geological disposal*, A White Paper by Defra, BERR and the devolved administrations for Wales and Northern Ireland, June 2008.

² *Work programme for 2009/10 (draft)*. West Cumbria MRWS Partnership Document 13.1 draft. 25th January 2010.

³ The Environment Agency, Health and Safety Executive's Nuclear Directorate and the Department for Transport.

2 – What regulatory bodies are involved in the implementation of MRWS? What are their roles and objectives?

2.1 The regulatory bodies involved in the implementation of MRWS are:

Environment Agency

The Environment Agency is responsible in England and Wales for the enforcement of environmental protection legislation in the context of sustainable development. Its remit is wide and its activities cover, for example, environmental pollution, waste management, flood risk management, water resources, fisheries and conservation.

The Environment Agency's principal aims are to protect or enhance the environment, and to promote sustainable development.

The Environment Agency is responsible in England and Wales for regulating disposals of radioactive waste from nuclear licensed sites and other premises using radioactive substances. Disposals of radioactive waste include discharges into the atmosphere, surface waters and groundwater, disposals by transfer to another site and disposal to land including geological disposal.

Health and Safety Executive (HSE)

The statutory body responsible for the enforcement of health and safety law on nuclear sites in Great Britain. HSE is the licensing authority for nuclear installations in Great Britain.

HSE's Nuclear Directorate (ND) includes:

The **Nuclear Installations Inspectorate (NII)**, regulating the nuclear, radiological and industrial safety of nuclear installations.

NII's mission is *"to protect people and society from the hazards of the nuclear industry"*

The **Office for Civil Nuclear Security (OCNS)** regulating security arrangements in the civil nuclear industry, including security of nuclear material in transit.

OCNS's objective is to ensure that security remains both effective and proportionate

The **UK Safeguards Office (UKSO)** working with the UK nuclear industry and others with safeguards⁴ reporting requirements, and safeguards inspectors from the European Commission and the IAEA, to make sure that the safeguards measures applied are both effective and efficient

UKSO's objective is to make sure that the safeguards measures applied are both effective and efficient;

Department for Transport (DfT)

The Secretary of State for Transport is the competent authority in the UK for regulating the safety of transport of all radioactive material for all modes of transport (land, air and sea transport)⁵. The responsibilities for the functions of

⁴ 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.

⁵ It should be noted that transport infrastructure responsibilities for road lie with DfT, the Highways Agency and the relevant local authority. Transport responsibilities for rail lie with DfT, the Office for Rail Regulation and Network Rail. The split of responsibilities between these organisations for the specific case of a GDF at a particular location is unlikely to be clear until the full scope of the demand on the infrastructure is known.

the competent authority are shared according to their specificity between the Department for Transport's Dangerous Goods Division (DfT-DGD), the Civil Aviation Authority and the Maritime and Coastguard Agency.

DfT-DGD must certify that all package designs requiring competent authority approval⁶ and associated transport arrangements comply with statutory regulations. DfT-DGD is also responsible for regulating the safety of transport operations.

DfT's regulatory roles and responsibilities are to ensure robust, independent regulation in relation to statutory responsibilities for ensuring that national, EU and international safety, security and environmental legislation and standards are met. The UK competent authority has been independently audited by the International Atomic Energy Agency which found that the regulatory framework in the UK for the transport of radioactive material is well developed; and that the UK is committed to a sound safety culture in its transport regulations.

Planned developments within HSE and DfT

2.2 The Department for Work and Pensions Minister announced on 8th February 2011 the intention to establish an Office for Nuclear Regulation (ONR) as a statutory corporation. The ONR will bring together the Nuclear Directorate of the HSE and the functions of the Radioactive Materials Transport Team within DfT's Dangerous Goods Division in a single public body outside the civil service. Pending the necessary legislation the immediate focus will be to ensure that the ONR as an Agency of HSE is established and operational from 1 April 2011.

2.3 The restructuring will not change the substance or standards of regulation or compromise the independence of the nuclear regulatory body, and will not affect the decisions it takes or the international obligations the Government requires it to meet.

3 – What regulatory frameworks are in place and/or being developed?

3.1 The regulators have processes and procedures in place to ensure that those responsible for radioactive waste carry out their duties in accordance with the law. For projects which involve long timescales, such as the geological disposal facility, the regulators' involvement falls into two parts –

- Early engagement and advice.
- Formal regulatory permissioning

Early Engagement and Advice

3.2 For projects which involve long timescales, such as the Geological Disposal Facility, the regulators' role, prior to any formal application, is to provide advice. Such advice will assist developers in preparing submissions for regulatory approval. Advice

DfT's policies for the national transport infrastructure are currently under review. That review is due to be completed shortly. In the interim the West Cumbria MRWS Partnership may be interested in the current policy statements which are published on DfT's website at <http://www.dft.gov.uk/pgf/>. Implementation of such policies is, in general, through the planning system.

Policy guidelines for preferences as between road and rail transport will not be confirmed until the above-mentioned review is complete and a new policy statement has been published.

⁶ A graded approach to safety is adopted, whereby those packages that contain radioactive material below internationally agreed thresholds do not require competent authority approval. The nature of the radioactive material associated with the Geological Disposal Facility is such that competent authority approval of those packages will be required. The competent authority deploys a compliance assurance programme to satisfy itself that regulatory requirements are being met across all package designs.

is framed to give developers guidance on issues⁷ that may arise, while avoiding direct involvement of the regulators in the design process. The regulators' approach is based upon early and continuing interaction. Interaction is especially important at the strategy development, options assessment and concept stages, where developers can seek the regulators' views about:

- improving safety and environmental protection;
- reducing the risk of unnecessary expenditure or delays by identifying, and if possible resolving, any significant regulatory issues at this early stage.

3.3 Early engagement with a developer would also provide a basis for early dialogue with stakeholders on the regulators' views regarding issues within their respective remits. Regulators will make information widely available on the environmental and operational safety of the facility, subject to considerations such as national security.

3.4 Regulators will make sure that advice provided to a developer or information provided in dialogue with stakeholders during the early stages of developing a geological disposal facility will not compromise their independence.

Formal Permissioning Process for a Geological Disposal Facility

3.5 Any application for permission to build a geological disposal facility will be subject to regulatory consideration in successive stages. Figure 1 illustrates the proposed regulatory process (for the Environment Agency and the HSE-NII), and shows the hold points beyond which the applicant could not proceed without regulatory agreement. The Regulators' high level expectations for each of the stages are set out in Table 1.

3.6 UK Government has amended the legislative powers available to the Environment Agency to enable it to undertake a staged regulation process more effectively. The legislative process to amend the Environment Agency's powers was completed in April 2010⁸.

