

Office for Nuclear Regulation
An agency of HSE

**Public consultation on the Office for Nuclear Regulation (ONR)
Interpretation of “bulk quantities” of radioactive matter
for the purposes of Section 1 of the Nuclear Installations Act 1965 (NIA)
and the Nuclear Installations Regulations 1971**

Dear Colleague,

I wish to consult you on the Office for Nuclear Regulation (ONR) proposed approach to the definition of “Bulk Quantities” of radioactive material for the purposes of Section 1 of the Nuclear Installations Act 1965 (NIA) and the Nuclear Installations Regulations 1971.

The nuclear site licensing regime currently applies to a set of defined activities, which includes the storage of bulk quantities of radioactive matter. However, there is no clear definition of what constitutes ‘bulk quantities’ of radioactive matter.

Government has started work on implementation of the 2004 protocol to the Paris Convention – this relates to the provision of third party liability provision for nuclear installations which is currently linked to nuclear licensing. This will address bringing disposal of radioactive material into the liability regime and will look at possibilities for exemption of small quantities of material from the applicability of the Paris Convention.

In the meantime, ONR has to enforce the law as it is currently in force and guidance has been sought by a number of interested parties on what constitutes “bulk quantities” for the purposes of section 1 of the NIA 1965.

Pending any amendment to section 1 of the 1965 Act, ONR will interpret “bulk quantities” with respect to storage as a quantity of radioactive material at or above one hundred times the levels set out in Schedule 2 of the Radiation (Emergency Preparedness and Public Information) Regulations (REPPIR) 2001. Where multiple isotopes are present, the formula provided in REPPIR Schedule 2 will apply.

The draft ONR Position Statement is at Annex A. The supplementary background document at Annex B provides the detailed reasons for taking, and further explanation of the practical implications we envisage as a result of, the proposed approach.

HSE has developed the approach following initial discussions with relevant stakeholders. This has helped us to prepare for the formal consultation, in particular in defining areas where clarity is needed. [Summary reports](#) of the workshops are available. Following those workshops, the ONR has considered stakeholder comments in preparing the attached Draft Interim Position Statement. However, we recognise that we may still need to clarify some issues and address some concerns. We will therefore be holding an additional information session during the consultation period on Monday 24 October at ONR Headquarters at Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS. You will need to register to attend this event by completing the [online form](#).

Public Consultation

The ONR now wishes to receive your considered opinions on the proposed approach. The Consultation Documents including a feedback form are posted in the [Consultations](#) area of the HSE Website but please do not feel constrained by this format if there are additional issues that you wish to raise.

Please send your responses by 12 December 2011 and any enquiries before that date to:

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ONR will consider and report on your views in finalising the proposed position statement and the supporting background information.

Yours sincerely,

Dr Mike Weightman
HM Chief Inspector of Nuclear Installations and Head of ONR

DRAFT INTERIM POSITION STATEMENT

Interpretation of “bulk quantities” of radioactive matter for the purposes of Section 1 of the Nuclear Installations Act 1965 (NIA) and the Nuclear Installations Regulations 1971

Purpose

This statement describes the Office for Nuclear Regulation (ONR) approach to the interpretation of “bulk quantities” in relation to the storage of radioactive matter for the purposes of Section 1 of the Nuclear Installations Act 1965 (NIA) and the Nuclear Installations Regulations 1971.

This statement provides clarity for ONR inspectors and prospective operators of nuclear installations who may be considering whether they need to apply for a nuclear site licence.

Interim Status

ONR is aware that the Government is involved in work which may result in further amendments to the NIA 1965 and in particular, the requirement for certain storage facilities to be licensed under NIA 1965.

This position statement will apply until such time as relevant amendments are made to the NIA 1965 and the NIR 1971

Scope

A site may only be used to install or operate an installation designed or adapted for the storage of bulk quantities of radioactive matter (that is matter which has been produced or irradiated in the course of production of nuclear fuel) if a licence has been granted for that site under section 1 of the NIA 1965.

