IMPROVED REGULATORY ARRANGEMENTS FOR THE CONDITIONING OF INTERMEDIATE LEVEL RADIOACTIVE WASTE ON NUCLEAR LICENSED SITES

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

Regulators' Position Statement - December 2003

EXECUTIVE SUMMARY

The Government's consultation papers on "Managing Radioactive Waste Safely" (MRWS) and "Managing the Nuclear Legacy" highlighted the issues around the management of the large quantities of intermediate level radioactive waste (ILW) which currently exist and will be generated over the next century. Subsequently, Government has decided to establish a Nuclear Decommissioning Authority (NDA) to take responsibility for the liabilities on civil public sector nuclear sites. This will include setting the strategy for decommissioning and waste-management programmes, which are likely to cost billions of pounds of expenditure lasting decades in the future. Following the consultation papers, Defra, SE and DTI accepted a proposal from the Health & Safety Executive (HSE), the Environment Agency (EA) and the Scottish Environment Protection Agency (SEPA), collectively referred to as the regulators, aimed at improving current regulatory arrangements for conditioning[†] ILW on nuclear licensed sites. The Government departments expressed a wish to receive further details, including a Regulatory Impact Assessment. This position statement presents these further details and is based on the outcomes from a twelve-month review of the technical details of the regulators' proposal with stakeholders.

The aim of the regulators is to improve current regulatory arrangements by bringing the management of ILW under closer regulatory scrutiny. However, it is important to note that there will be no changes to the legislation under which the HSE and the environment agencies regulate. In practice, the regulation of proposals to condition ILW will continue to be exercised by HSE through the nuclear site licence granted under the Nuclear Installations Act 1965. HSE's procedures will not change from their normal way of dealing with new and modified processes or plant. HSE will, as at present, seek the advice of the EA or SEPA in accordance with the terms set out in existing Memoranda of Understanding (MoU). In the case of proposals to condition ILW, the EA or SEPA will provide advice particularly on the long-term disposability[‡] of the proposed wasteform. HSE require this advice because of the potential safety aspects of any re-working of packaged wastes that might be necessary to satisfy the EA's or SEPA's long-term environmental protection concerns. The regulators will introduce the improved regulatory arrangements progressively during 2004.

The improved regulatory arrangements aim to ensure that ILW is managed in a sustainable way taking into account long-term environmental considerations. The regulators consider that the improved arrangements will thereby provide stakeholders with:

- greater regulatory certainty with respect to the eventual disposability of conditioned ILW;
- confidence that any necessary foreclosure of future ILW management options has been decided in an open and transparent and systematic way; and
- joint decision-making about ILW conditioning, taking into account the HSE's requirements for safe interim storage and minimising the risks to public and workers, and the environment agencies' requirements for longer-term environmental protection.

Stakeholders will benefit from:

- Increased public confidence in waste-management arrangements arising from the independent examination and assessment of ILW conditioning proposals thereby ensuring:
  - that proper emphasis is given to both safety and long-term environmental considerations;
  - increased transparency in decision making by following a clear and transparent regulatory process; and
  - an appropriate and proportionate balance is determined between costs and benefits.
- Much greater business certainty for the nuclear industry, Nirex and the NDA at a time when these organisations are committing significant resources to ILW conditioning. This will apply at all stages

[†] 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 ease of use the terms are generally condensed to "conditioning" and this practice is followed in this document except where it is necessary to refer to one of the stages specifically.

[‡] In the context of this report, 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", and in turn "disposability", is used generically in this report 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.

arising from early interaction with the regulators thereby avoiding wasted effort, potential delays and costs resulting from developing inappropriate waste-management strategies.

- Formalisation of the regulators' joint working arrangements which should minimise the possibility of conflicting requirements.
- Earlier dialogue between the regulators and key stakeholders which should ease the regulatory path to consents under the Nuclear Installations Act 1965 (NIA 65) for building ILW conditioning plants and to authorisations under the Radioactive Substances Act 1993 (RSA 93) for disposal of waste packages.
- Clear documentation of the basis for current regulatory decisions that could inform future implementation of a waste disposal strategy.
- Opportunities for the regulators to make comments on the development by Nirex of its phased disposal concept (PDC).
- Opportunities for the regulators to understand and scrutinise modifications made by Nirex to the PDC arising from their assessment of ILW conditioning proposals.
- Arrangements for the regulators to maintain and develop their assessment expertise, and to prepare properly for the possible future receipt of applications for the construction and operation of any repository.

In order to achieve these benefits, the regulators' approach consists of putting in place arrangements for improved regulatory oversight which focuses on the following three inter-linked aspects of ILW conditioning:

- the development by Nirex of the PDC which may provide the basis for a reference safety and environmental design for an eventual disposal route;
- ILW conditioning proposals for which Nirex are able to issue a Letter of Comfort (LoC); and
- proposals for challenging wastes, for which it may not be possible to demonstrate, in a timely manner, compliance with all the Nirex waste packaging specifications but for which a pressing safety need to process the waste exists.

These improved regulatory arrangements are flexible enough to accommodate any changes in UK long-term waste-management policy that might arise from the review to be undertaken by the Committee on Radioactive Waste Management (CoRWM) under the Government's "MRWS" process. Moreover, the arrangements will have the flexibility to accommodate any changes to the role of Nirex, and possible legislative changes arising from the draft Energy Bill under which the NDA will come into effect.

The HSE will be primarily concerned with issues related to on-site safety and the environment agencies will be concerned with issues related to long-term environmental protection, in particular the ultimate disposability of the conditioned waste. The regulators are now working on new joint guidance to support the improved regulatory approach. This guidance will build on the HSE's and EA's extant guidance on nuclear safety cases and the conditioning of ILW respectively and take into account the suggestions on its form and content provided by stakeholders.

The regulators' future aim is to introduce progressively a risk-based procedure for filtering ILW conditioning proposals to allow them to prioritise their efforts on more difficult and/or contentious proposals.

Agreements between the regulators and Nirex provide for scrutiny of Nirex's on-going work. This involves examining Nirex's PDC and how Nirex apply this to their assessment of ILW conditioning proposals and the issuing of Letters of Comfort (LoC) and/or Letters of Advice (LoA). This will also involve examination of the fitness for purpose of Nirex's use of the PDC and LoC at a time when CoRWM is carrying out its review and the final radioactive waste-management option has not been determined.

The environment agencies' maximum total costs for implementing these regulatory improvements are estimated at £0.35M in 2003/04 rising to about £1.85M per year thereafter. These costs are small, with possible savings arising from the improved regulatory process, compared to current costs for developing and implementing ILW conditioning proposals, and tiny compared to the overall industry cost of £1 billion per year for cleaning up the nuclear legacy. These estimated costs and benefits are presented in the form of a Regulatory Impact Assessment.

CONTENTS

INTRODUCTION
Aims and Benefits

BACKGROUND
Nuclear Decommissioning Authority
Intermediate Level Waste
Role of Nirex

IMPROVED REGULATORY ARRANGEMENTS

PRELIMINARY CONSULTATION
October '02 Workshop
First Informal Technical Review
Second Informal Technical Review
Formal Review

SCOPE OF THE IMPROVED REGULATORY ARRANGEMENTS
ILW / LLW
ILW / LoC
Challenging Wastes

WORKING ARRANGEMENTS
Nirex Phased Disposal Concept
ILW Conditioning Proposals
Guidance
Openness

REGULATORS' RESOURCE REQUIREMENTS, COSTS AND COST RECOVERY
Resource Requirements
Costs
Cost Recovery - Industry
Cost Recovery - Nirex
Regulatory Impact Assessment

REFERENCES

ANNEXES
Annex A: HSE/EA/SEPA Proposals for Improved Regulation of ILW Conditioning
Annex B: Current Regulatory Arrangements
Annex C: International Obligations
Annex D: Preliminary Consultation
Annex E: Regulatory Impact Assessment

IMPROVED REGULATORY ARRANGEMENTS FOR THE CONDITIONING OF INTERMEDIATE LEVEL RADIOACTIVE WASTE ON NUCLEAR LICENSED SITES

INTRODUCTION

1. 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 intermediate level radioactive waste (ILW) which currently exist and will be generated over the next century. Subsequently, Government has decided to establish a Nuclear Decommissioning Authority (NDA) to take responsibility for the liabilities on civil public sector nuclear sites. This will include setting the strategy for decommissioning and waste-management programmes, which are likely to cost billions of pounds of expenditure lasting decades in the future. Following the consultation papers, Defra, SE and DTI accepted a proposal from the Health & Safety Executive (HSE), the Environment Agency (EA) and the Scottish Environment Protection Agency (SEPA), collectively referred to as the regulators, aimed at improving current regulatory arrangements for conditioning[†] ILW on nuclear licensed sites. A copy of the joint letter is at Annex A. The Government departments expressed a wish to receive further details, including a Regulatory Impact Assessment[(3)]. This position statement presents the further details and is based on the outcomes from a twelve-month review of the technical details of the regulators' proposal with stakeholders.

Aims and Benefits

2. The regulators' approach is to bring the management of ILW under closer regulatory scrutiny. However, there will be no changes to the legislation under which the HSE and the environment agencies regulate. In practice, the regulation of proposals to condition ILW will continue to be exercised by HSE through the nuclear site licence granted under the Nuclear Installations Act 1965. HSE's procedures will not change from their normal way of dealing with new and modified processes or plant. HSE will, as at present, seek the advice of the EA or SEPA in accordance with existing Memoranda of Understanding (MoU). In the case of proposals to condition ILW, the EA and SEPA will provide advice particularly on the long-term disposability[‡] of the proposed wasteform. HSE require this advice because of the potential safety aspects of any re-working that might be necessary to satisfy the EA's or SEPA's long-term environmental protection concerns. The regulators' plan to introduce the improved regulatory arrangements progressively during 2004.

3. The aims of the regulators' approach are to ensure that ILW is managed in a sustainable way taking into account the implications of the long-term environmental considerations. The regulators consider that the improved arrangements will thereby provide stakeholders including the general public, nuclear industry, Nirex, and the forthcoming NDA, with:
   - greater regulatory certainty with respect to the eventual disposability of conditioned ILW;

[†] 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 ease of use the terms are generally condensed to "conditioning" and this practice is followed in this document except where it is necessary to refer to one of the stages specifically.

[‡] In the context of this report, 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", and in turn "disposability", is used generically in this report 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.

- confidence that any necessary foreclosure of options has been decided in a transparent and systematic way; and
- joint decision-making about ILW conditioning, taking into account the HSE's requirements for safe interim storage and minimising the risks to public and workers, and the environment agencies' requirements for longer term environmental protection.

