CONDITIONING OF INTERMEDIATE LEVEL RADIOACTIVE WASTE ON NUCLEAR LICENSED SITES

Provision of Advice by the Health and Safety Executive, the Environment Agency and the Scottish Environment Protection Agency

Guidance to Industry

SEPA Scottish Environment Protection Agency

HSE Health & Safety Executive

Environment Agency

FOREWORD

This guidance is issued jointly by the Health and Safety Executive, the Environment Agency and the Scottish Environment Protection Agency (together referred to as "the regulators"). Following the guidance is not compulsory and you are free to take other action. But, if you do follow the guidance you will normally be doing enough to comply with the law as interpreted by the regulators at the time of writing and the regulators may refer to this guidance as illustrating good practice.

Given the long timescales involved in radioactive waste management, you should be aware that standards, legislation and national policy might change. While this guidance forms the best advice that the regulators can give at present, nothing in this guidance overrides, or is intended to pre-empt, the ability of the regulators to discharge their statutory powers and duties in accordance with legislation, standards and policy applicable at the time.

In particular, this guidance does not in any way place any of the regulators under any obligation to ensure that the following will be successful:

- A submission by a nuclear site licensee to the Health and Safety Executive for a consent or agreement to proceed with a proposal for the conditioning of intermediate level radioactive waste;
- An application by a nuclear site licensee to the Environment Agency or the Scottish Environment Protection Agency for an authorisation to dispose of radioactive waste.

This guidance will be reviewed periodically with the aim of ensuring that it continues to provide sound advice.

EXECUTIVE SUMMARY

The purpose of this guidance is to provide a single, overarching document to explain the regulatory process and provisions associated with the conditioning of intermediate level radioactive waste (ILW) on nuclear licensed sites in the UK. It is primarily intended for use by nuclear site licensees. The guidance is applicable to all types of ILW, and to certain low level radioactive waste (LLW) that cannot, at present, be disposed of at a low level waste disposal facility. This document complements the Health and Safety Executive's (HSE) and the Environment Agency's extant guidance to inspectors on nuclear safety cases and the conditioning of ILW, respectively.

The conditioning of radioactive wastes on nuclear licensed sites in the UK is regulated by the HSE under the terms of the conditions attached to the nuclear site licence. When assessing the suitability of a nuclear site licensee's safety case to treat radioactive waste, HSE consult the relevant environment agency (the Environment Agency or the Scottish Environment Protection Agency) in accordance with the respective Memorandum of Understanding. As part of this assessment process, HSE take full and meaningful account of any environmental issues as advised to them, before issuing a consent or agreement. HSE seek the relevant agency's advice in order to be satisfied that the proposal adequately addresses long-term environmental protection concerns, particularly those regarding the long-term disposability of the proposed waste form.

A key component of the safety case is the ILW Conditioning Proposal. This documentation underpins the development and implementation of the licensee's plans to condition ILW, and details the associated justification in safety and environmental terms. It exists for the benefit of the licensee and should be maintained, together with the associated audit trail, for use when an authorisation for disposal to a facility is finally sought.

The scope, form and content of the ILW Conditioning Proposal is the responsibility of the licensee and, because the scope and complexity of every ILW conditioning project is different, it will depend upon the specific details of each case. However, in all cases the ILW Conditioning Proposal should be fit for purpose and should be agreed with the regulators at an early stage. All plans to condition ILW need an up to date ILW Conditioning Proposal, but not all ILW Conditioning Proposals will warrant formal submission of the underpinning documentation to the regulators. Instead, a priority system being developed by the regulators will be operated to "call in" particular proposals.

Where appropriate, the regulation of ILW conditioning on licensed nuclear sites is carried out in partnership based on the principles of early interaction and joint working as set out in the HSE/Environment Agency document "Working Together on Nuclear Sites". Thus, the regulation of ILW conditioning is considered by all the regulators as a process that requires continual dialogue between the nuclear industry and the regulators, against a background of formal regulatory hold points beyond which the licensee will require regulatory permission to proceed. The regulatory process set out in this guidance is designed to be flexible and efficient, and to avoid unnecessary delay. In particular, interactions are important at the conceptual and options assessment stages in order to seek the views of the regulators at an early stage.

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Glossary

This glossary provides a definition of key words and phrases for the manner in which they are used in this guidance document.

ALARP (As Low As Reasonably Practicable). ALARP means that all measures that are not unreasonably costly should be taken to reduce risk. This is usually achieved by the establishment and/or use of relevant good practices and standards.

Assessment. Activities carried out to determine that requirements are met and that processes are adequate and effective.

Authorisation. Permit granted by the environment agencies for the disposal of radioactive waste.

BPEO (Best Practicable Environmental Option). The Royal Commission on Environmental Pollution defined BPEO to be the option that is "*the outcome of a systematic and consultative decision-making procedure which emphasises the protection and conservation of the environment across land, air and water. The BPEO procedure establishes, for a given set of objectives, the option that provides the most benefit or least damage to the environment as a whole, at acceptable cost, in the long term as well as in the short term.*" The regulators expect that a BPEO will include appropriate consideration of all factors that may influence the choice of option including operational safety, environmental impact, cost and practicability.

BPM (Best Practicable Means). BPM is a term used by the environment agencies in authorisations issued under the Radioactive Substances Act. Essentially, it requires operators to take all reasonably practicable measures in the design and operational management of their facilities to minimise discharges and disposals of radioactive waste, so as to achieve a high standard of protection for the public and the environment. BPM is applied to such aspects as minimising waste creation, abating discharges and monitoring plant, discharges and the environment. It takes account of such factors as the availability and cost of relevant measures, operator safety and the benefits of reduced discharges and disposals. If the operator is using BPM, radiation risks to the public and the environment will be as low as reasonably achievable.

Cm 2919. A Government White paper published in 1995 entitled "Review of Radioactive Waste Policy: Final Conclusions".

Conditioning. The processing of radioactive waste to achieve passive safety for interim storage and to prepare it for eventual disposal. Such processing can be considered to involve treatment, conditioning and packaging stages. For brevity "conditioning" is used in this document to include all stages of the process, except where it is necessary to refer to one of the stages specifically.

CoRWM. The Committee on Radioactive Waste Management, which is reviewing the UK's options to manage solid wastes for which no long term strategy currently exists. It is expected that CoRWM will make its recommendations to Government during summer 2006.

Decommissioning. The process whereby a nuclear facility, at the end of its economic life, is taken permanently out of service and its site made available for other purposes. In the case of a nuclear power station, this normally involves three stages. Immediately after the final closure, radioactive material such as nuclear fuel and operational waste is removed; then the buildings surrounding the reactor shield are dismantled; and finally the reactor itself is dismantled.

Discharge. The release of aerial or liquid waste to the environment.

Disposability. The degree to which conditioned waste meets the standards and specifications for final disposal.

Disposal. The emplacement of waste in an authorised, specialised facility constructed for its long-term management and for which the primary expectation is not one of retrieval.

Environment Agencies. The Environment Agency or the Scottish Environment Protection Agency. (Note that for the purposes of this guidance the Environment and Heritage Service, who have regulatory responsibility for RSA 93 matters in Northern Ireland, are not included in this definition because there are no nuclear licensed sites in Northern Ireland.)

Hold point. A point beyond which the licensee needs regulatory permission in order to proceed.

ILW. Intermediate level waste, with radioactivity levels which exceed the upper boundary for low level waste (LLW), but which does not generate significant amounts of heat.

ILW Conditioning Proposal. Documentation detailing proposals to condition ILW and the associated justification in safety and environmental terms. This definition includes proposals that contain the justification for long-term storage without immediate conditioning.

Integrated Waste Strategy (IWS). An integrated waste strategy is an outline overall plan, taking into account environmental principles, that can be applied consistently to all actual and potential sources of waste, both radioactive and non-radioactive, within the scope of the strategy. The scope may extend to the whole of a complex nuclear site or even to multiple sites. A BPEO study may be needed to identify an optimised strategy.

Letter of Comfort (LoC)[†]. Under its Letter of Comfort system, in the context of a phased approach to disposal, Nirex provides guidance to the nuclear industry on its requirements for the packaging and transport of ILW. Nirex issues LoCs in three stages, which successively assess the suitability of proposals against the requirements for safe disposal against Nirex's phased disposal concept.

Licensee. The legal entity which has the responsibility for operating a UK nuclear industry facility under the terms and conditions of the nuclear site licence.

LLW. Low level waste, which contains radioactive materials that together do not exceed 4 Gigabecquerels per tonne alpha or 12 Gigabecquerels per tonne beta/gamma activity.

Managing Radioactive Waste Safely (MRWS). The government programme to determine policy for the long-term management of the UK's higher activity radioactive waste.

National Inventory. The inventory of radioactive waste in the UK (managed by Nirex for the Department for Environment, Food and Rural Affairs).

Nuclear Licensed Site. Any site which is the subject of a licence granted by the HSE (under the Nuclear Installations Act 1965) to the licensee for the purposes of installing or operating a nuclear installation on that site.

Options Assessment Process. A systematic and consultative decision-making procedure to establish the option which best meets the given set of objectives.

Packaging. The operation of producing a container filled with the waste or waste form.

Passive Safety. Passive safety requires radioactive waste and materials to be immobilised in a form that is physically and chemically stable and stored in a manner that minimises the need for control and safety systems, maintenance, monitoring and human intervention.

Phased Disposal Concept (PDC). Nirex's preferred option for a deep geological disposal facility for ILW (developed by Nirex).

[†] Change in terminology: At the time of writing, Nirex were in the process of changing the terminology "Letter of Comfort" such that LoC will stand for "Letter of Compliance" as from January 2005. To avoid confusion and to maintain consistency with quoted reference material, the term "Letter of Comfort" is used throughout this document: as such, the terms "Letter of Comfort" and "Letter of Compliance" are interchangeable in this guidance. Nirex will produce separate guidance on the application of its Letter of Compliance process, which will include details of the new terminology.

Regulators. The Health and Safety Executive, the Environment Agency and the Scottish Environment Protection Agency. (Note that other regulatory bodies are involved in the management of UK radioactive waste but, in this document, this definition is limited to the authors of this guidance).

Repository. A nuclear facility where waste is emplaced for disposal.

Safeguards. Measures to verify that States comply with their international (i.e. Treaty) obligations not to divert civil nuclear material into weapons programmes.

Safety Case. A collection of arguments and evidence to demonstrate the safety of a facility or activity.

Secondary Waste. Waste that results from applying treatment, handling or storage technology to a waste or product stream of a process.

Segregation. The physical separation of wastes according to type and/or characteristics.

Storage. Placement of waste in any facility with the intent to retrieve it at a later time.

Sustainable Development. This is commonly defined as "Development that meets the needs of the present generation without comprising the ability of future generations to meet their own needs".

Treatment. Any operation that changes the chemical or physical characteristics of the waste.

Waste Container. The packaging material containing the waste form.

Waste Form. The physical and chemical form of the waste after treatment and/or conditioning (resulting in a solid product). The waste form is a component of the waste package.

Waste Management. All administrative and operational activities involved in the handling, pre-treatment, treatment, conditioning, transport, storage and disposal of radioactive waste.

Waste Package. The package of material destined for disposal including the waste container and the waste form.

1 Introduction

1.1 Purpose

The purpose of this guidance is to provide a single, overarching document to explain the regulatory process and provisions associated with the conditioning[†] of intermediate level radioactive waste (ILW) on nuclear licensed sites in the UK. The main aims of the guidance are to:

- provide a comprehensive source of information that can be used by nuclear site licensees and inspectors, and the wider stakeholder audience;
- set out the information that regulators would expect to see included as part of the safety case; and
- advise licensees of the process to obtain regulatory acceptance of their proposals to condition ILW.

Suggestions provided by key stakeholders from Government, industry and advisory committees on the form and content of this document have been taken into account. This document is available on the regulators' websites in accordance with their respective policies of openness and transparency.

This guidance complements the Health and Safety Executive's (HSE) and the Environment Agency's extant guidance to inspectors on nuclear safety cases and the conditioning of ILW, respectively. These two documents are available on the HSE and the Environment Agency's websites (see subsection 3.5) and explain the detailed assessment process undertaken by the regulators to examine ILW Conditioning Proposals.

1.2 Background

The Government's consultation papers on "Managing Radioactive Waste Safely" (MRWS)[1] and "Managing the Nuclear Legacy"[2] highlighted the issues around the management of the large quantities of ILW that currently exist and will be generated over the next century. Subsequently, Government decided to establish the Nuclear Decommissioning Authority (NDA) to take responsibility for the liabilities on civil public sector nuclear sites. The NDA's remit includes setting the UK strategy for decommissioning and clean-up, and implementing that strategy by means of waste management programmes, which are likely to cost billions of pounds over a number of decades.

Following the consultation papers referred to above, the Department for Environment Food and Rural Affairs (Defra), the Scottish Executive and the Department for Trade and Industry (DTI) accepted a proposal from HSE, the Environment Agency and the Scottish Environment Protection Agency (SEPA), (collectively referred to as "the regulators"), aimed at improving the regulatory arrangements for conditioning ILW on nuclear licensed sites. The improvements were initiated to address the regulators' concerns that the nuclear industry was regulating itself with respect to the conditioning of ILW. The proposed arrangements aimed to bring the consideration of waste conditioning within the regulators' processes and were to be implemented through joint regulatory working arrangements. The Government departments expressed a wish to receive further details. In response to this, a Position Statement[3] was issued by the regulators, which explained the improved regulatory arrangements and was informed by the outcomes from a twelve-month review of the regulators' proposal with key stakeholders. (The Position Statement details the improvements to the regulatory process and the reasoning behind these changes, and should be consulted if further information on this topic is required). In the Position Statement, the regulators set out a joint commitment to produce guidance explaining the improved regulatory process for evaluating proposals from licensees to condition ILW on nuclear licensed sites. This document fulfils the regulators' commitment in this area.