3.7 An indicative process for staged regulation is shown in Figure 2. Under staged regulation, a developer would need to apply for an environmental permit before starting intrusive investigations at a candidate site, for example, drilling boreholes to investigate the geological structure. Staged regulation would also bring in a series of subsequent hold points each requiring decisions as the development programme progresses. At each hold point, the developer would need to submit an updated safety case to provide continuing assurance that the site will meet regulatory requirements. For, example, if satisfied with the updated environmental safety case, the Environment Agency would grant an amended environmental permit to allow the next phase of development work to proceed. For a geological disposal facility, the developer will be the NDA's delivery organisation, which is currently its Radioactive Waste Management Directorate.

3.8 There will be strong links to the land-use planning regime. Land-use planning is not the focus of this document, nevertheless it is clear that our regulatory processes will interact with those of planning regulators. An indication of these links under a staged regulatory process is provided in Figure 2.

⁷ The matters to be addressed during regulatory interactions are generally described as 'issues'. This term should be interpreted very broadly. It may for example include operator's proposed courses of action, new projects or activities, events and investigations of interest to regulators, including responses to regulatory requirements. Similarly, on a regulator's part, it may for example include any particular regulatory concerns, investigations and audits and their outcomes, and changes to regulatory processes.

⁸ In April 2010, the Environmental Permitting (England and Wales) Regulations 2010 came into force (<http://www.defra.gov.uk/environment/policy/permits/guidance.htm>).

3.9 Planning regulators must consult the Environment Agency under the processes for Strategic Environmental Assessment and Environmental Impact Assessment.

Permission to operate a Geological Disposal Facility – Nuclear Site Licence

3.10 Operating a Geological Disposal Facility will be subject to a nuclear site licence granted by the HSE-NII. The Nuclear Site Licensing process is described in detail in the publication “The licensing of nuclear installations”⁹. Key points in the process are set out in Annex 1.

Regulating the security of a Geological Disposal Facility – Site Security Plan

3.11 The Office for Civil Nuclear Security (OCNS) regulates security at civil licensed nuclear sites in the United Kingdom¹⁰. OCNS’ regulatory responsibilities and the obligations placed upon the civil nuclear industry comprise Site Security, Transport Security, Information Security and Personnel Security (Vetting) and are laid down in the Nuclear Industries Security Regulations 2003¹¹ (NISR 03). In order to comply with the Site Security requirements of NISR 03 every civil licensed nuclear site must have a Site Security Plan. Site Security Plans detail the standards, procedures and arrangements that are to be kept in place to ensure the security of a nuclear premises, nuclear material or sensitive nuclear information. SSPs are drawn up by the Operators and are approved by OCNS. They are ‘live’ documents, subject to an annual review and are amended as appropriate.

Permission to dispose of waste in a Geological Disposal Facility

3.12 The disposal of a radioactive waste in a Geological Disposal Facility will require permission from the Environment Agency granted as an environmental permit. To operate such a facility the operator needs to have an environmental safety case that satisfies the requirements of the Environment Agency. The environmental safety case will demonstrate that members of the public and the environment are adequately protected, at the time of disposal and in the future. Further detail on the requirements are available in the document “*Geological Disposal Facilities on Land for Solid Radioactive Wastes: Guidance on Requirements for Authorisation*” (often referred to as the ‘GRA’) issued in February 2009¹² as a revision to earlier guidance.

Joint Guidance on the Management of Higher Activity Wastes on Nuclear Licensed Sites

3.13 How the waste is managed prior to disposal is important to determine the quality of the final disposal package. In particular, we should note that packaged wastes created today are expected to form part of the multiple barrier system designed to limit radionuclide release in a disposal facility. The Regulators have joint working arrangements to scrutinise the waste management activities for higher activity wastes on licensed nuclear sites¹³. These arrangements ensure that appropriate oversight is taken of the longer term impacts of current waste management activities.

⁹ The licensing of nuclear installations. Available at <http://www.hse.gov.uk/nuclear/notesforapplicants.pdf>

¹⁰ OCNS publishes annual reports summarising its activities. Available at <http://www.hse.gov.uk/nuclear/ocns/publications.htm>

¹¹ Nuclear Industries Security Regulations 2003. Available at <http://www.opsi.gov.uk/si/si2003/20030403.htm>

¹² *Geological Disposal Facilities on Land for Solid Radioactive Wastes: Guidance on Requirements for Authorisation*, February 2009. Available at <http://publications.environment-agency.gov.uk/pdf/GEHO0209BPJM-e-e.pdf>

¹³ Details are available in the documents “*Fundamentals of the Management of Radioactive Waste, An Introduction to the Management of Higher-level Radioactive Waste on Nuclear Licensed Sites*” and “*The*

Permission to transport wastes – approval of packages and transport arrangements

3.14 Waste will need to be transported from interim stores to the site of the geological disposal facility once it is operational. The requirements for the safe transport of radioactive material by road, rail and sea stem from international agreements and European Directives. These requirements have been implemented in UK legislation setting out what types of transport package are allowed, how much radioactivity they are allowed to contain, and how they should perform against specified tests. Approval from the transport regulator is required for certain package designs, their shipments and the quality programmes associated with the design and manufacture of transport packaging, the filling of the packages with waste and the handling and transporting of the waste. The transport regulator responsible for granting approvals is the DfT.

Disposal System Safety Case

3.15 The NDA would need to develop a Disposal System Safety Case (DSSC) to cover safety, environmental and transport aspects of any future geological disposal facility.

3.16 The regulators will examine relevant parts of the DSSC as it develops. They will give advice during early interactions with the NDA and shall define specific requirements and/or conditions when considering submissions from the operator for proposed activities under regulatory control. The DSSC will need to satisfy the requirements of all regulators. (It will thus, for example, need to include an environmental safety case – see para. 3.11 above.)

Joint Regulatory Office

3.17 The Environment Agency and HSE have set up a Joint Regulatory Office. This provides a single contact point for communities and other interested parties. Discussions are currently underway between the regulators to develop a specification for the Joint Regulatory Office and, as an initial step, a joint website has been established, <http://www.environment-agency.gov.uk/geo-disposal>. Further information, reports and briefing sheets will be added to the page as appropriate.

4 – When do regulators get involved and therefore how can they exert influence?

4.1 The regulators have no formal regulatory role at present but are already involved in the implementation of MRWS through early engagement with NDA, Government, local authorities and other stakeholders. This period of informal engagement will continue until the Environment Agency receives an application, as part of staged regulatory process, to proceed with intrusive site investigation (that is, for drilling of boreholes) at a candidate site (or sites). The Environment Agency will work closely with the other regulators when deciding whether to grant an environmental permit to allow site investigation to proceed. It is anticipated that a nuclear site licence granted by HSE and an amended environmental permit granted by the Environment Agency would need to be in place before the start of any underground operations.

4.2 During the period of early engagement, the Regulators expect developers to discuss with them:

- any issues likely to be significant to the Regulators;
- reasons for their actions or intentions;

- the options being considered, their merits and the reasons for selecting any preferred option;
- any dependencies on their actions by third parties;
- the management of change throughout all phases of the project.