4. The regulators consider that stakeholders will benefit from these improved arrangements in the following ways:
   - Increased public confidence in waste-management arrangements arising from the independent examination and assessment of ILW conditioning proposals thereby ensuring:
     - that proper emphasis is given to both safety and long-term environmental considerations;
     - increased transparency in decision making by following a clear and transparent regulatory route map; and
     - an appropriate balance is determined between costs and benefits.
   - Much greater business certainty for the nuclear industry, Nirex and the NDA, at a time when they are committing significant resources to ILW conditioning. This will apply at all stages arising from early interaction with the regulators thereby avoiding wasted effort, potential delays and costs resulting from developing inappropriate waste-management approaches.
   - Formalisation of the regulators' joint working arrangements will benefit the nuclear industry, Nirex and the NDA by minimising any possibility of conflicting requirements.
   - Earlier dialogue between the nuclear industry, Nirex, the NDA, regulators and other key stakeholders will ease the regulatory path to consents under Nuclear Installations Act '65 (NIA'65) for building ILW conditioning plants and to authorisations under the Radioactive Substances Act 1993 (RSA '93) for disposal of waste packages.
   - Clear documentation of the basis for current regulatory decisions that could inform future implementation of a waste disposal strategy.
   - Opportunities for the regulators to make comments on the development by Nirex of its phased disposal concept (PDC).
   - Opportunities for the regulators to understand and scrutinise modifications made by Nirex to the PDC arising from their assessment of ILW conditioning proposals.
   - Arrangements for the regulators to maintain and develop their assessment expertise, and to prepare properly for the possible future receipt of applications for the construction and operation of any repository under the NIA '65 and RSA '93.

5. This position statement focuses primarily on the improved arrangements that the environment agencies will follow when providing advice to the HSE following submission of proposals from the nuclear industry to HSE to condition their ILW. It also includes information on the arrangements that the EA and SEPA have put in place for their regulatory scrutiny of the work of Nirex. A Regulatory Impact Assessment (RIA), covering the environment agencies' improved arrangements, is included at Annex E. The regulators are now working on joint guidance to support the improved regulatory approach. This guidance will build on the HSE's and EA's extant guidance on nuclear safety cases and the conditioning of ILW respectively and will take into account the suggestions on its form and content provided by stakeholders.

BACKGROUND

6. In September 2001, Defra and the Devolved Administrations consulted on proposals for developing a policy for managing solid radioactive waste in the UK[(1)]. Included in this

consultation was an invitation to comment on current regulatory arrangements and the possibility of the environment agencies being given a new statutory power over the storage of radioactive wastes on nuclear licensed sites. Subsequently, HSE, EA and SEPA jointly set out proposals for the "improved regulation of the treatment and conditioning of intermediate level waste on nuclear licensed sites" in the form of letters sent to Defra and SE. A copy of the letter sent to Defra is included at Annex A.

7. The regulators initially considered the following two options for bringing this work more clearly into their current regulatory processes:
   - Option 1: HSE would use the existing nuclear site licensing provisions under the Nuclear Installations Act 1965 to regulate proposals made by nuclear site licensees to condition ILW. The requirement to gain EA/SEPA agreement would be effected through HSE consulting EA or SEPA under respective Memoranda of Understanding (MoU) between the HSE and both environment agencies.
   - Option 2: New legislation would be needed to grant EA/SEPA regulatory powers regarding industry proposals to condition ILW. These new powers would be exercised in parallel with HSE's regulatory regime.

8. Option 1 was accepted by Defra, SE and DTI as the preferred way forward, subject to considering further details, as it does not require new legislation and, therefore, could be implemented more quickly.

Nuclear Decommissioning Authority

9. The UK has a significant nuclear legacy arising from Government funded work, going as far back as the 1940s. The DTI is proposing radical changes to current arrangements to tackle this legacy and clean-up nuclear sites [(2)]. An Energy Bill is undergoing due processes, and if it becomes law the NDA will be established and take responsibility for the liabilities on civil public-sector nuclear sites. The Bill also proposes that the regulators become statutory consultees in developing the NDA's decommissioning and clean-up strategy. The Liabilities Management Unit (LMU) of the DTI, has been given the remit of preparing the ground for the NDA. In advance of the NDA, the regulators and the LMU are meeting regularly to co-ordinate their approaches to work for which the NDA will ultimately be responsible. This includes the management of ILW. The NDA will establish waste-management plans with site licensees, and agree these plans with the regulators, as described in draft Memoranda of Understanding between the NDA and regulators.

Intermediate Level Waste

10. In addition to the nuclear facilities themselves, such as fuel cycle plants and power stations, the legacy includes large volumes of ILW. These wastes are currently stored safely on nuclear licensed sites in the UK pending a decision on their long-term future.

11. Interim storage of ILW will continue to be needed until a final management option is implemented. Because these wastes will remain hazardous for thousands of years, their conditioning must take account of long-term safety and environmental issues, and storage of these wastes will need to be maintained under conditions of passive safety with minimal need for human intervention. ILW is being conditioned now and considerable further quantities will need to be conditioned to produce passively safe wasteforms that improve the safety of interim (50 - 100 years) storage.

Role of Nirex

12. Currently, most proposals from the nuclear industry to condition ILW are put to Nirex[†] for assessment. Typically, these submissions can be made at any of the following three stages of a waste-management project:
    - Conceptual stage: Based on outline information on the anticipated waste volumes, packaging proposals and development plans.
    - Pre-commitment: Based on final design specifications, prior to a waste producer making significant financial commitment to construction of a facility.
    - Final: Prior to a facility commencing operation – a review of the 'as-built' data to ensure it meets the requirements.

13. Nirex assess these proposals against safety criteria it has developed for the storage, transport, handling and possible disposal of ILW. Nirex has developed its own standards and assessment criteria based on generic concepts and supporting safety assessments of transport, handling and disposal systems. Using their assessment criteria, Nirex currently assess all proposals made by nuclear site operators to condition ILW for conformity with its:
    - standards and specifications;
    - packaging principles; and
    - phased disposal concept (PDC).

14. Long-term issues relating to the eventual disposal of conditioned wastes are currently addressed by Nirex under the LoC process by assessing proposals for compatibility with its PDC. However, the Government is currently reviewing policy for radioactive waste management. The Committee on Radioactive Waste Management (CoRWM) will be carrying out a review of waste-management options over the next 2 to 3 years under the "Managing Radioactive Waste Safely" process. Phased Disposal is just one of the options under consideration. With a view to addressing this uncertainty, Nirex has carried out studies to test the robustness of its packaging specifications and standards against other management options. Nirex considers that these studies(4) have shown the PDC and continued application of the LoC process to be appropriate in terms of being compatible with a range of waste-management options, including various combinations of storage and emplacement underground. It is noted that the issue of compatibility of the PDC and LoC process with other waste-management options will be explored further at a RWPG-sponsored workshop, convened by Defra, in early 2004.

15. Nirex categorise conditioning proposals from industry to obtain a LoC depending on the degree to which they conform with their standards etc. and whether the proposal falls within previous assessments that Nirex have carried out. Nirex use the following three categories:
    - Category 1 - proposals with the greatest significance for the design and safety of transport and disposal systems.
    - Category 2 - proposals that fall outside Nirex's experience but nevertheless are consistent with existing assessment methods.
    - Category 3 - proposals that conform fully and are within Nirex's experience.

[†] Nirex was formed in 1982 and incorporated as a private limited company – United Kingdom Nirex Ltd – in 1985, to provide radioactive waste disposal services. Nirex is financed and owned by the main waste producers: BNFL, UKAEA and British Energy in proportion to the volumes of waste they produce. In addition, the MoD contributes to the funding of Nirex. In an announcement made in July of 2003 Government stated that it "will consult Nirex shareholders on the best way of making Nirex independent of industry and under greater government control." An announcement as to the appropriate way forward for Nirex is awaited.

16. Proposals are allocated an initial category. These can be changed up or down by Nirex's further assessment. It is possible for some Category 1 and 2 proposals to be reclassified as Category 2 or 3, if further assessment by Nirex reveals that the proposal is acceptable or the PDC can be developed to accommodate the waste.

17. Where a proposal conforms with these requirements, Nirex will provide endorsement to the waste producer in the form of a Letter of Comfort (LoC). This is not an automatic outcome and the LoC may have conditions or caveats attached to it placing specific requirements on the waste producer. It is normal for Nirex to issue Letters of Advice (LoA) during the course of their assessment. In circumstances where a proposal does not conform, Nirex generally issues a LoA explaining why a proposal is unacceptable and advising the applicant on the aspects requiring further development. The type of LoC which may be issued depends on the stage of the proposal. Thus at the early design stage a conceptual LoC may be issued; whereas at the pre-active commission stage a final LoC may be issued.

IMPROVED REGULATORY ARRANGEMENTS

18. The regulators' view is that the current regulatory arrangements, summarised at Annex B, do not provide for satisfactory regulatory oversight and scrutiny of the decision-making related to ILW conditioning proposals through the "Industry Proposal - Nirex Letter of Comfort" process. In particular, the regulators are concerned that the current arrangements do not comply with the requirements of the UK's international obligations summarised at Annex C. This is because it is Nirex who currently endorse ILW conditioning proposals from nuclear waste producers, and, in view of the current association between Nirex and the nuclear industry, these arrangements effectively correspond to the industry regulating itself. Furthermore, future assessments about ILW conditioning will need to be made carefully, in the context of emerging Government policies on decommissioning and radioactive waste management. Also, as progress is made towards a final waste-management solution, stricter regulatory control will be needed as to what can and what cannot be placed in any final waste-management facility.

19. The regulators have therefore agreed with Defra, SE and DTI that there would be benefit in bringing industry's proposals to condition ILW more clearly into the HSE's and environment agencies' regulatory frameworks. In doing so, the HSE would look to ensure that proposals to condition ILW are appropriate to interim storage; and the environment agencies would assess proposals to ensure that resulting wasteforms would be suitable for ultimate disposal in the context of emerging waste-management options. The regulators' improved regulatory arrangements will be sufficiently flexible to accommodate any changes in the UK's policy on the long term management of radioactive waste which may arise from the review to be carried out over the next 2 to 3 years by CoRWM. They will also have the flexibility to accommodate any changes to the role of Nirex, legislative changes that might arise from the draft Energy Bill and any changes to the PDC and LoC process that might be recommended by CoRWM.

20. In order to implement Option 1 referred to in paragraph 7, the regulators have been working together to identify the scope of work and their resource requirements, and to develop working procedures and arrangements to recover their costs.

PRELIMINARY CONSULTATION

21. The regulators have held discussions with several interested parties at key stages of their development work. These are summarised below. Details of the issues raised are

summarised at Annex D. The outcomes from this extended technical review underlie this position statement.

October '02 Workshop

22. A workshop involving representatives from industry, Nirex, government departments and advisory bodies was held in October 2002 to provide an early opportunity for external input to the regulators' deliberations. Overall, feedback was supportive of the proposed improvements.

First Informal Technical Review

23. The issues from the Workshop were taken into account in a first draft of a Technical Review document, which was made available to industry and departmental contacts in February 2003 to obtain their initial views on the scope, content and layout. This was followed up in April and May with bilateral discussions to explore the received comments more fully.

Second Informal Technical Review

24. Comments from the first review were taken into account in a second draft of the Technical Review document. This was made available to industry and departmental contacts for further consideration in June / July 2003.

Formal Review

25. Comments from the second informal review were addressed in a final draft of the Technical Review document. This was made available to industry and departmental contacts for further consideration in August-October 2003.

SCOPE OF THE IMPROVED REGULATORY ARRANGEMENTS

26. ILW is defined in Command 2919[(5)] 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 consequently the term "ILW" covers a multitude of waste types, activities and half-lives. In addition there are a number of LLW waste streams that are unsuitable for disposal at Drigg; such wastes are considered, for convenience, along with ILW.

