

Regulatory scrutiny of RWMD's work relating to geological disposal of radioactive waste: Summary of work (April 2010 to March 2012)

Issue 1.0 March 2013

We would welcome your feedback on this document.

Please send comments to:

geological.disposal@environment-agency.gov.uk

or to:

GDF Programme Office,
Nuclear Regulatory Group,
Environment Agency,
Ghyll Mount,
Penrith 40 Business Park,
Penrith,
Cumbria
CA11 9BP

For more information on how we regulate geological disposal visit the joint Regulators' web site at:

<http://www.environment-agency.gov.uk/geological-disposal>

Published by:

Environment Agency
Horizon house, Deanery Road,
Bristol BS1 5AH
Email: enquiries@environment-agency.gov.uk
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Foreword

This is a joint publication by the Environment Agency (EA) and the Office for Nuclear Regulation (ONR)¹

In this document we provide a summary of the work we carried out between April 2010 and March 2012 to scrutinise, and advise on, the work of the Nuclear Decommissioning Authority (NDA) Radioactive Waste Management Directorate (RWMD), relating to implementing geological disposal for higher activity radioactive waste. This includes work to oversee RWMD's Letter of Compliance process through which it provides waste packaging advice to nuclear site operators. We explain what we looked at, our key messages to RWMD to the end of the reporting period (March 2012), and our planned work areas for 2012/13. We provided RWMD with a pre-publication version of this document for comment on factual accuracy.

This work forms part of our continuing programme to review RWMD's work related to geological disposal. As independent Regulators, we are committed to making our work open and transparent.

¹ The Office for Nuclear Regulation (ONR) was formed in April 2011 from the Nuclear Directorate of the HSE. It was joined by the Radioactive Materials Transport team from the DfT in July '11. This report covers a period (2010 to 2012) while these changes were happening.

Executive summary

This report summarises the work we carried out, between April 2010 and March 2012, to scrutinise and advise on the work of the Nuclear Decommissioning Authority's (NDA) Radioactive Waste Management Directorate (RWMD) on implementing geological disposal (including its provision of packaging advice to nuclear site operators via its Letter of Compliance (LoC) process).

Key outcomes from our work are:

- We provided comment on regulatory matters to help RWMD improve its 'Disposability Assessment Policy and Principles' (DAPPs) which will be a key document in support of operational and decommissioning activities at nuclear licensed sites. We expect RWMD's final published document in 2012/13 will have addressed our comments.
- We provided comment on RWMD's developing disposability assessment procedures and waste packaging guidance and RWMD has committed to updating its documentation in 2012/13. RWMD now publishes executive summaries from its Letter of Compliance process, on the NDA web site, which we think is a significant step forward.
- Through our review of RWMD's generic Disposal System Safety Case (gDSSC), we helped RWMD understand what is required from its environmental, operational and transport safety cases to support any application for development and operation of a Geological Disposal Facility (GDF).
- We consider that RWMD's gDSSC provides confidence, to a degree appropriate at this early stage in implementing geological disposal, that a safety case for a GDF in the UK could be made, providing a suitable site is available.
- We set out clearly a list of recommendations to help RWMD develop its Disposal System Safety case (DSSC) in the future. RWMD has told us how it is addressing (or intends to address) these recommendations. We will monitor progress through our ongoing scrutiny work.
- We worked with RWMD to help improve its 'Permissions schedule for geological disposal of higher activity radioactive waste'. We consider it now sets out clearly the sequence of submissions, assessments and permissions needed to implement a GDF, and provides a good baseline for further development as implementation of Managing Radioactive Waste Safely (MRWS) progresses.
- Our discussions with RWMD on our requirements and expectations of an Initial Site Evaluation (ISE) (to support any application for a permit to start intrusive site investigation) helped us develop our internal guidance for regulatory review of an ISE and helped guide RWMD's work in developing an ISE.
- We worked with RWMD to explain our requirements on sustainability and environmental assessment, enabling them to develop documents that will address our regulatory requirements.
- RWMD has made good progress towards developing as a prospective site licence company. We established regular, working-level interaction with RWMD to review their progress in this respect, so that NDA can develop its RWMD into an organisation that we are satisfied is suitable to hold the necessary permits and licences to build and operate a GDF. Our input informed and helped RWMD improve a number of key management documents such as its business case (for subsidiary formation), and its Safety and Environmental Prospectus.

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1. Introduction

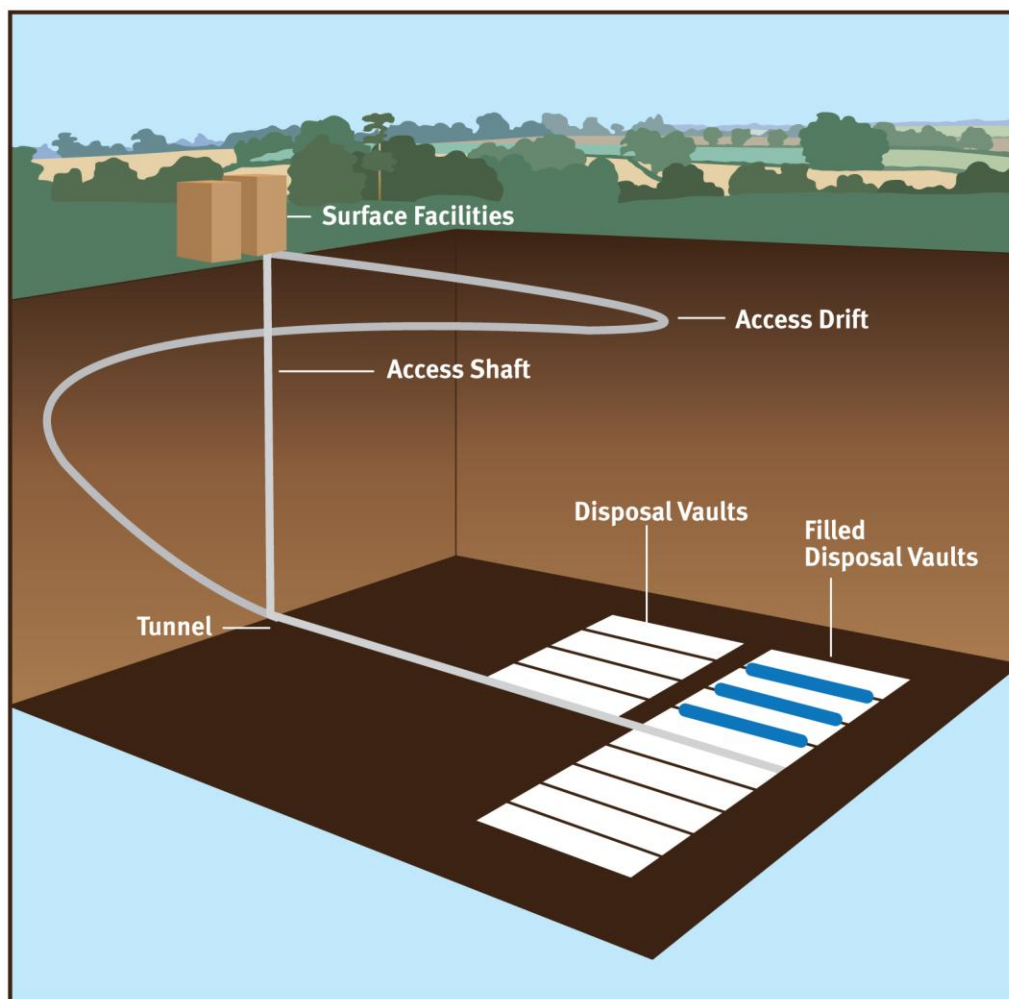
Radioactive waste arises from the UK's historic and ongoing nuclear power, research and defence programmes. To date there is no disposal route for the waste generated that is termed Higher Activity Waste (HAW). Instead, HAW is stored on nuclear sites awaiting a disposal solution. HAW continues to be produced from nuclear sites and in smaller amounts from other users of radioactive material such as industry, hospitals and universities. New nuclear power stations, proposed for England and Wales, would add to the amount of waste produced.

Government policy for the long-term management of HAW is explained in the Managing Radioactive Waste Safely (MRWS) White Paper (Cm 7386, June 2008) [1] – 'A framework for implementing geological disposal' and comprises geological disposal preceded by safe and secure interim storage. The Department for Energy and Climate Change (DECC), supported by the Nuclear Decommissioning Authority (NDA), is leading the MRWS process. The NDA's Radioactive Waste Management Directorate (RWMD) is responsible for implementing a programme to develop a geological disposal facility (GDF). Figure 1 illustrates the general expected layout of a GDF.

The EA and ONR will regulate any future GDF for radioactive waste in England and Wales. We are working together to make sure that any future facility meets the required high standards for environmental protection, safety, security and radioactive waste transportation. Prior to formal regulation, we (the Environment Agency (EA), the Health and Safety Executive (HSE) and the Department for Transport (DfT))¹ established agreements with RWMD to provide advice and scrutiny of matters within our respective regulatory remits in relation to implementing geological disposal.

Our early dialogue will enable RWMD to understand our permitting and licensing requirements and prepare any applications to us, including, for example, the associated safety cases that we require in support of permitting or licensing applications. Similarly, our scrutiny work will allow us to prepare for any applications we receive from RWMD, in order to respond in an informed and timely manner. We hope that our work will also be useful to others in introducing our standards and requirements for a GDF and in providing insight into how we will ensure these are met in any future applications.