4.3 In return the Regulators will advise developers on:

- which issues are of interest to them;
- which issues they might regard as important;
- the planned regulatory processes;
- the implications for statutory consultees and views on involving other stakeholders;
- the intended 'end points' of the regulatory processes.

4.4 Advice is framed to give developers guidance on regulatory issues that may arise, while avoiding direct involvement of the regulators in the design process.

4.5 The regulators are already involved in early engagement by voluntary agreement with NDA's Radioactive Waste Management Directorate. This allows regulators to provide advice on, for example, organisational development, and technical programmes including R&D and oversight of specific activities such as provision of waste packaging advice to nuclear site licensees. Further details of the regulators' work are provided in Annex 3. As part of the process, we make information available through reports produced by the Environment Agency's Nuclear Waste Assessment Team and our existing web-site.

5 – How can the community and/or Partnership influence the regulatory process?

5.1 When assessing an application for an environmental permit for the disposal of radioactive waste, the Environment Agency undertakes several activities to engage with local communities. These activities include considering an appropriate scope of consultation, developing documentation to explain the regulatory assessments that have been undertaken, drafting an environmental permit and distributing documents for consultation. In some cases, the consultation may include public surgeries or drop in sessions in local communities. Responses to the consultation are taken into account in the Environment Agency's decision on whether to grant an environmental permit.

5.2 Similar arrangements would apply under staged regulation, which would provide early stakeholder engagement because the statutory regulatory process would start before any intrusive site investigation is undertaken at any candidate site (or sites) for a geological disposal facility. The Environment Agency would consult on its decision on whether to grant an environmental permit and this would involve dialogue with local communities and other interested parties.

5.3 The Environment Agency and HSE have set up a website for a Joint Regulatory Office for the prospective geological disposal facility, where we publish reports of our assessments. The Partnership (and others) will have the opportunity to comment on those assessments via the joint or individual regulators' websites.

5.4 In addition, we have given the Partnership individual contacts to whom members of the Partnership can address questions and provide comment. These are:

HSE: Mick Bacon
mick.bacon@hse.gsi.gov.uk
 0151 951 4099

EA: Gavin Thomson
gavin.thomson@environment-agency.gov.uk
 0191 285 0746

An example: stakeholder influence in developing regulatory guidance

5.5 In 2006, the UK environment agencies started a process for updating their regulatory guidance on the requirements for authorisation of solid radioactive waste disposal facilities (the GRA). An important first stage of the process was to hold two stakeholder workshops (involving the representatives from Government, regulators, the nuclear industry, local authorities, universities, NGOs and the wider public) to consider the draft specification for the updated guidance. The workshops provided a helpful and informative cross-section of views on the draft specifications and clearly indicated that separate versions of the guidance for near-surface disposal facilities and for geological facilities were needed.

5.6 In mid 2007, the UK environment agencies held two further workshops to seek stakeholder input to inform development of the content of the guidance. These workshops provided valuable direction on stakeholders' expectations of the guidance in terms of, for example, the information the guidance should contain and how it should be presented. The environment agencies have taken further account of stakeholders' views in developing final versions of the guidance.

6 – To what extent are the regulators independent?

Health and Safety Executive

6.1 HSE is given direct responsibility for the enforcement of the nuclear safety regulatory system and its independence as a regulator is ensured by HSWA74. There are also governmental mechanisms in place to maintain regulatory independence. HSE is sponsored by the Department for Work and Pensions, which has no role in promoting nuclear technology or responsibilities for facilities or activities. However, the Secretary of State for Trade and Industry is answerable to Parliament for civil nuclear safety in the UK. In this respect HSE can provide factual information to this Minister on matters of nuclear safety regulation, but this Minister is not responsible for HSE's nuclear regulatory actions. HSE works closely with a number of other governmental authorities as it relates to nuclear installation activities. Memoranda of understanding have been established and the independent role and authorities of HSE are well established and understood.

Environment Agency

6.2 The Environment Act 1995 established the Environment Agency and places both general and specific duties on the Environment Agency with regard to conservation and sustainable development. The Environment Agency is an Executive Non-departmental Public Body that is independent of the undertakings it regulates. The Environment Agency is governed by a Board consisting of 15 members including the Chairman and the Chief Executive. The Board is responsible to the Secretary of State for Environment, Food and Rural Affairs and, as an Assembly Sponsored Public Body, it is also responsible to the Welsh Assembly Government. It is through Ministers that the Environment Agency is accountable to Parliament.

6.3 Ministers expect the Board to ensure that the Environment Agency fulfils its statutory duties, in the light of the guidance and directions which they provide, and to ensure that the organisation operates with propriety, regularity, economy, efficiency and effectiveness. The Board delegates the Environment Agency's day-to-day management to its Chief Executive and staff.

6.4 The Board provides an important separation between the Environment Agency's day-to-day decision-making and Ministers. This provides independence in our regulatory role.

6.5 Under the EPR 10 (see 3.6), the Secretary of State or the Welsh Ministers can require any application to be sent to them for determination (regulation 62). This would

be an exceptional step and likely to be taken only if the application involves issues of more than local importance – for example, if the application:

- is of substantial regional or national significance
- is of substantial regional or national controversy, or
- may involve issues of national security or of foreign governments.

Any decision on the need for determination by the Secretary of State or Welsh Ministers would be made solely on those grounds, with no consideration of the substantive merits of the application itself.

The regulator must consult as normal, but would send any representations to the Secretary of State or the Welsh Ministers. The Secretary of State or the Welsh Ministers may choose to arrange a hearing, and would normally do so if the regulator or the operator asks for one.

6.6 Under the ‘polluter pays’ principle, the Environment Agency charges industry for its regulatory activities. The nuclear industry and other users such as hospitals and universities are charged for the regulation of radioactive substances such that the majority of funding for these activities is derived from charges rather than Government grants. The Environment Agency can also charge for advice through voluntary agreements with operators or developers. This provides a mechanism to support early engagement although, as noted above, we would make sure that any advice we might provide would not compromise our regulatory independence. The Environment Agency consults on and publishes its charging scheme each year.

Department for Transport

6.7 DfT is a central government department independent of sponsorship of the nuclear industry. It manages a wide portfolio, including several agencies. Dangerous Goods Division operates within the central Department and comprises an Inspectorate dedicated to act on behalf of the Secretary of State as the UK Competent Authority for the transport of radioactive material. The regulations for road and rail transport of radioactive material are made under the Health and Safety at Work etc. Act 1974, and Dangerous Goods Division Inspectors follow HSE’s Enforcement Policy Statement and Enforcement Management Model.

6.8 DfT does not charge industry for permissioning activities, although when DfT transfers to the Office for Nuclear Regulation it is anticipated that a charging scheme would be introduced.

7 – What resources and resource plans are in place and/or are being developed?