This statement sets out how ONR will determine whether an installation is designed or adapted to store bulk quantities of such matter for the purposes of licensing under the NIA 1965.

ONR Objective

In interpreting “bulk quantities” of radioactive matter, ONR aims to:

- Ensure a robust, targeted, proportionate, consistent, and transparent approach to regulating the management of radioactive matter;
- Focus on maintaining a licensing regime on those hazards that require it, without imposing inappropriate obligations on industry when there is adequate regulatory oversight in place;

- Secure public confidence; and
- Continue to protect people and society from hazards of the nuclear industry.

Interim interpretation of “bulk quantities”

For these purposes, ONR will interpret “storage of bulk quantities of radioactive matter” as storage of quantities of radioactive matter at or above 100 times the levels set out in Schedule 2 to REPPiR 2001. Where multiple isotopes are present, ONR will follow the formula in Schedule 2 to REPPiR.

ONR will disregard:

- (a) any quantity of irradiated fuel – installations designed or adapted for storage of such material require a site licence by virtue of section 1(1)(b) NIA 1965 and regulation 6(1)(b) of NIR 1971;
- (b) in accordance with NIR regulation 6(1), any radioactive matter which is stored incidental to carriage; and
- (c) sealed sources as defined in the Ionising Radiations Regulations 1999.

Proposals to clarify the licensing requirements for the storage of radioactive matter in Great Britain.

Technical Background Document

1 Introduction

This document provides background information relevant to public consultation on proposals to clarify some aspects of the licensing requirements for the storage of radioactive matter in Great Britain, in particular, in relation to the threshold values of bulk quantities at which licensing will apply.

Section 2 outlines the current legislative and regulatory position and Section 3 describes the need for clarification. Section 4 outlines the principles underpinning the Office for Nuclear Regulation (ONR)'s approach to regulation while Section 5 describes the approach identified for consideration. Section 6 summarises the proposed position.

Annex A describes the methodological basis of the ONR's approach including some worked examples for the purpose of clarification.

2 The Current Position

This section outlines the current legislative and regulatory position for licensing of the storage of radioactive matter in Great Britain. The following sub-sections:

- Summarise relevant aspects of existing arrangements for licensing nuclear sites and the related nuclear liability regime; and
- Identify links between the nuclear site licence and safety.

2.1 Licensing of Nuclear Sites

The main legislation covering the safety of workers and the general public at nuclear installations in Great Britain, is the Health and Safety at Work Act 1974 (HSW74) and associated statutory provisions, which include the Nuclear Installations Act 1965 (NIA65) (as amended). NIA65 provides a system of regulatory control in which a licence is granted to a corporate body to use a site for specified activities.

The scope of the NIA65 licensing regime encompasses various types of activity. Specifically, NIA65, together with the Nuclear Installations Regulations 1971 (NIR71), requires that a Nuclear Site Licence is in force before a site may be used for the purpose of installing or operating any nuclear reactor (excluding a reactor used in a means of transport) or any other installation which may be 'prescribed'. In addition to nuclear power stations, installations currently prescribed in the NIR71 are those used for:

- Manufacturing fuel elements from enriched uranium or plutonium.
- Producing alloys or chemical compounds from enriched uranium or plutonium.
- Processing irradiated nuclear fuel except where this is just for assay or similar purposes.
- Storage of:
 - Fuel elements containing enriched uranium or plutonium.
 - Irradiated nuclear fuel.
 - Bulk quantities of radioactive matter which has been produced or irradiated in the course of the production or use of nuclear fuel.
- Extraction of plutonium or uranium from irradiated materials, or for enriching uranium.
- Production of isotopes from irradiated material for industrial, chemical and other purposes.
- Manufacturing rigs incorporating enriched uranium or plutonium for subsequent irradiation in a reactor.
- Installing a sub-critical nuclear assembly in which a neutron chain reaction can be maintained.