[†] The processing of ILW to achieve passive safety for interim storage and to prepare it for eventual disposal consists of treatment, conditioning and packaging stages. For brevity the terms are condensed to "conditioning" in this document except where it is necessary to refer to one of the stages specifically.

1.3 Regulatory Arrangements for ILW Conditioning

HSE regulates the conditioning of radioactive wastes on nuclear licensed sites in the UK under the terms of the conditions attached to the nuclear site licence[†]. When preparing safety cases for HSE under the requirements of Licence Condition 14, licensees should include aspects relating to the conditioning of their ILW. Where appropriate, the conditioning of ILW will be subject to the agreement or consent of HSE under Licence Conditions 19, 20, 21 or 22. When assessing the safety cases, HSE will consult the relevant environment agency, in accordance with the respective Memorandum of Understanding (MoU), and will take full and meaningful account of any environmental issues as advised, before issuing a consent or agreement. (For the purposes of this document the action of granting an agreement or consent under the relevant Licence Condition is referred to as a "permission"). HSE will seek the relevant agency's advice in order to be satisfied that the licensee has considered long-term environmental protection concerns, particularly those relating to the long-term disposability[‡] of the proposed waste form.

In outline, the arrangements provide for regulatory oversight of the following three interlinked[§] aspects of ILW conditioning:

1. proposals from licensees to condition all types of ILW, including those wastes that are challenging to characterise, retrieve or condition;
2. the Nirex "Letter of Comfort" system, which is the regulators' preferred route for licensees to demonstrate that ILW Conditioning Proposals meet the relevant international packaging standards and the anticipated requirements for final disposal;
3. the development by Nirex of their "Phased Disposal Concept" (PDC) which provides the current UK reference design for a deep geological disposal facility for ILW.

This guidance focuses on the first of the aspects described above, with the aim of ensuring that proposals to condition ILW give proper emphasis to safety, radioactive waste management and long-term environmental considerations whilst having due regard to costs and benefits. As a separate part of the improved arrangements, the environment agencies (Environment Agency and SEPA) have set in place programmes of work to scrutinise the LoC assessment process and the associated development by Nirex of the PDC, to seek assurance on their fitness for purpose.

It is the regulators' intention that this guidance should assist licensees by:

- increasing the transparency of regulatory decision-making, and streamlining the path to permissions, by providing a clear and transparent regulatory process involving early dialogue between the nuclear industry, the regulators, Nirex, the NDA, and other stakeholders;
- providing much greater business certainty for the nuclear industry at a time when it is committing significant resources to ILW conditioning. The arrangements will apply at all stages and early interactions with the regulators are encouraged, to avoid wasted effort, potential delays and costs resulting from the development of inappropriate waste management approaches;

[†] Certain wastes, bearing nuclear materials, are subject to the safeguards requirements of the Euratom Treaty and to the terms of the UK safeguards agreement with Euratom and the IAEA pursuant to the Nuclear Non-Proliferation Treaty (NPT). Provision must be made, in discussion with the Euratom safeguards inspectorate and, where necessary, the IAEA, to meet these requirements.

[‡] In the context of this guidance, and in light of the ongoing MRWS programme to determine policy for the long-term management of the UK's higher activity radioactive waste, the term "disposal" is used to mean the emplacement of waste in an authorised, specialised facility constructed for its long-term management and for which the primary expectation is not one of retrieval. "Disposability" is used to refer to the degree to which conditioned waste meets the standards and specifications for final disposal.

[§] These three aspects are inter-linked because Nirex use their PDC as the basis to judge whether the proposed form of the waste package and the conditioning steps to be taken would allow the ILW to be disposed of if the PDC option were chosen.

- providing a clear, auditable document trail of the basis for current regulatory decisions that could inform future implementation of a waste disposal strategy.

Where appropriate, the regulation of ILW conditioning on any licensed nuclear site is carried out in partnership based on the principles of early interactions and joint working as set out in the HSE/Environment Agency document "Working Together on Nuclear Sites"[4]. The regulators wish to be engaged constructively at all stages: their role is one of challenging and seeking assurance that a licensee's proposal and Nirex's advice satisfies the regulators' requirements. Thus, the regulatory process is based on a process of continual dialogue between the nuclear industry and the regulators, against a background of formal regulatory hold points (see subsection 6.2).

Although the impact of radioactive (and non-radioactive) waste discharges and disposals is an integral part of the consideration of any waste management operation, these are regulated separately by the appropriate environment agency. Applications to discharge or dispose of radioactive wastes will continue to be made directly by the licensee to the appropriate environment agency - not through HSE as indicated for the other aspects discussed in this guidance.

1.4 How the CoRWM Review Affects this Guidance

The regulators expect the licensee to make a case for the disposability of conditioned ILW against the waste acceptance criteria of an appropriate disposal facility. Acceptable waste management options for the UK's ILW are currently under review, led by the Committee on Radioactive Waste Management (CoRWM). The regulators recognise that the statements in the Government White Paper Cm2919[5] that imply a commitment to disposal as the long-term management option may be amended on completion of CoRWM's review. However, a cross-government policy group, the Radioactive Waste Policy Group (RWPG), has considered the arrangements that should be in place to address disposability requirements while CoRWM's work is underway. The RWPG noted that work to check the compatibility of ILW packaged under the Nirex Letter of Comfort (LoC) arrangements had shown a good level of compatibility with the range of options likely to be considered by CoRWM. The RWPG concluded[6,7] that, on the balance of probabilities, waste destined for eventual disposal in an ILW facility should continue to be packaged under the existing LoC arrangements: these arrangements should be kept under review, however, it would not be acceptable to defer packaging during CoRWM's review of options. The LoC process will, therefore, continue to play an important role in demonstrating that ILW Conditioning Proposals meet the anticipated requirements for final disposal to an ILW facility.

2 Scope

2.1 General

This guidance is applicable to the conditioning of all types of ILW on nuclear licensed sites, and to certain low level waste (LLW) that cannot, at present, be disposed of to an LLW disposal facility. For ease of use, the term "ILW" is used throughout this guidance to mean these types of waste. Where appropriate, licensees are advised to make early contact with the regulators to discuss whether their LLW falls within the scope of this guidance.

This guidance applies at all stages of the regulatory process. In particular, interactions between the licensee and the regulators are important at the conceptual and options assessment stages (especially for more challenging proposals) in order to gain the regulators' views at an early stage. Not all proposals will warrant formal submission to the regulators. Instead, a priority system will be operated to "call in" particular proposals. The decision whether a submission to HSE is necessary is a matter that will usually be resolved between the licensee and the local HSE/NII site inspector. In the event that HSE, in consultation with the appropriate environment agency, decide that the licensee should make a submission, then the form of that submission, and the extent to which the various parts of this guidance apply, will be a matter for resolution during the early interaction between the licensee and the regulators.

2.2 Categories of Waste

ILW is defined in Cm2919 as waste "with radioactivity levels exceeding the upper boundaries for low level waste[†], but which does not require heating to be taken into account in the design of storage or disposal facilities". This is a very broad definition and the term "ILW" covers a multitude of waste types with varying activities and half-lives. As noted above, this guidance is also applicable to certain LLW that cannot, at present, be disposed of to a low level waste disposal facility.

2.3 Waste Management Options

The extent to which this guidance applies will depend on the waste management option that the licensee chooses and justifies to the regulators in their proposals.

3 Legislation and Standards

3.1 Legislation

HSE regulate spent fuel management and radioactive waste management on all the nuclear licensed sites in the UK. The main legislation covering the safety of workers and the general public at nuclear installations in the UK is the Health and Safety at Work Act 1974[8] and associated statutory provisions, which include the Nuclear Installations Act 1965 (as amended)[9] and the Ionising Radiations Regulations 1999[10].

The disposal of radioactive waste (including transfers between sites) and the discharge of radioactive substances in airborne and liquid discharges from any facility, including nuclear licensed sites, is regulated by the Environment Agency in England and Wales, SEPA in Scotland and the Department of the Environment in Northern Ireland, under the Radioactive Substances Act 1993[11] and the Environment Act 1995[12].

In addition to the legislation referred to above, which is the subject of this guidance, there are other nuclear regulatory requirements that may have to be complied with as follows.

The Competent Authority in the UK for approval of packages for the transport of radioactive material is the Radioactive Materials Transport Division of the Department for Transport. A DfT Guide[13] sets out requirements for applications requiring UK Competent Authority approval, which is based on the requirements set out in IAEA guidance[14].

The Nuclear Industry Security Regulations 2003[15] deal with ensuring the security of nuclear material and related equipment and information. The Office for Civil Nuclear Security (OCNS)[‡] enforces them.

The safeguards provisions of the Euratom Treaty[16] and of the UK's safeguards agreement with Euratom and the IAEA[17] apply to nuclear material (i.e. plutonium (all isotopes), natural, depleted, and enriched uranium, and thorium) contained in certain kinds of waste in the UK. These safeguards are based on nuclear materials accountancy measures, whereby the European Commission (in the case of Euratom safeguards) and the IAEA are provided with declarations of nuclear material inventories (i.e. how much material there is and where it is, so-called nuclear materials accountancy reports), and information on relevant aspects of the design of the nuclear facilities concerned. The safeguards inspectorates of the Commission and/or the IAEA perform inspections to verify that nuclear material is present as declared, and that relevant aspects of facility design are as declared. The safeguards requirements of the UK's safeguards agreement with Euratom and the IAEA are now supplemented by an Additional Protocol to that agreement[18], and the application of all safeguards measures in the UK is described further on the non-proliferation section of the Department of Trade and Industry website (www.dti.gov.uk/non-proliferation/safeguards.htm)

[†] The upper boundaries for low-level waste are 4 GBq/te of alpha and 12 GBq/te of beta/gamma.

[‡] The Office for Civil Nuclear Security is an independent unit within DTI responsible for the regulation of security in the civil nuclear industry.

Further details of legislation relevant to ILW conditioning are given in Appendix A.

3.2 Policy

Until Government announces any new policy as a result of current deliberations led by CoRWM[†], the regulators will continue to ensure that the framework described in Cm2919 is implemented in accordance with the duty on them described in that White Paper[‡]. Key points relevant to ILW conditioning, from Cm2919 and amendments from the recent decommissioning policy review, are detailed in Appendices B and C respectively.

The regulators recognise that the statements in Cm2919 that imply a commitment to disposal as the long-term management option may be amended following completion of the CoRWM review. Regardless of this uncertainty, the Government has stated that it will continue to develop a policy and regulatory framework which ensures that:

- radioactive wastes are not unnecessarily created;
- any wastes that must be created are safely and appropriately managed and treated;
- such wastes are then safely disposed of at appropriate times and in appropriate ways.

3.3 International Standards

A number of international organisations contribute towards the policy framework relevant to ILW conditioning in the UK, each with a distinct role. These organisations and their roles are detailed in Appendix D.

The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management[19], which came into effect in June 2001, acts through a process of international peer review of countries' policies and practices for the management of spent fuel and radioactive waste. It has been ratified by over twenty-five countries (including the UK).

In ratifying the Joint Convention, the UK has agreed to provide for effective protection of individuals, society and the environment, by applying at the national level suitable protective methods as approved by the regulatory body. Furthermore, the UK is required to ensure that the framework of its national legislation has due regard to internationally endorsed criteria and standards. Key points from the Joint Convention relevant to ILW conditioning are described in Appendix E.

3.4 International Safeguards in the UK

Civil nuclear material in the UK is subject to the safeguards provisions of the Treaty establishing the European Atomic Energy Community (the Euratom Treaty) and to the terms of the UK's safeguards agreement with Euratom and the IAEA (see www.dti.gov.uk/non-proliferation/safeguards.htm for further information). Nuclear material form is a factor in determining the safeguards measures to be applied, and safeguards agreements provide for less onerous measures for material in waste. However, categorisation of material as waste for safeguards purposes may not always align with waste categorisation for other purposes, and so the detail of applicable safeguards measures will be a matter for discussion with the safeguards authorities.

3.5 Regulatory Guidance and Principles

Government policy and international standards form the basis for the regulators' own principles and guidance. Key guidance documents produced by the regulators with respect to ILW conditioning are listed below:

[†] Until CoRWM has delivered its recommendations and consequent decisions have been made, Government is uncommitted to any specific long-term radioactive waste management policy or its means of delivery.

[‡] Cm2919, paragraph 52(2) the regulators *"…have the duty to ensure that the framework described above is properly implemented in accordance with their statutory powers"*.

- *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* Nuclear Safety Directorate, March 2001. (www.hse.gov.uk/nsd/waste1.pdf)
- *"Environment Agency Guidance on the Conditioning of Intermediate Level Waste"* Environment Agency.
- *"Radioactive Substances Act 1993, Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Guidance on Requirements for Authorisation"* Environment Agency, Scottish Environment Protection Agency and Department of the Environment for Northern Ireland, 1997.

A summary of the standards and guidance relevant to ILW conditioning, to which the regulators work, is given in Appendix F.

4 UK Organisational Responsibilities

4.1 Licensees

Licensees bear the prime responsibility for safety and environmental protection relating to activities carried out on their site. They produce safety cases to justify ILW conditioning operations, which should take account of safety, radioactive waste management and environmental protection considerations.

As provided under their own arrangements under the site licence, or if so specified by HSE, licensees must not proceed with ILW conditioning operations without the permission of HSE.