7.1 A geological disposal facility has certain technical aspects that differ from those of other nuclear facilities such as its sub-surface location and the very long timescales involved. The Environment Agency has specialist staff with the necessary training and experience to support its regulatory role in radioactive waste disposal including any future geological disposal facility. Many of these staff are located in our Nuclear Waste Assessment Team based in Penrith. Figure 3 provides an overview of Radioactive Substances Regulation within the Environment Agency.

7.2 During an assessment of an environmental safety case for a geological disposal facility, the Nuclear Waste Assessment Team would also be able to call on wider Environment Agency internal expert resources in areas such as hydrogeology, groundwater protection and chemically hazardous wastes. These resources are already available and are being used; the Environment Agency used its internal knowledge and experience of the groundwater conditions in west Cumbria to inform its recent review of the British Geological Survey’s draft screening report of Allerdale and Copeland.

7.3 Should proposals to host a geological disposal facility go ahead (either in west Cumbria or elsewhere in England or Wales) then the current regulators programme team would be expanded. Initial planning and communication is underway. For example, the Environment Agency could bring in external experts, under contract, to support the review of an environmental safety case. Such experts could include, for example, specialists in seismic interpretation and site characterisation. The Environment Agency has experience in using such experts from both the UK and from overseas, for example, to support its assessment of the environmental safety case for the Low Level Waste Repository.

7.4 In HSE, no new additional skills have been identified as currently needed. HSE continually reviews its resources and skill requirements to ensure that its resources are commensurate with its projected work. In this respect, work on a future geological disposal facility would involve a projection of the likely skills and resources required, and recruitment would be tailored to meet this need.

7.5 The regulators will be liaising with RWMD on plans for the development of a geological disposal facility to predict regulatory resource requirements and ensure that the resource we maintain continues to match the requirement for regulating the GDF as the project develops. This has implications both for numbers of staff and for types and levels of expertise.

7.6 The regulators consider that, at present, we have the level of resource with relevant qualifications and experience that we need. If substantive progress is made with the geological disposal programme over the coming years, we would expect the level of resource that we need to progressively increase. The types of skilled resource required may also change if a geological disposal facility programme progresses.

7.7 The MRWS Site Selection process is presently in its early stages. Therefore significant uncertainties exist in, for example, which sites will be selected for investigation, how many sites will be selected for investigation and when site investigations will start. We use our early engagement with local and national government, communities and NDA to help us understand the likely direction and pace of future development so that we can respond appropriately.

7.8 Regulatory decisions will always be made by our regulatory staff taking account of advice from experts from both the nuclear and the non-nuclear parts of our organisations. We might also engage independent contractors to provide specialist advice to inform our decisions. We recognise, however, that there is only a limited pool of people having relevant expertise. The geological disposal facility developer is likely to wish to retain the services of a significant part of that pool and there may also be competition for UK expertise from overseas. We are conscious of and careful to avoid conflicts of interest, in which the same contractor does work for both the developer and the regulators. To avoid such conflict of interest, we might use independent overseas experts to support our work.

7.9 Ultimately, sufficient resource will only be available if sufficient numbers of young people become suitably trained and qualified. Partly because of the prospective geological disposal facility, the regulators are participating in the recently-established National Skills Academy for Nuclear, the national nuclear graduate scheme, EMPower MSc studentships and developing a strategy for nuclear knowledge management.

Figure 1. Schematic of the proposed regulatory process (Environment Agency & HSE).

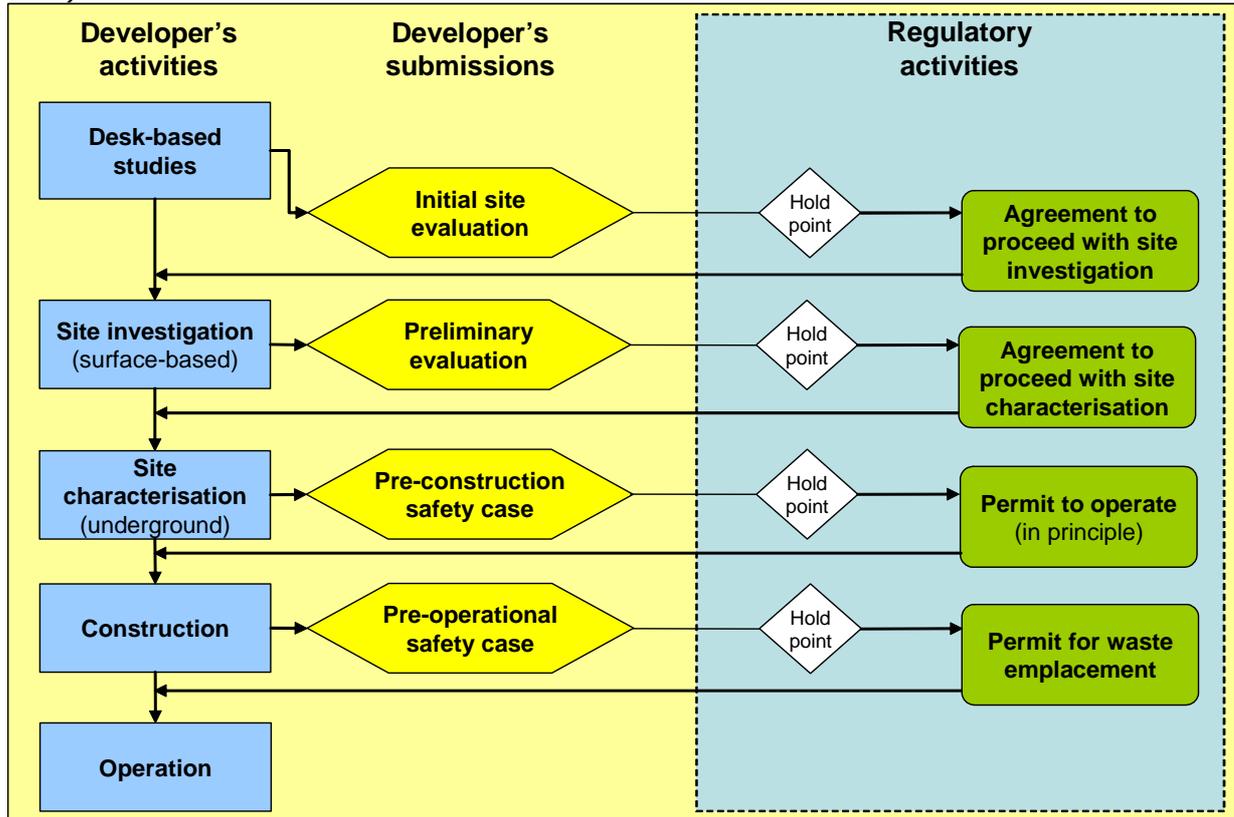


Table 1. The Regulators' expectations.