27. The scope of the improved regulatory arrangements covers all types of ILW. It may be useful, for the purpose of understanding our approach, to subdivide ILW into three broad classes. **These classes are for illustrative purposes only to help describe how the regulatory arrangements in these instances may work. They are not being proposed by the regulators as "formal" classifications of ILW.** The three classes are:
- "ILW/LLW": ILW whose radioactivity can be reduced to allow its disposal as LLW at Drigg.
- "ILW/LoC": ILW (and LLW which is unsuitable for disposal at Drigg) for which conditioning proposals can be processed by Nirex with a reasonable degree of confidence of achieving a LoC.
- "Challenging wastes": ILW (and LLW which is unsuitable for disposal at Drigg) which is difficult to characterise, retrieve or condition.

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

The specific considerations that apply to each of these classes are as follows.

ILW / LLW

28. These wastes are classified as ILW because at the time of their creation their level of radioactivity exceeds the activity limits for LLW. Nevertheless, waste-management options exist to reduce the radioactivity of the ILW to allow its disposal as LLW. These options include storage for decay and/or processing to recover radionuclides.

29. Examples of this class of wastes include:
    - Nuclear Submarine Programme wastes: untreated ILW in the form of resins are stored in containers within facilities regulated by the HSE until such time as the activity of these resins naturally decays to LLW. The process of decay storage makes the resins suitable for final disposal as LLW at BNFL Drigg. Certain materials within these resins might mean that the resins are subjected to third-party processing before BNFL Drigg can accept them.
    - Amersham Health wastes: ILW is overpacked in a Nirex compatible container and then stored in purpose built storage facilities, which incorporate multi-layers of containment. Wastes of differing forms or types are segregated and stored in a safe and passive form. The store is designed so that some ILW can be retrieved and conditioned for disposal as LLW following natural decay. Other ILW is stored to await the development of future treatment processes for the recovery and re-use of valuable radionuclides.

30. The regulators' approach essentially involves no change to the current arrangements for regulation of this class of ILW. HSE will, of course, retain its discretion to intervene in accordance with its statutory powers, in consultation with the environment agencies. To that end, the regulators will expect to be kept informed by the waste producer of their on-going arrangements for managing this class of wastes. The regulators will continue to keep these arrangements under review. However, 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 disproportionate costs for treatment, conditioning and packaging.

ILW / LoC

31. The RWMAC / NuSAC report[6] in June 2002 provided an "overview of progress with conditioning and packaging". This identified that up until 31 March 2001, Nirex had issued LoCs for 69 packaging proposals with a total ILW volume of 74,000m^3. The vast majority of these issued LoCs are for current and forecast operational wastes. It is this "Industry Proposal - Nirex Letter of Comfort" process that the regulators will wish to examine in the early years of implementation of the improved regulatory arrangements. The working arrangements set out in the next section focus on this process.

Challenging Wastes

32. Challenging wastes is a term used in this document to refer to certain types of legacy wastes[†] that are difficult to characterise, retrieve or condition. They include:

[†] At a RWPG-sponsored workshop, attended by representatives from industry, regulators and government, held on 28 November 2003 at Defra it was concluded that the existing LoC assessment processes can be used for all legacy wastes and that early dialogue, between the operators, regulators and Nirex, on the short- and long-term drivers for packaging are necessary. The concept of a separate Interim Safe Storage (ISS) was rejected.

- wastes that are difficult to access under current storage arrangements (e.g. Dounreay shaft, Sellafield B41 and B38 silos);
- material for which immobilisation is difficult (e.g. some plastics, HEPA filters, filter beds, some ion exchange resins, bagged or containerised wastes and super compacted hard wastes); and
- materials with significant inherent hazards (e.g. reactive metals, pyrophoric materials, significant fissile content wastes and low temperature irradiated graphite possessing Wigner energy).

33. Although difficulties with achieving a conceptual LoC may be recognised at an early stage of considering management options for challenging wastes, the regulators wish to see faster progress in this area. The regulators' arrangements will be flexible and efficient so as not to unduly cause delay. The regulators anticipate that consideration of proposals for dealing with these wastes will become an important focus of their work. The regulators will look for the licensee to produce a rationale for the conditioning of their ILW on a case-by-case basis. The regulators recognise that it may be necessary to revisit the rationale as more information becomes available. The rationale should include the following elements:

- The long-term aspects of disposability have been satisfactorily considered (noting that Nirex's criteria[†] can be modified in the light of assessments of real cases provided that the environmental safety case is not jeopardised);
  - showing that all Nirex safety criteria can be met for the packaging proposal; or
  - showing that, for the specific waste stream being assessed, it is not necessary to meet all of the Nirex general safety criteria; or
  - 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.
- A systematic and transparent demonstration of the way decisions have been reached.
- A demonstration that an appropriate balance between short-term actions and long-term commitments has been achieved.

34. The regulators recognise that it may not be practicable to demonstrate compliance, in a timely manner, with all of the Nirex work package specifications, because the necessary information (e.g. on waste characterisation) cannot be obtained without first retrieving the waste. Nevertheless, early and continued involvement of Nirex to select preferred options for packaging of historic ILW is necessary. The process allows for three successful outcomes from a 'disposability' viewpoint which would enable the issue of a LoC:

- All Nirex safety criteria can be met for the packaging proposal.
- Assessments of the packaging proposal show 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 Nirex general safety criteria needs now (thus defining a 'compliance gap') but credible plans are in place for developing future re-work schemes with a view to achieving a 'disposable' form.

35. In these cases, the HSE and relevant environment agency would only give their approval where:

- all options to condition ILW have been fully assessed;
- the Nirex LoC process has been exhausted; and
- any 'compliance gap' is fully understood and credible plans are in place to address it.

[†] this includes the possibility of Nirex re-addressing pessimisms through, for example, commissioning R&D to address uncertainties in the PDC.

While it is recognised that interim conditioning might sometimes be necessary to reduce 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 would be looking for the waste to be packaged in a manner that facilitates later conditioning to achieve such full LoC coverage at a later date.

WORKING ARRANGEMENTS

36. These working arrangements will provide for improved regulatory oversight of the following three inter-linked aspects of ILW conditioning:
    - the development by Nirex of the "phased disposal concept" which provides the reference safety and environmental design for an eventual disposal route;
    - proposals from site operators for waste conditioning for which Nirex are able to issue a LoC; and
    - proposals from site operators for conditioning of challenging wastes for which difficulties with achieving a LoC may be recognised at an early stage but for which a pressing need to process the waste exists.

37. 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 allow the ILW to be disposed of both safely and with minimum environmental impact. Where a proposal does not fit the current reference PDC, Nirex will consider making changes to the PDC. If they can be made within the overall safety and environmental requirements then the PDC may be changed and a LoC issued possibly with caveats and/or a LoA for the waste-conditioning proposal. If they cannot be made, Nirex cannot issue a LoC and will inform the proposer using a LoA.

Nirex Phased Disposal Concept

38. At present the Nirex PDC remains under development as a reference repository design and there are currently no site-specific plans. Nevertheless, the regulators see advantages in bringing this development work under closer regulatory scrutiny, with regard to its focal point for LoC applications, and its fitness for purpose. The HSE, the EA and SEPA have Agreements in place with Nirex to do this. Under these Agreements, scrutiny of the Nirex PDC process will enable the regulators to:
    - develop an understanding and confidence in the proposed concepts;
    - provide opportunities to make comments;
    - maintain and develop regulatory expertise and steer Nirex's assessment concepts;
    - prepare properly for the possible future receipt of applications for the construction and operation of any repository under NIA'65 and RSA'93;
    - understand and scrutinise modifications to the PDC arising from the assessment of ILW conditioning proposals;
    - examine the fitness for purpose of Nirex's use of the PDC and LoC at a time when CoRWM is carrying out its review and the final radioactive waste-management option has not been determined;
    - ensure that Nirex's approach does not rule out any relevant long-term waste-management option; and
    - publicise the regulators' views at any point.

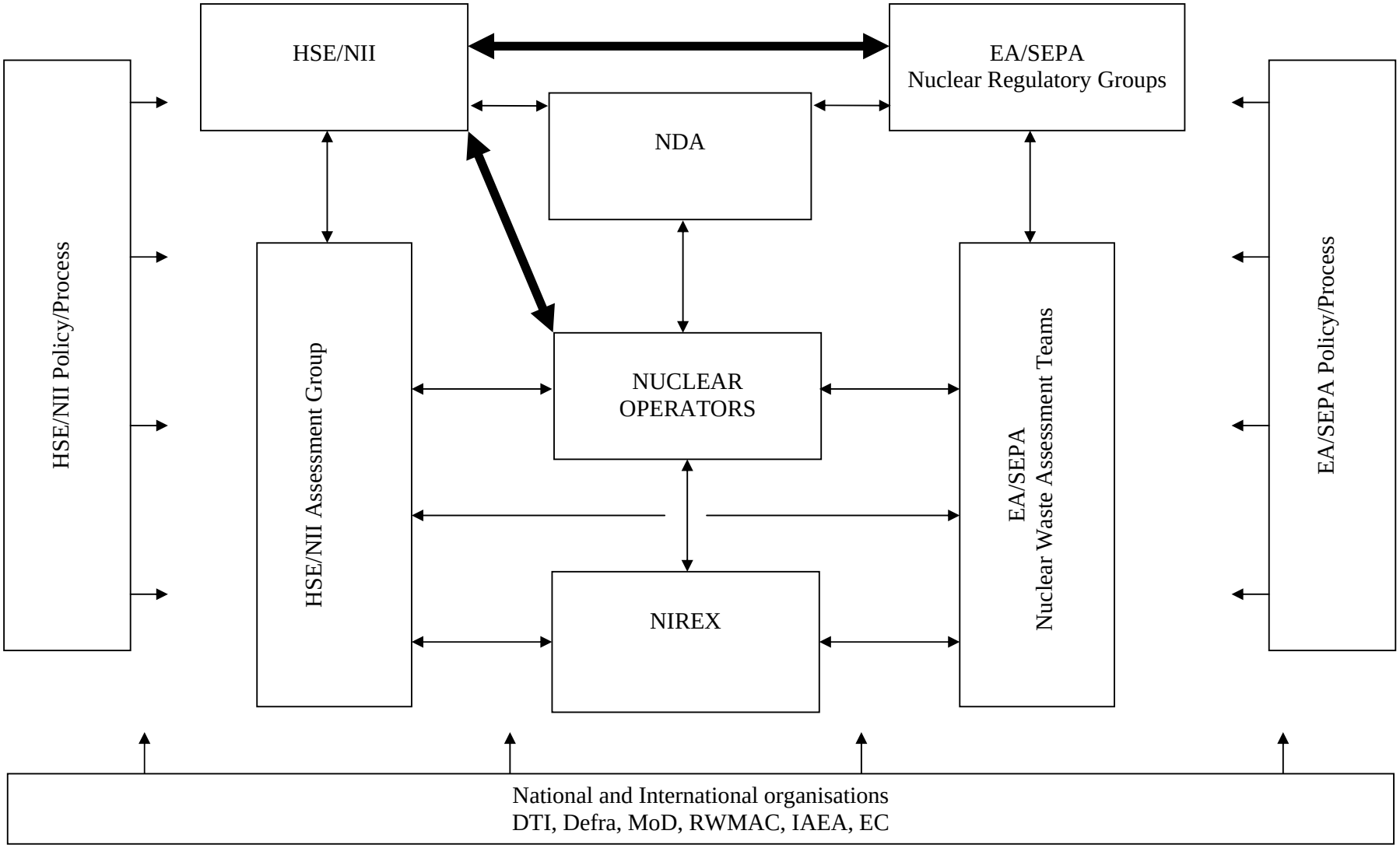
39. It is the regulators' intention with regard to the development of the Nirex PDC to:
    - examine the feasibility and suitability of Nirex's concepts;

- compare the PDC development and LoC assessment work against internationally recognised good practice;
- assess how Nirex derive their specifications and guidance from these concepts;
- critically review how Nirex assess ILW conditioning proposals against their concepts, specifications and guidance, and scrutinise any consequential changes to the concepts;
- look in detail at specific waste-management issues, such as criticality and Wigner energy in graphite; and
- examine the compatibility of waste-package specifications with different long-term waste-management options.