4.2 HSE/NSD

The Health and Safety Executive, through its Nuclear Safety Directorate (NSD), secures effective control of health, safety and radioactive waste management at nuclear sites for the protection of the public and workers.

HSE is responsible for regulating the conditioning of ILW through conditions attached to the nuclear site licence.

Under the terms of relevant Memoranda of Understanding (MoU), HSE consults the Environment Agency or SEPA and will not give permission for ILW conditioning without taking full and meaningful account of any environmental issues raised.

4.3 The Environment Agency & SEPA

The Environment Agency and SEPA have a leading role in protecting and improving the environment. The Environment Agency is responsible for matters in England and Wales. SEPA has similar responsibilities in Scotland.

The environment agencies are responsible for authorising, under RSA93, any disposal, discharge or off-site transfer associated with ILW conditioning.

Under section 37(3) of the Environment Act 1995 (EA95), the Environment Agency or SEPA may provide advice *"as respects any matter in which they have skill or experience"*. On this basis, the environment agencies, in response to being consulted under the terms of their respective MoU with HSE, give advice to HSE on issues related to environmental protection. In particular, the environment agencies give advice regarding the long-term disposability of conditioned waste, and matters relating to the need to ensure that ILW is managed in a sustainable way, taking into account long-term environmental considerations. Under section 37(1) of EA95, the environment agencies charge HSE for that advice.

In addition, separate agreements between the environment agencies and Nirex allow the agencies to scrutinise the Nirex PDC with regard to its role as a basis for assessing LoC applications, and its fitness for purpose.

4.4 Nirex

In relation to the conditioning of ILW, Nirex operate the Letter of Comfort process designed to give assurance that conditioned wastes will meet the safety criteria that it has developed[†] for the storage, transport, handling and disposal of ILW. By this process, Nirex gives advice to licensees that can be used in the formulation of proposals to condition ILW and the licensee's safety case.

4.5 NDA

From April 2005, the Nuclear Decommissioning Authority (NDA) will take responsibility for the decommissioning and clean up of all civil public-sector nuclear sites in the UK[20]. This responsibility includes the management of ILW. The NDA is currently establishing waste-management plans with site licensees, and has a duty to agree these plans with the regulators, as described in the Energy Act 2004.

5 ILW Conditioning Proposal / Safety Case

5.1 ILW Conditioning Proposal as Part of the Safety Case

In this guidance an "ILW Conditioning Proposal"[‡] is the term used for all the documentation produced by the licensee, detailing proposals to condition ILW, and the associated justification in safety and environmental terms. The ILW Conditioning Proposal will form part of the overall "safety case" for the plant, process or site as appropriate, i.e. the suite of documentation which, when taken together, justifies the safety of an installation throughout its life. HSE's guidance on nuclear safety cases[21] provides detailed guidance on safety cases, in general, and should be read in conjunction with their guidance to inspectors on radioactive materials and waste[22].

The process to obtain regulatory permission for an ILW Conditioning Proposal is discussed in detail in Section 6. The process is likely to be staged and, if required, the proposal would be submitted to the regulators when permission is needed. The points at which permission is required to proceed are referred to in this document as regulatory "hold points". Thus, the ILW Conditioning Proposal is a "live" document and should be updated, refined and reviewed at each stage of the plans. Further guidance about the ILW Conditioning Proposal is included as a question and answer discussion at Annex A.

5.2 Content of ILW Conditioning Proposals.

The ILW Conditioning Proposal exists for the benefit of the licensee and should be maintained, together with the associated audit trail, for use when an authorisation for disposal to a facility is finally sought from the environment agencies. As the licensee's plans progress, the proposal should be reviewed and updated as appropriate. As with any part of the safety case, the scope, form and content is the licensee's responsibility, hence this guidance does not prescribe the detail or the depth that should be addressed: this will depend upon the specific details of each conditioning proposal.

The proposed scope, form and content of an ILW Conditioning Proposal should be agreed with the regulators as early as possible in the life of a project. Not all projects will need to cover all the aspects listed below. Rather, the proposal should be fit for purpose and cover relevant topics to the degree of detail required[23,24]. It may comprise either a compendium of documents or a standalone document. Whatever the form, its scope and content should address the safety, radioactive waste management and environmental protection issues discussed in this guidance, so far as they are relevant to, and to the extent necessary for, the proposal.

It is important that the ILW Conditioning Proposal is seen as part of the overall safety case for the plant, process or site. Therefore, where aspects related to the proposal have already been covered elsewhere in the safety case, these only require cross-referencing, rather than repeating or

[†] Ultimately, proposals must satisfy the requirements of HSE and the Department of Transport regarding the operational safety and the off-site transport requirements respectively.

[‡] Note that, for the purposes of this guidance the term "ILW Conditioning Proposal" is also applicable to proposals that contain the justification for long term storage without immediate conditioning.

duplicating the work to produce them. Where many documents are being assembled to support the proposal, it may be useful to produce a top tier, summary safety report that provides a structured route through the relevant documentation and indicates how the various references support the safety case.

An ILW Conditioning Proposal may cover, but may not be limited to, the following main topics (subsections 5.2.1 to 5.2.5) to the extent that they are relevant to the proposal. Further details and references to further guidance are given in Appendix G.

5.2.1 Description of the ILW Conditioning Proposal

The ILW Conditioning Proposal should describe and substantiate, as appropriate, details of:

- the waste streams (including their source of arising, characteristics, inventory and quantities);
- the relevant buildings and plant involved (e.g. for conditioning or storage);
- site conditions (including adequacy of current storage arrangements and any containment issues);
- the proposed waste management processes including, where appropriate:
  - details of the methods to be used for the segregation and characterisation of wastes and the practicable steps taken to avoid dilution of ILW;
  - evidence that the (segregated) waste streams can be characterised to the level necessary to ensure compliance with the specifications for waste packaging (e.g. with respect to potential variability or heterogeneity);
  - description of the techniques adopted to prevent or minimise ILW arisings (including how any secondary wastes generated during conditioning will be prevented or minimised).
  - demonstration that an effective route can be provided for any future processing of the wastes that might be required to produce a disposable waste form;
- how the waste will be conditioned, including details of:
  - how passive safety will be achieved;
  - the intended specification for the waste form (presented in a format suitable for external audit to ensure compliant packages have been produced);
  - how the inventory of individual packages will be controlled and measured, including demonstration that any heterogeneity or variability in the waste stream can be accommodated within the specifications for the final waste form;
  - how conditioned waste that does not meet specifications will be processed;
  - the arrangements for quality assurance and records.

5.2.2 Options Assessment

The ILW Conditioning Proposal should include details of the assessments that have been undertaken to identify and justify the preferred option including information on:

- the options and processes considered to convert the raw waste into a disposable product (including any necessary pre-treatment stages);
- the reasons and assumptions used to reject options;
- the reasons, assumptions, uncertainties, calculations and conclusions for selecting the preferred option(s), including comparison of the safety and environmental performance of the preferred option(s) with the options that were not selected;

- how the preferred option is consistent with the integrated waste management strategy;
- details of any stakeholder or public consultation, if appropriate;
- the use of, and implications for, existing waste disposal routes if the preferred option is selected.

5.2.3 Plant, Process and Site Safety

The ILW Conditioning Proposal should address general safety issues associated with the plant, process and site as appropriate, including:

- how the licensee will ensure that the risk to workers and the public through exposure to radiation is ALARP;
- discussion of the contamination and radiation controls required;
- how any conventional hazards will be addressed;
- how criticality will be prevented prior to disposal;
- how any safeguards issues will be addressed;
- how fire protection and the prevention of explosions will be addressed;
- plans for maintenance work and eventual decommissioning.

5.2.4 Storage of ILW

Where the licensee anticipates a substantial period of storage before the waste is finally removed from the site, the ILW Conditioning Proposal should address the arrangements for such storage of the conditioned waste, including:

- details of the storage capacity requirements;
- the timescale for storage;
- demonstration that the conditioned wastes will remain within the agreed specification for final disposal throughout the storage period;
- how passive safety will be achieved;
- the integrity of the storage arrangements;
- details of ventilation requirements and the filtration of airborne releases;
- environmental monitoring arrangements;
- how the stored waste will be inspected and retrieved.

5.2.5 Disposability of Waste

The ILW Conditioning Proposal should include a demonstration that, following conditioning, the ILW will be compatible with existing or potential future management and disposal options. If the anticipated final disposal option is to an existing, authorised disposal site (e.g. where the strategy is for decay storage and then disposal of the LLW at an appropriate licensed waste facility) then the licensee should demonstrate how the waste will meet the acceptance criteria for that disposal site. Otherwise it should include:

- assessment of the implications of the proposal in terms of the likely performance of a future repository for ILW. The assessment should evaluate the potential impact on the performance of the facility as well as the potential impact on the radiological consequences that might arise from such a facility;

- demonstration that the proposed packaging and conditioning strategy uses Best Practicable Means (BPM) to minimise the long-term environmental impact and to ensure doses are as low as reasonably achievable (ALARA);
- demonstration that the proposed strategy will not lead to significant increases in the possibility of a neutron chain reaction in a disposal facility, through the local accumulation of fissile material;
- assessment of the long-term performance and degradation of the waste containers;
- evaluation of any reactions that may take place between the waste and the conditioning matrix;
- evaluation of the long-term performance of the waste form e.g. assessment of the potential for cracking and chemical degradation;
- assessment of the potential for gas generation from the wastes in the long term;
- consideration of the impact of toxic materials as a result of release from a repository and environmental impacts that might arise during, or as a result of, operations;
- assessment of the potential impact from any detrimental effects due to chemical species that may be present in the wastes or might reasonably be expected to form e.g. enhancement of radionuclide solubility through chemical complex formation;

5.2.6 Radioactive Waste Discharges and Disposals

Although the impact of radioactive waste discharges and disposals is an integral part of the consideration of any operation, these are regulated separately by the appropriate environment agency (Environment Agency or SEPA). Applications relating to this aspect will be made directly by the licensee to the appropriate agency – not through HSE as indicated for the other aspects discussed in this guidance.

5.2.7 Summary of a Typical Proposal Structure

References to key information sources on ILW conditioning that licensees are advised to consider when compiling information for ILW Conditioning Proposals, are shown in Table 1 for each of the topics discussed in subsections 5.2.1 to 5.2.5. Appendix G provides references to further sources of information for each of these topics.

5.3 The Role of the Nirex LoC Process in the Development of an ILW Conditioning Proposal

As part of their assessment criteria, the regulators expect that conditioned wastes will meet the relevant international packaging standards and the anticipated requirements for final disposal. Unless ultimate disposal to an existing disposal facility is planned, the regulators would normally expect licensees to seek an assessment via the Nirex Letter of Comfort (LoC) process. The LoC process will therefore be an important input to the proposal.

From a “disposability” viewpoint the LoC process allows for three successful outcomes (i.e. those that enable the issue of a LoC):

- all Nirex safety criteria can be met for the packaging proposal;
- assessment of the packaging proposal shows that, for the specific waste stream being assessed, it is not necessary to meet all of the Nirex general safety criteria;
- it is not possible to demonstrate compliance with all the Nirex general safety criteria now (thus a defined “compliance gap” exists) but in Nirex’s view the licensee has demonstrated credible plans to remove the compliance gap in the future to produce a packaged wasteform that will be acceptable to Nirex.

Table 1: ILW Conditioning Proposals - Key Information Sources

Topic	Key Guidance
Description of the Proposal	*"IAEA Safety Standards Series No WS-G-2.5"* IAEA, Vienna 2003 – Section 4.6. *"IAEA Safety Standards Series No WS-R-2"* IAEA, Vienna 2000 – Section 5.
Options Assessment	*"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* HSE - Section 6.5 and Appendix 2. The environment agencies *"Guidance to Regulators on the Assessment of BPEO Studies"* will be published on their respective web sites. *"A Review of the Application of BPM within a Regulatory Framework for Managing Radioactive Wastes"* (in preparation – Environment Agency, SEPA & the Environment and Heritage Service of Northern Ireland)
Plant, Process and Site safety	*"HSE Safety Assessment Principles for Nuclear Plant"* HSE. *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* HSE.
Storage	*"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* HSE.
Disposability	*"Guidance on the Conditioning of Intermediate Level Waste"* Environment Agency. *"Radioactive Substances Act 1993, Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Guidance on Requirements for Authorisation"* Environment Agency, SEPA and the Department of the Environment for Northern Ireland, 1997. *"The Principles of Radioactive Waste Management"* IAEA Safety Series No 111F, IAEA, Vienna 1995 – Principle 5. *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* HSE - Section 6.4. *"Waste Package Specifications for Intermediate Level Waste"* N/007 (under revision), Nirex. *"Guidance on the Preparation of Letter of Comfort Submissions"* T/REP/20632, Nirex.

In some cases, the licensee's options assessment for ILW conditioning might show that it is not reasonably practicable to produce a package to the standards required to obtain a LoC. Also, for certain wastes, the regulators recognise that it may not be practicable to demonstrate compliance, in a timely manner, with all of the LoC specifications, because:

- this would delay the treatment of the waste to the extent that immediate safety concerns would become overriding; or
- the necessary information (e.g. on waste characterisation) cannot be obtained without first retrieving the waste.

In certain cases, such as those just described, the regulators could agree to proposals involving packaging without a LoC. In these instances, early and continued involvement of Nirex is desirable, to understand the difficulties in complying with Nirex safety criteria. In particular, it is likely that much of the assessment associated with the LoC will still be necessary in order to understand the potential problems with future disposal, to justify the decision, and to put in place contingencies (such as plans for further conditioning in the future) to address such problems.