Stage	Regulators' Expectations
Initial Site Evaluation	<ul style="list-style-type: none"> • Largely qualitative views on the feasibility of constructing a geological disposal facility. • Evaluation of whether a facility might meet the regulator's principles and requirements. • Consideration of siting issues such as density of local population in respect of potential emergency arrangements. • Conceptual views on the operational aspects of the facility.
Preliminary evaluation	<ul style="list-style-type: none"> • Qualitative arguments supported by some quantitative assessment based on available site knowledge and data. • Environmental safety evaluation would need to be consistent with our guidance – but not necessarily show quantitative performance criteria are met. • Developing views on the conventional safety aspects of construction. • Developing views on the operational aspects of the facility.
Preconstruction safety case	<ul style="list-style-type: none"> • Updated safety case to take account of knowledge and understanding gained during construction. • Confirmation that the disposal system meets the principles and requirements of the Regulators. • The safety case must show how the safety assessment principles have been met and demonstrated through a commissioning programme.

Figure 2. Indicative links between staged regulation, nuclear site licensing and the planning process (taken from the GRA).

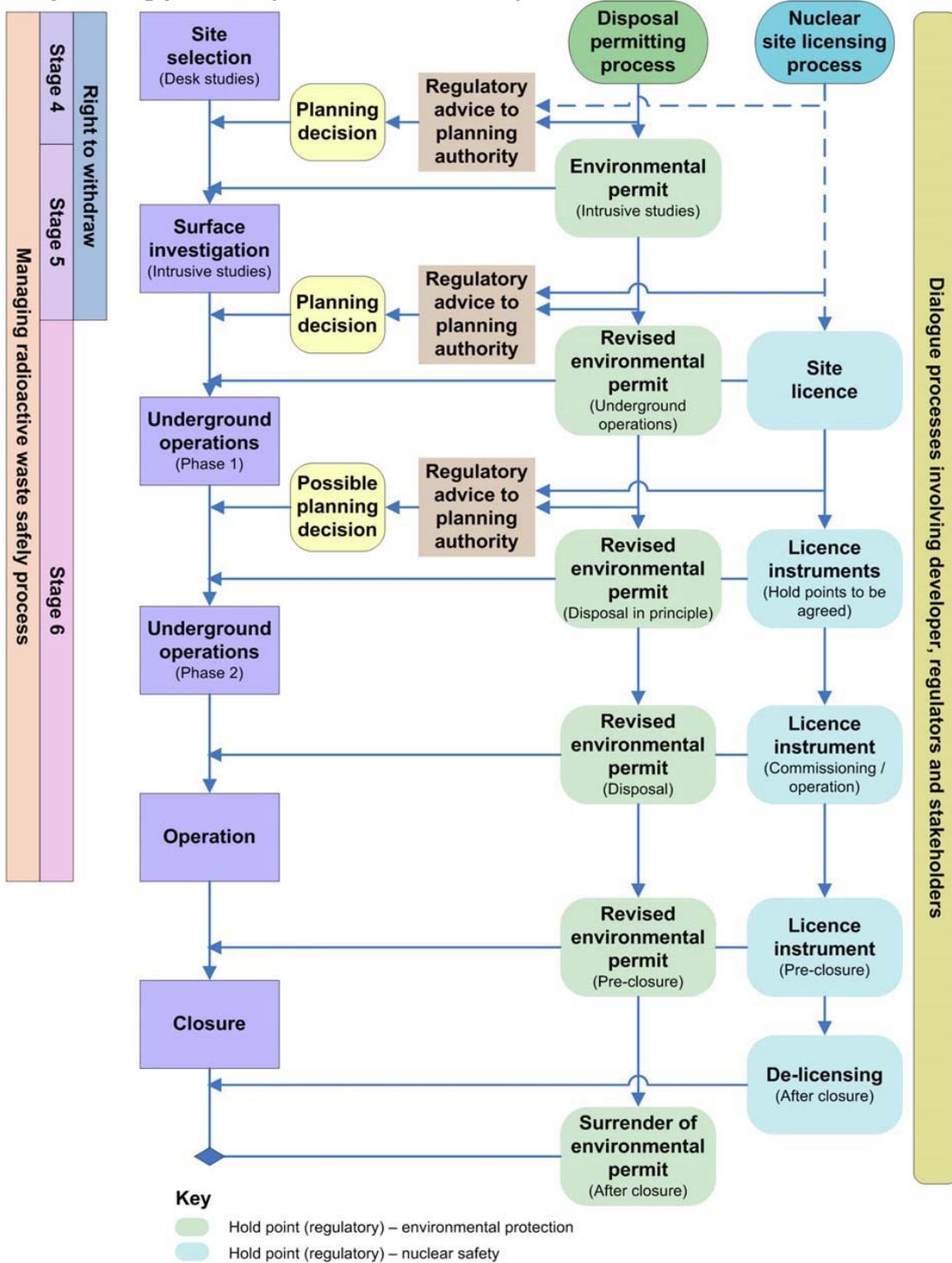
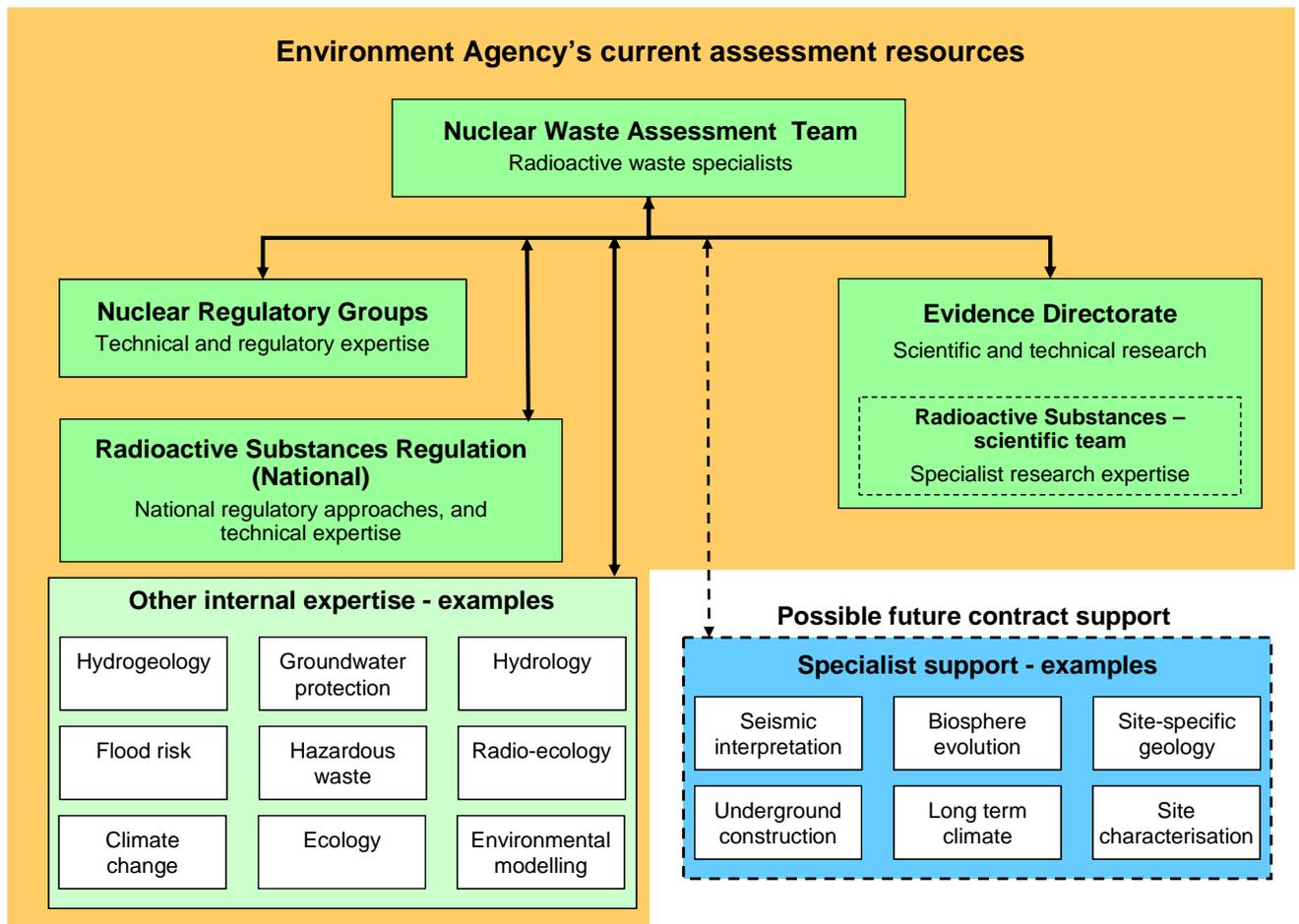