Each year we develop a programme of work to scrutinise RWMD's work relating to implementing geological disposal. This includes work to oversee RWMD's Letter of Compliance process through which it provides waste packaging advice to nuclear site operators. This report provides a summary of the work we carried out between April 2010 and March 2012. Our programme is organised into eight areas of work (or "tasks"). We report the advice we have provided to RWMD during the reporting period (April 2010 to March 2012) in these eight work areas in sections 2 to 9, and for each work area we conclude by discussing our priorities for scrutiny in 2012/13.



Operational geological disposal facility

Figure 1 Illustration of the general expected layout of a geological disposal facility

1.1. Our role in geological disposal

The Environment Agency

In addition to many other duties, the Environment Agency is responsible for regulating disposals of radioactive waste from nuclear licensed sites, and other premises that use radioactive substances. Disposals of radioactive waste include any discharges into the atmosphere, surface waters and groundwater, disposals by transfer to another site and disposal to land including geological disposal.

The Environment Agency will regulate the development of any future GDF under the Environmental Permitting (England and Wales) Regulations 2010, using a process known as 'staged regulation'. This process only applies to geological disposal. Figure 2 illustrates how staged regulation might work, up to the start of disposal operations at a GDF. Staged regulation provides regulatory control from very early in the development of a GDF and enables us to maintain regulatory control throughout each stage of development from the start of intrusive site investigation, through construction and operation, and eventually to closure. The developer will

need regulatory approval before each stage of development can begin and, in particular, disposal of radioactive waste will not be allowed without the appropriate environmental permit.

The Office for Nuclear Regulation

The Office for Nuclear Regulation was launched on 1 April 2011 as an agency of the Health and Safety Executive. The ONR brings together the safety and security functions of HSE's former Nuclear Directorate together with the functions of the Department of Transport's former Radioactive Materials Transport Team, which was responsible for regulating the transport of radioactive material by road, rail or inland waterway. Formation of the ONR brings regulation of civil nuclear safety, radioactive material transport safety, and nuclear security into one organisation. The ONR seeks to secure the protection of people and society from the hazards of the nuclear industry, by ensuring compliance with relevant legislation and by influencing the nuclear industry to create an excellent health, safety and security culture.

1.2. Implementing MRWS: The regulatory process

No decisions have yet been made on selecting a site or the timetable for developing a GDF. DECC is leading the process of identifying a site for a GDF. We have no formal regulatory role in selecting a site for a GDF. During the site selection stage, we will provide advice and comment on environmental, safety and transport matters within our regulatory remits and we will aim to make this advice available to the public.

Should a site be selected for developing a GDF, we would be responsible for making sure that any future facility meets the required high standards for protecting people and the environment when it is being developed, while it is operating, and after it has closed, and we would be responsible for granting the necessary licences and permits throughout this period. Regulatory control is likely to be required for many decades and possibly for more than a century. Figure 3 shows the links between a possible development programme for a geological disposal facility and the regulatory processes.

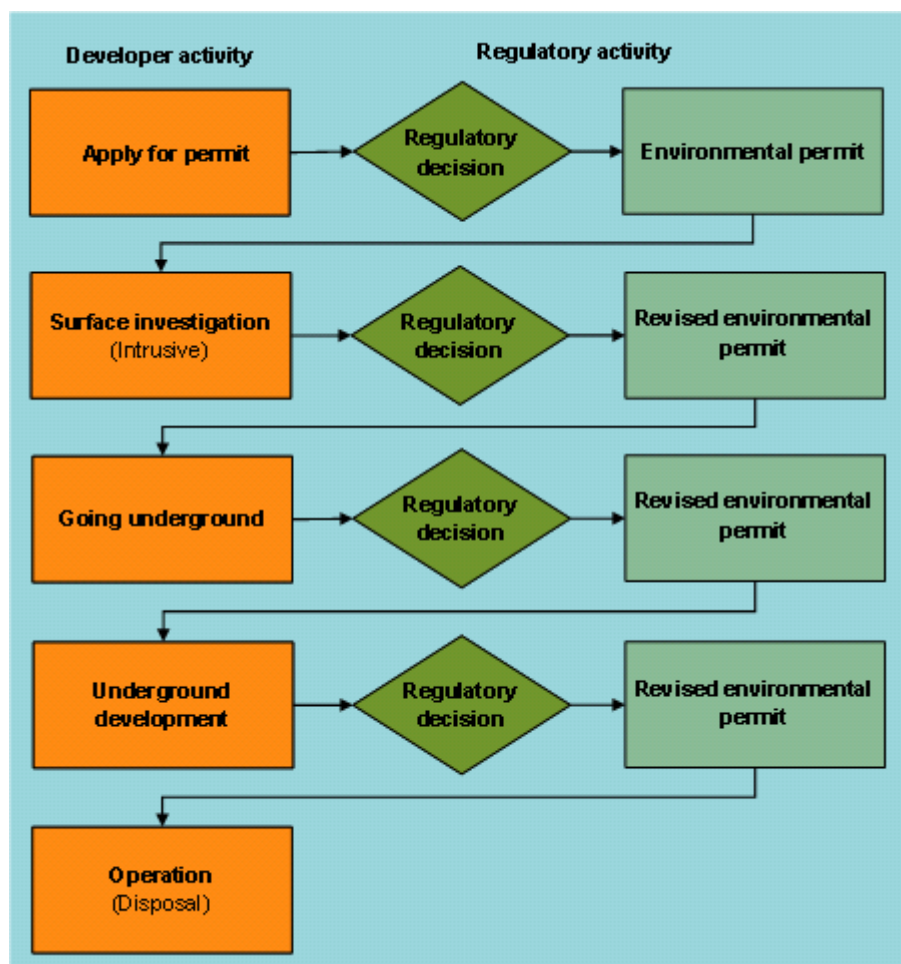


Figure 2 Environment Agency: Staged regulation

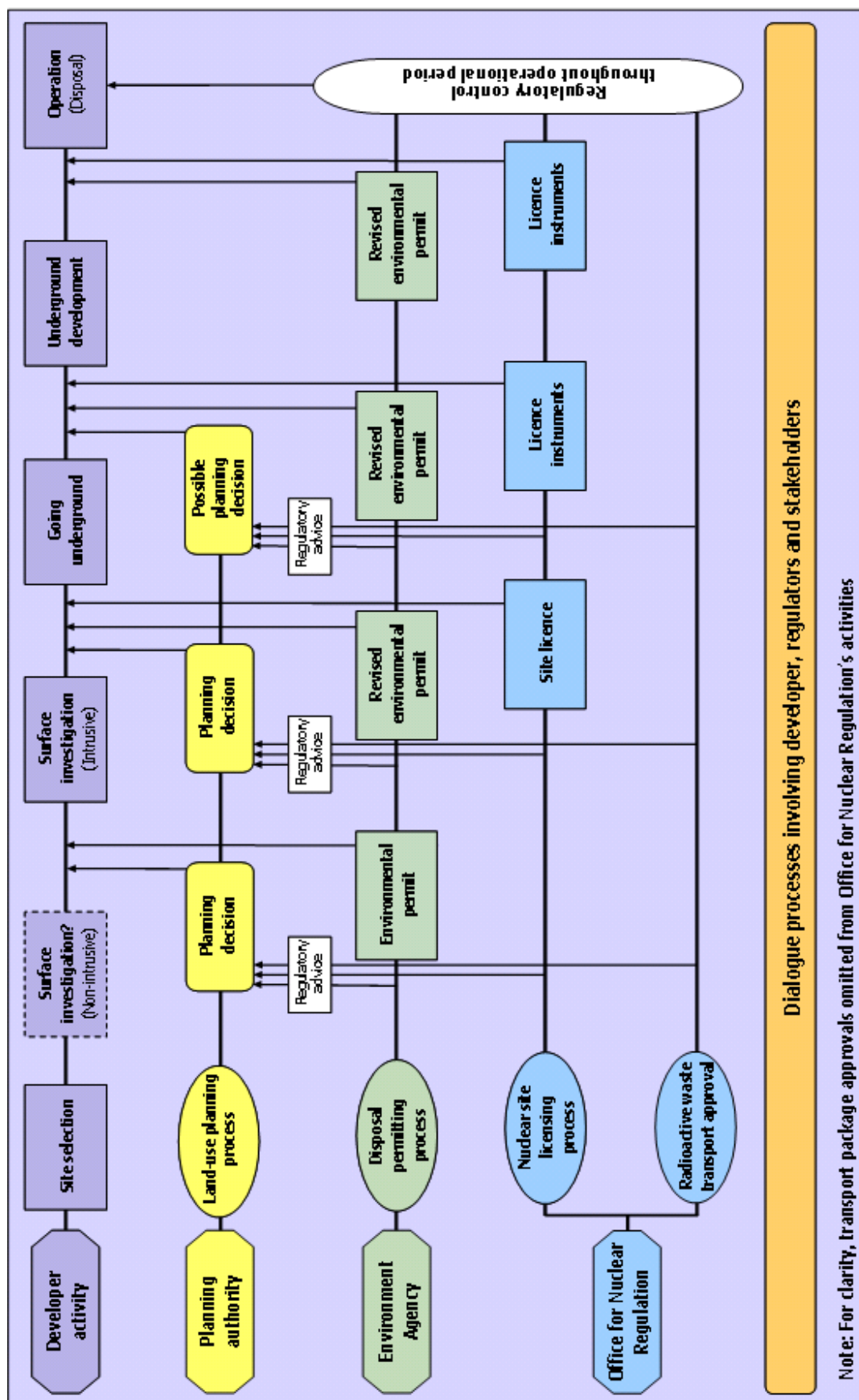


Figure 3. Links between a possible development programme for a geological disposal facility and the regulatory processes

2. Planning for implementing geological disposal

We want RWMD to understand the licensing and permitting activities necessary to enable it to take forward its responsibilities for developing a GDF. In particular, we will explain what information we need from RWMD in its applications and supporting documentation at each stage in the process. We want to avoid unnecessary delays that might result if RWMD provided inappropriate or incomplete information in support of any licence or permit application.