In such cases, the HSE and relevant environment agency would only give their permission where:

- all options to condition the ILW have been assessed;
- any "compliance gap" is fully understood and credible plans are in place, and have been agreed with the regulators, to address it.

While it is recognised that interim treatment might sometimes be necessary to reduce the hazard, this will need to be balanced against the regulators' strong preference to avoid the need for further reworking or repackaging. In all such cases the regulators will be looking for the waste to be packaged in a manner that facilitates later conditioning in accordance with Nirex safety criteria.

5.4 Basis for Regulatory Acceptance

Proposals to condition ILW will be assessed against the standards and principles identified in Section 3 (and further detailed in Appendices A to F). In particular, the regulators will expect proposals to demonstrate:

- consistency with radioactive waste management and decommissioning strategies;
- the use of modern standards and good practice;
- adequate control and containment of radioactive waste;
- the safe storage of radioactive waste for the necessary period, to acceptable environmental standards and with sufficient monitoring to ensure that safety and environmental protection standards are maintained;
- that radioactive waste can be retrieved after an appropriate period in a form that would be suitable for disposal;
- adequate management of the ageing of structures, plant and waste packages;
- that the long-term aspects of disposability have been satisfactorily considered by:
  - meeting acceptance criteria for established disposal sites; or
  - showing that all Nirex safety criteria can be met (noting that Nirex's criteria can be modified in the light of assessments of real cases[†], provided that their environmental case is not jeopardised); or

[†] This includes the possibility of Nirex re-addressing its pessimisms through, for example, commissioning research to address uncertainties in the PDC.

  - where it is not possible to demonstrate compliance with all Nirex general safety criteria in the short term, showing that credible plans are in place for developing future re-work schemes with a view to achieving a "disposable" form; or
  - showing that, for the specific waste stream being assessed, it is not necessary to meet all of the Nirex general safety criteria.
- decisions have been reached in a systematic and transparent way and are documented appropriately;
- that an appropriate balance between short-term actions and long-term commitments has been achieved.

The regulators recognise the need to adopt an approach that takes a balanced view of all relevant factors in assessing proposals from licensees, including safety, radioactive waste management and environmental performance, cost and practicability. Licensees' proposals will be scrutinised, and, where necessary, robustly challenged, on a case by case basis to yield transparent, consistent, judgements.

Given the extended periods of storage that are now likely, and regulatory concerns about the existing storage conditions of some ILW waste streams, the regulators consider that, for these wastes, emphasis should be placed on the implementation of programmes to achieve passively safe storage as soon as reasonably practicable. Proposals to store ILW for long periods prior to conversion to a disposable form will be given due consideration. However, the regulators will expect such proposals to justify how the delay involved represents best practice, and also to demonstrate how and when conversion to a disposable product will be achieved.

5.5 Options for Disposal as LLW

Waste management options exist for some ILW, to reduce its radioactivity to allow its disposal as LLW. These options include storage for decay and/or processing to recover radionuclides. These wastes are classified as ILW because, at the time of their creation, their level of radioactivity exceeds the activity limits for LLW. However, if the licensee can assure the regulators that the waste will be disposed of as LLW, the disposability of the waste forms will be assessed against their chosen disposal route (e.g. the acceptance criteria for the disposal facility at Drigg) rather than using the Nirex LoC assessment process. Storage requirements will still have to be met, in particular the requirement that the waste should be, so far as is reasonably practicable, in a passive safe form. Relevant factors include the form of the waste and the anticipated timescales for storage. The regulators' approach provides continuity with the previous arrangements for the regulation of this class of ILW. To that end, the regulators will expect to be kept informed by the waste producer of their ongoing arrangements for managing this class of wastes. The regulators will continue to keep these arrangements under review. Provided the storage continues to be managed with due regard to operational and environmental safety and protection, the regulators will not expect producers of such wastes to pursue different approaches to those currently employed, which may result in grossly disproportionate costs for treatment, conditioning and packaging.

6 Regulatory Permissioning Process

6.1 Overview

The regulatory process for granting permission for ILW conditioning is based on early and continual involvement of the regulators in the development of conditioning proposals, as described by the principles set out in the HSE/Environment Agency document "Working Together on Nuclear Sites"[4]. In particular, interactions are important at the options assessment and concept stages in order to seek the regulators' views. This complements the formal, staged system of hold points for regulatory permission.

Although early dialogue is not a legal requirement[†], the regulators believe it is the only way to achieve a streamlined and effective regulatory process that prevents unnecessary and costly delays. The regulators' role is one of challenging and providing constructive criticism with the aim of ensuring that a licensee's proposal (including, where applicable, any advice from Nirex) satisfies the regulators' requirements.

The regulation of proposals to condition ILW is exercised through the nuclear site licence issued by HSE. As part of the conditions of a nuclear site licence in the UK, the operator must have in place a detailed safety case justifying the safety of the plant throughout its life. Any subsequent alteration to the site facilities, e.g. the modification of existing plant/processes or the construction of new plant, requires the preparation of a safety case and, where appropriate, permissioning by the HSE. The conditioning of ILW not previously authorised for treatment either constitutes a modification to existing plant, regulated by Licence Condition 22, or it involves the construction or installation of new plant, regulated by Licence Condition 19. Application for permission is made using the licensee's arrangements under the appropriate Licence Condition or as a result of HSE specifying the need for such an application.

6.2 The Process for Obtaining Regulatory Permission for an ILW Conditioning Proposal

The process for obtaining regulatory permission for an ILW Conditioning Proposal is designed to be flexible and efficient, and to avoid undue delay. Licensees are requested to inform the regulators at an early stage of their intention to condition ILW, so that constructive dialogue can commence.

For all appropriate wastes, the licensee is required to prepare an ILW Conditioning Proposal documenting how safety, radioactive waste management and environmental issues will be addressed. However, not all ILW Conditioning Proposals will warrant formal submission of their associated documentation to the regulators. Instead, a priority system will be operated (under development at the time of writing) to "call in" particular proposals. The decision to "call in" a proposal will be based on a number of technical and strategic factors. For example, proposals may be selected for detailed scrutiny on the grounds that:

- Major strategic or policy issues arise;
- The proposed waste package will be unable to fully meet the requirements for a LoC;
- The proposed waste package is only able to meet the requirements for a LoC subject to further work or modifications to the PDC;
- The proposed process is novel and/or major technical questions arise in relation to the process;
- It has not been demonstrated adequately that the proposed strategy is the best overall option taking account of safety, environmental and other considerations.

In general, proposals that relate to small proportions of the national inventory are less likely to be examined than those that relate to a major proportion of the national inventory. Other proposals may be selected on a sample basis, to provide assurance that the LoC process is operating satisfactorily.

If a licensee can show that, using already proven processes, waste is to be conditioned in a single stage to a form that fully meets the requirements of a LoC assessment, then there may not be substantial regulatory involvement, and the regulators may decide not to request that an ILW Conditioning Proposal is submitted or invoke the permissioning process.

Proposals will be assessed against the legislation, standards, principles and statutory duties of the regulators described in this and other guidance documents. The legislation and standards (described in more detail in Appendix F) place obligations on licensees to show how individual conditioning

[†] If new-build facilities are required that involve nuclear materials, it should be noted that 200 days notice before commencement of building is required to meet Euratom legislation.

proposals fit with wider waste management plans, hence decisions about the conditioning of particular waste streams should not be made in isolation.

The process for obtaining regulatory permission for ILW Conditioning Proposals will be staged, with arrangements for continual dialogue, to provide regulatory hold points beyond which a licensee cannot proceed without regulatory agreement. These formal hold points and the associated timescales are a matter for negotiation between the licensee and the HSE (in conjunction with the appropriate environment agency) on a case-by-case basis depending on the complexity and magnitude of the proposal. At each hold point, clearly documented decisions will be given by HSE as to whether regulatory permission is granted for the licensee to proceed to the next stage. The hold points would normally apply at those stages at which action is taken (e.g. construction, commissioning, modification and operation).

The agreed system of hold points aims to provide a staged approach to formal permission, rather than a timetable for interaction with the regulators.

6.3 Typical Project Stages

The project stages for a typical ILW conditioning project are outlined in Table 2, together with the roles (in the context of this guidance document) of the regulators and Nirex. The prime interests[†] of the HSE and the environment agencies, of direct relevance to waste conditioning and storage, are described for each of these stages in order to explain more fully the anticipated timings of the interactions between the licensees and the regulators.

It is recognised that, in practice, projects may not be developed or implemented in such discrete stages. Of key importance to the project is the need for the licensee to interact at an early stage with the regulators and to produce an ILW Conditioning Proposal, which may be reviewed, revised or refined as appropriate as the project progresses.

6.3.1 Site waste management plans

The regulators will expect meetings with licensees on a regular basis to discuss site waste management plans in order:

- to understand the intent of these plans;
- to allow early identification of issues;
- to understand the implications for their work planning.

In the case of certain legacy wastes, the NDA will also be involved in these discussions, so that national strategy implications are addressed.

6.3.2 Options Assessment Process

Dialogue with the regulators will be expected during the options assessment process, so that a common view is agreed as to the most appropriate waste management strategy to adopt, as a basis for ongoing discussions.

As part of the options assessment, BPEO and BPM studies will be expected and should be made available to regulators. The regulators will wish to satisfy themselves that appropriate studies have been carried out and they will express a view on their adequacy in relation to each regulator's responsibilities. It should be noted that the LoC assessment process does not include work on BPEO and BPM.

[†] For the purposes of this document, only those regulatory interests of direct relevance to waste conditioning and storage are covered. In particular, HSE will have wider interests in respect of nuclear safety that will be regulated under the nuclear site licence conditions. Any discharges to the environment will be regulated separately by the environment agencies under the Radioactive Substances Act 1993.

Table 2: Roles during the Development and Implementation of ILW Conditioning Proposals

Licensee Activity	Nirex	HSE	Environment Agency/SEPA
Stage 1 - Site waste management planning		Assess "fit for purpose" at intervals	Assess "fit for purpose" at intervals
Stage 2 - Options Assessment Process	May be asked by licensees for advice on whether options will meet the Nirex safety criteria or for conceptual stage LoC assessment	Seek early dialogue on options	Seek early dialogue on options. Critical evaluation of key ILW conditioning documents (e.g. BPEO report and LoC) in the context of waste management plans.
Stage 3 - Conceptual design	Conceptual stage LoC assessment	Through discussion with the licensee and the appropriate agency, HSE will set out a regulatory process appropriate to the project. This may involve hold points. Assess suitability of ILW Conditioning Proposal, taking into account the appropriate environment agency's comments. Decide whether to give permission to commence construction.	Critical evaluation of key ILW Conditioning Proposal documents and environmental issues relevant to disposability
Stage 4 - Detailed design	Pre-construction stage LoC assessment		
Stage 5 - Construction			
Stage 6 - Commissioning	Final stage LoC assessment	Consider the ILW Conditioning Proposal as developed, taking into account the appropriate agency's comments. Decide whether to give permission to commence operation.	Critical evaluation of key ILW Conditioning Proposal documents and environmental issues relevant to disposability
Stage 7 - Operation	Advice on compliance with respect to packaging specifications and assessment of the implications of non-compliant packages	Inspection of process to ensure that packages are within agreed design envelope. HSE will take enforcement action if necessary. (Any discharges to the environment will be regulated separately by the environment agencies). The environment agencies will ensure that operations are conducted in accordance with the requirements to use BPM to optimise waste management arrangements.	
Stage 8 - Storage	Advice on the implications of storage conditions and package monitoring requirements	Periodic inspection of stored wastes to consider package condition, records etc. HSE will consider taking enforcement action where non-conformance with an agreed proposal, as notified through a Licence Instrument, is found. (Any discharges to the environment will be regulated separately by the environment agencies). The environment agencies will ensure that operations are conducted in accordance with the requirements to use BPM to optimise waste management arrangements.	

The interests of the environment agencies will include the disposability of the final waste form and the type and quantity of secondary wastes, including discharges to the environment. HSE's interests will be concentrated on safety and on-site radioactive waste management aspects, in particular the safety of any conditioning processes and plants involved, the safety issues arising from any future re-working of the conditioned waste and the safety of the storage of the waste packages.

6.3.3 Conceptual Design

The licensee will be expected to inform the regulators at the conceptual stages of any ILW management project via the appropriate HSE site inspector. At this stage, the regulators will form an initial view as to the level of regulatory scrutiny required. The regulators will operate a priority system to allow prioritisation of their efforts on more difficult and/or contentious proposals.

6.3.4 Detailed Design and Construction

The regulators' interests are likely to involve a watching brief on progress and emerging problems, plus an interest in ensuring that the issues or concerns identified during the earlier phases of work are being addressed and closed out. The majority of the ILW Conditioning Proposal should be complete before construction commences. The start of construction is likely to be one of the hold points in the regulatory process beyond which the licensee may not proceed without HSE's permission.

6.3.5 Commissioning

The regulators' main interest will be that of confirming that the plant is capable of functioning in a manner to produce waste packages to the specification agreed at the detailed design and construction stage.

6.3.6 Operation

The regulators' interest will be in confirming that the plant is producing waste packages to specification.

6.3.7 Storage

The regulators will be interested in the state of the packages and the integrity of the store until removal of the waste to a final disposal facility.