Figure 3. Overview of Radioactive Substances Regulation in the EA.



Annex 1. Further details of the Nuclear Site Licensing process

Assessment of the safety case

HSE will scrutinise the developing safety case to decide whether the operations at the site will be adequately safe. The applicant will generally maintain dialogue with HSE throughout the development of the safety case and as aspects of the design reach the point where their safety can be assessed and submissions are made to HSE. HSE may seek independent data and advice from external sources to help assess the applicant's submissions.

The licensee's organisation

A licence can be granted only to a corporate body and is not transferable. It follows that the licensee must be a company which is also a user of the site. Before granting a licence HSE must be satisfied that the applicant will be using the site for licensable activities and will have an adequate management structure, capability and resources to discharge the obligations and liabilities connected with holding that licence. HSE expects an applicant to develop and submit a safety management prospectus demonstrating its commitment to health and safety. It should provide a clear statement about the company, its structure and how it proposes to operate. HSE expects a licence applicant to have the capability within its own organisation, in terms of staffing and expertise, to understand the safety case for all the nuclear facilities on the site and the limits under which it must be operated. The licensee will need to understand the safety significance of any bought-in expertise and take responsibility for its implementation. This requirement is known as the Intelligent Customer capability.

Mandatory consultation

NIA65 places a requirement on HSE to consult the appropriate environment agency (EA in England and Wales, SEPA in Scotland) before granting a new nuclear site licence. This is to ensure that granting a new licence will not conflict with the relevant environment agency's environmental protection responsibilities, or prejudice any legal process under the Radioactive Substances Act 1993 (RSA93) or other environmental legislation. The arrangements for this consultation are set out in Memoranda of Understanding between HSE and each agency.

Public body notification

HSE has a discretionary power under section 3(3) of NIA65 to Direct a licence applicant to serve notice on certain public bodies local to the site in question. This is to ensure that relevant public bodies have an opportunity to comment and to suggest anything that, from the point of view of their own statutory responsibilities, ought to be provided for in the conditions attached to the licence. Such bodies include local authorities, emergency services, river authorities, fisheries committees, statutory water undertakings, national parks authorities where appropriate and other public or local authorities.

In deciding whether to Direct an applicant to undertake public body notification, the key factors considered by HSE are the significance of the development applied for, the related impact on public bodies' duties and activities associated with a site, and consistency with previous use of HSE's discretionary powers.

HSE regulation post-licensing

Once a licence has been granted to allow installation of new facilities, HSE's regulatory activities will focus on equipment procurement, construction, installation and commissioning issues and the development of the licensee's organisation. HSE will often use the powers provided by the site licence conditions to apply a number of regulatory hold-points. Hold-points are agreed between the regulator and the licensee and are linked to defined activities requiring HSE's consent before they may proceed. Hold-points provide regular 'review points' during the project, and are vital for both

licensee and regulator, as they give a formalised framework for resolving concerns before they become critical.

HSE's Safety Assessment Principles (SAPs)

The SAPs¹⁴ apply to the assessment of safety cases for nuclear facilities that may be operated by potential licensees, existing licensees, or other dutyholders. The principles relate to nuclear safety and radioactive waste management, and provide HSE's inspectors with a framework for making consistent regulatory judgements on safety cases. The principles are supported by Technical Assessment Guides (TAGs), and other guidance, to further assist decision making by the nuclear safety regulatory process (see the HSE website). The SAPs also provide nuclear site dutyholders with information on the regulatory principles against which their safety provisions will be judged. However, they are not intended or sufficient to be used as design or operational standards, reflecting the non-prescriptive nature of the UK's nuclear regulatory system.

¹⁴ Safety Assessment Principles for Nuclear Facilities, HSE 2006.
<http://www.hse.gov.uk/nuclear/saps/saps2006.pdf>

Annex 2. Further details of the disposal permitting process

The following text is taken from the recently updated Guidance on Requirements for Authorisation and provides some further detail of the disposal permitting process that would be undertaken by the Environment Agency during a staged regulatory process.

5.4 Staged authorisation¹⁵

5.4.1 If suitable powers are provided, staged authorisation would start when a developer decides to proceed with intrusive site investigation at a candidate site (or sites). An indicative process for staged authorisation is shown in Figure 5.2.

5.4.2 Staged authorisation would provide:

- strong, independent environmental regulation, with enforceable regulatory decisions from the outset of intrusive site investigation;
- hold points beyond which a developer cannot proceed without regulatory approval;
- assurance to us, a potential host community, local and national government, and other interested parties that there are good reasons for proceeding with the next stage of development and that the facility is likely to meet environmental safety requirements;
- a greater degree of regulatory certainty for the developer. Statutory regulatory decisions should provide a better basis for a developer's planning timetable and investment programme, compared with a process based solely on voluntary agreement and regulatory advice.

5.4.3 Staged authorisation would also benefit potential host communities, other interested parties and the general public by providing a clearly defined basis for discussion of environmental matters. This would help to provide reassurance over the development path being followed.