2.1. The application and permissioning process

We continued to provide advice to RWMD on our expectations of the submissions required under the staged permitting process and the planning of its work to produce them.

Permissions schedule

RWMD's 'Permissions Schedule for Geological Disposal of Higher Activity Radioactive Waste' sets out diagrammatically the sequence of submissions, assessments and permissions needed to implement a GDF, and provides detail about them, and the associated regulatory processes, in the accompanying text. The Permission Schedule covers:

- Environmental protection.
- Safety.
- Land-use planning.
- Transport safety.
- Nuclear security.
- Non-proliferation (nuclear safeguards).
- Certain non-permissioning activities associated with the site selection process.

We provided comment [2, 3, 4, 5, 6] on RWMD's draft permissions schedule [7, 8] at various stages of development. Our comments included the need to:

- Clarify the status and purpose of the generic assessment process.
- Group together all permissions relating to environmental protection, to clarify that the scope of environmental protection extends beyond radiological aspects.
- Include a section which addresses the requirements for RWMD to develop into a body that the Regulators consider is capable of holding the various licences and permits needed to develop, operate and close a GDF.
- Use the term "Candidate Site Evaluations" for the set of documents that RWMD plans to prepare within MRWS Stage 4, rather than "Initial Site Evaluation reports", to avoid confusion with the Initial Site Evaluation (ISE) required at MRWS Stage 5.
- Engage with ONR over its plans to provide initial nuclear and transport safety assessments when applying for planning permission to carry out intrusive site characterisation activities (MRWS Stage 5).

We were satisfied with the way RWMD responded to our comments in producing the published version [9]. We consider this final version now provides a good baseline for further development as implementation progresses and we note that RWMD intends to update the document periodically

to reflect changes to legislation and regulatory requirements. For example, there is uncertainty as to how the Management and Administration of Safety and Health at Mines Regulation 1993 will apply to the development of a GDF, and we will engage with RWMD on this as the programme progresses. We will maintain our dialogue with RWMD with respect to the developing Permissions Schedule, through our ongoing scrutiny programme.

Steps towards implementation

RWMD published its "Steps towards implementation" report in July 2010 [10]. We provided comment on drafts (as reported in our 2009/10 annual review) and we are satisfied that RWMD has taken our comments into account adequately in this published version. In particular, we note that RWMD restructured the document significantly, in response to our suggestions. The document now presents information clearly (including a number of helpful diagrams and photographs) and in a format and language accessible to wide range of audiences.

Initial Site Evaluation (ISE) and Preliminary Environmental Safety Evaluation (PESE)

An ISE is required to support an application for an environmental permit to start intrusive site investigation at a candidate site for a GDF (MRWS Stage 5). We met with RWMD to discuss our draft internal guidance to assessors. We explained that their ISE will need to:

- Explain why the candidate site has been selected for investigation.
- Describe the proposed site characterisation programme and its objectives and success criteria.
- Provide an overview of the proposed development programme including any supporting Research and Development (R&D).
- Explain how information obtained through intrusive site investigation is likely to be used to inform a subsequent PESE, that we would expect in support of any application to proceed with underground development.
- Address all relevant environmental considerations including groundwater protection, waste management, waste discharge and water abstraction.

Our specific expectations for an ISE are set out in the Environment Agencies' Guidance on Requirements for Authorisation (GRA) [11]:

"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 for such a facility.

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.

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."

Our ISE guidance provides advice to our assessors for reviewing an ISE. Once completed we will publish this guidance to provide information for interested people. We are preparing similar internal

guidance for reviewing a PESE; this is still being developed and, in due course, will also be released externally for information.

2.2. Acceleration of implementation

The Government [12] wanted to go forward with the ambition of seeing the first waste put into a geological disposal facility by the end of 2029 and tasked NDA to look at opportunities for accelerating progress. Ministers emphasised that it was not Government's intent to rush the public engagement or local decision making processes, but rather to look at some of the later technical stages and scheduling to ensure ongoing focus on efficiency, innovation and effective programme management.

We provided advice to RWMD on its draft report on acceleration of implementation, noting that any options for acceleration would need to be consistent with the MRWS volunteerism process, and would need to meet the regulatory requirements. We encouraged RWMD to highlight in the report the potential risks, consequences, and uncertainties associated with acceleration, in order that their significance is not underestimated. RWMD took our advice into account for its initial report that it submitted to DECC and published [13]. Ministers have since asked The Committee on Radioactive Waste Management (CoRWM) and The Royal Academy of Engineers to review RWMD's work. We will continue to engage with RWMD on the future development of its programme.

2.3. Planning assumptions

We reviewed the planning assumptions that RWMD used to develop the site selection process plans (for Stage 4 & initial Stage 5) & the accompanying Gantt Chart covering MRWS Stage 4 & initial boreholes permissions [14]. We suggested RWMD could improve the documents by using terminology consistent with the MRWS White Paper and we provided a number of detailed comments on the specific assumptions presented in RWMD's document [15].

We requested RWMD to clarify whether it intends to review and update the assumptions in the documents when necessary, and whether it intends to publish these documents.

2.4. GDF programme planning

We attended a meeting with RWMD to discuss its geological disposal programme planning activities and future plans. The meeting was also attended by members of CoRWM, who prepared and published a note of the meeting [16]. RWMD's "five year plan" presents its preparations for MRWS Stage 4 through to the early part of Stage 5 (a period of about 9 years), noting that Stage 4 cannot start until there is a positive Decision to Participate (DtP) and a Siting Partnership is in place. RWMD's Provisional Implementation Plan (PIP) describes the skills and resources required to implement geological disposal. RWMD is currently updating the PIP, to align it with the five year plan, and intends to publish a summary of it. We will continue to review RWMD's PIP as it develops.

2.5. RWMD's draft engagement profiles

We provided comment [17] on RWMD's draft engagement profile paper [18]. We believe the paper provides a useful framework for our current interactions. We noted, that it should be a live document, updated as the programme develops to take account of any changes in the nature and requirements for engagement. We also pointed out that we would not want the framework to

constrain or prevent informal interactions for early stage discussions on new or developing issues. RWMD agrees with these points. We stressed that we must maintain our position as independent regulators, and re-iterated that before formal regulation begins we are not making regulatory decisions but we are providing advice and guidance to ensure RWMD understands our requirements. We expect RWMD to minimise, as far as possible, the amount of information that it produces under a secure classification, to enable easy sharing. Before any meeting we will encourage RWMD to provide clear aims for the meeting, supporting documentation in good time for adequate consideration and preparation, and to ensure key messages and decisions are recorded for future reference.

2.6. 2012/13 programme

A priority area for us during 2012/13 will be to review RWMD's developing ISE and PESE work, and our permitting processes and permit requirements for intrusive site investigations, to support efficient transition to MRWS Stage 5 at any suitable candidate site(s) following any DtP.

We will provide advice and comment on RWMD's plans for implementing geological disposal, looking, for example, at its business and organisational baseline plans, its permissions schedule and any programme acceleration documentation.

We will also examine RWMD's strategies and plans for dialogue with third parties including potential community siting partnerships, general public, planning authorities and other interested groups.

3. Disposal system specification and design

When RWMD designs its geological disposal system, we want to ensure that the resulting product gives the best possible safety and environmental performance, taking into account Government's requirement to consider retrievability and reversibility in its work programme.

In the early design stages this necessitates taking into account the full range of potential geological environments, facility designs and inventories and being open to consideration of reasonable alternatives to the established designs. RWMD's thinking should not be constrained by earlier geological disposal work in the UK, and viable options should not be ruled out before the characteristics of a final site are known.

We also want RWMD to establish a clear, transparent approach in developing the disposal system that allows them (and others) to understand and assess the design options that have been considered, the decisions on alternative options that have been made in the course of development, the reasons for those decisions, and their impacts of the DSSC.

We will achieve this by continuing to provide advice on RWMD's work in developing a geological disposal system, including generic designs; optioneering studies; and concepts for Spent Fuel (SF), co-location of HAW and Intermediate Level Waste (ILW), and new build wastes. We will assess and monitor RWMD's concept change control and the associated management procedures.

3.1. RWMD's optioneering studies

Government policy is to pursue the geological disposal of higher activity radioactive waste, whilst recognising that future research and development may identify new technologies, solutions or options for dealing with some wastes (such as borehole disposal for certain types of waste). NDA has been tasked by Government, in section 4.32 of [1], to maintaining knowledge and awareness of such developments and therefore it needs to maintain its scientific capability on this important aspect. RWMD's technical note [19] addresses how it intends to do this. We reviewed earlier versions [20, 21] and encouraged RWMD to present the information in such a way that it conveyed correctly the message that consideration of alternative waste management options is a realistic and sensible approach and not simply a burden imposed by Government. We suggested RWMD could provide more information on the 'products' that people might expect to see, and on how RWMD would practically assess any new developments to determine how they might affect its decisions on disposal concepts. We think the final version is a good document that shows the breadth of RWMD's efforts to keep developments in radioactive waste management under review and ensure alternative options continue to be considered.