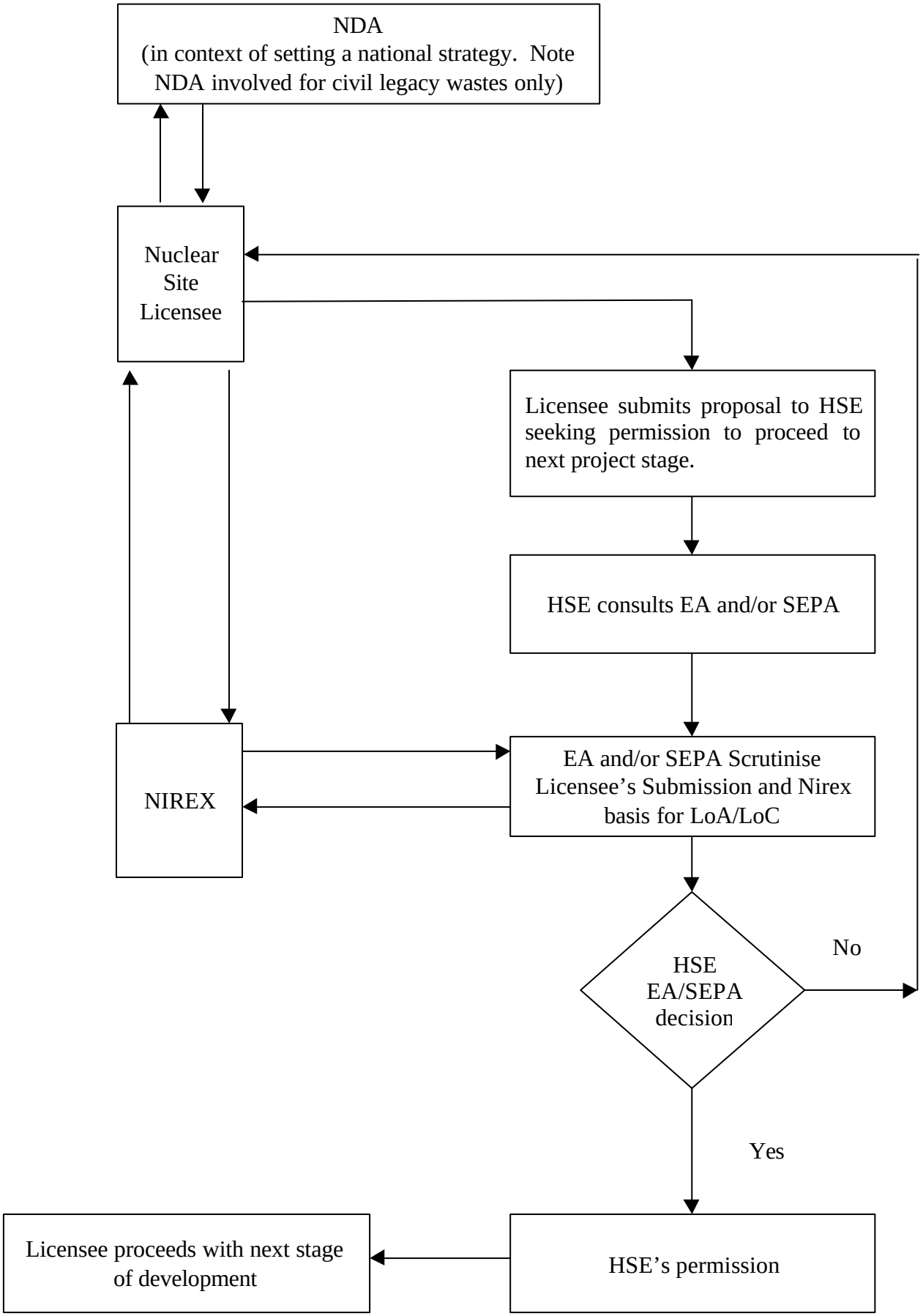
The flowchart at Figure 1 illustrates the formal procedural stages that are envisaged. (Early dialogue with the regulators is a key component of the regulatory arrangements but is not represented in the figure for reasons of simplicity). It is emphasised that the arrangements are designed to be flexible and efficient so as to avoid undue delay. In practice, continual dialogue between all the parties concerned will ensure, as far as possible, that actions are carried out in parallel.

7 Regulatory Scrutiny During ILW Conditioning & Storage

The regulators consider that compliance checking of waste packages is an important regulatory function. Key issues that the regulators will consider when they conduct audits during the conditioning and storage of ILW include:

- **Operation of appropriate quality management systems.** The licensee should demonstrate that appropriate management systems are in place to control the production of packages to the required specification and that this system is adhered to in practice.
- **Characterisation of the inventory of radioactive and non-radioactive wastes in each package.** The licensee's approach to characterisation of the waste should be capable of providing adequate information on the radioactive and non-radioactive inventories in each package to allow the regulators to confirm they are acceptable for final disposal. The licensee should be able to demonstrate that controls are in place to ensure that no unacceptable items or materials are contained within the packages produced.

Figure 1: Flowchart Showing the Processes for Regulatory Approval of a Typical, Staged ILW Conditioning Proposal (to be viewed in conjunction with the main text)



- **Conditioning to the agreed specifications, including demonstration of the compliance of packages.** The licensee should ensure that sufficient data are available to allow verification that the packaged wastes meet the specifications defined in the extant safety case.
- **Storage in appropriate conditions to ensure that the acceptability of the waste form for disposal is not compromised.** The licensee should demonstrate that all relevant waste stores are operated in a manner that will ensure that no significant degradation of the packaged waste will occur prior to emplacement in a disposal facility.
- **Maintenance of data records for each package.** The licensee should record and store sufficient data on each package (and the component raw waste) to support the needs of future safety and environmental assessments. The licensee should ensure that data are recorded in a form suitable for access and retrieval over the long time periods that may be associated with ILW storage.

The regulators will address the requirements of compliance checking by conducting periodic audits of plant used to manage, package and condition the waste. Either the HSE or the environment agencies or both may undertake these audits. The licensee must have procedures in place to address any non-compliance and the HSE must be informed concerning any significant non-compliance that arises.

These arrangements will be carried out as part of the normal inspection activities of the regulators, and enforced under existing regulatory powers as for any activity on a nuclear licensed site.

8 References

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17. *"Agreement of 6 September 1976 Between the United Kingdom of Great Britain and Northern Ireland, the European Atomic Energy Community and the Agency* [IAEA] *in connection with the Treaty on the Non-Proliferation of Nuclear Weapons"* the text of which is published by the IAEA as Information Circular (INFCIRC) number 263.

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20. "*Energy Act 2004"* The Stationery Office Limited (ISBN 0 10 542004 2).

21. *"Guidance on the Purpose, Scope and Content of Nuclear Safety Cases"* Technical Assessment Guide T/AST/051: HSE, NSD (www.hse.gov.uk/nsd/tast/tast051.htm)

22. *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* HSE, NSD, March 2001. (www.hse.gov.uk/nsd/waste1.pdf)

23. *"Predisposal Management of Low and Intermediate Level Radioactive Waste"* IAEA Safety Standard Series Safety Guide No. WS-G-2.5, 2003.

    (www-pub.iaea.org/MTCD/publications/PDF/Pub1150_web.pdf)

24. *"Predisposal Management of Low and Intermediate Level Radioactive Waste Including Decommissioning Requirements"* IAEA Safety Standard Series Safety Guide No. WS-R-2.

APPENDIX A

Legal Framework - Overview

In the UK there are two principal strands to the legislative and regulatory framework governing radioactive waste management. These relate to health and safety, derived from the Health and Safety at Work etc. Act 1974 (HSWA74)[†] and related legislation, and environmental protection, derived from the Environment Act 1995 (EA95)[‡] and related legislation. In addition, the safeguards requirements of the Euratom Treaty and the UK's safeguards agreement with Euratom and the IAEA may be applicable.

The Health and Safety Executive (HSE) regulate radioactive waste management on all of the UK's nuclear licensed sites. The main legislation covering the safety of the public and workers is HSWA74 and associated statutory provisions, which include the Nuclear Installations Act 1965 (as amended) (NIA65)[§]. Disposal, discharge and off-site transfer or accumulation of radioactive waste in the UK is regulated by the environment agencies. The main legislation covering environmental protection is EA95 with enactments relating to radioactive substances consolidated in the Radioactive Substances Act 1993 (RSA93).

Other relevant legislation is derived through other legislative routes:

- Requirements relating to environmental impact assessments are, with some exceptions, implemented through planning legislation;
- Road transport of radioactive material comes under a framework enforced by the Department of Transport; and transfrontier shipments come under directly applicable European legislation, or European requirements implemented under the European Communities Act.

1. Health and Safety Legal Framework

Health and Safety at Work Act

HSWA74 lays out the basis for regulation of health and safety in Great Britain. It provides a non-prescriptive regime of general duties to reduce risks from work activities to as low as reasonably practicable. Where appropriate, regulations or relevant statutory provisions under the Act set out more specific requirements. The main legislation governing the safety of nuclear installations is HSWA74 and the associated relevant statutory provisions of the NIA65. HSWA74 set up two bodies responsible for implementing the regulatory framework, the Health and Safety Commission (HSC) and the HSE.

Nuclear Installations Act 1965 (as amended)

Under NIA65 (as amended), no site may be used for the purpose of installing or operating a nuclear installation unless a licence has been granted by the HSE. Sections 1, 3 to 6, 22 and 24A of NIA65 are relevant statutory provisions of HSWA74 (i.e. these sections of pre-existing law are subject to HSWA74 arrangements for regulation and enforcement). NIA65 makes provision for HSE to define in the licence the use to which a site may be put and to attach conditions to a licence in the interests of safety or for the handling, treatment and disposal of nuclear matter. HSE also has powers under this Act to determine when a licensee's period of responsibility for the site is ended.

2. Environmental Protection Legal Framework

Environment Act 1995

EA95 provided for the establishment of the Environment Agency and the Scottish Environment Protection Agency. It sets the basis for the regulatory framework with respect to environmental

[†] *"Health and Safety at Work etc Act 1974."* HMSO 1974, ISBN 0-10-543774-3.
[‡] "*Environment Act 1995*" HMSO 1995, ISBM 0-10-542595-8.
[§] *"Nuclear Installations Act 1965."* HMSO 1965, ISBN 0-10-850216-3.

protection in the UK. Under EA95, the environment agencies are responsible for regulating the use of radioactive materials and the disposal of resulting waste. The environment agencies exercise these powers to grant or refuse applications for authorisations under the Radioactive Substances Act 1993 (RSA93)[†]. EA95 also places general duties on the environment agencies with respect to conserving and enhancing the environment, the conservation of natural resources and a duty to take into account the likely costs and benefits of exercising its powers. In addition the environment agencies are required to implement UK Government guidance, and therefore must have regard to this in all of their functions.

Radioactive Substances Act 1993

The main UK legislation under which radioactive waste disposal is controlled is the Radioactive Substances Act 1993 (RSA93). All forms of radioactive waste, including discharges of liquid and gaseous effluent, are regulated under this Act. Under RSA 93, no person may dispose of radioactive waste except in accordance with an authorisation issued by the relevant environment agency, or except where the waste is excluded by the Act or by an Exemption Order. In granting any authorisation to dispose of radioactive waste, the environment agencies may attach such limitations or conditions as they think fit. Best Practicable Means (BPM) is one such condition of authorisations granted by the environment agencies under RSA93, in accordance with the radioactive waste management policy set out in Cm 2919. Through this condition, the environment agencies require operators to apply BPM so as to minimise the amount of radioactive wastes that are first generated, as well as to minimise the release of radioactivity to the environment.

3. International Safeguards

Safeguards are measures to verify that States comply with their international (i.e. Treaty) obligations not to divert nuclear materials for nuclear explosives. Civil nuclear material in the UK is subject to the safeguards provisions of the Treaty establishing the European Atomic Energy Community (the Euratom Treaty) and to the terms of the UK's safeguards agreement with Euratom and the IAEA (see www.dti.gov.uk/non-proliferation/safeguards.htm for further information). These safeguards are based on nuclear materials accountancy measures, whereby the European Commission (in the case of Euratom safeguards) and the IAEA are provided with declarations of nuclear material inventories (i.e. how much material there is and where it is, so-called nuclear materials accountancy reports), and information on relevant aspects of the design of the nuclear facilities concerned. The safeguards inspectorates of the Commission and/or the IAEA perform inspections to verify that nuclear material is present as declared and that relevant aspects of facility design are as declared.

[†] *"Radioactive Substances Act 1993."* HMSO 1993, ISBN 0-10-541293-7.

APPENDIX B
Cm2919[†]

Some key points of policy relevant to ILW conditioning are as follows:

1 Cm2919 paragraph 50:

"Radioactive waste management policy should be based on the same basic principles as apply more generally to environment policy, and in particular that of sustainable development…This principle is outlined at greater length in Sustainable Development – the UK Strategy (Cm2426[‡]), which also sets out the following supporting principles:

- Decisions should be based on the best possible scientific information and analysis of risks;
- Where there is uncertainty and potentially serious risks exist, precautionary action may be necessary;
- Ecological impacts must be considered, particularly where resources are non-renewable or effects may be irreversible;
- Cost implications should be brought home directly to the people responsible – the polluter pays principle."

2 Cm2919 paragraph 51:

"…radioactive waste should be managed in ways which protect the public, workforce and the environment…it is recognised that a point is reached where additional costs of further reductions in risk exceed the benefits arising from the improvements in safety achieved and that the level of safety, and the resources required to achieve it, should not be inconsistent with those accepted in other spheres of human activity."

3 Cm2919 paragraph 52:

"…the government will maintain and continue to develop a policy and regulatory framework which ensure that:

- Radioactive wastes are not unnecessarily created;
- Such wastes as are created are safely and appropriately managed and treated;
- They are then safely disposed of at appropriate times and in appropriate ways.