Subsequent sections of this document discuss the interpretation of storage of bulk quantities of radioactive material, which is not defined in NIA65 or NIR71.

2.2 Nuclear Liabilities

NIA65 implements the provisions of the 1960 Paris Convention on Nuclear Third Party Liability in the Field of Nuclear Energy and the 1963 Brussels Convention Supplementary to the Paris Convention (Figure 2). NIA65 places an absolute liability upon licensees as regards injury to persons or damage to property arising from a nuclear occurrence without proof of fault on the licensee's part.

A licensee must ensure that sufficient funds are available, by insurance or other approved means, to meet third-party claims within the limits prescribed in NIA65. Two liability limits are established in NIA65; a higher limit and a lower limit for certain prescribed sites.

The Nuclear Installations (Prescribed Sites) Regulations 1983 prescribe the sites to which the lower limit of liability applies. Essentially, the sites prescribed are the sites of small installations. They are prescribed by reference to the type and designed thermal output of any nuclear reactor with its associated fuel, and by reference to the activity of other radionuclides which may also be present. The regulations provide for cases where nuclear material of different levels of activity is present, as well as for overall limits for mass of fissile material.

NIA65 was amended by the Energy Act 1983 in order to, amongst other things, take account of two Protocols that amend the Conventions and increase the amounts of the liability limits to £20 million and £140 million for the two types of sites. In the first quarter of 2011, Government has consulted further on new proposals to update NIA65 to incorporate changes agreed in 2004 to the Paris and Brussels Conventions. The main changes proposed are in three areas:

- increase in the categories of damage for which operators are liable including damage related to the environment;
- widening the geographical scope of those that are eligible to claim compensation; and
- a significant increase in the financial liability of the operator from currently £140 million to €1,200 million

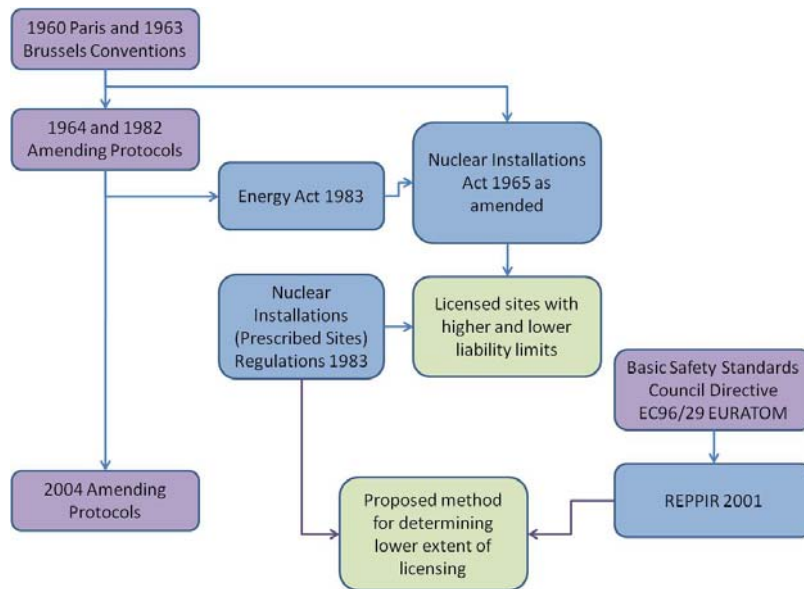


Figure 2 Relationships between relevant international conventions and directives (purple) and UK legislation (blue).

2.3 Nuclear Safety

The licensing of nuclear sites is the responsibility of the Health and Safety Executive (HSE) who delegate this to the Office for Nuclear Regulation (ONR). ONR’s primary goal is to ensure that those it regulates have no major nuclear accidents.

NIA65 allows HSE to attach conditions to nuclear site licences as necessary or desirable in the interests of safety, or with respect to the handling, treatment or disposal of nuclear matter. ONR perform this function on behalf of HSE

The licence conditions are non-prescriptive and set goals that the licensee is responsible for meeting, amongst other things by applying detailed safety standards and safe procedures for the facility.