We reviewed [22] RWMD's proposed approach to optioneering [23]. We suggested that RWMD should identify the key technical issues and interdependencies which may constrain future options assessment, from the work it has commissioned. We made a number of suggestions as to how RWMD could improve the document, such as:

- Including a forward programme for optioneering in the context of the overall decision-making framework.
- Presenting the lessons learnt from the historical 'Nirex Multi Attribute Decision Analysis (MADA)' exercise undertaken for site selection and how RWMD has improved on that.

- Avoiding giving the impression that site characterisation and construction will proceed without any 'surprises' or challenges – some of which may necessitate a 'roll-back' in the step-wise process and a re-assessment of options that were previously discarded.

We reviewed [24] four contractor reports provided by RWMD in relation to disposal concept options [25, 26, 27, 28]. For any future documentation, based on these studies, we explained that we would like RWMD to demonstrate how it intends to use information derived from its illustrative examples to actually shape their disposal concept selection process, and to provide assurance that future concept optioneering will not be constrained by the illustrative examples used to date. We noted we would also like RWMD to explain how its work relates to options appraisal work in support of the Strategic Environmental Assessment (SEA) and the Letter of Compliance process. For a co-located facility (disposing of HLW & SF with ILW), we will expect RWMD to identify and analyse thoroughly specific issues relating to interaction of various types of wasteform, and the different engineered barrier systems. With regards to deep borehole disposal, we suggested that RWMD could develop a timeline showing what information would need to be known (or resolved) by when, if the option of borehole disposal for certain types of waste was to be pursued further.

3.2. GDF design principles and objectives

We reviewed [29] RWMD's design principles for a GDF [30]. We provided detailed comment on the scope and application of the principles, in our response. We recognise that RWMD has taken on board many of our comments on previous drafts but we still have concerns with overall clarity and we believe RWMD may be unnecessarily complicating the classification/categorisation of design principles. RWMD's document contains three sets of principles:

- Fundamental Principles.
- Principles for the Design Process.
- Principles for the Design.

RWMD's intention appears to be to embrace all these under the term 'GDF Design Principles', as in the title of the technical note. We noted that fundamental principles are broader than just design principles, and that principles for the design process are, for all intents and purposes, the same as design principles. We suggested it is not helpful to split principles for the design process from principles for the design or to include the phrase 'Safety, Environmental, Security and Safeguards Principles for the Design Process' in the title (which might suggest that the principles for the design process are the main focus of the document). We previously suggested that RWMD should list waste transport principles separately from facility design principles. RWMD did not consider that would be helpful, yet security and safeguards principles have been segregated, and we remain of the opinion that transport principles should similarly have their own section.

We reviewed [31] RWMD's draft technical note [32] which sets out the design objectives for a GDF. We provided some suggestions, on earlier drafts, for how RWMD might clarify some of the objectives, align them better with the environment agencies' GRA [11], and integrate this with its SEA and Environmental Impact Assessment (EIA) work. In general we think the latest draft [32] is a good document.

3.3. Radiation Protection Policy Manual (RPPM)

We reviewed RWMD's RPPM [33], and suggested how RWMD might improve it [34], in particular to align it with the environment agencies' GRA [11].

3.4. Concept change control

We expect the developer of a GDF to have in operation a suitable procedure for managing the change of any key work areas (GRA Requirement 4: Environmental safety culture and management system [11]). The demonstration by RWMD of such behaviour, through its management system, is important in building our confidence that it is an organisation capable of holding the necessary permits and licences.

In October 2011 RWMD embarked on a review of its change control arrangements [35] and invited comments to inform the review. We met with RWMD to discuss change control and we provided RWMD with our comments [36] on its document and our feedback about discussions at the meeting. The key issues we highlighted are as follows:

- RWMD's current work programme is generic. There will be significant changes when RWMD develops site-specific studies and designs. It is not clear to us how RWMD has considered the move from generic to site-specific studies in developing the change control process and we are uncertain whether the current procedure is adequately designed for RWMD's future work programme.
- Presently thirty two of RWMD's generic documents are subject to the formal procedure for managing changes to the generic concepts. We are unclear why RWMD considers it is necessary to apply formal change control management to some of these (for example, the R&D status reports which would be subject to routine change reflecting advances in knowledge and understanding) while excluding others (such as R&D Plans and Programmes).
- The four-level categorisation scheme that RWMD uses does not take into account environmental significance. We suggest that RWMD reviews its classification scheme to explicitly include environmental significance.

We asked RWMD to provide some examples of change control requests at various levels of categorisation in order for us to plan an audit of RWMD's use of its concept change management procedure.

3.5. RWMD's management of Issues and the Issues Register

RWMD provided the first of two reports on its approach to issues management [37] that included the issues which had been raised up till then. We considered these documents ahead of a meeting with RWMD in March 2011 aimed at RWMD clarifying its process for managing issues and for the Regulators to gain confidence that RWMD is managing them appropriately.

We stressed [38] that RWMD must be vigilant in identifying future changes that may escalate the significance of issues that had previously not been identified as key issues (previously termed 'Concept Issues'), particularly where new information may impact on previous regulatory decisions and result in the need for them to be revisited.

We agreed that RWMD's issues process should help to promote transparent, justifiable decision-making, which should improve stakeholder confidence in the concept. We urged RWMD to build feedback loops into its process to help ensure that issues are resolved. We confirmed that RWMD should provide formal responses to any issues raised by us and inform us when the potential issues register and key issues lists are published. We will continue to review the process through the scrutiny programme.

3.6. Concept selection process

At a meeting with RWMD to discuss its Concept Selection Process [39] we noted [40] that:

- Its interim explanatory document should include more discussion of uncertainty, highlighting key uncertainties, explaining their impact and how RWMD plans to manage this.
- It should also clarify how RWMD envisages screening and selecting concepts at the start of Stage 4. For example, whether it will involve some sort of MADA, whether it will be via internal decision (possibly involving external experts), and whether the decision process would be made available for scrutiny.

RWMD will revise its concept selection process, based on comments received at the meeting, and publish it in a technical note. The process will become part of RWMD's management system. We note that it is likely that RWMD will need to review and revise this process once it has applied it. We will keep track of future developments via the ongoing scrutiny programme.

3.7. Offsetting of surface/underground facilities and drift design

We commented [41] on RWMD's note for the West Cumbrian MRWS Partnership 'Statement on separation distance between a surface facility and underground vaults'. We considered that the note lacked underpinning evidence to support the range of separation distances assumed. RWMD addressed some of our comments when it revised the note and resubmitted it to the West Cumbria MRWS Partnership [42].

3.8. Understanding controls on the performance of engineered barrier systems in repositories for high-level radioactive waste and spent fuel

To inform our regulatory scrutiny, we commissioned a study to better understand processes that could influence the performance of the engineered barriers, and hence the long-term safety performance of a GDF for HLW. It used a combination of literature reviews and an expert workshop to identify key factors which may have an influence on repository performance.

Our study considers a number of theoretical host environments. It explores the implications for waste form design, waste packaging and repository design, by looking at our current understanding of processes that could influence the long-term performance of a repository. Our report [43] is available on the Environment Agency website.

3.9. 2012/13 programme

In 2012/13 we will consider and discuss RWMD's plans for, and progress on, disposal system optioneering, design and specification; and the development and implementation of management systems associated with the design process (such as concept change control, concept selection and issues management).

4. Safety case development

We want RWMD to understand exactly what we require it to demonstrate (and when) through its environmental, operational and transport safety cases (collectively referred to by RWMD as the DSSC), particularly when these are developing during Stages 4 and 5 of the MRWS process. We note that RWMD might choose to continue to develop its gDSSC to support any formal submissions to us. Although development of a gDSSC is not part of our licensing and permitting process, we will continue to comment on relevant documents if requested by RWMD, in order to help it understand our requirements for later, site-specific, safety cases.

RWMD will need to develop an ISE for each candidate site that it proposes to take forward for intrusive site investigations. This must be followed, in due course, by a PESE for any site(s) that RWMD proposes to take forward for underground operations. The ISE and PESE will support RWMD's permit applications at the relevant stages. RWMD has told us that during its intrusive site investigation phase it is likely also to begin preparing a site-specific Environmental Safety Case (ESC) for each site being investigated.

RWMD will need to maintain consistency between its strategies and plans for developing a GDF and its generic and site-specific safety cases, its ISE and PESE, and any recommendations arising from our past and future reviews of these.

4.1. Review of RWMD's generic Disposal System Safety Case

RWMD published its gDSSC [44] in December 2010 as part of its programme to implement geological disposal. No site had been selected for geological disposal at this stage, therefore its gDSSC does not focus on any specific site; instead it includes generic environmental, operational and transport safety cases for a hypotheticalal GDF.

The gDSSC represents an early, but important, stage in the development of RWMD's approach for demonstrating the safety of any future GDF. Although RWMD's gDSSC is not a formal regulatory submission to us, we reviewed it to provide our early views on RWMD's safety case preparations, and we took account of the generic nature of the component safety cases in our comments.

The scope of our regulatory review of the gDSSC was to:

- Identify whether there are any fundamental issues that would prevent a future safety case for a GDF being made.
- Make recommendations for RWMD to consider when developing any future safety case and to identify any specific areas where the case would need to be strengthened.
- Assist us in providing information and advice to the Government, any stakeholders or communities, including the West Cumbria MRWS Partnership, and the planning authorities in support of the MRWS process.
- Determine whether the 2010 gDSSC is consistent with the regulatory expectations set out in HSE's Safety Assessment Principles [45] and the GRA [11], noting that RWMD is at the early stage in the MRWS process.