…within that framework, the producers and owners of radioactive waste are responsible for developing their own strategies…They should ensure that:

- they do not create waste management problems which cannot be resolved using current techniques or techniques that could be derived from current lines of development;
- where it is practical and cost effective to do so, they characterise and segregate waste on the basis of physical and chemical properties and store it in accordance with the principles of passive safety (i.e. the waste is immobilised and the need for maintenance, monitoring or other human intervention is minimised) in order to facilitate safe management and disposal;
- they undertake strategic planning, including the development of programmes for the disposal of waste accumulated at nuclear sites within an appropriate timescale and for the decommissioning of redundant plant and facilities. The programmes should be acceptable to the regulators and discussed with them in advance."

[†] *"Review of Radioactive Waste Management Policy: Final Conclusions."* Cm2919 HMSO July 1995.
[‡] "*Sustainable Development – the UK Strategy."* Cm2426 HMSO January 1994.

4 Cm2919 paragraph 113:

"The Government believes that where the demands of safety are overriding, waste must be treated as necessary to improve storage conditions. In addition, where early treatment of waste will secure worthwhile safety benefits, or worthwhile economic benefits without prejudicing safety, the general presumption against action which might foreclose future waste management options may be relaxed. The relevant costs and commercial risks must be borne by the owner of the waste. Decisions by operators and regulators will need to have regard to all the relevant factors, including the following:

- The need for continuing safe storage of waste, treated and/or contained as necessary;
- The benefits of placing waste in a chemically and physically stable form, so that safety may be achieved by passive means;
- The risk that treated waste will be incompatible with future disposal requirements and the practicality of reworking treated waste in the future, for disposal or for a further period of storage, should this be necessary;
- The state of storage facilities, including the benefits which would be derived from refurbishment or upgrading;
- The need to minimise waste degradation, secondary waste arisings and releases to the environment;
- The need to minimise dependence on active safety systems, maintenance, monitoring and human intervention;
- The retrievability of waste for disposal".

APPENDIX C

MRWS[†] & Decommissioning Policy Review

MRWS

Included in the Managing Radioactive Waste Safely (MRWS) consultation are several policy related statements of direct relevance to the conditioning, packaging and storage of ILW. The first statement (MRWS paragraph 7.8) refers to a 1998 review of the storage of ILW by the HSE and asserts that:

"We…fully expect nuclear licensees to take appropriate action where necessary to ensure these stores remain safe. The presumption should be that stores will need to last for at least 50 years…Where wastes are held in a raw untreated state, whether as a result of historical arising or current operations, these should be made passively safe, in a form that does not close down any long-term management options, as soon as is practicable."

The second statement (MRWS paragraph 7.11) is that an effective regulatory regime should achieve the following:

- give proper emphasis to safety and long-term environmental considerations;
- maintain containment of radioactivity and prevent leakage so that wastes can do no harm to people or the environment;
- provide for any necessary steps to prevent unauthorised release of radioactivity into the environment to be taken promptly;
- where waste needs to be packaged or treated to achieve passive safety, to ensure that this is done promptly;
- provide assurance that processing and storage of wastes do not prejudice future waste management options;
- provide adequate opportunities for consulting, and informing the public;
- provide an appropriate balance between costs and benefits; and
- ensure transparency in setting standards and in the regulatory processes.

Decommissioning Policy Review

The Government has recently completed a consultation to update and replace previous statements set out in paragraphs 120-131 of Cm2919[‡]. Policy matters of particular relevance to the management of ILW that have been incorporated within this decommissioning policy review include:

That the Government considers that decommissioning strategies should seek to avoid the creation of radioactive wastes in forms which may foreclose options for safe and effective long-term waste management.

- By the use of Best Practical Means (BPM), strategies should minimise the volumes of radioactive wastes that are created, particularly the volume of ILW. Wherever possible wastes should not be created during decommissioning until an appropriate management solution is, or will shortly be, available for use, and

[†] *"Managing Radioactive Waste Safely. Proposals for developing a policy for managing solid radioactive waste in the UK."* Department of Environment, Food and Rural Affairs (Defra), National Assembly for Wales (NAW), Department of the Environment for Northern Ireland and Scottish Executive (SE), September 2001.

[‡] *"Review of Radioactive Waste Management Policy: Final Conclusions."* Cm2919 HMSO July 1995.

- Unless alternative arrangements come into effect in future, the Government confirms that operators should continue to process their decommissioning wastes, where appropriate, in accordance with Letter of Comfort arrangements[†]. Wastes might be stored on the site of production or on another site and these options should be considered and the reasons for the chosen option stated.

[†] Nirex guidance will be examined by HSE as part of its examination of the safety case for the site. HSE will consult the appropriate environment agency as part of this examination.

APPENDIX D

Role of International Organisations

The UK Government's radioactive waste management policy is framed within the context of international and national guidelines and regulations. At the international stage, a number of organisations contribute towards this policy framework, each with a distinct role, set out as follows.

1 International Commission on Radiological Protection

The International Commission on Radiological Protection (ICRP) is an independent body of experts set up to provide guidance on a range of topics relating to the protection of man from the harmful effects of ionising radiation.

For practices involving the use of radioactive substances the system of radiological protection is based on the three principles of justification of practices, optimisation of protection and dose limitation as set out in ICRP60[†]. ICRP60 may be revised in light of the consultation ongoing at the time of writing.

2 International Atomic Energy Agency

The International Atomic Energy Agency (IAEA) was founded by the UN as an autonomous inter-governmental organisation to prevent the proliferation of nuclear weapons, and foster research and development in nuclear energy.

The IAEA safety fundamentals sets out principles for radioactive waste management are incorporated within the policies set out in Cm2919[‡]. IAEA Safety Standards set the international baseline for good practice regarding nuclear safety.

The UK also takes a leading part in developing IAEA international guidelines on nuclear security and participates in IAEA programmes to advise on their implementation at national level. IAEA safeguards are applied in the UK according to the terms of the UK's safeguards agreement with Euratom and the IAEA (*"Agreement of 6 September 1976 Between the United Kingdom of Great Britain and Northern Ireland, the European Atomic Energy Community and the Agency* [IAEA] *in connection with the Treaty on the Non-Proliferation of Nuclear Weapons"* published by the IAEA as Information Circular (INFCIRC) number 263) and the Protocol additional to that agreement.

3 Euratom

The Treaty establishing the European Atomic Energy Community (Euratom) provides a role for the European Commission in a number of aspects of nuclear activities in the Community. These include:

- radiation protection of the work force and the public (Chapter III);
- the supply of nuclear fissile materials for the developing nuclear power sector (Chapter VI);
- the safeguards provisions of Chapter 7 of the Treaty (reporting elements of which are amplified in Commission Regulation (Euratom) No 3227/76 of 19 October 1976, to be replaced by COM (2002) 99 (revised) *"Commission Regulation (Euratom) on the Application of Euratom Safeguards"*).

Legislation on radiation protection in the European Union is governed by the Euratom Treaty and the Directives. These Directives impose on Member States the obligation to establish and maintain systems for the accountancy and control of nuclear materials subject to international safeguards and to inform the public in general, and exposed workers in particular, on ionising radiation and

[†] *"1990 Recommendations of the International Commission on Radiological Protection",* ICRP Publication 60, Annals of the ICRP, 21 1-3, 1991.
[‡] *"Review of Radioactive Waste Management Policy: Final Conclusions."* Cm2919 HMSO July 1995.

radiation protection, leaving Member States the flexibility as to the choice of method to comply with the requirements.

- *"Commission Regulation (Euratom) No 3227/76"* is the directive for nuclear material safeguards in the European Union.
- *"The Basic Safety Standards Directive (96/29/Euratom)"* of 13 May 1996 is the framework directive for radiation protection in the European Union. It deals with radiation protection of exposed workers and the public.

4 Other International Organisations

Other international organisations are involved in influencing the UK's radioactive waste management policy and include the International Radiation Protection Association, the Nuclear Energy Agency of OECD, the International Maritime Organisation and the United Nations.

APPENDIX E

Joint Convention

Key points from the Joint Convention[†] relevant to ILW conditioning (see Article 11. General Safety Requirements) are:

- "each Contracting Party [Government] shall take the appropriate steps to ensure that at all stages of radioactive waste management individuals, society and the environment are adequately protected against radiological and other hazards";
- "in so doing, each Contracting Party shall take the appropriate steps to:
  - ensure that criticality and removal of residual heat generated during radioactive waste management are adequately addressed;
  - ensure that the generation of radioactive waste is kept to the minimum practicable;
  - take into account interdependencies among the different steps in radioactive waste management;
  - provide for effective protection of individuals, society and the environment, by applying at the national level suitable protective methods as approved by the regulatory body, in the framework of its national legislation which has due regard to internationally endorsed criteria and standards;
  - take into account the biological, chemical and other hazards that may be associated with radioactive waste management;
  - strive to avoid actions that impose reasonably predictable impacts on future generations greater than those permitted for the current generation;
  - aim to avoid imposing undue burdens on future generations".

In regulating the conditioning of ILW[‡], the regulators have regard to, inter alia, the following internationally endorsed criteria and standards:

- *"The Principles of Radioactive Waste Management"* IAEA Safety Series No 111F, IAEA, Vienna 1995;
- *"Predisposal Management of Radioactive Waste, Including Decommissioning: Safety Requirements"* IAEA Safety Standard Series No. WS-R-2;
- *"Predisposal Management of Radioactive Waste"* IAEA Safety Standard Series Safety Guide No. WS-G-2.5;
- *"Storage of Radioactive Waste"* Draft IAEA Safety Guide DS292.

[†] *"Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management."* INFCIRC/546 , IAEA, 24 December 1997.

[‡] Article 20 of the Joint Convention places the onus on the Government to ensure that regulators remain independent of organisations that are involved in spent fuel or radioactive waste management.

APPENDIX F

Summary of Standards

The following sets out a summary of the various standards and guidance relevant to the conditioning of ILW, aligned to the topics of the IAEA radioactive waste fundamental principles.

1 Protection of Human Health

IAEA Fundamental Principle 1 requires that "*radioactive waste shall be managed in such a way as to secure an acceptable level of protection for human health*". This principle is covered by the Health and Safety at Work Act 1974 (HSWA74) in which section 2(1) states:

"*It shall be the duty of every employer to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all his employees.*"

And section 3(1) states

"*It shall be the duty of every employer to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby are not thereby exposed to risks to their health or safety.*"

These requirements are taken forward through relevant statutory provisions of the HSWA74 including the Nuclear Installations Act 1965 (NIA65) and the Ionising Radiations Regulations 1999 (IRR99).

The key element of this standard is that risks should be reduced as low as reasonably practicable (ALARP). HSE has produced extensive guidance on how this should be applied:

- *"Reducing Risks Protecting People"* HSE Books, 2001. www.hse.gov.uk/risk/theory/r2p2.pdf
- *"Principles and Guidelines to Assist HSE in its Judgements that Duty-holders have Reduced Risk As Low As Reasonably Practicable"* www.hse.gov.uk/risk/theory/alarp1.htm
- *"Assessing Compliance with the Law in Individual Cases and the Use of Good Practice"* www.hse.gov.uk/risk/theory/alarp2.htm
- *"Policy and Guidance on Reducing Risks As Low As Reasonably Practicable in Design"* www.hse.gov.uk/risk/theory/alarp3.htm
- *"Demonstration of ALARP"* HSE, Nuclear Safety Directorate T/AST/005 www.hse.gov.uk/nsd/tast/tast005.pdf
- *"Safety Assessment Principles for Nuclear Plants"* www.hse.gov.uk/nsd/saps.htm

Other relevant references are:

- UK Policy - Cm2919 paragraph 51
- Joint Convention Articles 11 & 24

2 Protection of the Environment

IAEA Fundamental Principle 2 requires that "*Radioactive waste shall be managed in such a way as to provide an acceptable level of protection of the environment*".

The Joint Convention requires that "*each contracting party shall take the appropriate steps to… provide for effective protection of individuals, society and the environment, by applying at the national level suitable protective methods as approved by the regulatory body, in the framework of its national legislation which has due regard to internationally endorsed criteria and standards*" (Joint Convention Article 11);

UK policy is that *"ecological impacts must be considered, particularly where resources are non-renewable or effects may be irreversible"* (Cm2919 paragraph 50);

"…radioactive waste should be managed in ways which protect the public, workforce and the environment….it is recognised that a point is reached where additional costs of further reductions in risk exceed the benefits arising from the improvements in safety achieved and that the level of safety, and the resources required to achieve it, should not be inconsistent with those accepted in other spheres of human" (Cm2919 paragraph 51).

Section 4 of the Environment Act 95 sets out the principal aim for the Environment Agency, namely, *"(subject to and in accordance with the provisions of this Act or any other enactment and taking into account any likely costs) in discharging its functions so to protect or enhance the environment, taken as a whole, as to make the contribution toward attaining the objective of achieving sustainable development"* as described in Ministerial Guidance. Ministerial Guidance[†] was issued by the Government to the Agency in December 2002. (SEPA's functions are described in Section 31 and include similar objectives in achieving sustainable development)

Other relevant provisions of EA 95 include Section 5 which sets out the statutory purpose for which the Agency's pollution control powers, including its powers under RSA 93, must be exercised, namely *"preventing or minimising, or remedying or mitigating the effects of, pollution of the environment"*.

The *"Guidance on Requirements for Authorisation"*[‡] sets out the overall performance requirements of the environment agencies with respect to any proposal for the development, operation and closure of repositories for LLW and ILW. Proposals for ILW conditioning should lead to waste packages that can be disposed in a repository, i.e. that are consistent with all of the requirements set out in the *Guidance on Requirements for Authorisation*.