ONR’s inspectors establish whether a licensee has demonstrated that it understands the hazards associated with its activities and how to control them adequately. This is based on, amongst other things, the licensee’s safety case.

The safety case is the totality of documented information and arguments developed by the licensee that substantiate the safety of the facility, activity, operation or modification in question. The safety case provides a written demonstration that relevant standards have been met and that risks have been reduced to a level that is as low as reasonably practicable. The safety case is not a one-off set of documents prepared to obtain a Nuclear Site Licence, but is an holistic, living framework that underpins all safety related decisions made by the licensee.

The link between the nuclear license and nuclear

licensing restrictions or other regulatory burdens on facility operators where they are not needed.

3. Risk-Based Regulation – The ONR ensures safety by pushing for progressive reduction of hazards. In doing so, ONR will focus on the ‘high hazard’ facilities and activities.
4. Better Regulation – The ONR does not want interpret legislation such that it would either duplicate or be inconsistent with related regulatory regimes.

5 Options for Consideration

By considering the wording and intentions of NIA65, and taking note of the contents of the Paris Convention, ONR identified three options for determining whether the storage of particular quantities of radioactive matter would constitute “bulk quantities” under NIA65.

These options are described in sub-section 5.2 below for the purpose of explaining ONR’s decision process. For the reasons set out in sub-section 5.3, ONR has developed a favoured option, but we are still open to comments on the other options before we finalise our position.

5.1 Exclusions

Common to all of the options described below are the following exclusions that already exist in the wording of NIR71:

- Matter which have not been produced or irradiated in the course of the production of nuclear fuel (e.g., naturally-occurring radioactive material).
- Matter in storage incidental to carriage.

In its definition of “radioactive products or waste” the Paris Convention excludes “radioisotopes outside a nuclear installation which have reached the final stage of fabrication so as to be usable for any industrial, commercial, agricultural, medical, scientific or educational purpose”. This exclusion is not explicitly included in NIA65 or associated legislation.

The definition of sealed source in the Ionising Radiations Regulations 1999 (IRR99) is “...a source containing any radioactive substance whose structure is such as to prevent, under normal conditions of use, any dispersion of radioactive substances into the environment, but it does not include any radioactive substance inside a nuclear reactor or any nuclear fuel element”. Hence, risks from sealed sources are much lower than for unsealed sources.

Regulation 27 of IRR99 requires the employer to ensure that the design, construction and maintenance of any article containing or embodying a radioactive substance, including its bonding, immediate container or other mechanical protection, is such as to prevent the leakage of any radioactive substance ... in the case of a sealed source, so far as is practicable (not just reasonably practicable) and to ensure that suitable tests are carried out at suitable intervals to detect leakage of radioactive substances from any sealed source.

The High Activity Sealed Radioactive Sources and Orphan Sources Regulations 2005 contain provisions aimed at preventing exposure to radiation resulting from the inadequate control of high-activity sealed radioactive sources. They establish a more detailed and rigorous regime of regulatory control and site security than is currently provided for under existing legislation, for those sources that represent the greatest risk.

Given these existing regulatory provisions for sealed sources, extending the licensing regime to sealed sources by including them in interpreting “bulk quantities” would do little, if anything, to reduce, or better control, risks.

Therefore, pending Government decisions on implementation of the Paris Convention, ONR intend to disregard *sealed sources*⁴ (which clearly meet the Paris Convention exclusion) in considering the quantity of matter to be judged as “bulk quantities”.