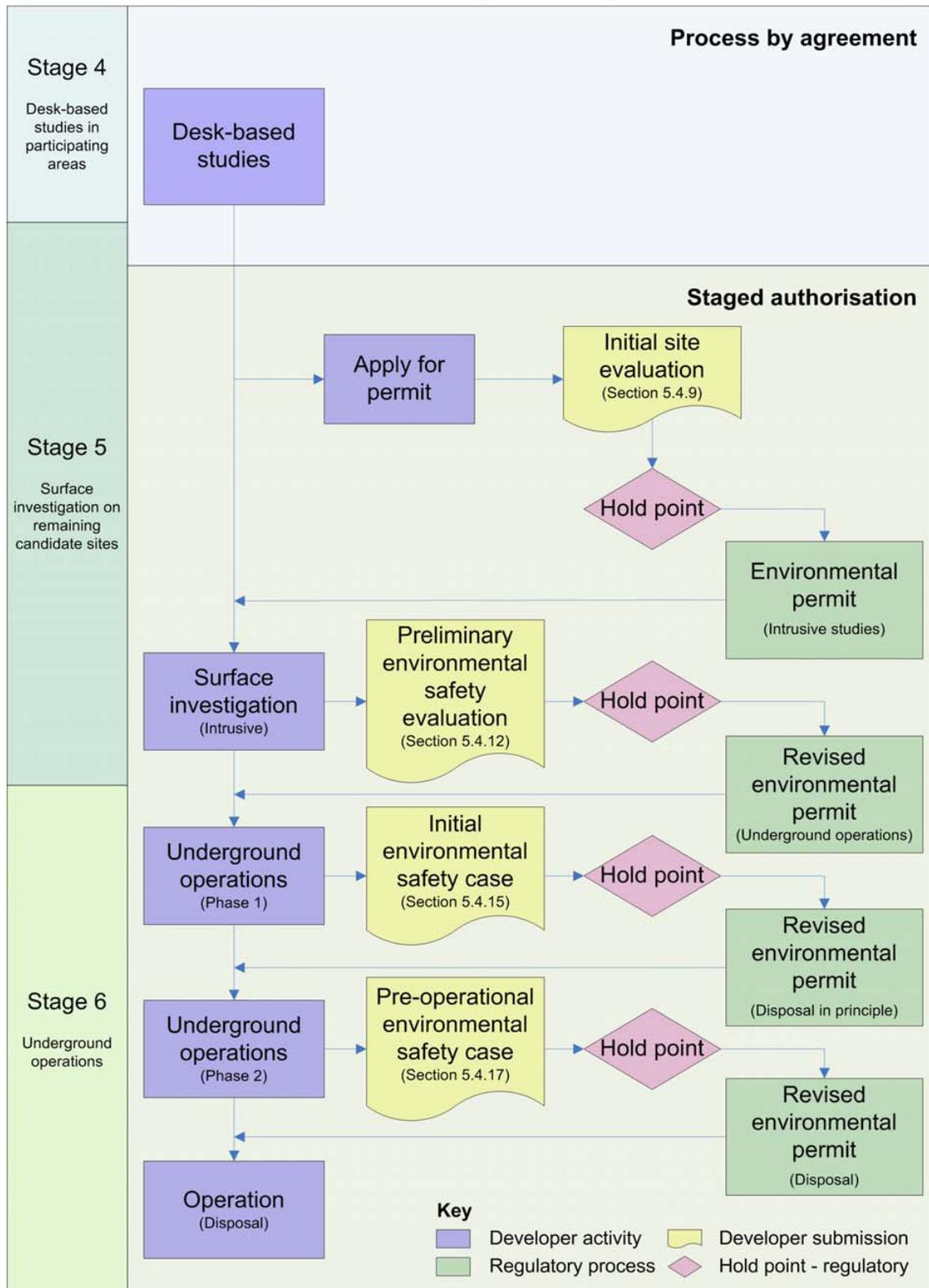
5.4.4 As part of staged authorisation, we shall agree a series of hold points at important stages in the facility development programme with the developer. Some possible hold points are shown in Figure 5.2 and these are discussed further below in paras 5.4.9-5.4.19. At each hold point, the developer will need to submit an updated environmental safety case to provide continuing assurance that the site will meet regulatory requirements. If we are satisfied with the environmental safety case at a particular hold point, we shall grant approval for the facility to continue to be developed beyond the hold point. We shall do this through an environmental permit, subject to limits and conditions we consider appropriate at that time. The authorisation conditions might specify actions such as research and development work that the developer will need to carry out before the next hold point.

5.4.5 At each hold point, the developer will need to provide a forward work programme for us to review. This will identify the proposed work during the next phase of development including discussion of how any regulatory issues will be addressed. It could also include a proposed programme of published submissions for regulatory review covering, for example, site investigation, engineering design work or supporting research and development studies. We shall review proposals and submissions and publish our findings as part of a continuing process of discussions with the developer, the potential host community and other interested parties.

¹⁵ **Note:** Since publication of the Guidance on Requirements for Authorisation, the preferred term has become staged regulation rather than staged authorisation. This better reflects the Environmental Permitting Regulations that will be used to implement staged regulation.

5.4.6 Between hold points, our intention will 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.

Figure 5.2 Indicative process for staged authorisation of a geological disposal facility
MRWS
process
Indicative activities in developing a geological disposal facility



5.4.7 The nature and content of the environmental safety case will depend on what is known and understood about the selected site, the stage of development of the

facility and what decisions have to be made at the time. In paras 5.4.9 to 5.4.19 below, we give an indication of what we might expect at some potential hold points. The hold points and types of environmental safety case are illustrative and will be subject to discussion and agreement between us and the developer at an early stage of any programme for developing a geological disposal facility. Also we shall aim to agree hold points that coincide with other decision points in the development programme such as submission of planning applications or regulatory hold points under the Nuclear Installations Act 1965 (HMSO 1965).

- 5.4.8 It is expected that staged authorisation will start with an application by the developer for an environmental permit to proceed with intrusive site investigation. We shall discuss the timing, nature and content of the application with the developer. This is likely to be after one or more sites have been selected for intrusive site investigation, for example, before any programme of borehole investigations starts. At this point, the developer would be planning to commit a significant amount of money and time to evaluating one or more potential sites for a geological disposal facility.
- 5.4.9 **Initial site evaluation** – At the hold point before an intrusive site investigation programme begins, we would expect an ‘initial site evaluation’, giving largely qualitative views on the feasibility of constructing a geological disposal facility at the potential site and whether such a facility might meet the principles and requirements of this guidance. We shall need to understand from the initial site evaluation how the developer might construct the environmental safety case (See Chapter 6 and 7) for such a facility.
- 5.4.10 If the developer has made an acceptable application and submitted a suitable initial site evaluation then we could grant an environmental permit to proceed with site investigation subject to any conditions or limits that might be imposed. The developer could then proceed with site investigation including borehole studies to investigate the geological formation at the selected site or sites.
- 5.4.11 At this stage, our regulatory aim will be to ensure that any proposed intrusive site investigation will not compromise the integrity of a candidate site to the unacceptable detriment of the long-term environmental safety case for a possible geological disposal facility. We shall also want to ensure the adequacy of a developer’s proposals for collecting information and data to support a decision to start underground operations.
- 5.4.12 **Preliminary environmental safety evaluation** - A developer might decide to proceed with underground operations (Underground operations (Phase 1) in Figure 5.2) at a candidate site, to provide additional information to inform the developing environmental safety case for a geological disposal facility. We shall require a developer to submit a ‘preliminary environmental safety evaluation’ to support a request for a revised environmental permit. This might present qualitative arguments supported by limited quantitative assessment based on available site knowledge and data. At this hold point, the preliminary environmental safety evaluation would need to be consistent with this guidance.
- 5.4.13 Subject to the outcome of a regulatory review of the preliminary environmental safety evaluation we could grant a revised environmental permit, with appropriate limits and conditions, to allow the developer to start underground operations, including underground excavations for investigating the characteristics of the geology.
- 5.4.14 At this stage, we would expect a developer to be able to demonstrate that underground operations would not compromise the integrity of a candidate site to the unacceptable detriment of the environmental safety case for a possible