ILW Conditioning Proposals

40. When considering ILW conditioning proposals, it is not the regulators' intention to replace nor duplicate the current nuclear industry - Nirex LoC, LoA and PDC processes. These fundamental principles are well established in the nuclear industry and their merits are recognised both by industry, the regulators and government. Rather, the regulators intend to build on this process by introducing an over-arching regulatory framework. Figure 1 illustrates how this combined working for the HSE and the environment agencies will take place in the context of national policy and international obligations in response to the submission of a proposal for ILW conditioning from the nuclear industry. This is not intended to be a sequential process whereby industry first obtains a LoC from Nirex and then makes a submission to the regulators. Rather, this will be a process based on continuous dialogue between the nuclear industry and the regulators with some formal regulatory hold points based around safety submissions. In particular, early interactions are important at the optioneering and design studies that underlie the Conceptual LoC in order to gain the regulators' views. The formal hold points apply at those stages at which action is taken (e.g. construction, commissioning, modification and operation). The arrows in bold print identify the formal regulatory steps in the submission and assessment of an ILW conditioning proposal. The arrows in normal print identify the wider and many informal communications which can be expected to take place during the assessment by the regulators. The regulators appreciate that the proposed streamlined and effective regulatory framework can only be achieved by their early and continuous involvement in the development of an ILW conditioning proposal. Nevertheless, it is important to understand that although the regulators wish to be engaged constructively at all stages, their role is one of challenging and ensuring that a licensee's proposal and Nirex's advice satisfy the regulators' requirements.

Figure 1: Combined Regulatory Working



41. The intention of the proposed new regulatory arrangements for ILW conditioning proposals is to build on what exists now and not supersede them. In many respects what is being proposed is a formalisation of current arrangements which are followed in an ad-hoc manner. In practice, regulation of individual proposals for ILW conditioning will continue to be exercised through HSE's nuclear site licence granted under the NIA'65 after consultation with the environment agencies. The way in which HSE currently deals with safety case submissions will form the basis for dealing with ILW conditioning proposals.

42. The content and form of that part of the required safety case submission detailing an ILW conditioning proposal will be agreed as early as possible in the life of a project. The actual submission should be fit for the purpose and may comprise either a compendium of correspondence or a stand-alone document.

43. Whatever the form, it will need to address the safety and environmental protection issues to be identified in joint guidance to be published by the regulators. This new guidance will be based on the HSE's and EA's extant guidance [7,8]. Copies of the extant guidance may be accessed now on the HSE's and EA's websites and provides information on the issues the regulators will expect to be addressed.

44. HSE will consult the EA and SEPA under the terms of the relevant MoU. EA and SEPA will examine the parts of the safety case submission that are relevant to environmental protection, and in particular the long-term disposability of the conditioned waste, and advise HSE as to issues/concerns accordingly. Only when the regulators are jointly content will HSE give permission to condition the ILW in accordance with the submission. It is intended that the process will be staged, with arrangements for continuous dialogue, to provide suitable regulatory hold points beyond which a licensee could not proceed without regulatory agreement. Within the current nuclear site licensing regime, hold points and the associated timescales are a matter for negotiation between the licensee and the HSE, on a case-by-case basis.

45. The flowchart at Figure 2 illustrates the procedural stages that are envisaged.

46. For the future, it is the regulators' intention to develop a proportionate approach for dealing with submissions from the nuclear industry to focus effort on those more difficult or contentious proposals, in particular challenging wastes. The regulators have decided that in the early years of operating these new arrangements to look at Nirex's assessment procedures and view, but not necessarily examine in detail, as many conditioning proposals as possible. In part, this is to gain understanding and confidence in the Nirex concepts and processes of dealing with all categories of proposals. This will give the regulators the opportunity to develop further their approach.

47. Thereafter, the regulators will introduce a risk-based[†] procedure to act as a filter and allow effort to be prioritised. This will be without prejudice to HSE's powers to 'call in' any proposal regardless of categorisation. A way in which this risk-based procedure might work is for the regulators to take account of Nirex's categories when reviewing LoCs and LoAs and any issues of concern raised by Nirex in their assessment process. The filter would then typically provide for the following approach:

[†] In this context 'risk' should be understood in a wide context, including hazard, environmental implications and other factors, such as the volume or nature of the ILW for which a conditioning proposal is being made.

- For a Nirex Category 1 proposal, the relevant agency will consider carrying out a detailed review of the Nirex assessment output to determine whether any of the issues relating to the disposability and reworkability of the proposed waste packages mean that the proposal is not acceptable to the relevant environment agency.

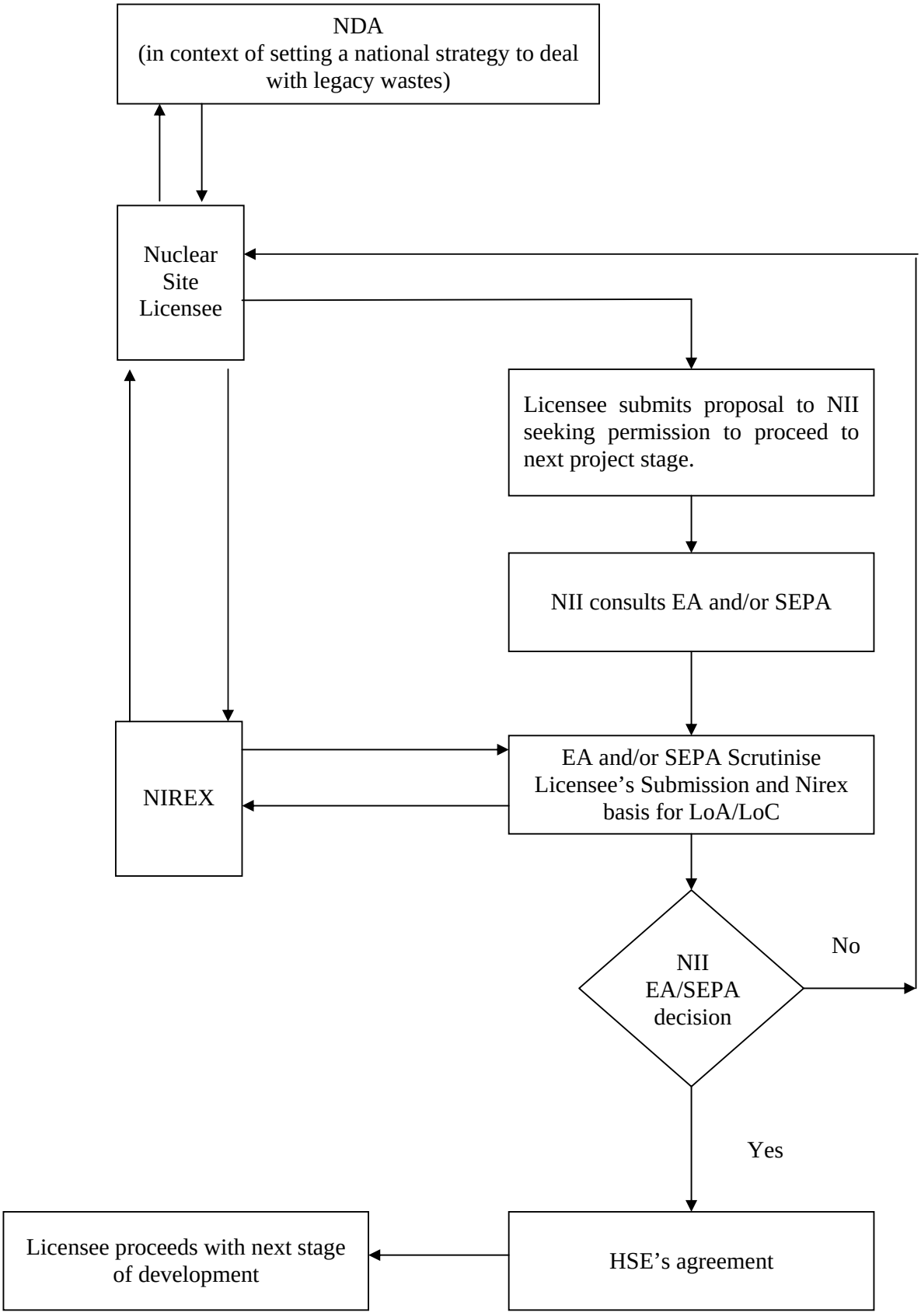
- For a Nirex Category 2 proposal the extent of regulatory review will depend upon whether the Nirex assessment reveals that the performance of the proposed waste package falls within the previously agreed bounding conditions and limitations. If it does, then the relevant environment agency review would be as for a Category 3 proposal. If it does not, the proposal becomes a Category 1 proposal and the approach set out for Category 1 proposals will be followed.

- For a Nirex Category 3 proposal, the relevant environment agency's review of the output of Nirex assessments will be limited to ensuring that:
  - it understands and has confidence in the background work that has led to Nirex's decision;
  - an assessment has been carried out by Nirex;
  - the basic information, such as the waste inventory and waste packaging proposal, is consistent with that contained in the best practicable environmental option (BPEO) study for the waste;
  - a final LoC has been issued (a final LoC may be issued with caveats and with a LoA where issues have to be resolved by information provided by active commissioning or operational experience); and any issues of concern can be readily addressed.

48. The following mechanisms, for filtering out proposals of little regulatory significance are still under consideration:
    - (A) – All proposals become (HSE) Category 1 submissions and are referred to regulators.
    - (B) – As for (A), but regulators filter out some proposals for the licensee to continue as self-regulation.
    - (C) – Industry carries out filtering system.
    - (D) – No specific scheme for ILW conditioning, but rely on inspectors 'calling in' proposals of interest.

49. The regulators' approach is to work with the nuclear industry and the LMU/NDA to establish criteria on which to base a filter mechanism. A standard way of assessing the risk / hazard posed by an ILW stream will be required. BNFL's development of a Hazard Indicator for assessing hazard may be helpful. The filtering mechanism will evolve through interactions of the waste producers, the LMU/NDA and the regulators. When developed in more detail, and at appropriate times, progress about the filtering mechanism will be reported to other stakeholders.