5.2 Defining ‘Bulk Quantities’

Before setting out the proposed approach to determining where licensing under NIA65 should apply, it is appropriate to consider the possibilities for defining bulk quantities:

- *Volume*: One approach would be to define bulk quantities in terms of the volume of material. A common sense view might be that, for example, anything less than a 200 litre drum would be considered to be less than a bulk quantity, while anything of the size of a half-height ISO container (such containers are used for the accumulation and transport of Low Level Radioactive Waste (LLW) and for its disposal at the Low level Waste Repository (LLWR) in Cumbria) or more, would be considered to be a bulk quantity. A problem with considering volume alone, however, is that some radioactive wastes possess very little radioactivity and even very large volumes of such wastes may present little risk. Conversely, very small volumes of high activity material may represent substantial risks that would clearly warrant licensing. Hence ONR does not intend to follow this option.
- *Risk / potential dose*: An alternative approach would be to use the risk (or potential dose) associated with the radioactive content of the material as the basis for defining what constitutes a bulk quantity. However, a problem with using risk or potential dose is that they are not directly measurable quantities in the same sense as, for example, volume or radioactivity, and thus enforcement would be very difficult. Uncertainties over the conduct of the risk and dose assessments, and over any determinations of the need for licensing made on the basis of such quantities, mean that ONR does not intend to follow this approach.

⁴ *Sealed sources*. A *source* is an apparatus, a radioactive substance or an installation capable of emitting ionizing radiation or radioactive substances (Council Directive 96/29/EURATOM). A *sealed source* means a source containing any radioactive substance whose structure is such as to prevent, under normal conditions of use, any dispersion of radioactive substances into the environment, but it does not include any radioactive substance inside a nuclear reactor or any nuclear fuel element (The Ionising Radiations Regulations 1999, IRR99).

- *Radioactivity*: The proposed approach is to use the radioactivity of the material (e.g., in Bq) for defining what constitutes a bulk quantity. Within this approach, there could be consideration of the total radioactivity of the materials, or of the radioactivity of individual radionuclides, or of the radioactivity of groups of radionuclides. This is easily enforceable and if quantities are defined by radioisotope, a correlation with risk can be achieved. Hence a definition of bulk quantities in terms of radioactivity is ONR's preferred option.

5.3 ONR's Proposed Approach

ONR's proposed approach to defining bulk quantities of radioactive matter would treat all industrial sectors in the same way and would involve determining whether a particular storage facility requires licensing under NIA65 by comparing the amount of radioactivity (in Bq) that it is designed or adapted to contain with a pre-defined criterion value based on data in existing legislation.

ONR suggests that subject to the exclusions referred to above, only facilities with radioactive material in quantities exceeding *100 times the levels set out in Schedule 2 of the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR)* should be subject to the nuclear licensing regime. The basis on which this figure is proposed is set out in Annex A.

Trial studies made so far suggest that a criterion set at 100 times the levels set out in Schedule 2 of REPPIR, with the exclusions mentioned above applied, would not require any existing non-nuclear activities to be licensed. Only two current nuclear licensed sites are licensed on the basis of storage of radioactive material. Both equalled or exceeded the 100x REPPIR Schedule 2 figure when licensed.

This option would have the advantage of (relative) simplicity and consistency across all industrial sectors. It should be easy for an operator to understand whether the storage of its radioactive material would require licensing, and for ONR to make and support such determinations. However, the use of radioactivity as the criterion does not equate directly to the risk associated with the materials and, in particular, does not take into account the form of the radioactive material, which can be an important consideration when assessing risk. The largest disadvantage of using a simple activity figure has been addressed by excluding sealed sources from the consideration. Given the conclusion of trial studies that use of this criterion would not affect the "status quo" we believe that the benefits of using a simple activity figure outweigh the disadvantage of not being directly related to the actual risk in each particular circumstance.

6 Interim interpretation of “bulk quantities”

ONR will interpret “storage of bulk quantities of radioactive matter” as storage of quantities of radioactive matter at or above 100 times the levels set out in Schedule 2 to REPPIR 2001. Where multiple isotopes are present, ONR will follow the formula in Schedule 2 to REPPIR.