geological disposal facility. We would also expect a developer to have in place a work programme aimed at collecting information and data to support a decision to move to the next stage of development.

- 5.4.15 **Initial environmental safety case** – A developer might decide to proceed to a second, substantially increased, phase of underground operations (Underground operations (Phase 2) in Figure 5.2). At this hold point we would require the developer to submit an 'initial environmental safety case' to support a request for a variation to the environmental permit.
- 5.4.16 The initial environmental safety case will need to provide enough evidence to inform a decision on whether we can grant an authorisation for disposal in principle. The authorisation could include a condition that a 'pre-operational environmental safety case' will be required before any radioactive waste can be placed in the facility. It could also include conditions specifying scientific and technical work deemed necessary to inform a decision to move to the next stage of development and to support the pre-operational environmental safety case.
- 5.4.17 **Pre-operational environmental safety case** – At this final hold point before waste is placed in the disposal facility we would expect a 'pre-operational environmental safety case', updated to take account of knowledge and understanding gained during underground operations. This will need to show that the disposal system meets the principles and requirements of this guidance. It will provide a basis for us to decide whether to grant an amended authorisation to allow waste disposal to start.
- 5.4.18 We would expect the pre-operational environmental safety case to provide a sound scientific and technical basis for a decision to grant a revised authorisation to allow solid radioactive waste to be placed in the facility. We would also expect the developer to set out a programme of work to provide information and data to inform decisions on further development of underground facilities that might be required to meet operational needs.
- 5.4.19 After any environmental permit for disposal has been granted, a geological disposal facility will be subject to the same regulatory process that applies to other nuclear facilities. This will require periodic reviews of the authorisation over the lifetime of the facility and submission by the operator of an updated environmental safety case at agreed intervals. The regulatory process would continue beyond closure of the facility and would only end when we accept surrender of the environmental permit. This decision would be based on regulatory review of a final environmental safety case submitted by the operator after closure of the facility (see Section 5.6).

Annex 3. Current regulatory scrutiny

The Regulators are continuing to review the NDA's scientific and technical programme that supports the development of a geological disposal facility, in advance of any formal regulatory submission, in order to provide early advice and avoid unnecessary delays and possible problems later on. The Environment Agency's Nuclear Waste Assessment Team has a formal agreement with the NDA to scrutinise the work of the NDA's Radioactive Waste Management Directorate (RWMD). This includes assessing the RWMD's work on geological disposal concepts and the Letter of Compliance Process¹⁶. The following reports are available, upon request, from the Environment Agency (Nrg.North@environment-agency.gov.uk):

- Nirex's Derivation of the 2003 Assessment Inventory and Implications of the Associated Uncertainties Environment Agency Report NWAT/Nirex/04/001, published December 2004;
- NWAT Assessment of Nirex's Approach to the Setting of Fissile Limits for Waste Packages and Assessment of Possible Post-closure Criticality Events. Environment Agency Report NWAT/Nirex/04/002, published April 2005;
- Review of Nirex's Letter of Compliance Process. Environment Agency Report NWAT/Nirex/05/001, published November 2005;
- Review of Nirex Report: 'The Viability of a Phased Geological Repository Concept for the Long-term Management of the UK's Radioactive Waste';
- Review of the New Style Nirex Letter of Compliance Assessment Report. Environment Agency Report NWAT/Nirex/05/003, published November 2005;
- Review of the New Style Nirex Letter of Compliance Assessment Report. Environment Agency Report NWAT/Nirex/05/004, published February 2006;
- Review of the Context of the Nirex Generic [post closure] Performance Assessment. Environment Agency Report NWAT/Nirex/06/001, July 2007;
- Review of Nirex's Understanding and Representation of Near-field Processes in the Phased Geological Repository Concept. Environment Agency Report NWAT/Nirex/06/002 published March 2007;
- NWAT Scrutiny of NDA/RWMD work: Annual Review 2001/2008. Environment Agency Report NWAT/NDA/RWMD/08/001, published March 2008;
- The longevity of ILW packages for geological disposal: A Review. Environment Agency Report NWAT/Nirex/06/003, published August 08;
- Review of the Nirex Research Programme. Environment Agency Report NWAT/Nirex/06/005 published August 2006;
- Gas generation and migration from a deep geological repository for radioactive waste: A review of Nirex/NDA's work. Environment Agency Report NWAT/NDA/RWMD/2008/002, published September 2008;
- Joint regulatory review by the Environment Agency, HSE and DfT of the NDA's development of an organisation to implement geological disposal of radioactive waste, published December 2009;
- Environment Agency scrutiny of NDA/RWMD's work relating to the geological disposal facility: Annual Review 2008/09, published January 2010;
- Environment Agency scrutiny of NDA/RWMD's work relating to the geological disposal of higher-activity: Annual Review 2009/10, published November 2010;
- Geophysical surveying techniques to characterise a site for a geological disposal facility: A review of recent developments and NDA's proposals. Environment Agency report (in prep).

The Health and Safety Executive, the Environment Agency and the Department for Transport will operate a joint issues resolution process when they assess the RWMD's submissions supporting implementation of geological disposal. The issues resolution process is intended to capture issues that the regulators consider may impact on future

¹⁶ Through the Letter of Compliance process, NDA's RWMD advise licensees on whether proposed waste packages are expected to be suitable for geological disposal.

regulatory decisions, that cannot otherwise be addressed quickly and simply by discussing them directly with RWMD¹⁷.

The management and subsequent disposal of radioactive waste covers a wide range of activities including:

- Storage, either in an untreated form or packaged for disposal;
- Treatment for storage or disposal;
- Transport to a disposal or storage site;
- Disposal.

All these activities shall be subject to control by the application of existing and/or development statutory arrangements, as discussed elsewhere in this document.

¹⁷ You can find more information on the joint issues resolution process on the regulators' joint website <http://www.environment-agency.gov.uk/business/sectors/111766.aspx>