Figure 2: Procedural stages



50. The HSE will be primarily concerned with issues related to on-site safety, including aspects of radioactive waste management, and the environment agencies will be concerned with issues related to environmental protection, and in particular long-term disposability of the conditioned waste. Table 1 sets out the respective roles for HSE, the environment agencies and Nirex which will apply to the different stages of an ILW conditioning proposal. The regulators believe that it would be sensible and beneficial to use HSE's existing mechanism for regulatory hold points. An appropriate number of hold points would be agreed between the licensee and the regulators on a case-by-case basis depending on the complexity and magnitude of the proposal. These would be points at which clearly documented decisions on whether regulatory approval to proceed or not to the next stage had been made.

51. At all stages, HSE will have the formal regulatory responsibility, exercised principally through the nuclear site licence. However, HSE will take its regulatory decisions in consultation with the appropriate environment agency. Ideally, ways forward will be found that fully meet the requirements of both safety and environmental protection. Where this is not reasonably practicable, HSE will seek to agree with the appropriate agency the best balance between safety and environmental protection issues. In practice, the regulators envisage continuing dialogue between the licensee, HSE and the relevant environment agency under arrangements such as the agreed 'Working Together' arrangements (see Annex B). In this way most of the work should be done before the final hold points, such that there are no surprises when HSE/NII come to issue a Licence Instrument (Consent or Agreement to proceed).

52. The regulators' strong preference is for a waste package that meets the requirements for future long-term waste management without the need for re-working, such as further conditioning or re-packaging. The LoC process will therefore be an important part of the 'safety case' put forward. In some cases, the optioneering stage might show that it is not reasonably practicable to produce a package with a conceptual LoC, or that this will delay the treatment of the waste to an extent that immediate safety concerns become overriding. In such cases, the regulators could agree to proposals involving packaging without a LoC. However, it is likely that much of the assessment associated with the LoC will still be necessary to understand the potential problems with future disposal, justify the decision in the light of this and to put in place contingencies such as plans for further conditioning in the future to address such problems.

Table 1: Roles during the Development and Implementation of ILW Conditioning Proposals

Operators	Nirex	HSE	EA/SEPA
Site waste management plans		Review at intervals	Review at intervals
Options assessment Optioneering/BPEO	May be asked by operators for advice on which options likely to be acceptable or asked to provide conceptual LOCs for some options	Seek early dialogue on options	Seek early dialogue on options Critical evaluation of BPEO report and advice/LoCs from Nirex
Conceptual design	Conceptual LoC may be sought if not already obtained	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. Consider the safety case as developed, taking into account the appropriate agency's comments. Decide whether to give permission to commence construction.	Critical evaluation of advice/LoCs from Nirex
Detailed design	May be asked for 'pre-commitment LoC'		Critical evaluation of advice/LoCs from Nirex
Plant construction			
Commissioning	Will be asked for final LoC	Consider the safety case as developed, taking into account the appropriate agency's comments. Decide whether to give permission to commence operation.	Critical evaluation of advice/LoCs from Nirex:
Operation	Advice on compliance requirements for disposability and assess implications of non-compliant packages.	Inspection of process to ensure that packages are within agreed design envelope. HSE will take enforcement action if necessary.	
Post-operation	Advice on storage conditions and 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.	

53. Table 1 sets out typical stages for a waste-conditioning project. Taking each of these stages in turn, the prime interests of the HSE[†] and the environment agencies are described below:

- ***Site waste management plans*** **-** The regulators will seek meetings with the nuclear operators 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 and the implications for their work planning. In the case of challenging and/or Category 1 wastes, the NDA will also be involved in these discussions to ensure that national strategy implications are addressed.

[†] NOTE: for the purposes of this document, only those regulatory interests of direct relevance to waste conditioning and storage are covered. HSE will have wider interests in respect of nuclear safety that will be covered under their regulation under the nuclear site licence conditions.

- ***Optioneering*** **-** The consideration of waste-management options, including 'best practicable environmental option' and 'best practicable means' studies, 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. This would allow the industry to develop the preferred option in confidence. The availability of a LoC does not in itself provide evidence that the necessary work on BPM and BPEO has been carried out and that the proposed option complies with the agencies' requirements of BPM and BPEO. The environment agencies' interests will concentrate on the disposability of the final wasteform and the type and quantity of secondary wastes, including discharges to the environment. HSE's interests will concentrate on safety aspects, in particular those of the safety of any conditioning processes and plants involved, the safety of any possible need for future re-working of the conditioned waste and the safety of the storage of the waste packages.

- ***Conceptual design/functional specification*** **-** This will frequently overlap, or sometimes precede the option assessment. The regulators' interest will be in the validity of the option in delivering a waste package capable of being stored safely for long periods while taking into account the need for the waste to be ultimately disposed of.

- ***Detailed design and construction*** **-** The regulators' interests are likely to be 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.

- ***Plant commissioning*** **-** The regulators' main interest will be that of confirmation that the plant is capable of functioning in a manner to produce waste packages within the final specification at the detailed design and construction stage.

- ***Operation*** **-** The regulators' interest will be in confirming that the plant is producing waste packages within the originally agreed design envelope.

- ***Post-operation*** **-** The regulators will be interested in the state of the packages and the store during storage on waste producers' sites.

Guidance

54. The extant guidance[7,8] referred to at paragraphs 5 and 43 already details the HSE's and the EA's requirements with regard to nuclear safety cases and the conditioning of ILW respectively. The regulators are now working on new joint guidance to support the improved regulatory approach. This new guidance will build on the HSE's and EA's extant guidance on nuclear safety cases and the conditioning of ILW respectively. It will take into account the suggestions on its form and content provided by stakeholders and learning being gained with the process and approach used for on-going work on proposals for managing wastes in the Sellafield Legacy Ponds and Silos.

Openness

55. The regulatory arrangements will provide for a systematic and documented approach to be followed by the regulators. It is intended that the process followed by the regulators will be open and transparent. Whilst there is no requirement to place documents onto public registers, information requested under the Environmental Information Regulations would be

provided in accordance with the regulators' existing arrangements including provisions for restricting access to confidential information. Additionally, relevant documents could be made available to Local Community Liaison Committees, and to future NDA Stakeholder Fora, and periodic reports to the Advisory Committees. Reports to the Nuclear Industry Liaison Group, highlighting specific issues, will be provided by the regulators. The views of the Office of Civil Nuclear security (OCNS) and others, as appropriate, will be sought.

REGULATORS' RESOURCE REQUIREMENTS, COSTS AND COST RECOVERY

Resource Requirements

56. HSE do not intend to increase staff numbers to deal with this work, hence they will not place any additional charge to industry.

57. The environment agencies will need to recruit new staff with the necessary expertise to carry out this work. A combination of in-house staff supported, where necessary, by consultants to provide specific expertise is planned. The EA has established a Nuclear Waste Assessment Team (NWAT) comprising of 6 full time technical staff to deal with these improved regulatory arrangements and existing commitments related to LLW disposals at Drigg. A Team Manager and four Nuclear Waste Assessors (one to lead on Nirex work, two to lead on ILW conditioning proposals and one to lead on additional Drigg work) have been recruited to join the existing Assessor working on the Drigg post closure safety case. SEPA plans to recruit up to four Nuclear Waste Assessors. These effort levels will be achieved by the end of 2004 and will be reviewed in later years if workloads require. The EA and SEPA will co-operate closely, particularly during 2004 so as to maximise the benefits arising from their similar work and put in place consistent requirements, procedures and standards.

Costs

58. The environment agencies' total charge on industry and Nirex will be about £0.35M in 2003/04. This will rise to a maximum of £1.85M in 2004/05 when the agencies' resources will be at full complement and a contingency for possible specialist consultant support of £0.5M is included. Consultants may be employed to advise on specific issues for which the agencies do not have the requisite expertise. If consultant support is required the waste producer will be kept informed of both the technical scope and cost, and the output will be made available to the relevant waste producer. The per annum charges arising from internal staff costs (i.e. not including the contingency for consultant support) on the nuclear industry and Nirex are broken down for SEPA and the EA in Table 2 covering the period 2003/04 to 2005/06.

Table 2: Environment Agencies' Estimated Charges on Industry and Nirex (2003/04 to 2005/06)

CHARGE PAYER	YEAR	EA £K	SEPA £K
Nuclear industry	2003/04	100	20
	2004/05	600	300
	2005/06	650	400
Nirex	2003/04	180	50
	2004/05	250	200
	2005/06	200	100

Notes

1 The above costs are for internal staff only.

2 The costs vary from year to year because:
- in the first year the agencies will focus on Nirex's underpinning concepts and procedures in relation to its PDC;
- not all staff will be in place at the beginning of the first year;
- all staff will be in place at the beginning of the second year; and
- the focus will shift in the second and third years to assessment of individual ILW conditioning proposals submitted by the nuclear industry.

3 Additional annual charges of up to £0.5M may arise from 2004/05 onwards from the use by the agencies of consultants to advise on specific issues for which they do not have the requisite expertise.

4 Charges on Industry will arise as a result of the work undertaken by the agencies described in more detail at the second and third bullet points of paragraph 36.

5 Charges on Nirex will arise as a result of the work undertaken by the agencies described in more detail at the first bullet point of paragraph 36.

Cost Recovery - Industry

59. The EA and SEPA will recover their costs of providing advice on proposals to condition ILW from the HSE in accordance with Financial MoUs between HSE and the relevant environment agency. In turn the HSE will recover these costs from site licensees under established procedures.

60. The Financial MoUs between the HSE and EA, and HSE and SEPA will reflect the position whereby:
- the environment agencies will be providing advice to HSE on the longer term environmental protection aspects of ILW conditioning proposals and in particular the disposability of conditioned wastes so that HSE can make judgements on the safety case for the proposed facility or changed process; and
- the HSE have the final regulatory authority under NIA '65 and exercise it through the nuclear site licence conditions.

61. Charges will be based on actual work done by each of the regulators on individual proposals. In-house costs will be computed on the basis of time spent, as recorded by the regulator's staff on time sheets, and charged at the individual regulator's current daily unit charge[†]. External support costs will be the actual contract costs, without any additions. Consequently, individual site licensees will only incur charges for work done on proposals they have submitted and the figures provided at paragraph 58 should be seen as maxima for the industry. The bases of the charges will be transparent through the invoices issued by HSE and the environment agencies' established time recording systems and daily unit charges.

Cost Recovery - Nirex

62. The costs incurred by each of the regulators when scrutinising the work of Nirex will be recovered from Nirex in accordance with Agreements referred to in paragraph 38. The Agreement between Nirex and HSE has been in existence for several years. The Nirex / EA Agreement came into effect on 1 June 2003 after consultation with Nirex's shareholders.

[†] Note: The EA's daily unit charge will be the equivalent of the unit charge notified annually to nuclear site operators in England and Wales under its Charging Scheme for Radioactive Substances Act regulation. Similarly, SEPA's daily unit charge will be the equivalent of the unit charge notified annually to nuclear site operators in Scotland under The Radioactive Substances act 1993 Fees and Charges (Scotland) Scheme.

The SEPA / Nirex Agreement came into effect as of 1 September 2003. Similar to the charges on industry, charges will only arise for work done and the figures provided at paragraph 58 should be seen as maxima for Nirex.

63. As per the arrangements with industry, the bases of the charges on Nirex will be transparent through the invoices issued by each of the regulators and their established time recording systems and daily unit charges.