An internationally accepted approach to the assessment of impacts on non-human species does not exist. The Environment Agency is taking a strong role in several initiatives to address this gap, most recently in the construction of an IAEA Action Plan intended to co-ordinate the work of relevant international organisations. However, anticipating the need for early progress the Agency has sponsored a research programme intended to allow it to implement its assessment obligations under the Habitats Directive.

The principal publications under this programme are:

- *"Impact Assessment of Ionising Radiation on Wildlife"* D Copplestone, S Bielby, S R Jones, D Patton, P Daniel, and I Gize, Environment Agency R&D Publication 128, Environment Agency, Bristol, 2001.
- *"Habitats Regulations for Stage 3 Assessments: Radioactive Substances Authorisations"* D Copplestone, M Wood, S Bielby, S R Jones, J Vives and N A Beresford, Environment Agency R&D Report P3-101/1A, Environment Agency, Bristol, 2003.

3 Protection Beyond National Borders

IAEA Fundamental Principle 3 requires that *"Radioactive waste shall be managed in such a way as to assure that possible effects on human health and the environment beyond national borders will be taken into account"*.

Normally, the assumption is made that the protection of people close to a site ensures that people in other countries are protected to standards well within appropriate levels. (Consideration of other exposure pathways may be made to justify this assumption). However, there may be instances

[†] *"The Environment Agency's Objectives and Contributions to Sustainable Development: Statutory Guidance"* December 2002

[‡] *"Radioactive Substances Act 1993, Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Guidance on Requirements for Authorisation"* Environment Agency, SEPA and DoENI, 1997.

where the presence of radioactivity in other countries is a cause of concern, even though potential exposures are very low. Such matters are dealt with on a case-by-case basis.

Specific account must be taken of the possible effects beyond national borders in submissions that must be made under Article 37 of the Euratom Treaty.

There is no specific international guidance other than that on protection of human health.

4 Protection of Future Generations

IAEA Fundamental Principle 4 requires that *"Radioactive waste shall be managed in such a way that predicted impacts on the health of future generations will not be greater than relevant levels of impact that are acceptable today"*.

Legislation for the protection of human health applies to impacts predicted on future generations in the same way as it does for the present.

5 Burdens on Future Generations

IAEA Fundamental Principle 5 requires that *"Radioactive waste shall be managed in such a way that will not impose undue burdens on future generations"*.

UK policy is that *"radioactive waste management policy should be based on the same basic principles as apply more generally to environment policy, and in particular that of sustainable development…*[i.e.]*…development which meets the needs of the present without compromising the ability of future generations to meet their own needs*. (Cm2919 paragraph 50)

In particular *"producers and owners of radioactive waste…should ensure that they do not create waste management problems…*[and hence a burden on future generations to resolve them]*…which cannot be resolved using current techniques or techniques that could be derived from current lines of development"*. (Cm2919 paragraph 52)

One such problem that is relevant is the disposability of the radioactive waste. *"Decisions by operators and regulators will need to have regard to all the relevant factors, including:*

- *…the risk that treated waste will be incompatible with future disposal requirements…;*
- *…the practicality of reworking treated waste in the future, for disposal or for a further period of storage, should this be necessary…;*
- *…the retrievability of waste for disposal"*.

(Cm2919 paragraph 113)

The requirements for dealing with disposability in a safety case, and the role of the Nirex Letter of Comfort assessment process are discussed in the main text of this guidance.

Other relevant References:

- Joint Convention Article 11;
- IAEA WS-R-2 paragraph 5.2.

6 Minimisation of Radioactive Waste Generation

IAEA Fundamental Principle 7 requires that *"Generation of radioactive waste shall be kept to the minimum practicable"*.

It is UK Policy that *"the Government will maintain and continue to develop a policy and regulatory framework which ensure that radioactive wastes are not unnecessarily created"* (Cm2919 paragraph 52(1))

This is supported by Licence Condition 32, attached to all licences issued under NIA 65, which requires the licensee to *"make and implement adequate arrangements for minimising so far as is*

reasonably practicable the rate of production and total quantity of radioactive waste accumulated on the site at any time and for recording the waste so accumulated".

"Plant design should be such that so far as reasonably practicable the quantity of radioactive waste (including secondary waste) and scrap arising during commissioning, operation and decommissioning is minimised". (HSE Safety Assessment Principles p294)

Relevant references are:

- Joint Convention Article 11;
- IAEA WS-R-2, paragraphs 5.5 - 5.8;
- IAEA WS-G-2.5 paragraphs 4.7 - 4.9;
- HSE T/AST/024.

7 Radioactive Waste Strategies and Interdependencies

IAEA Fundamental Principle 8 requires that *"Interdependencies among all steps in radioactive waste generation and management shall be appropriately taken into account"*.

"Interdependencies exist among all steps in the management of LILW, from the generation of the waste to its disposal. In selecting strategies and activities for the predisposal management of LILW, planning should be carried out for all the various steps so that a balanced approach to safety is taken in the overall management programme and conflicts between the safety requirements and operational requirements are avoided. There are various alternatives for each step in the management of LILW. To ensure safety, all the different steps should be evaluated, both as isolated steps in the process and also as part of an integrated system in which the steps are complementary and mutually dependent. For example, treatment and conditioning options for LILW are influenced by the established or likely acceptance requirements for a repository". (IAEA WS-G-2.5 paragraphs 4.1)

Acceptance requirements for a repository (disposability) are discussed under principle 7 in the previous section.

One of the principle ways in which the regulators expect this issue to be addressed is through the production of radioactive waste strategies. *"A waste management strategy should define a structured approach that is co-ordinated for individual nuclear facilities on the same or different sites. It should be consistent with the licensee's strategies for decommissioning, and should be regularly reviewed and updated, and take account of changing circumstances. In selecting a preferred strategy, it is expected that a licensee will follow an approach that ensures that all relevant factors are taken into account. The process should be systematic, comprehensive and transparent"*. (T/AST/024 Appendix 2)

Other relevant references are:

- Cm2919 paragraphs 52 & 113;
- Joint Convention Article 11;
- IAEA WS-R-2 paragraph 4.2.

8 Safety of Facilities (Passive Safety)

IAEA Fundamental Principle 9 requires that *"The safety of facilities for radioactive waste management shall be appropriately assured during their lifetime"*.

NIA65 Licence Condition 14(1) requires the licensee to *"…make and implement adequate arrangements for the production and assessment of safety cases consisting of documentation to justify safety during the design, construction, manufacture, commissioning, operation and decommissioning phases of the installation"*.

The safety case needs to take account of a number of issues with respect to radioactive waste management, including:

- **Characterisation and Segregation:** *"So far as is reasonably practicable, radioactive material and radioactive waste should be characterised and segregated in order to facilitate safe and effective management and disposal"*. (HSE T/AST/024 section 6.8)
- **Passive Safe Storage:** *"So far as is reasonably practicable, radioactive material and radioactive waste should be stored in a passively safe state"*. (HSE T/AST/024 section 6.9)
- **Timescales for Interim Storage:** *"For radioactive wastes for which there is presently no disposal route or some other long-term option, licensees should plan for a significant period of interim storage"*. (HSE T/AST/024 section 6.10).
- **Inspection and Retrieval in Storage:** *"Any future storage facilities or modifications to existing facilities should be designed to facilitate inspection, retrieval and remediation of the waste and the facilities"*. (HSE T/AST/024 section 6.11).

Relevant references include:

- Cm2919 paragraphs 52 and 113;
- HSE Safety Assessment Principles 296, 297, 298, 306, 313;
- HSE T/AST/024.

APPENDIX G

Guidance on the Content of Proposals to the HSE for ILW Conditioning

The contents of a typical ILW Conditioning Proposal are described below (aligned with Section 5.2 of the main guidance document), together with references to further guidance where available.

1 Description of the Proposal

The proposal should be described in terms of the processes and plant/facilities involved, and their interaction with other activities and processes on the site.

- *"Predisposal Management of Low and Intermediate Level Radioactive Waste"* IAEA Safety Standards Series No WS-G-2.5, IAEA, Vienna 2003 – Section 4.6.
- *"Predisposal Management of Radioactive Waste including Decommissioning"* IAEA Safety Standards Series No WS-R-2, IAEA, Vienna 2000 – Section 5.

2 The Options Assessment Process

The consideration of waste-management options, including "best practicable environmental option" and "best practicable means" studies, will be expected and should be made available to regulators. The regulators will wish to satisfy themselves that this has been carried out and will express a view on its adequacy in relation to each regulator's responsibilities.

- The environment agencies have completed their Guidance to Regulators on the Assessment of BPEO Studies and were in the process of publishing this on their respective web sites at the time of writing.
- A review of the Application of BPM within a Regulatory Framework for Managing Radioactive Wastes (in preparation - Environment Agency, SEPA & EHSNI).

The submission should indicate how the option chosen fits into the licensee's overall radioactive waste management strategy.

- *"The Principles of Radioactive Waste Management"* IAEA Safety Series No 111F, IAEA, Vienna 1995 – Principle 8.
- *"Predisposal Management of Radioactive Waste including Decommissioning"* IAEA Safety Standards Series No WS-R-2, IAEA, Vienna 2000 – Section 4.
- *"Predisposal Management of Low and Intermediate Level Radioactive Waste"* IAEA Safety Standards Series No WS-G-2.5, IAEA, Vienna 2003 – Section 4.1-4.5.
- *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* www.hse.gov.uk/nsd/waste1.pdf – Appendix 2.

3 Plant, Process and Site Safety

3.1 Secondary Waste Minimisation

The proposal should indicate how the production of secondary wastes is minimised.

- *"The Principles of Radioactive Waste Management"* IAEA Safety Series No 111F, IAEA, Vienna 1995 – Principle 7.
- *"Predisposal Management of Radioactive Waste including Decommissioning"* IAEA Safety Standards Series No WS-R-2, IAEA, Vienna 2000 – Section 5.5-5.8.
- *"Predisposal Management of Low and Intermediate Level Radioactive Waste"* IAEA Safety Standards Series No WS-G-2.5, IAEA, Vienna 2003 – Section 4.7-4.9.
- *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* www.hse.gov.uk/nsd/waste1.pdf - Appendix 5.

- *"Safety Assessment Principles for Nuclear Plants"* HSE 1992 www.hse.gov.uk/nsd/saps.htm SAPs p294.

3.2 Characterisation and Segregation

The proposal should show how waste has been characterised and segregated to facilitate safe and effective management and disposal.

- *"The Principles of Radioactive Waste Management"* IAEA Safety Series No 111F, IAEA, Vienna 1995 – Principle 9.
- *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* www.hse.gov.uk/nsd/waste1.pdf - section 6.8.
- *"Safety Assessment Principles for Nuclear Plants"* HSE 1992 www.hse.gov.uk/nsd/saps.htm SAPs p302.

3.3 General Safety Case Requirements

- *"Safety Assessment Principles for Nuclear Plants"* www.hse.gov.uk/nsd/saps.htm.
- *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* www.hse.gov.uk/nsd/waste1.pdf - Appendix 3.
- *"Predisposal Management of Radioactive Waste including Decommissioning"* IAEA Safety Standards Series No WS-R-2, IAEA, Vienna 2000 – Section 7.

The submission should demonstrate the safe operation of the proposed radioactive waste facility (or facilities) for the projected life of the facility (facilities). Aspects to be covered (that are not covered above) are:

i) Protection against radiation exposure/ Reduction of risk to ALARP

- *"Work with Ionising Radiation Ionising Radiations Regulations 1999: Approved Code of Practice and Guidance"* HSE Books 2000: ISBN 0-7176-1746-7: Regulations 7 & 8.
- *"The Principles of Radioactive Waste Management"* IAEA Safety Series No 111F, IAEA, Vienna 1995 – Principle 1.
- *"Predisposal Management of Radioactive Waste including Decommissioning"* IAEA Safety Standards Series No WS-R-2, IAEA, Vienna 2000 – Section 2.
- *"Predisposal Management of Low and Intermediate Level Radioactive Waste"* IAEA Safety Standards Series No WS-G-2.5, IAEA, Vienna 2003 – Section 2.
- *"Reducing risks protecting people"* HSE Books 2001 www.hse.gov.uk/risk/theory/r2p2.pdf.
- *"Principles and Guidelines to Assist HSE in its Judgements that Duty-holders have Reduced Risk As Low As Reasonably Practicable"* www.hse.gov.uk/risk/theory/alarp1.htm.
- *"Assessing Compliance with the Law in Individual Cases and the Use of Good Practice"* www.hse.gov.uk/risk/theory/alarp2.htm.
- *"Policy and Guidance on Reducing Risks As Low As Reasonably Practicable in Design"* www.hse.gov.uk/risk/theory/alarp3.htm.
- *"Demonstration of ALARP"* HSE, Nuclear Safety Directorate T/AST/005 www.hse.gov.uk/nsd/tast/tast005.pdf.
- *"Safety Assessment Principles for Nuclear Plants"* HSE 1992 www.hse.gov.uk/nsd/saps.htm SAPs pp1 – 14.

ii) Protection of the Environment / Use of BPM to minimise discharges to the environment

- *"The Principles of Radioactive Waste Management"* IAEA Safety Series No 111F, IAEA, Vienna 1995 – Principle 2.
- *"Predisposal Management of Radioactive Waste including Decommissioning"* IAEA Safety Standards Series No WS-R-2, IAEA, Vienna 2000 – Section 2.
- *"Predisposal Management of Low and Intermediate Level Radioactive Waste"* IAEA Safety Standards Series No WS-G-2.5, IAEA, Vienna 2003 – Section 2.

iii) Contamination and radiation control

The submission should address the control of access to areas for waste processing and storage and the control of movement between radiation zones and contamination zones.