ONR will disregard:

(a) any quantity of irradiated fuel – installations designed or adapted for storage of such material require a site licence by virtue of section 1(1)(b) NIA 1965 and regulation 6(1)(b) of NIR 1971;

(b) in accordance with NIR regulation 6(1), any radioactive matter which is stored incidental to carriage; and

(c) sealed sources as defined in the Ionising Radiations Regulations 1999.

7 References

1960 Paris Convention on Nuclear Third Party Liability.

1963 Brussels Supplementary Convention on Nuclear Third Party Liability.

2004 Protocol to Amend the Brussels Supplementary Convention on Third Party Liability.

2004 Protocol to Amend the Paris Convention on Nuclear Third Party Liability.

Revised text of the Exposé des Motifs of the Paris Convention, approved by the OECD Council on 16th November 1982

Defra, BERR and the Devolved Administrations for Wales and Northern Ireland, 2008. Managing Radioactive Waste Safely: A Framework for Implementing Geological Disposal, Cm 7386.

Defra, DTI and the Devolved Administrations, 2007. Policy for the Long Term Management of Solid Low Level Radioactive Waste in the United Kingdom

Energy Act 1983.

Energy Act 2004.

European Commission, 1996. Laying down Basic Safety Standards for the Protection of the Health of Workers and the General Public against the Dangers Arising from Ionizing Radiation. Council Directive 96/29/EURATOM.

Health and Safety at Work etc Act 1974.

HSE (1992) The Tolerability of Risk from Nuclear Power Stations. Sudbury, UK: HSE Books.

HSE (2001) Reducing Risks, Protecting People (2nd ed.). Sudbury, UK: HSE Books.

HSE (2005) Criterion for De-licensing Nuclear Sites. Nuclear Industries Security Regulations 2003. Statutory Instrument 2003 No. 403,

Nuclear Installations (Increase of Operators' Limits of Liability) Order 1994. Statutory Instrument 1994 No. 909.

Nuclear Installations (Prescribed Sites) Regulations 1983. Statutory Instrument 1983, No. 919.

Nuclear Installations Regulations 1971, Statutory Instrument 1971 No. 381.

Radiation (Emergency Preparedness and Public Information) Regulations 2001. Statutory Instrument 2001 No. 2975.

Radioactive Substances Act 1993.

The Ionising Radiations Regulations 1999. Statutory Instrument 1999 No. 3232.

The Nuclear Installations Act 1965.

Annex A Derivation of a Numerical Criterion for Interpreting ‘Bulk Quantities’

Notes on the Nuclear Installations (Licensing and Insurance) Act, 1959’

The ‘Notes on the Nuclear Installations (Licensing and Insurance) Act, 1959’ gives the following explanation as to why the phrase ‘bulk quantities’ was introduced.

*“On second reading Mr Richard Fort suggested that the scope of section 1(1)(b) as originally drafted was unnecessarily wide (Commons, 9.2.59, col. 900). The paragraph was therefore amended in Committee (Standing Committee B, 21.4.59, cols. 9-18) with a view to excluding as far as possible the types of installation to which there was no question of extending the Act. Processes ancillary to the production of atomic energy but giving off no radioactivity, such as the manufacture of graphite blocks or beryllium cans, do not require the imposition of the kind of controls and obligations contemplated in the Act. **Nor does the treatment, storage of disposal of radioisotopes in small quantities or of the less radioactive types.** Such operations could have been covered by Regulations under the Bill as originally drafted, though there was no intention of exercising the power in their case.*

*(from a statement by Mr Maudlin (Standing Committee B, 21.4.59, cols 10-11) –The third category is installations for “the storage, processing or disposal of nuclear fuel or of bulk quantities of other radioactive matter...” The point is to cover only the assembly of such quantity of radioactive matter as can be of danger which ought to be dealt with by the licensing system. By bringing in the words “bulk quantities” we have met the point made in the house and in another place that the Bill could be applied to places where radionuclides are kept in very small quantities and therefore where no real danger was involved. The purpose of the Amendment should commend itself to the Committee. It ensures that the fusion process is covered but it ensures that the **Bill does not cover certain processes or activities not of themselves of a dangerous character and therefore not needing to be licensed.**”*

Exposé des Motifs’ of the Paris Convention

The ‘Exposé de motifs’⁵ of the Paris Convention lists several activities which are not meant to be included and cites the lack of risks of an exceptional nature as a reason for exclusion from the liability regime.