We presented RWMD with our initial review findings at a meeting in June 2011. One of our key points was the need for continuing dialogue with us on the gDSSC going forward, specifically regarding how RWMD will use it at different stages of MRWS and how they will update it. In July 2011 we explained to CoRWM and the West Cumbria MRWS Partnership our ongoing work on the gDSSC. We published a paper setting out our main early comments from the review in February 2011 [46] and published our full report in December 2011 [47].

We concluded that the broad structure of the gDSSC is acceptable in terms of the general coverage of the documents and of the links between them, and that the documentation is of a generally high quality. The gDSSC provides confidence, to a degree appropriate at this early stage in implementing geological disposal, that a safety case for a GDF in the UK could be made, providing a suitable site is available. Our position is subject to the reservations set out in our report.

We provided the following top-level recommendations to help RWMD improve its gDSSC in the future and progress towards producing a fit-for-purpose site-specific safety case for a GDF:

- RWMD should explain the future role of the gDSSC and develop a clear route map to show how it might develop the gDSSC into a site-specific DSSC.
- RWMD should aim to reduce repetition and overlap between documents in the gDSSC, better address the needs of different audiences, and aim to produce a stable and enduring suite of safety case documents. RWMD should clarify how it will apply change control to its suite of documents and the statements they contain.
- RWMD should consider a wider range of waste inventories in future revisions of the gDSSC given the current uncertainties.

Our report also presents a number of more detailed recommendations, relating to each component safety case in the gDSSC. We will consider RWMD's response to our review through our ongoing scrutiny programme.

4.2. Environmental Safety Case Strategy Report

We provided comments [48, 49] on RWMD's provisional ESC Strategy Report [50]. We think it is a useful document, and it contains no "show-stoppers", but it could be improved. We noted that its main shortfall is that it fails to present a coherent approach to managing unquantifiable uncertainties that affect the ESC.

We suggested that RWMD should apply tight definitions to the terms "data", "information", "knowledge" and "understanding" and use them appropriately and consistently throughout the document.

The provisional ESC Strategy document does not:

- indicate how and where climate change will be addressed
- mention human intrusion (other than in relation to the generic Post Closure Safety Assessment (PCSA))
- make reference to chemotoxic or non-radiological hazard assessments
- make reference to the use of safety functions or methodology development in this area.

We expect these matters to be included in future iterations of the ESC Strategy document.

We suggested RWMD could enhance its generic ESC to make it suitable to support site identification and assessment during Stage 4 of the MRWS Site Selection process. We also suggested RWMD should review its work on model development (referenced in its draft ESC Strategy report) which relates largely to work carried out by Nirex, to ensure that it is adequate for use within MRWS.

4.3. 2012/13 programme

Emphasis under this task in 2012/13 will be on monitoring progress towards addressing the recommendations from our recent review of the gDSSC, ensuring RWMD develop appropriate

Environmental, Operational and Transport Safety strategies, and reviewing RWMD's plans for developing the generic ESC ahead of MRWS Stage 4.

5. Sustainability and environmental assessment

Government is committed to ensuring that the NDA's GDF programme fully assesses and accounts for environmental impact and sustainability issues through the application of Strategic Environmental Assessment (SEA), Sustainability Appraisal (SA) and Environmental Impact Assessment (EIA). The Government expects the NDA to undertake SA, meeting the requirements of the SEA Directive. RWMD developed a strategy for SA and environmental assessment in 2009 which describes how it plans to approach this work. RWMD is developing its approach to the SA (incorporating SEA) as part of its GDF programme. The EA is a statutory consultee for SEA and EIA. This gives us the opportunity to influence the SA/SEA and EIA processes and ensure RWMD's assessments consider fully all potentially significant environmental effects. We will continue to provide advice and guidance to RWMD on environmental assessment by participating on the NDA RWMD's Sustainability Assessment Group (SAG), previously named the Environmental Assessment Advisory Panel (EAAP).

5.1. The role of the Sustainability Assessment Group

The purpose of the SAG is to give RWMD advice on developing and implementing its approach to environmental and socio-economic assessment. The scope of the SAG includes reviews of RWMD specifications, proposals, plans and documentation for developing its environmental and socio-economic assessment at the different stages of the MRWS programme. At later stages, the SAG will also be asked to review the proposed structure and contents for the SEA and EIA documentation, with a particular focus on whether it is likely to meet regulatory requirements, is in line with good practice and will be successful in communicating the key messages to the target audiences. The EA will provide informal (at SAG meetings) and formal (documented in letter responses) comments on RWMD's developing approaches and methodologies.

Through participating in the SAG we will provide regulatory advice on RWMD's early draft documents. We discussed, with RWMD, the current role of SAG as peer review for pre-consultation documents and agreed that there is a role for the SAG as peer reviewer during MRWS stage 4. SAG also provides this role once consultation documents have been published. We agreed with other SAG members that RWMD needs to define clearly the peer review role and objectives, so it can assess whether documents meet these objectives.

5.2. Generic Environmental Sustainability Report for a Geological Disposal Facility

In our comments on RWMD's draft Generic Environmental Sustainability report [51] we agreed in general with RWMD's methodical approach and the issues considered, but we had some concerns over the quality of RWMD's assessment of impacts. We suggested areas in which RWMD could strengthen its SEA process. RWMD took our comments into account to produce its final report [52].

5.3. Strategic Environmental Assessment

RWMD circulated an initial draft of its SEA scoping report [53] to the SAG in October 2010, in order to facilitate discussion. We provided comment by letter [54] and at the December 2010 SAG

meeting. We agreed with RWMD's overall approach but highlighted a number of points for it to consider, such as improving the clarity of its explanations and the level of detail in some areas, and a need to update its SEA to reflect any potential new impacts or changes that may result from revisions to its GDF programme.

RWMD intends to publish 3 scoping documents for SEA for consultation in 2012/2013:

- Health Impact Assessment (HIA) and Equalities Impact Assessment (EqIA).
- Habitats Regulation Assessment (HRA).
- Strategic Transport Assessment (STA).

RWMD will produce a high level document which will sit above these and will share the drafts with the SAG so that the panel can provide direction.

We commented [55] on RWMD's draft proposed approach to SEA [56] noting that there were some significant changes from earlier drafts, most notably:

- The removal of SEA objectives and the setting of a baseline-led (vs. objective-led) approach to assessment.
- The altered role of the SEA process in the site selection approach (which will be MCDA-led, with SEA providing information on the likely effects of programme implementation).
- A two-phase assessment process, the first phase being largely generic, assuming the lack of specific development sites, whilst the second phase will be site-specific once candidate sites have been identified.

We understand the need to make these changes but expressed concern about the value of the new approach. RWMD provided a response to each of our comments [57] and suggested how it would address them in a revised version. We received RWMD's revised document [58] for discussion and comment via the February 2012 SAG. The SAG agreed with RWMD's overall proposed SEA approach, but noted a few pointers, such as:

- RWMD should build more quantification of effects into the SEA process.
- RWMD should clarify the links between the SEA and the STA, HRA, HIA and EqIA, and the site selection process.
- The impacts of a GDF on climate and the impacts of climate on a GDF should be covered.
- It is important to bring out the positive (enhancement) effects of a GDF.
- RWMD's approach to dealing with uncertainty in the SEA should be consistent with that for other assessments.

RWMD provided a draft document identifying the research required to establish an environmental (Climate Change and Biodiversity) and socio-economic baseline for SEA and EIA. We discussed this at the February 2011 SAG meeting and we provided comment in a later letter [59]. We consider that this draft report presents a comprehensive review of the available literature, published guidance and models, and we made some suggestions particularly with regard to flood risk forecasting.

We contributed towards RWMD's uncertainty workshop, in October 2011, where the emphasis was on uncertainty in the SEA. We noted that SEAs often fail to address uncertainty effectively and are encouraged that the findings of the workshop will feed into on-going development of RWMD's approach to the SEA.

5.4. Habitats Regulation Assessment

RWMD is to act as the competent authority, responsible for the HRA, and it will consult with statutory consultees. Natural England (NE) is the 'Lead' advisor for this aspect of the HRA. The EA

has limited input to the HRA but we will provide comment on issues which fall within, or are related to, our remit.

We commented [60] on RWMD's draft HRA methodology report [61] and discussed it at the September 2010 SAG meeting. RWMD's amended version [62] addressed our comments adequately.

We received RWMD's draft HRA screening and scoping report in October 2011. We agreed with members of the SAG (at the September 2011 meeting) that RWMD could include more on compensatory measures and set out in detail other relevant plans and programmes. RWMD advised the SAG that it does not intend to undertake any detailed survey work at this stage, but it may do so at a later date.

RWMD's proposed approach for the HRA involves reusing plan level HRA information at project level. Members of the SAG suggested that RWMD's consultation document should explain how the plan and project level HRA link with the site selection process. NE has clarified with RWMD how it is dealing with combined effects, e.g. how air quality impacts for transport routes could affect several sites. SAG members noted that local transport issues are key and RWMD should make the links between the HRA and STA clear.

5.5. Strategic Transport Assessment

We discussed RWMD's draft methodology and scoping report for its Strategic Transport Assessment [63, 64] at the June 2011 SAG meeting. We suggested RWMD might factor sustainable transport into the STA and look at the total rather than the net impact.

RWMD is developing its transport safety strategy. RWMD will need to engage with ONR as part of developing its transport safety strategy. We suggested that RWMD should identify opportunities for enhancements, such as cycle paths, and we reminded RWMD of the need to include closure of the GDF within the scope of the STA. RWMD also needs to consider socio-economic factors, e.g. catchment area for GDF workforce, with respect to transport infrastructure.