- *"Work with Ionising Radiation; Ionising Radiations Regulations 1999: Approved Code of Practice and Guidance"* HSE Books 2000: ISBN 0-7176-1746-7: Regulations 16 & 18, 19.
- *"Safety Assessment Principles for Nuclear Plants"* HSE 1992 www.hse.gov.uk/nsd/saps.htm SAPs pp104 – 113.

iv) The prevention of criticality

- *"Safety Assessment Principles for Nuclear Plants"* HSE 1992 www.hse.gov.uk/nsd/saps.htm SAPs p46, pp284 – 293.

v) The control of liquid and gaseous effluents

- *"Safety Assessment Principles for Nuclear Plants"* HSE 1992 www.hse.gov.uk/nsd/saps.htm SAPs pp301 – 304.

vi) Ventilation and the filtration of airborne releases

- *"Safety Assessment Principles for Nuclear Plants"* HSE 1992 www.hse.gov.uk/nsd/saps.htm SAPs pp239 – 242.

vii) Euratom and IAEA safeguard requirements

The submission should address Euratom and IAEA safeguards requirements.

- Chapter 7 of the Treaty establishing the European Atomic Energy Community (Euratom) and *"Commission Regulation (Euratom) No 3227/76 of 19 October 1976 Concerning the Application of the Provisions of Euratom Safeguards"*. To be replaced by COM (2002) 99 (revised) *"Commission regulation (Euratom) on the Application of Euratom Safeguards"*.
- *"Agreement of 6 September 1976 Between the United Kingdom of Great Britain and Northern Ireland, the European Atomic Energy Community and the Agency* [IAEA] *in connection with the Treaty on the Non-Proliferation of Nuclear Weapons"* the text of which is published by the IAEA as Information Circular (INFCIRC) number 263.
- *"Protocol Additional to the Agreement between the United Kingdom of Great Britain and Northern Ireland, the European Atomic Energy Community and the International Atomic Energy Agency for the application of safeguards in the United Kingdom of Great Britain and Northern Ireland in connection with the Treaty on the Non-Proliferation of Nuclear Weapons"* Vienna, 22 September 1998 [Cm 4282].

Additional information is available at the non-proliferation section of the Department of Trade and Industry website (www.dti.gov.uk/non-proliferation/safeguards.htm) and from the UK Safeguards Office itself.

viii) Non-radiological hazards

The HSE provide extensive guidance in this area, much of which can be accessed via their website www.hse.gov.uk.

ix) Fire protection and the prevention of explosions

- *"Safety Assessment Principles for Nuclear Plants"* HSE 1992 www.hse.gov.uk/nsd/saps.htm SAPs pp141 – 143.

x) Maintenance work and eventual decommissioning

- *"Decommissioning on Licensed Nuclear Sites"* HSE Guidance for Inspectors, March 2001. www.hse.gov.uk/nsd/decomm1.pdf.

xi) Inventory control

- *"Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* HSE Guidance for Inspectors, March 2001. www.hse.gov.uk/nsd/waste1.pdf.

xii) Quality Assurance and Records

The submission should describe the Quality Assurance arrangements to ensure that waste products comply with relevant specifications, and should cover the procurement of the container and raw materials, the packaging process, the quality of the final product and all necessary records.

- *"Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations"* IAEA Safety Series No. 50-C/SG-Q, Code and Safety Guides Q1-Q14 IAEA 2001. www-pub.iaea.org/MTCD/publications/PDF/ss_50_c_sg_q_cd/Start.pdf
- *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* www.hse.gov.uk/nsd/waste1.pdf - Section 6.12 and Appendix 7.
- *"Predisposal Management of Radioactive Waste including Decommissioning"* IAEA Safety Standards Series No WS-R-2, IAEA, Vienna 2000 – Sections 6 & 8.
- *"Safety Assessment Principles for Nuclear Plants"* HSE 1992 www.hse.gov.uk/nsd/saps.htm SAPs p298, pp317 – 320.

4 Storage of Radioactive Waste

4.1 Storage capacity

The submission should indicate the storage capacity requirements in relation to the proposal, how they are to be achieved including contingencies for foreseeable events.

4.2 Timescale for Storage

The submission should indicate the expected timescales for storage of radioactive waste and address any implications for safety and environmental protection.

- *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* www.hse.gov.uk/nsd/waste1.pdf - Section 6.10.

4.3 Passive Safety

The submission should indicate how safety and environmental protection are assured during the projected storage period for the radioactive waste. This should accord with the principles of passive safety.

- *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* www.hse.gov.uk/nsd/waste1.pdf - Appendix 4.

- *"Safety Assessment Principles for Nuclear Plants"* HSE 1992 www.hse.gov.uk/nsd/saps.htm SAPs p296.

4.4 Inspection and Retrieval in Storage

The submission should show how proposed storage facilities provide for inspection, retrieval and remediation of the waste.

- *"Predisposal Management of Low and Intermediate Level Radioactive Waste"* IAEA Safety Standards Series No WS-G-2.5, IAEA, Vienna 2003 - Sections 4.10-4.13 & 5.38-5.46.
- *"Predisposal Management of Radioactive Waste including Decommissioning"* IAEA Safety Standards Series No WS-R-2, IAEA, Vienna 2000 – Section 5.21-5.30.
- *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* www.hse.gov.uk/nsd/waste1.pdf – Sections 6.8 & 6.10 and Appendices 4, 5 & 6.
- *"Safety Assessment Principles for Nuclear Plants"* HSE 1992 www.hse.gov.uk/nsd/saps.htm SAPs p298.

5 Disposability

5.1 Existing Waste Disposal Routes

The submission should show how use is being made of existing disposal routes (if applicable) and complies with the relevant Conditions for Acceptance.

- *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* www.hse.gov.uk/nsd/waste1.pdf - Section 6.5.

5.2 Compatibility with Future Management and Disposal Options

The submission should indicate how the radioactive waste management proposal takes account of possible future management or disposal options for the radioactive waste. Unless some other viable long-term option has been identified (e.g. decay storage and then disposal to a low level waste facility) then this is likely to require an assessment as provided in the Nirex Letter of Comfort process. This would ensure that disposal of waste packages to an ILW repository is consistent with the requirements for long-term safety and environmental performance.

- *"The Principles of Radioactive Waste Management"* IAEA Safety Series No 111F, IAEA, Vienna 1995 – Principle 5.
- *"Guidance for Inspectors on the Management of Radioactive Materials and Radioactive Waste on Nuclear Licensed Sites"* www.hse.gov.uk/nsd/waste1.pdf - Section 6.4.
- *"Safety assessment principles for nuclear plants"* HSE 1992 www.hse.gov.uk/nsd/saps.htm SAPs p295 & p306.
- *"Environment Agency Guidance on the Conditioning of Intermediate Level Waste" Environment Agency*.
- *"Radioactive Substances Act 1993, Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Guidance on Requirements for Authorisation"* Environment Agency, Scottish Environment Protection Agency and Department of the Environment for Northern Ireland, 1997.
- *"Waste Package Specifications for Intermediate Level Waste"* N/007 (under revision), Nirex.
- *"Guidance on the preparation of Letter of Comfort Submissions"* T/REP/20632, Nirex.

ANNEX A
Questions and Answers

During the consultation on this guidance many questions were asked, some of which have been addressed in the main text, others are addressed in the following question and answer section.

Questions addressed here fall into the following main categories:

- **Regulation** – the process of interacting with the regulators;
- **Letter of Comfort** – the role of the letter of comfort process;
- **Nirex** – the role of Nirex;
- **Other Disposal Concepts** – the use of other disposal routes than those covered by the phased disposal concept;
- **Intelligent Customer** – the need for licensees to be able to understand advice given by Nirex;
- **Liabilities** – where do liabilities lie at the various stages?

All questions and answers should be read in the context of the guidance given in the main text.

1) REG – Regulation

Question REG-1: How do I initiate the process of early interaction?

The point of contact will be NII's site inspector. Licensees should discuss proposals with him/her and agree a way forward.

Question REG-2: Will information provided to the regulators be made publicly available?

The Freedom of Information Regulations will apply to all information held by regulators. If any information is commercially confidential, or should be withheld from disclosure for any other reasons, the licensee should make this clear to the regulator together with the reasons behind such a judgement. However, the presumption will be that information will be released on request unless there is good reason, in accordance with the Regulations, for that information to be withheld.

2) LOC - Letter of Comfort

Question LOC–1: Is it necessary to obtain a Letter of Comfort?

The safety case produced by the licensee should adequately address the long-term future of the waste, including its disposability. At present, for wastes that may be expected to go into an ILW repository, the regulators consider that the only credible way of doing this is to judge proposals against the Phased Disposal Concept developed by Nirex – i.e. to use the assessment process that backs up the Letter of Comfort (LoC). It is therefore the assessment behind the LoC that is important to the regulators, not the LoC document itself. A licensee may wish to obtain the LoC document for other purposes, e.g. for future dealings with a repository operator.

Question LOC-2: Is a Letter of Comfort sufficient to satisfy regulatory requirements?

No. The regulators expect the licensee to be able to demonstrate that he/she understands the disposability aspects of the safety case, in presenting the assessment behind the LoC. See also question IC-1.

Question LOC-3: How far is it necessary to pursue the LoC process if the likely outcome is that a LoC will not be possible?

If the likely "best option" does not fully comply with the Phased Disposal Concept, then the regulators expect the licensee to pursue the LoC assessment process to the extent necessary to:

- understand why this is the case;
- understand the "compliance gap";
- be able to express the consequences of implementing this option;
- be able to propose future actions to enable the waste to be disposed of, this may be:
  - proposals for reworking the waste;
  - restrictions that may need to be put on the operation, location or design of a repository.

Question LOC-4: What if the requirements for a LoC conflict with BPEO requirements?

It may be that in such a case a waste form that fully complies with LoC requirements is not the best option. See Question LOC-3.

Question LOC-5: What happens if proves impossible to meet LoC requirements and no way can be found to address the compliance gap?

The regulators cannot cover all eventualities in the guidance. Ultimately it is the licensee's responsibility to provide his own solutions and defend them to the regulators. Through early

interaction the regulators are committed to providing what advice they can on a case-by-case basis to assist the licensee in coming up with the most appropriate solution.

3) NRX – Nirex

Question NRX-1: What happens if Nirex's advice or criteria change in the future?

There is no guarantee that this will not happen. It is therefore important that the licensee understands Nirex's advice, its provenance and the implications for his business. See also question IC-1.

Question NRX-2: What liability does Nirex retain for the advice it provides?

Any liability in respect of advice given will be a contractual matter between the licensee and Nirex. From a regulatory point of view, the licensee is responsible for the production and presentation of the safety case including any advice it receives from Nirex.

Question NRX-3: What is the status of advice received from Nirex?

Advice from Nirex to licensees has no special status in law. Its value is set by the expertise backing the advice and the recognition of that expertise by the regulators, government, the industry and other stakeholders. The regulators scrutinise the Nirex Letter of Comfort process (and the Phased Disposal Concept that underpins it) to ensure it is fit for purpose.

Question NRX-4: Is Nirex a regulator?

No. Nirex provides advice to the nuclear industry. Nirex own and develop the Phased Disposal Concept and operate the Letter of Comfort process.

4) ODC – Other Disposal Concepts

Question ODC-1: What if the anticipated disposal option for an ILW stream is not the ILW repository?

The safety case will have to be judged against the disposal criteria for the anticipated disposal route. For example, if the plan is to decay store waste so that it can be disposed of as LLW, then this should be tested against the "Conditions for Acceptance" for the low level waste facility at Drigg. The regulators are unlikely to accept proposals relating to disposal options where no criteria have yet been developed, particularly if the option is aimed at avoiding assessment against the PDC.

Question ODC-2: What process should be used if the plan is to condition for storage rather than for eventual disposal?

The regulators are unlikely to accept a safety case that does not address the eventual disposal of radioactive waste.

5) IC - Intelligent Customer

Question IC-1: What do licensees need to do to ensure that they understand the disposability aspects of the safety case sufficiently to satisfy the regulators?

As a general requirement, HSE expects licensees to be able to understand and support all aspects of the safety case and the facility operation over the full facility lifetime - including decommissioning and disposal.

When taking advice from Nirex or a contractor to support a safety case, the licensee needs to know what is required and be able to specify the request for advice appropriately, to understand the advice received and the context in which that advice sits.

The level of in-house capability that a licensee has to have will depend upon its circumstances and needs to be determined on a case-by-case basis. There may well be some circumstances where the licensee needs, through its own employees, to have in-depth capability. But in other situations

another licensee could fulfil its duties by having sufficient staff with general technical capabilities with the ability to question intelligently the advice. A number of factors will need to be taken into account in determining the level of in-house resource. In terms of disposability, the further away a safety case goes from meeting the standards necessary for a straightforward Letter of Comfort, the greater the need for in-house technical capability to understand and present the safety case.

6) L – Liabilities

Question L-1: Who is liable for work to be done in the future, e.g. reworking or repackaging, given the anticipated role of the NDA?

Under the Nuclear Installations Act, the site licensee retains responsibility for any (radiological) harm that may arise from activities on the site until a licence is granted to another body or there is no longer any danger from ionising radiations. The ownership of liabilities in terms of work that has to be done on NDA sites in the future is a contractual matter between the licensee and the NDA. For non-NDA sites this will be a matter for the licensee.