In conclusion, “bulk quantities” of radioactive matter should be of a dangerous character and represent risks of an exceptional nature to be included in a licensing regime.

Nuclear Installations (Prescribed Sites) Regulations 1983

Some indication of which sites should be included within the scope of the NIA65 licensing regime may be derived from The Nuclear Installations (Prescribed Sites) Regulations 1983. These prescribe the sites (through the quantity of radioactive material present) for which the lower limit of liability per incident under Section 16(1) of NIA65 applies (see paragraph 2.2 above).

⁵‘Exposé des Motifs’ of the Paris Convention, approved by the OECD Council on 16th November 1982

These quantities are:

Annex A Table 1			
Group definition	Typical isotopes	Sealed Sources	Other Forms
Radionuclides with A2 ⁶ values not exceeding 0.01 Ci	plutonium alpha emitters and americium.	200 Ci (~ 7 TBq)	20 Ci (~0.7 TBq)
Radionuclides with A2 values between 0.01 and 1 Ci	enriched uranium, Plutonium 241 and some radium and thorium isotopes	2000 Ci (~70 TBq)	200 Ci (~7 TBq)
Radionuclides with A2 values between 1 and 100 Ci	Most fission products	50,000 Ci (~1800 TBq)	5000 Ci (~180 TBq)
Radionuclides with A2 values greater than 100 Ci	Iron 55, Tritium, Iodine 129	500,000 Ci (~18000 TBq)	50,000 Ci (~1800 TBq)

The levels in the Nuclear Installations (Prescribed Sites) Regulations 1983 set the boundary for the lower level / upper level of liability provision. It is clear that there is an intention that sites with lower inventories should be licensed, albeit with a reduced requirement for liability provision – hence the NIR83 levels can be taken as an upper bound and the appropriate figure for “bulk quantities” must be substantially less than this to allow for some licensed sites to be in the lower liability range.

Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR)

REPPIR sets out requirements for assessment of risks and emergency preparedness where there may be off-site impact from radioactive material (i.e. a risk, though not necessarily exceptional, to the public at large). Schedule 2 of REPPIR gives amounts of radioisotopes above which REPPIR will apply.

Schedule 2 of REPPIR was derived on the basis of the whole inventory being released in an accident and resulting in a dose of 5mSv to the most exposed individual (defined as a radiation emergency). This is therefore a very conservative indicator of off-site risk.

Together with the comments in the “Notes on the Act” and the “expose de motifs” of the Paris Convention, this would indicate that licensing should only be considered in cases well above where REPPIR should ‘just apply’ i.e. the appropriate level for “bulk quantities” should be much greater than Schedule 2 of REPPIR.

Interpretation of “bulk quantities”

⁶ A2 values are the values in Curies specified for single radionuclides in paragraphs 403 to 405 of the Regulations for the Safe Transport of Radioactive Materials published by IAEA (1973 edition) and for mixtures of radionuclides in paragraphs 406 - 411 of those Regulations.

From the above we can derive that **Schedule 2 REPPIR < bulk quantities < NIR83**. To take this forward it is necessary to convert the NIR83 values into multiples of REPPIR Schedule 2. It should be noted that the objective here is to find a “representative” multiplier to convert between NIR83 and REPPIR. The NIR83 figures are not risk based, but based on transport limits. Once a representative multiplier has been established then by using multiples of REPPIR Schedule 2, levels for all isotopes will be equivalent in terms of potential off site risk and the differences in ratios referred to below will be irrelevant.