5.6. Health Impact Assessment

The SAG discussed RWMD's Health Impact Assessment Methodology document [65] at the February 2012 meeting. The group considered that the document sets out a process, not a methodology for how the assessment will be done. The SAG felt that quantifying the magnitude of impacts might be unrealistic and favoured an environmental detriments approach that looks at activities and mitigating measures and their possible outcomes and impacts. We noted that RWMD needs to continue the HIA process beyond a period of monitoring to determine any measures that need to be taken if impacts are detected. We are not the lead organisation for the HIA and will only comment on issues within, or related to, our remit.

5.7. Stakeholder Engagement

RWMD is working hard to engage with different stakeholder groups in the MRWS process. RWMD has asked SAG members to provide feedback on good community engagement techniques. RWMD shared its draft stakeholder engagement plans at the February 2012 SAG meeting and we will provide comment in due course, through our ongoing scrutiny programme.

5.8. Geological Disposal Implementation Plan document

We provided comment on RWMD's developing Project Definition document [66] at the December 2011 SAG meeting. RWMD agrees with the SAG members that the report needs to clarify the uncertainties relating to the stated manpower figures, and to consider including manpower graphs and profiles in the document. The group also thought the report should be clearer with respect to uncertainties related to geology, disposal concept and the inventory of waste for disposal. SAG members stressed that communities will want to understand what a GDF might look like. RWMD indicated that the surface facilities will be very similar for all concepts and thought that people will be most concerned about noise and transport issues rather than below ground design variants.

RWMD will develop this document further and we will continue to engage with RWMD on this through our ongoing scrutiny programme.

5.9. Review of Environmental Information Requirements

"Review of Environmental Information Requirements" is a high level report produced by RWMD and Jacobs [67] setting out the environmental and socio-economic information, and more specific information requirements, of the environmental assessments. RWMD intends to incorporate it (with two other reports) into a Requirement Management System in due course. SAG members thought the report was generally well put together with some minor areas for improvement. RWMD will use it as a planning/scene-setting tool which will help to make sure legal assessment requirements have been met. RWMD needs to produce a list of documents being prepared, along with a definition of their purpose and how they link with each other. SAG members suggested including ecosystems services approach and longer term impacts, e.g. from and on climate change - Jacobs agreed this will be included in baseline reporting.

RWMD has reviewed what has already been done and looked at research requirements going forward with regards to baseline forecasting for programming purposes. SAG members suggested RWMD should explain up front the tools used for forecasting, e.g. modelling, expert groups, etc.

RWMD proposes to review Climate Change data from the UK Climate Projections 2009 (UKCP09) to find trend projections going forward including looking at regional data for trend analysis over the operational period of the facility. It also proposes to undertake a biodiversity literature review and to run a workshop to undertake assessment using the ecosystem model. RWMD also intends to look at statistics in order to determine social trends.

5.10. 2012/13 programme

Key RWMD activities for 2012/13 relate to preparations for SEA and other associated assessments during MRWS Stage 4. We will focus our efforts on reviewing RWMD's approach to SEA and suggesting opportunities to improve the SEA process to help RWMD achieve better environmental outcomes for its GDF programme.

6. Research and Development

We want to be assured that the best scientific knowledge and engineering practice will underpin the design of any future geological disposal system and its implementation. We expect to see RWMD undertaking a comprehensive R&D programme informed by wider national and international research or implementation programmes. We want RWMD to address, in a timely manner, the technical and scientific issues that have a bearing on its safety case. This will help RWMD to avoid unnecessary delays when requesting regulatory approval for the various stages of geological disposal, for example it would reduce the likelihood of us needing to specify R&D actions mid-way through any licensing or permitting process.

We will achieve this by reviewing RWMD's overall approach to determining, prioritising and delivering the necessary R&D. This will include engagement on, and review of, RWMD's work in progressing specific technical and scientific issues. We will review the effectiveness of RWMD's research programme in terms of:

- Identifying research needs.
- Specifying work packages.
- Delivery against the programme.
- Use of the outcomes.

We will expect RWMD to address any gaps or areas for improvement.

6.1. Our engagement on R&D

We reviewed RWMD's R&D Programme overview and status reports as part of our review of the gDSSC [47]. Its Status Reports encompass the following R&D areas: criticality, package evolution, biosphere, near field evolution, gas, radionuclide behaviour, geosphere and waste package accident performance. We intend to review any updates through the scrutiny programme.

We attended a colloids strategy meeting with RWMD in March 2011. The aim of the meeting was to better understand the role of colloids in transporting radionuclides from a GDF to the biosphere and the associated risks, and to identify areas requiring more R&D. The meeting helped in our overall understanding of the status of the colloids issue and has identified key areas of R&D for RWMD to address.

We attended a meeting with RWMD and CoRWM in August 2011 [68] to discuss the links between R&D and the gDSSC, and RWMD's processes for prioritising its R&D programme and identifying knowledge gaps. We observed that site characterisation needs were set out in RWMD's R&D Overview Programme in February 2011 but these do not match the needs set out in the new Site Characterisation documents. It was agreed that consistency is required between the needs identified in all documents, and it is important that R&D and technical needs are clearly identified, articulated and explained.

We attended a conference in October 2011, hosted by, Loughborough University, to discuss the current status of science and technology and future R&D needs for a GDF [69]. The overarching theme of this conference was 'sound science'. The outcome will be the publication of a special issue of the Mineralogical Society Magazine [70]. RWMD is striving to make its R&D more visible and subject to peer review and challenge, as we have consistently asked. RWMD stated at the conference that it is seeking to bring further peer reviewed work into the public domain, and to offer the learned societies the opportunity to provide independent oversight of its work. We support and encourage RWMD in publishing more peer reviewed work and making its work more amenable to independent scrutiny. RWMD is hoping to repeat a similar conference approx every 2 years.

We met with representatives of RWMD's research team in March 2012 in order to further understand the process aspects of RWMD's R&D including its Technical Strategy, R&D Strategy, R&D Programme and Status Reports. One specific focus was on how RWMD identifies research needs and prioritises its R&D. RWMD provided a summary of ongoing work in a number of areas. Since this meeting we have further engaged on the details of the R&D programme and this will be reported in a future review of the scrutiny programme.

6.2. 2012/13 programme

We will sample a number of active, priority research areas. In the near term we will review the output of R&D work relating to criticality and non aqueous phase liquids, as these are areas where RWMD has told us it has made considerable progress. Our reviews will focus on the specification of research projects and how RWMD has, or will, use the outcomes within the programme, with a particular emphasis on whether RWMD's research aligns with the needs at the current stage in the MRWS programme. We will continue to review RWMD's efforts in presenting its R&D programme to a wide audience.

7. Site evaluation and characterisation

The process for identifying one or more candidate sites during a future MRWS Stage 4 (desk-based studies in participating areas) and for deciding which should be taken forward for characterisation during Stage 5 (surface investigations on remaining candidates) is outside our regulatory remit. However, we will support the process by providing information and comment on environmental matters within our remit and will review the final outputs from MRWS Stage 4 to inform the decision-making process.

We want to ensure that RWMD has appropriate plans and procedures in place to undertake the wide range of site evaluation and characterisation activities required to support the MRWS process, including development of the ISE(s), PESE(s) and generic and, in the longer term, site-specific ESCs. In particular, we want to ensure that RWMD's plans and actions for future investigations are consistent with our permit requirements for intrusive site investigations.

7.1. Site identification and assessment

We provided comment [71] on RWMD's early draft documents [72, 73] in May 2010 and discussed these, and subsequent changes, at the July and August 2010 Regulatory Interface Management (RIM) meetings. We noted, in particular, that RWMD should clarify, in the document, that we have no formal regulatory role in the site selection process, but that we will provide advice and comment to RWMD and to any Community Siting Partnership(s), as necessary, during site selection. We agreed that there should be a well-defined process for selecting candidate sites, and that this might emerge from a process of engagement and negotiation with local communities. We suggested the document should explain how the process will allow a fair decision to be reached between candidate sites in different locations and that this is set out explicitly upfront, to avoid potential disagreements and delays later on.

RWMD committed to the development of site identification and assessment methodologies to support the framework for site identification and assessment being developed by DECC [74] by improving its early draft document, taking into account comments received from Regulators and others.

We attended a workshop in October 2011 with RWMD and the Nuclear Legacy Advisory Forum (NuLeAF) to give regulator views, and we also provided RWMD with our comments on the workshop subsequently [75]. We noted, in particular, that the phases of Site Identification ("Areas to sites") and Site Assessment that RWMD were proposing seem particularly complex and we were not convinced that they would help to discriminate among potential candidate sites or add sufficient value to outweigh the complexity they would introduce into a Multi-Criteria Decision Analysis (MCDA). We also suggested that RWMD should ensure that its sub-surface exclusion process would not lead to screening out areas inadvertently, because of sparse or uncertain data. We stressed that we have no formal regulatory role in site selection, but that we will provide advice and comment to RWMD and to any Community Siting Partnership(s), as necessary, during site selection. We agreed we would keep a watching brief on the development and application of RWMD's methodology for MRWS Stage 4, but noted the need for us to maintain our regulatory independence.

7.2. Geophysical surveying techniques

Achieving the permits and licences necessary to develop and operate a GDF will be a staged process (see fig 2, 'Staged Regulation') and RWMD will need to apply to the EA for a permit before it starts intrusive investigations at a candidate site. RWMD's application, at that stage, will include an ISE which could be supported by information gathered using geophysical surveys. We will evaluate the evidence supporting RWMD's application and we will issue a permit if we are satisfied that the proposals meet our regulatory requirements. RWMD's current plans are to undertake geophysical surveys early in Stage 5 to understand the geology of any candidate site, noting that the Government framework for site identification and assessment does not preclude undertaking such investigations earlier.