Regulatory Impact Assessment

64. Annex E presents a Regulatory Impact Assessment (RIA) covering the environment agencies' improved arrangements. It has been prepared in accordance with guidance issued by the Cabinet Office's Regulatory Impact Unit. The estimated costs and benefits of the proposed regulatory improvements, described in the preceding paragraphs, are presented in the context of the overall strategy for action proposed by Government in its document: "Managing the Nuclear Legacy". And the costs provided by the nuclear industry under the first stage of this review for the preparation of submissions for ILW conditioning to Nirex for a LoC and for carrying out the conditioning.

REFERENCES

(1) 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) and Scottish Executive (SE), September 2001.

(2) Managing the Nuclear Legacy. A strategy for action. DTI (UK), July 2002.

(3) Managing Radioactive Waste Safely. First Progress Report to the House of Commons Environment, Food and Rural Affairs Committee. December 2002.

(4) Compatibility of the Nirex Waste Package Specifications with Long-term Waste Management Options, UK Nirex Ltd. Nirex Report N/057.

(5) Command 2919. Review of Radioactive Waste Management Policy. Final Conclusions. London. HMSO. July 1995.

(6) Current Arrangements and Requirements for the Conditioning, Packaging and Storage of Intermediate Level Radioactive Waste. RWMAC/NuSAC, June 2002.

(7) Technical Assessment Guide. T/AST/051 Guidance on the Purpose, Scope and Content of Nuclear safety Cases. www.hse.gov.uk/nsd/tast051.htm.

(8) Environment Agency Guidance on the Conditioning of Intermediate Level Waste. www.environment-agency.gov.uk/commondata/105385/intermediate.pdf.

ANNEX A: HSE/EA/SEPA PROPOSALS FOR IMPROVED REGULATION OF ILW CONDITIONING

Our ref:
Your ref:

Date: 16 July 2002

Dinah Nichols
Director General, Environmental Protection
Defra
Ashdown House
123 Victoria Street
London
SW1E 6DE

Dear Dinah

IMPROVED REGULATION OF THE TREATMENT AND CONDITIONING OF INTERMEDIATE LEVEL RADIOACTIVE WASTE ON NUCLEAR LICENSED SITES

The future regulation of radioactive waste management on nuclear licensed sites, and in particular whether the environment agencies should be granted new statutory powers, was one of the matters raised in the recent Government consultation paper, "Managing Radioactive Waste Safely".

The Health and Safety Executive (HSE), the Environment Agency (EA) and the Scottish Environment Protection Agency (SEPA) have jointly been considering how improvements to regulation could be made whilst preserving the best features of the current system.

In view of the impending Ministerial announcement on the outcome of consultation, we consider it would be wise to brief Ministers on our proposals, and we should be grateful if you would flag these to Ministers before the announcement is made.

The three regulatory organisations are concerned that, at present, the nuclear industry regulates itself with respect to the treatment and conditioning of intermediate level waste (ILW) through the Nirex 'Letter of Comfort' process. There would be benefit in bringing the consideration of waste conditioning into the HSE and Environment Agencies' regulatory processes. In doing this, HSE would look to ensure that any ILW conditioning undertaken is appropriate to interim safe storage of waste, whilst the EA and SEPA would assess proposals to ensure that resulting waste forms would be suitable for ultimate disposal. This system would increase confidence in the waste management arrangements in that industry proposals would be independently examined and assessed.

In practice this would mean that, in addition to providing a safety case to HSE for construction and operation of the plant, a nuclear operator would submit proposals for waste treatment and conditioning. The HSE, EA and SEPA would examine relevant parts of the proposals and their agreement would be needed before the proposals could go-ahead.

This proposal has the flexibility to accommodate any future role for Nirex, and recognises that it is important that Nirex's expertise is maintained. Operators could contract Nirex to produce the part of the safety case relating to disposal.

There are two options for introducing this change. In the first option HSE would use existing conditions in nuclear site licences to regulate the process and the requirement to gain EA/SEPA agreement would be included in the relevant Memorandum of Understanding (MoU) between regulators. In the second option EA/SEPA would require new

regulatory powers and would exercise these in parallel with HSE's regulatory regime. The options are considered below:

1 Regulation through the Nuclear Site Licence

In this option, licensees would provide a 'safety case' for waste packaging proposals to HSE under nuclear site licence provisions. HSE would consult with EA/SEPA under the terms of the relevant MoU, and if all regulators were content, HSE would give permission for the treatment and packaging of waste as had been justified in the safety case. This process could be staged to provide early regulatory hold points and hence early regulatory involvement.

This proposal might require HSE to amend existing site licences, to give legal effect to this proposal and licensees would need to amend their arrangements under the site licence to ensure all relevant waste packaging proposals are brought to HSE's attention.

This option could be operated flexibly, allowing regulators to target their efforts on the more significant cases. It would also represent the minimum regulatory change from the present situation and could be introduced relatively quickly.

2 EA or SEPA issue an 'Authorisation' for ILW conditioning

In this option the EA or SEPA would issue an authorisation for wastes to be packaged. The authorisation would provide a statutory hold point beyond which a waste producer could not proceed without the regulators' agreement. This would be a 'staged' process that would allow early regulatory involvement.

In order to make provision for such arrangement, legislation would be needed and this may take some time. This option could be a fallback, in the event of the preferred option not delivering the expected results.

We have also given consideration to the role currently played by Nirex in advising on waste conditioning and storage. We feel that Nirex's advisory role is so interlinked with the ownership of the repository concepts that the best way forward would be to leave Nirex's work where it is and to introduce a streamlined and effective regulatory framework above it.

We propose that we implement Option 1 above. This could be introduced relatively quickly, as no changes to legislation would be required; we suggest that 1 April 2003 would be an appropriate start date.

We would introduce these new arrangements using a proportionate 'risk-based' approach, which would focus regulatory effort on the more challenging proposals from industry. In taking such an approach we would ensure that the regulatory process would be efficient and the burden on industry relatively modest. HSE and the agencies would need to recruit small numbers of staff and would recharge additional assessment effort to the nuclear industry; there would be no additional call on GIA funding.

We are, of course, willing to supply any supplementary information required and discuss any aspects with you or your staff. Appropriate contacts would be Laurence Williams, HSE; Jim Gray, Environment Agency; and Julie Tooley in SEPA.

We are writing in the same terms to David Rogers at the Scottish Executive.

Yours sincerely,

Timothy Walker	**Barbara Young**	**Patricia Henton**
Director General, HSE	**Chief Executive, Environment Agency**	**SEPA**

ANNEX B: CURRENT REGULATORY ARRANGEMENTS

B1. The Health & Safety Executive (HSE) regulates radioactive waste management on sites licensed under the Nuclear Installations Act 1965. The HSE may attach to site licences such conditions as it thinks fit with respect to the storage, treatment and disposal of nuclear matter – including radioactive waste.

B2. The environment agencies are responsible for regulating, under the Radioactive Substances Act 1993, routine disposals of all forms of radioactive wastes (solids, liquids and gases). On sites that are subject to a licence under NIA'65, the agencies have no statutory powers over waste storage. However, HSE have a statutory requirement to consult the agencies on radioactive waste management issues before issuing, amending or varying nuclear site licenses, or attaching conditions to them relating to radioactive waste management.

B4. In addition to statutory consultation requirements, the HSE and the EA defined the following combined goal in The Statement of Intent [(1)] issued in August 2001:

"The goals of both HSE and the EA are, together, to deliver effective and efficient regulation of the nuclear industry to maintain and improve standards of protection of people and the environment from the potential hazards from ionising radiations, and to ensure that radioactive wastes are appropriately managed in both the short and long term, in accordance with legislation, UK Government policy, and international obligations."

B5. SEPA and the HSE also work together towards these goals.

B6. These goals underlie the regulators' responsibilities and working arrangements on matters of mutual interest set down and agreed under respective MoUs. The objectives of the MoUs are to facilitate effective and consistent regulation by ensuring that:

- Activities of the HSE and agencies in relation to licensed nuclear sites are consistent, co-ordinated and comprehensive.
- The possibility of conflicting requirements being placed on licensees, or others operating on nuclear sites is avoided.
- Synergies are exploited and the appropriate balance of precautions is attained.
- Duplication of activity is minimised.
- Public confidence in the regulatory system is maintained.

B7. In early 2003 EA and HSE jointly issued the document "Working Together"[(2)] following discussion with the nuclear industry and Government Departments on ways of improving the effectiveness of HSE's and EA's regulation on nuclear sites. This identified, and made commitments to, some areas for improvement, including making the regulatory processes more transparent, more tripartite working with licensees and more emphasis on early interactions.

REFERENCES

(1) The Working Relationship Between HSE and EA on Nuclear Safety and Environmental Regulatory issues – A Statement of Intent. 8 August 2001.

(2) Working Together on Nuclear Sites. EA and HSE. January 2003.

ANNEX C: INTERNATIONAL OBLIGATIONS

C1. The UK is a signatory (and hence contracting party) to the Joint Convention on the Safety of Spent Fuel and on the Safety of Radioactive Waste Management [(1)]. Article 11 of the Convention requires that "each contracting party 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". The Convention requires that appropriate steps are taken to do this including:

- take into account interdependencies among the different steps in 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.

C2. The International Atomic Energy Agency (IAEA) has issued guidance [(2)] on requirements and methods for ensuring low and intermediate level waste package acceptability. That document includes guidance on development of waste acceptance criteria and on compliance with waste acceptance criteria. It states that in the absence of a final disposal route then waste package specifications should be used to determine the quality of packages produced. The waste package specifications should anticipate as far as possible eventual waste acceptance criteria so as to minimise any future re-conditioning needs.

C3. The European Commission has made speculative proposals for a Directive [(3)] on radioactive waste. This proposal gives priority to geological burial of waste as the safest method of disposal known at present. As currently drafted the Directive would require national programmes for the disposal of radioactive wastes including, in particular, deep burial of highly radioactive wastes. Member States would have to decide on burial sites (whether national or shared by several Member States) for highly radioactive wastes by 2008 at the latest and to have the sites operational at the latest by 2018. For low-activity, short-life waste, disposal arrangements would have to be ready at the latest by 2013. The implications of the proposed Directive are that proposals for waste treatment, conditioning and packaging take account of longer-term disposal programmes.

REFERENCES

(1) Joint Convention on the Safety of Spent Fuel and the Safety of Radioactive Waste Management.

(2) Requirements and methods for low and intermediate level waste package acceptability. IAEA-TECDOC-864. IAEA, Vienna. February 1996.

(3) Draft proposal for a Council Directive (Euratom) on the management of spent nuclear fuel and radioactive waste. November 2002.

ANNEX D: PRELIMINARY CONSULTATION

D1 The regulators have also had informal discussions with several interested parties at key stages of their development work. These are set out in more detail below.