To inform regulatory work, the EA commissioned a review [76] of the geophysical surveying techniques that could be used in a range of geological environments in England and Wales. The work also looked at how RWMD is planning to use geophysical surveying techniques to help it characterise potential candidate sites for a GDF. Our review will help us decide whether RWMD proposes to use appropriate techniques to gain the necessary understanding of the characteristics of the rock strata beneath a candidate site before it disturbs the site, and it is just one aspect we will consider before we could grant a permit to allow RWMD to commence intrusive investigations at a candidate site.

At the time of our review, several geophysical surveying techniques were being investigated and developed, by various organisations around the world, to improve data acquisition and interpretation for geological disposal. As a result of our review we recommended [77] that RWMD monitors the latest practical developments in geophysical techniques and seeks opportunities to incorporate relevant R&D into its programme. We will discuss these recommendations with RWMD to ensure it addresses them adequately before it carries out any characterisation activities at a candidate site or sites.

7.3. Our research on site characterisation

EA commissioned work [78] to identify the potential issues facing the developer when characterising potential candidate sites, that might need to be addressed during Stages 4 to 6 of the MRWS site selection process. This work aims to help us understand the uncertainties that may be involved during decision making; and to identify the kinds of investigations that could be undertaken. From this work we identified the following broad conclusions:

- The developer's plans should be flexible, iterative and underpinned by research. Near-term activities can obviously be planned in more detail than those for the longer term.
- When assessing the characteristics of a site, it is important to know when sufficient information has been collected at a particular stage.
- The management of data, information, knowledge and uncertainty is vital for a project of this nature.
- The developer should engage in an open and inclusive manner with communities. We will also need to engage with communities whilst maintaining our independence.
- Developing and maintaining the necessary skills and resources to support underground characterisation activities are particularly important for both the developer and the Regulators.

EA also commissioned a review of the regulatory use of geoscientific information in relevant international programmes [79]. The review report provides a useful resource for us to understand the progress made and lessons learnt in several advanced national radioactive waste disposal programmes for a relevant set of geological environments, providing examples of how other organisations have dealt with a range of issues that may be encountered during the MRWS process. In particular, it provides examples of how regulators have assessed geoscientific

information early in siting programmes for a range of geological environments and disposal facility concepts.

7.4. Preparations for integrating site investigation and characterisation activities

Experience from other national programmes has recognised that integration of activities during Stage 5 is necessary, but that it is a significant challenge for this stage in the development of a GDF. RWMD was also keen to explore whether the assumed timings for key programme milestones, such as the time at which the first borehole was drilled, following a Government decision on site selection, could be accelerated, and if so, what the necessary conditions are to achieve the acceleration.

We attended two workshops hosted by RWMD. The workshops included RWMD staff with experience in procurement, commercial contracts, project management, geosciences, engineering, concept selection and design, safety assessment and regulatory engagement, as well as members of its supply chain. In addition to observing, and commenting on, RWMD's activities we provided an explanation of our requirements for the ISE, which we will require from RWMD to support its application for an environmental permit to commence intrusive studies. RWMD intends to submit a report titled "Integrated Programme for Surface Based Investigations" which will take into account the output from these workshops. It will be available for regulatory review in 2012/13.

7.5. Borehole sealing

Before RWMD starts to drill any boreholes to support its surface investigations we require evidence that the boreholes can be sealed effectively. Any borehole must be effectively sealed after use to prevent groundwater contamination and mixing, and otherwise posing a hazard to groundwater in the area. Boreholes at any depth in the repository zone must be sealed to prevent them acting as a preferential pathway for radionuclides,

We received two reports on borehole sealing from RWMD [80, 81] as a basis for discussions with them in Sept 2011. At the meeting we discussed the latest borehole sealing techniques and design specifications, and RWMD presented the work it intends to carry out in 2012/13. This includes investigation of the factors influencing borehole design with particular emphasis on borehole sealing, and a review of the longevity of materials for use in sealing boreholes. We suggested that RWMD might find it useful to consider, at this stage, what further work on borehole sealing it would be reasonable to carry out in a generic sense. RWMD intends to prepare a report on borehole sealing in 2012/13 and we will continue to provide advice on developments.

7.6. 2012/13 programme

We will review aspects of RWMD's Site Characterisation Project and its plans and approaches in moving from desk-based studies to site characterisation. RWMD's key activities relating to site characterisation during 2012/13 will be related to the development of generic plans for gaining a conceptual understanding of candidate sites and the contracting strategy for surface based investigation. Our regulatory focus in 2012/13 will include:

Assessing RWMD's state-of-readiness to support MRWS Stage 4 desk-based studies, including:

- Availability and application of key tools (e.g. data management system) and resources (e.g. integrated project teams) by RWMD.
- Development by RWMD of a clear technical specification to support site identification and assessment.

RWMD's proposals for site characterisation, including:

- The commercial strategy for surface-based investigations and links with Organisational Development.
- RWMD's generic proposals for site characterisation.
- The strategy for delivery of long-lead items and critical path activities.
- The existence of plans to enable development and implementation of site specific characterisation.
- Continued engagement on sealing of site characterisation boreholes.

8. Waste packaging advice and assessment

When requested, RWMD provides advice to nuclear site operators on the packaging of its HAW. Through its LoC process RWMD undertakes disposability assessments and, where appropriate, endorses an operator's approach with a Letter of Compliance (LoC). An LoC indicates that the operator's packaged waste is likely to meet the waste acceptance criteria for any future GDF. LoC advice is used by operators to inform their safety cases and is included as part of their Radioactive Waste Management Case (RWMC) for a particular wastestream.

We want RWMD to continue to assess packaging proposals for HAW against clear and consistent published specifications to ensure that HAW is packaged in a manner that makes it suitable for handling and disposal in a future GDF with no, or minimal, re-working. We also want RWMD and waste packagers to share best practice in waste packaging to avoid duplication of effort.

We will achieve our aims by considering RWMD's procedures and guidance relating to its LoC disposability assessments (including application of the process to High Level Waste (HLW), nuclear materials not currently classified as waste, and New Build waste; and eventual development of Waste Acceptance Criteria (WAC)). We also consider the specific advice RWMD gives to operators through its LoC process, and any revisions RWMD makes to its waste packaging specifications and supporting documentation, to ensure consistent advice is given.

8.1. Disposability Assessment Policy and Principles (DAPPs)

RWMD's Disposability Assessment Policy and Principles (DAPPs) document [82] was subject to considerable review and dialogue over the period covered by this report. We commented [83] that the document outlines RWMD's assessment policy and principles clearly and concisely. We suggested RWMD should clarify the distinction between the NDA and RWMD's interests and explain clearly how the independent credentials of disposability assessment are, and will be, maintained before, during and after its transition to an autonomous entity separate from the NDA. We asked RWMD to clarify whether the document refers to the current disposability assessment process or to the revised one which is foreseen to align with its gDSSC. We recognised that some of the principles have been reported previously [84] and we suggested RWMD might explain how these have evolved into the new principles presented in this document. RWMD responded [85] indicating how it intended to address our comments when it next updates its DAPPs.

When we met with RWMD to discuss our views regarding its DAPPs document we were generally content that RWMD had a clear and acceptable vision of the necessary changes. RWMD indicated that if a particular packaging approach is feasible but would be detrimental in terms of complexity, cost or other factors (such as resource use), RWMD would seek to satisfy itself that there was an overall net benefit. RWMD indicated that its "Non-nuclear environmental assessments", carried out as part of its LoC disposability assessment, would be one input to this. We clarified our expectation that RWMD will continue to present the basis upon which any LoC endorsement is given or withheld, in its assessment reports. We noted that the DAPPs will have strategic implications for waste packaging and will therefore be of significant interest to key stakeholders (especially waste packagers). We suggested that RWMD should make the DAPPs readily available to external audiences (e.g. via the NDA website) as a standalone document and publicise their existence. We also encouraged RWMD to engage with key stakeholders over proposals for major changes to the DAPPs and to make them aware of subsequent consequences.

We agreed that there would be benefit in further dialogue before RWMD publishes the document, and that we would like to consider any revision. RWMD has indicated that it intends to produce a

revised version of the DAPPs for our consideration, taking into account the Regulators comments, in autumn 2012.

8.2. Proposals for updating the packaging specifications for Higher Activity Radioactive Wastes

We welcomed RWMD's proposals [86] to review its packaging specifications for HAW. We believe that this is timely given the developments that have occurred since RWMD published the Generic Waste Package Specification (GWPS) in 2005. We highlighted [87] that RWMD needs to implement and demonstrate robust and transparent quality management and change control systems to maintain the integrity of its disposability assessment process. We suggested RWMD should provide further information on the Quality Management System that is being used to develop its revised specifications, the timescales for the move from using the current set of packaging specifications to the updated versions and how it will manage the process of change from the current set to the new set, such that the legitimacy of disposability assessments is maintained throughout. We suggested that RWMD produces a work instruction which defines how to use and incorporate any further development into the revised packaging specifications when assessing innovative packaging proposals. And also that it should be in place before any changes take place.

We were concerned that there was no reference to, or mention of, RWMD's DAPPs, which we think is a significant omission. It is important that RWMD establishes that the GWPS and any supporting guidance are aligned clearly with the policy and principles of disposability assessment.