October '02 workshop

D2 A workshop involving representatives from industry, Nirex, government departments and advisory bodies was held in October 2002 to provide an early opportunity for external input to our deliberations. Overall, feedback was supportive of the proposed improvements. The following specific issues were raised:

- It is not yet clear what the fundamental difference is between the new arrangement and the existing procedures. Clearly, a great deal of overlap between the two is envisaged.
- There will be a need to map the existing process and the new arrangements – e.g. what is expected of a Safety Case.
- In principle, the new arrangement needs to demonstrate added value, clear objectives, avoidance of duplication of work and the laying out of clear (and simple) objectives.
- The procedures must have a clear scope (are raw waste, interim safe storage etc. covered?).
- There will need to be an approach of practical application, with feedback allowing modification of the process, where required, in the light of experience.
- Clear Guidance, issued jointly by EA/SEPA/NII, for Inspectors and for licensees will be required.
- The arrangements need to be demonstrably transparent, accountable and proportionate etc.

First informal technical review

D3. These issues were taken into account in a first draft of the Technical Review document, which was made available to industry and departmental contacts in February 2003 to obtain their initial views on the scope, content and layout. This was followed up in April and May with bilateral discussions to explore the received comments more fully.

D4. The more significant comments, following the bilateral discussions, are summarised below:

- What is the scope of the "new" regulations?
- Phased disposal should not be assumed to be the preferred option.
- Practical difficulties with providing a detailed waste inventory at the pre-commitment stage.
- Are the "international obligations" supportive of the need for improved regulatory arrangements?
- Need to link the regulatory arrangements to the outcome of MRWS and emerging government policy.
- What is meant by a "safety case"?
- Further clarification of the risk based proportionate approach.
- Clarification of stage / hold points.
- Need for joint guidance from the regulators.
- Clarification of costs.
- Quality and need for the RIA…varied comments from "not required", through "adequate" to "unsatisfactory".
- Current operator costs.
- Future dialogue.

Second informal technical review

D5. These comments were taken into account in a second draft of the Technical Review document. This was made available to industry and departmental contacts for further consultation in June / July 2003.

D6. The more significant comments arising from this second stage informal review are summarised below:

- Much improved version of the first stage document which clearly takes into account earlier comments.
- Need to avoid the improved arrangements slowing progress with dealing with challenging wastes.
- Joint guidance welcomed as a mechanism for helping to resolve some of the existing potentially conflicting requirements.
- A standard way of assessing risk/hazard will be required when developing the proposed filter mechanism using a risk-based approach.
- Environment agencies need to balance their build up of resources against developing workloads.
- Cost recovery by the environment agencies via HSE/NII is the only acceptable option.

- Charges need to be transparent and equitably allocated to waste producers on the basis of the actual work undertaken by the regulators, rather than pro-rata to total waste volumes.
- Illustrative classes for ILW welcomed but a "short half-live ILW" class may be over prescriptive. Better to define this class by the strategic intent for its disposal i.e. intended for disposal; as LLW after decay and/or processing.
- Concern over the amount of detail that will be required in ILW conditioning proposals. Sight of proposed joint guidance requested as part of the review.
- Need to recognise better the Government's review of UK policy on the long-term management of radioactive waste and the short term (2-3 years) uncertainty that will exist.

Final formal technical review

D7. These comments were taken into account in a final draft of the Technical Review document. This was made available to industry, Government advisory bodies (RWMAC and NuSAC) and Government departmental contacts for further consultation in August 2003.

D8. The more significant comments arising from the formal review of the final draft are summarised below:

- Much support for involvement in: production of joint regulatory guidance, and the mechanism for filtering and prioritisation.
- Concern that the role of the NDA, especially for challenging wastes, has not been fully represented.
- That the UK Government and Devolved Administrations should sign onto the regulators' position statement.
- General concern that the regulators may become too focussed on the Nirex Phased Disposal Concept at a time when CoRWM are evaluating options.
- Concern that the revised arrangements may result in delays in the regulatory process.
- Need to consider an appropriate involvement with other relevant regulators (e.g. OCNS and Transport Regulators).
- That provision may be needed for an "appeals procedure".
- Concern that there is no 'time limit' at hold points for regulators to respond.
- Further classes of ILW may be needed for illustrative purposes, and that LLW that cannot be disposed of at Drigg should also be considered.
- How restricted and confidential documents can be handled within the context of an open and transparent process.
- Continued concern that the approach does not represent value for money to the industry and tax payer; and perhaps that an annual report be produced detailing the implementation of the approach.

ANNEX E: REGULATORY IMPACT ASSESSMENT

Introduction

E1. This Annex presents a regulatory impact assessment (RIA) covering the environment agencies' arrangements for the improved regulation of the conditioning of ILW on nuclear licensed sites. It has been prepared in accordance with guidance issued by the Cabinet Office's Regulatory Impact Unit[1]. The estimated costs and benefits of the proposed regulatory improvements described in the main body of this document are presented in the context of the overall strategy for action proposed by Government in its document: "Managing the Nuclear Legacy"[2] and costs provided by the nuclear industry under the first phase of this review.

Risks

E2. The current regulatory arrangements do not provide for any systematic and consistent assessment of either ILW conditioning proposals nor the development by Nirex of its phased disposal concept. Consequently, these activities are not subject to regulatory scrutiny. The regulators' established routes for ensuring transparency in decision making and public confidence are not being involved. There are therefore risks of ILW conditioning proposals and the phased disposal concept not meeting the regulators' requirements. These risks would be most likely to materialise many years hence after considerable expenditure by the nuclear industry and with the potential for further costly remedial work. Such remedial work could involve the need for waste packages to be over-packed resulting in late expenditure and an increased repository volume. In more extreme cases (e.g. chemical incompatibility), it could involve the need to break open packages using physical or chemical means and repackaging. This would be technically challenging, very expensive and would increase the overall volumes of waste for disposal.

Options

E3. The regulatory authorities considered the following three options for improving the regulation of ILW conditioning and the development of the phased disposal concept:

- Option 0: Do nothing.
- Option 1: Improve current arrangements by non-legislative means.
- Option 2: Seek new regulatory powers for the environment agencies.

E4. ***Do nothing***: This option would involve staying with the present arrangements. The regulators would not incur expenditure. HSE would not have to allocate staff from current resources nor would the environment agencies need to recruit staff with the necessary expertise. ILW conditioning and the development by Nirex of the phased disposal concept, which are strategically important elements of the Government's strategy for nuclear clean up, would be left outside of the regulatory process. As a result there would be a risk that key waste-management decisions could be made by the nuclear industry, Nirex and the Nuclear Decommissioning Authority (NDA) that would be unacceptable to the regulators many years hence. These could involve costly remedial action or be incapable of remediation thereby leaving a waste that could not be safely disposed of.

E5. ***Improve current arrangements:*** This option would involve building on the current regulatory arrangements to provide for a more systematic, consistent and transparent assessment of both ILW conditioning proposals and the development by Nirex of the phased disposal concept. The improved arrangements would be flexible so as to accommodate any changes with respect to the role of Nirex, or arising from the review of waste-management options to be carried out by CoRWM, or arising from the Energy Bill. There would be no need for legislation therefore the arrangements could be put in place relatively quickly through administrative changes. The HSE would re-allocate staff from existing resources. The environment agencies would have to recruit a small number of staff with the necessary expertise with consequential increases in expenditure. The regulators would need to recover their costs from the nuclear industry and Nirex as appropriate. The improved regulation would provide greater regulatory certainty to the decisions being made by the nuclear industry and Nirex with consequentially reduced risks of costly remedial work.

E6. ***New regulatory powers for the environment agencies:*** This option would require new legislation to provide the environment agencies with regulatory powers over the management and accumulation of radioactive wastes on nuclear licensed sites. The agencies would then exercise their new powers in parallel with HSE's regulatory regime. The agencies new powers should be sufficiently flexible to accommodate any changes with respect to the role of Nirex, or arising from the review of waste-management options to be carried out by CoRWM. The new legislation would have to take into account the draft Energy Bill. New legislation could take some time with consequential delays in achieving improved regulation at a time when the level of work

on ILW proposals is accelerating. The costs for the agencies, and thereby the nuclear industry and Nirex under cost recovery provisions, would be similar to those for the option of improving the current arrangements. The benefits in terms of regulatory certainty for decision making by the nuclear industry and Nirex would also be similar. However, there would be a greater risk that the HSE and EA/SEPA would not work as closely with the possibility of coming to conflicting decisions.

Initial Consultation

E7. Options 1 and 2 of improving current arrangements and seeking new regulatory powers were put to Defra and the SE on 16 July 2002 (see Annex A). The SE promptly replied to say they were content with option 1 of the regulators' proposals i.e. improving current arrangements. Defra officials wished to have further information about any implications for the future role of Nirex. This was in the context of what might emerge from their consultation based on Managing Radioactive Waste Safely that could result in Nirex being given a more independent role in future. Through informal discussions the regulators elicited Nirex's strong support for their proposals, and this in turn resulted in Defra confirming their support for option. They expressed a wish to receive further details. DTI, including the Liabilities Management Unit, also responded positively, acknowledging the merits of the regulators' case. As expected, they also expressed a wish to have further details of the proposed arrangements as these emerge.

E8. Option 1 does not require legislation and therefore can be implemented quickly. In order to implement this proposal the regulatory authorities worked together during 2003 to identify the scope of work and their resource requirements, and to develop working procedures and arrangements for recovery of their costs.

E9. Informal discussions were held with several interested parties. An Industry Workshop was held in October 2002 to provide an early opportunity for the nuclear industry and other key external stakeholders to input to the regulators' deliberations. A first draft of a Technical Review document setting out the proposal in greater detail was made available in February 2003 to contacts in the nuclear industry and relevant Government departments, including MoD. Received comments were discussed in a series of bilateral meetings held in April and May. Comments from the first review were taken into account in a second draft of the Technical Review document. This was made available to industry and departmental contacts for further consideration in June/July 2003. Comments from the second informal review were then addressed in a final version of the Technical Review document. This was made available to contacts in industry, Government advisory bodies and Government departments for review over ten weeks commencing in August 2003.

E10. Overall feedback was supportive of the proposed improvements to the current regulatory arrangements. Valuable technical and procedural comments were received and these have been addressed in the body of this document. The regulators are now in a position to bring the improved arrangements into operation in 2004.

Benefits

E11. The benefits arising from this improved regulation are:

- Increased public confidence in waste-management arrangements arising from the independent examination and assessment of ILW conditioning proposals thereby ensuring :
  - that proper emphasis is given to both safety and long-term environmental considerations;
  - increased transparency in decision making by following a clear and transparent regulatory route map; and
  - an appropriate balance is determined between costs and benefits.
- Much greater business certainty for the nuclear industry, Nirex and the NDA at a time when they are committing significant resources to ILW conditioning. This will be available at all stages arising from early interaction with the regulators thereby avoiding wasted effort, potential delays and costs resulting from developing inappropriate waste-management approaches.
- Formalisation of the regulators' joint working arrangements will benefit the nuclear industry, Nirex and the NDA by minimising any possibility of conflicting requirements.
- Earlier dialogue between operators, Nirex, the NDA, regulators and other key stakeholders will ease the regulatory path to consents under NIA'65 for building ILW conditioning plants and to authorisations under RSA'93 for disposal of waste packages.
- Clear documentation of the basis for current regulatory decisions that could inform future implementation of a waste disposal strategy.
- Opportunities for the regulators to make comments on the development of the PDC.
- Opportunities for the regulators to understand and scrutinise modifications to the PDC arising from the assessment of ILW conditioning proposals.

- Arrangements for the regulators to maintain and develop their assessment expertise, and to prepare properly for the future receipt of applications for the construction and operation of any repository under the NIA and RSA'93.

Resource requirements, costs and cost recovery

E12. The following three types of costs will be incurred:

- The regulators' costs associated with the assessment of proposals for ILW conditioning. These will be recovered from the site licensee making the proposal on a case-by-case basis.
- The regulators' costs associated with the assessment of the phased disposal concept being developed by Nirex. These costs will be recovered from Nirex.
- Charge payers own implementation costs i.e. the costs that the nuclear industry will incur in addressing the requirements of the regulators, whilst recognising that the arrangements are built on current regulatory requirements.
- Charge payers possible (policy) costs associated with the outcome of the regulatory process e.g. the production of the final regulatory approved waste package design.

Regulators' Costs

E13. HSE do not intend to increase staff numbers to deal with this work, hence they will not place any additional charge to industry.

E14. The agencies will need to recruit new staff with the necessary expertise to carry out this work. A combination of in-house staff supported, where necessary, by consultants to provide specific expertise is planned. The EA has established a Nuclear Waste Assessment Team (NWAT) comprising of 6 full time technical staff to deal with these improved regulatory arrangements and existing commitments related to LLW disposals at Drigg. A Team Manager and four Nuclear Waste Assessors (one to lead on Nirex, two to lead on ILW conditioning proposals and one to lead on additional Drigg work) have been recruited to join the existing Assessor working on the Drigg post closure safety case. SEPA plans to recruit up to four Nuclear Waste Assessor. These effort levels will achieved by the end of 2003/04 and will be reviewed in later years if workloads require. The EA and SEPA will co-operate closely, particularly during 2003/04 so as to maximise the benefits arising from similar work and put in place consistent requirements, procedures and standards.

E15. The regulators' total maximum charge on industry and Nirex will be about £0.35M in 2003/04. This will rise to about £1.85M in 2004/05, when the agencies' resources will be at full complement. It also includes a contingency of £0.5M for possible specialist consultant support. The per annum charges arising from internal staff costs (i.e. excluding any charges for consultant support) on the nuclear industry and Nirex are broken down in Table E1 by regulator for the period 2003/04 to 2005/06.

Table E1: Environment Agencies' Estimated Charges on Industry and Nirex (2003/04 to 2005/06)

CHARGE PAYER	YEAR	EA £K	SEPA £K
Nuclear industry	2003/04	100	20
	2004/05	600	300
	2005/06	650	400
Nirex	2003/04	180	50
	2004/05	250	200
	2005/06	200	100

Notes

1 The above costs are for internal staff only.

2 The costs vary from year to year because:
- in the first year the agencies will focus on Nirex's underpinning concepts and procedures in relation to its PDC;
- not all staff will be in place at the beginning of the first year;
- all staff will be in place at the beginning of the second year; and
- the focus will shift in the second and third years to assessment of individual ILW conditioning proposals submitted by the nuclear industry.

3 Additional annual charges of up to £0.5M may arise from 2004/05 onwards from the use by the agencies of consultants to advise on specific issues for which they do not have the requisite expertise.

4 Charges on Industry will arise as a result of the work undertaken by the agencies described in more detail at the second and third bullet points of paragraph 36.

5 Charges on Nirex will arise as a result of the work undertaken by the agencies described in more detail at the first bullet point of paragraph 36.

Cost Recovery

E16. The EA and SEPA will recover their costs of providing advice on proposals to condition ILW from the HSE in accordance with Financial MoUs that are being drafted. In turn the HSE will recover these costs from site licensees under established procedures.

E17. The Financial MoUs between the HSE and EA, and SEPA will reflect the position whereby:
- the environment agencies will be providing advice to HSE on the longer term environmental protection aspects of ILW conditioning proposals and in particular the disposability of conditioned wastes so that the HSE can make judgements on the safety case for the proposed facility or changed process; and
- the HSE have the final regulatory authority under NIA '65 and exercise it through the nuclear site licence.

E18. Charges will be based on actual work done by each of the regulators on individual proposals. In-house costs will be computed on the basis of time spent, as recorded by the regulator's staff on time sheets, and charged at the individual regulator's current daily unit charge[†]. External support costs will be the actual contract costs, without any additions. Consequently, individual site licensees will only incur charges for work done on proposals they have submitted and the figures provided at paragraph E15 should be seen as maxima for the industry.

E19. The bases of the charges will be transparent through the invoices issued by HSE and the environment agencies' established time recording systems and daily unit charges.

Cost recovery – Nirex

E20. The costs incurred by each of the regulators when scrutinising the work of Nirex will be recovered from Nirex in accordance with Agreements. The Agreement between Nirex and HSE has been in existence for several years. The Nirex / EA Agreement came into effect on 1 June 2003 after consultation with Nirex's shareholders. SEPA and Nirex are currently negotiating a similar Agreement. Similarly, charges will only arise for work done and the figures provided at paragraph E15 should be seen as maxima for Nirex.

E21. Again the bases of the charges will be transparent through the invoices issued by each of the regulators and their established time recording systems and daily unit charges.

Nuclear Industry Costs

E22. The global costs of cleaning up the nuclear legacy were estimated in "Managing the Nuclear Legacy"[(2)] at £48 billion in total with expenditure of £1 billion per year over the next ten years. The Sellafield site, Magnox Stations and Dounreay site account for 65%, 25% and almost 10% respectively of this cost. Current

[†] Note: The EA's daily unit charge will be the equivalent of the unit charge notified annually to nuclear site operators in England and Wales under its Charging Scheme for Radioactive Substances Act regulation. Similarly, SEPA's daily unit charge will be the equivalent of the unit charge notified annually to nuclear site operators in Scotland under The Radioactive Substances Act 1993 Fees and Charges (Scotland) Scheme.

expenditures (2002/03) by BNFL and UKAEA on legacy management are £1.08 billion and £ 276 million respectively. These cost estimates cover a broad span of activities of which ILW conditioning is one.

E23. Specific waste stream conditioning costs are not routinely compiled by the nuclear industry. However, crude estimates provided by the industry are in the range of £50-200k and £250-500k for conceptual and final submissions respectively to Nirex. Added to these are the nuclear industry's current funding of Nirex of about £11M per year. This represents the total running costs of Nirex. The cost charged directly to waste producers by Nirex for individual packaging assessments is typically in the order of £30k per assessment.

E24. The nuclear industry may incur some additional costs (beyond meeting the regulators' charges) in addressing the requirements under the improved regulatory process. However, these costs are already being incurred to a certain extent under current ad-hoc arrangements. The improved regulatory arrangements have the potential to reduce these costs through establishing a more systematic approach with greater clarity of requirements.

E25. The possible costs that industry might incur as a result of the outcome of the regulatory process (i.e. in terms of what they may need to do to condition ILW as a result of the regulators' assessments) are difficult to identify.

E26. The costs of processing the ILW/LLW class of wastes via the Nirex LoC route and leading to some form of early treatment, conditioning and packaging has been estimated by MoD at between £500k and £10-20M, depending on the waste stream. However, as the regulators make clear at paragraph 30 in the main part of the document, provided a review demonstrates that current priorities with regard to these wastes can be satisfactorily justified the regulators will not require any significant changes.

E27. For proposals achieving a LoC under the current arrangements costs have the potential to increase or decrease depending on the regulatory outcomes. Whatever, any increases can be confidently assumed to be small compared to the costs of any remedial action that might be required later to meet regulatory requirements for disposal.

E28. For challenging wastes the involvement of the regulators at the earliest stages of developing conditioning proposals has the potential to achieve more rapid progress at lower costs and minimal risk of later remedial work.

Cost balance

E29. Overall the costs, both direct and indirect, of the proposed improvements to the regulatory arrangements are considered to be:

- small compared to current costs for developing and implementing ILW conditioning proposals; and
- tiny compared to the overall estimated costs of £1 billion per year for cleaning up the nuclear legacy.

Securing compliance

E30. Compliance with the improved regulation will be secured through the HSE's existing arrangements, principally through the nuclear site licence under the Nuclear Installations Act 1965. These already provide adequate sanctions. The relationships with Nirex will be governed by Agreements.

Impact on small businesses

E31. The proposed improved regulation will only impact on the nuclear industry. There will be no impact on small businesses (e.g. non-nuclear uses of radioactive substances). A small business is defined in the European Union as a firm with:

- Less than 50 employees.
- Less than 7 million euros annual turnover.
- Less than 5 million euros annual balance sheet total. No more than 25% of the business owned by another enterprise (which is not a small business).

Competition assessment

E32. The impact of the improved regulation on the competitiveness of the nuclear industry and Nirex, and thereby the working of the NDA, has been assessed using the following competition filter test published by the Office of Fair Trading (OFT)[3].

Question	Answer: Yes or No
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	Yes
Q2: In the market(s) affected by the new regulation, does any firm have more than 20%?	Yes
Q3: In the market(s) affected by the new regulation, does any firm have more than 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential firms that existing firms do not have to meet ?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential firms that existing firms do not have to meet ?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9; Would the regulation restrict the ability of firms to choose the price, quality, range or location of their products ?	No

E33. The OFT advises that "yes" answers indicate a possible competition concern. However, where more than half the answers are "no" the OFT advice is that the regulation is unlikely to have a significant detrimental effect on competition.

E34. The nuclear industry has a small membership. Competition within this small group is unlikely to be affected by the improved regulatory arrangements, nor are they likely to affect new firms. Instead, they should assist the entry of new firms, and the role of the NDA, by making the regulatory process more transparent.

Further consultation

E35. The regulators will continue to work with the nuclear industry on the details to introduce the proposed improved regulation.

Monitoring and evaluation

E36. The regulators will liaise with the LMU and the industry to establish arrangements by 2004 for keeping the improved regulatory requirements under review and for ensuring their effectiveness. (This might be addressed through the NILG). In particular, during the implementation of the new arrangements the regulators will keep their approaches and requirements under review so as to ensure that a proportionate risk-based approach is employed. This will be intended to focus regulatory effort on the more challenging proposals from industry, thereby, ensuring that the regulatory process is efficient and the burden on industry relatively modest

Recommendations

E37. This regulatory impact assessment details the regulators' evaluation of the impact of improving the regulation of ILW conditioning through a combination of assessment of specific proposals brought forward by nuclear

sites and of the phased disposal concept being developed by Nirex. The benefits of this improvement would be to provide for independent scrutiny of an important element of the Government's strategy for nuclear clean up and minimise regulatory uncertainty in the long-term management of nuclear wastes. The overall costs are small, with possible savings, compared with current costs for developing and implementing ILW conditioning proposals, and tiny compared to £1billion per year for cleaning up the nuclear legacy. As a result of this assessment the regulators recommend that:

- The regulators' joint proposal for improving the regulation of ILW conditioning is approved by their sponsoring departments (i.e. Defra, SE and DTI) in consultation with other interested departments (e.g. MoD).
- The regulators keep these arrangements under review as the Government's strategy for managing the nuclear legacy unfolds.

REFERENCES

(1) Better Policy making and Regulatory Impact Assessment. Consultation Version. Cabinet Office.

(2) Managing the Nuclear Legacy. A strategy for action. DTI (UK) July 2002.