We reviewed RWMD's revised GWPS [88] and provided detailed comments [89] and highlighted some more general points:

- We agreed with RWMD on the need to rationalise its Disposal System Specification (DSS) and GWPS, to ensure that there are no overlaps or gaps, and to improve consistency.
- We noted, in particular, the need to apply and use certain terminology (such as "canister", "waste container" and "waste package") appropriately and consistently.
- The GWPS does not appear to include all the peripheral components required to undertake safe operations for handling, transport and disposal so we are unsure whether RWMD's claims relating to these operations are made consistently.
- RWMD should explain the difference between its assumptions in the generic ESC for an average of 500,000 years containment of some wastes (e.g. vitrified HLW) and the absence of any requirements in the packaging specifications.
- We provided a number of suggestions for RWMD to consider in relation to the coverage and consistency of the post-closure waste package safety function, criteria and high-level requirements it has developed.

8.3. Disposability assessment and Letter of Compliance process

RWMD has begun to routinely publish its LoC Executive summaries on the NDA website and we welcome this development.

In October 2011 the Regulators (EA, ONR and SEPA) met with RWMD to discuss their document "Evolution of the LoC Process and its Development", we generally agreed with the approach RWMD presented [25] for improving its disposability assessment process, in seven broad areas:

- Early notification by being more proactive in seeking information from waste packagers, examining lifetime plans and working with site-facing teams, and developing an 'order book' setting out outline plans (for LoC submissions) over the longer term.

- Joint working using a peer assistance framework to help produce concise and robust packaging proposals, and applying a preview approach.
- Iterative assessment designed to ensure the waste packager understands all action points and can define a clear way forward in addressing them.
- Collaborative peer reviews of waste packaging, involving the waste packagers and RWMD.
- Technical audit focussing on commissioning for waste packaging and operations.
- Information and measurement - to provide more regular updates to Regulators on LoC submissions and endorsements, and monitoring success (or otherwise) of improvements.
- There should be a greater onus on the waste producers themselves to periodically review the LoCs in line with updates to plant and the packaging specifications.

We also identified, at the meeting, some further improvements that RWMD could make to the LoC process and the associated documentation:

- RWMD's guidance should reinforce the benefit of using a staged approach to consider disposability, and of aligning operator safety case and RWMD LoC processes.
- RWMD should identify those waste producers having similar wastes and/or packaging options, with a view to standardising proposals where possible and reasonable.
- It is essential that the responsibilities of the waste producer are clear, particularly where increased collaborative working might be lead to a perception of RWMD directing packaging proposals, with endorsement thereby being perceived as a foregone conclusion.
- RWMD needs to define what waste owners must do when they transfer waste between sites or organisations so that the LoC remains valid.

RWMD committed to updating its disposability assessment procedures and waste packaging guidance and we will continue to engage with RWMD on these through our ongoing scrutiny programme.

8.4. 2012/13 programme

We will continue to engage with RWMD as packaging specifications are revised to ensure that robust and transparent quality management and change control systems are implemented in order to maintain the integrity of the disposability assessment process. We will carry out an audit of RWMD's disposability assessment process with a particular focus on RWMD's management of change control.

9. Organisational Development

We want RWMD to establish and develop itself as an organisation that is capable of holding the necessary licences and permits to develop and operate a GDF.

We will seek assurance that RWMD is taking appropriate actions to develop into a prospective Site Licence Company (SLC), with a suitable organisational structure and management arrangements capable of holding the licences and environmental permits necessary to enable intrusive site investigations of candidate sites and ultimately undertake underground operations.

During the period covered by this report RWMD has consulted with government, its own staff and us, over its proposals for implementing a new organisational structure. The objective of the change being to deliver RWMD's programme mission and objectives in the most efficient manner and to establish an organisation which is capable of acting as an Intelligent Client, acting as the Design Authority for the GDF, and applying for and holding the necessary permissions and licences.

The change does not involve reducing skills or resources that are necessary to maintain the standards of safety and environmental protection. However the change relates to how those resources are organised and to accountabilities and responsibilities of staff in areas (such as disposability assessment, safety case and environmental assessments) that, if not adequately conceived or executed, could impact adversely on RWMD's ability to deliver its safety and environmental protection activities effectively.

9.1. RWMD's progress in developing as a prospective Site Licence Company to implement geological disposal

We expect RWMD to separate from NDA to become a wholly-owned subsidiary organisation SLC, capable of holding the environmental permits needed to carry out intrusive site investigations at a candidate site. And the organisation will need to be capable of holding a nuclear site licence before the start of underground operations. In 2009 we agreed with NDA and RWMD that the 'Prospective SLC' will:

- Provide separation between the strategic responsibilities of corporate NDA and RWMD's development work.
- Embody the culture, and demonstrate the competences, of a company that is to hold an environmental permit and a nuclear site licence, including having an independent assurance function.
- Be a stable organisation that meets the immediate needs of the business, its Regulators and others.

In November 2009 we carried out a joint regulatory review of RWMD's development as a 'prospective SLC' [90] and in March 2011 we followed this up with a two day inspection to assess RWMD's progress [91]. Our approach for the inspection was to sample and assess the governance, staffing and management arrangements as set down in RWMD's Safety and Environment Management Prospectus (SEMP) [92]. We treated RWMD as a prospective SLC and undertook interviews with a cross-section of staff from across the organisation including the Managing Director, members of the Executive Management Team, managers and staff. Our discussions were focussed on the four regulatory issues identified from our previous review, namely:

- Leadership and governance.
- Organisational design and capability (including core organisational competence).
- Control and assurance.

- Organisational learning.

From our review in March 2011 we concluded that RWMD had made good progress since November 2009 and is working well towards developing as a prospective SLC. RWMD's staff were open and honest in our discussions and had an enthusiastic approach to their work. We observed a good level of knowledge across the organisation and an understanding of the need to embed a nuclear safety and environment culture in RWMD's work.

We will continue to inform RWMD's efforts as it develops towards an SLC. We met with senior staff in RWMD to ensure full support and commitment to the task is maintained as a high priority, and we established a programme of monthly meetings with RWMD. We agreed that our engagement would cover a wider remit than our specific regulatory interests, addressing additionally, for example, the separation issues of IT, communication, unions and contracts. The purpose of the meetings is to work effectively to ensure the development of RWMD meets our requirements and to assess its state of readiness to become a wholly-owned subsidiary of the NDA with the capabilities expected of a possible future holder of an environmental permit and a nuclear site licence. RWMD developed and maintained an SLC Development Action Plan which we used as a framework for dialogue at these meetings.

We have commented [93, 94] on draft documents, and, through our ongoing dialogue, helped to inform the development of a number of RWMD's key documents, such as:

- RWMD's Business Case (for subsidiary formation).
- Management of Organisational Change Case [95].
- Safety & Environmental Management Prospectus [96].
- Implementation plan for provision of design authority [97] (as a precursor to RWMD preparing its "Design authority roles and the exercise of its functions").

We are preparing guidance for NDA/RWMD to enable them to understand our expectations for the evolution of RWMD into a separate corporate body. We will continue to provide regulatory advice and comment to RWMD as it implements its revised organisational management arrangements; this will involve working level interaction on specific topics. This approach is similar to the way we work with organisations that are under our regulatory control.

9.2. 2012/13 programme

We intend to follow up the November 2009 and March 2011 inspections with further more detailed reviews during 2012/13. The purpose of these reviews will be to examine RWMD's development and assess its state of readiness to become a wholly-owned subsidiary of the NDA with the capabilities expected of a possible future holder of an environmental permit and a nuclear site licence.

We will monitor and assess RWMD's progress in addressing the issues and recommendations we raised from the previous inspections. We will focus on assessing the implementation of organisational developments within RWMD that we expect from other successful SLCs. In particular, we will provide comment and advice on RWMD's preparations for the formation of a wholly owned subsidiary and its organisational compliance arrangements.

10. List of abbreviations

CoRWM	Committee on Radioactive Waste Management
DAPPs	Disposability Assessment Policy and Principles
DECC	Department for Energy and Climate Change
DfT	Department for Transport
DSS	Disposal System Specification
DSSC	Disposal System Safety Case
DtP	Decision to Participate
EA	Environment Agency
EAAP	Environmental Assessment Advisory Panel
EIA	Environmental Impact Assessment
EqIA	Equalities Impact Assessment
ESC	Environmental Safety Case
GDF	Geological Disposal Facility
gDSSC	generic Disposal System Safety Case
GRA	Guidance on Requirements for Authorisation
GWPS	Generic Waste Packaging Specifications
HAW	High Activity radioactive Waste
HIA	Health Impact Assessment
HLW	High Level Waste
HRA	Habitats Regulation Assessment
HSE	Health and Safety Executive
ILW	Intermediate Level radioactive Waste
ISE	Initial Site Evaluation
LoC	Letter of Compliance
MADA	Multi Attribute Decision Analysis
MCDA	Multi-Criteria Decision Analysis
MRWS	Managing Radioactive Waste Safely
NDA	Nuclear Decommissioning Authority
NE	Natural England
NuLeAF	Nuclear Legacy Advisory Forum
ONR	Office for Nuclear Regulation
PCSA	Post Closure Safety Assessment
PESE	Preliminary Environmental Safety Evaluation
PIP	Provisional Implementation Plan
R&D	Research and Development
RIM	Regulatory Interface Management
RPPM	Radiation Protection Policy Manual
RWMC	Radioactive Waste Management Case
RWMD	Radioactive Waste Management Directorate
SA	Sustainability Appraisal
SAG	Sustainability Assessment Group
SEA	Strategic Environmental Assessment
SEMP	Safety and Environmental Management Prospectus
SF	Spent Fuel
SLC	Site Licence Company
STA	Strategic Transport Assessment
UKCP09	UK Climate Predictions 2009
WAC	Waste Acceptance Criteria

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