Taking the ‘other forms’ column in Table 1 as ‘N’ and REPPIR Schedule 2 levels as ‘R’, over half of isotopes (56%) have a **N/R ratio** in the range 100 – 1000, with a further 19% in the range 1000 – 10000 and 16% in the range 10 - 100. This could be construed to be consistent with an assumption that the threshold for licensing should be substantially higher than that for the application of REPPIR.

This still leaves 9% of isotopes outside this range. There is a group of 19 isotopes (5% of total) with a N/R ratio of less than 10. These include all the isotopes of noble gases Argon, Krypton and Xenon as well as Ge71, W178, Br77, Ru97, Rh103m and Re187. Other than the noble gases, none of these isotopes figure prominently in routine operations at sites – Re187 is a naturally occurring isotope and would generally, therefore, be excluded from consideration.

There is also a group of 11 isotopes (4% of total) with a N/R of >10000. These include the transuranics Cf250, Cm248, Pu236, Cf254 and Cm244, and the naturally occurring isotopes Th228, Ac227, Ra224, Th230 and Sm147. None of these are “common” isotopes to be found on nuclear installations.

Of more interest is the position in such a comparison of the key isotopes that regularly feature significantly in nuclear type safety cases (See Annex A Table 2).

Isotope	Ratio	Isotope	Ratio	Isotope	Ratio
H-3	29	Mn-54	670	U-235	3330
C-14	67	Ru-106	670	U-238	3330
Cl-36	100	S-35	1000	Co-60	3330
Ru-103	100	Cs-137	2000	Tc-99	4000
Fe-55	250	I-131	2220	Pu-239	5000
Zr-95	250	Sr-90	2500	Ag-110m	6670
Ce-144	670	Cs-134	2860		

Taking the figures for Cs137 and I131 – being the isotopes that generally result in the bulk of risk from nuclear accidents, the overall N/R figure would appear to be around 2000xREPPIR Schedule 2. We therefore have the formula **1R < bulk quantities < 2000R**.

To allow for sites in the lower liability limit, we are therefore looking for a figure exceptionally greater than REPPIR Schedule 2 and substantially below NIR83.

Defining “bulk quantities” as: “100 x REPPIR Schedule 2” fits this formula well.

Case Study Application of 100 x REPPIR Schedule 2

We can consider four scenarios that would be representative of typical facilities where storage of radioactive materials occurs: a Commercial Storage facility; a Sterilisation Irradiator facility; a University; and a Hospital. The purpose of these examples is to demonstrate how to apply the criterion and exemptions – they do not purport to show whether typical facilities will or will not need a licence.

For each scenario, typical inventories of radioactive material have been prepared and the 100 x REPPIR criterion has been applied (See Annex A Table 3 below).

Conclusion

The analysis suggests that a level of 100 x REPPIR Schedule 2 would be a logical, reasonable, coherent, and sustainable criterion as to whether an inventory should be considered as “bulk quantities of radioactive matter”.

Annex A Table 3			
Examples of calculations using the suggested bulk quantities value to decide where a nuclear site licence is required			
The examples below are fictitious and designed to illustrate as many situations as possible.			
Facility	Source	Activity (TBq)	Quotient
Store	Cm 244	1.00E-03	2.50E-03
	H3	2.00E+03	2.86E-01
	I 125	3.00E-02	3.00E-03
	I 131	3.00E+00	3.33E-01
	Ir 192	2.00E+01	1.67E-01
	Kr 85	1.00E-02	1.00E-07
	Np 237	1.00E-02	2.00E-01
	Ra 226	1.00E-04	Exempt 1
	TOTAL		1.16
Nuclear Site Licence required			
Sterilisation Irradiator	Co 60	1E+18	Exempt 2
Nuclear Site Licence not required			
University	Cr 51	5.01E-03	1.67E-06
	C14	8.34E-02	2.78E-04
	I 125	4.00E-03	4.00E-04
	P 32	6.00E-03	6.00E-04
	P 33	2.00E-03	6.67E-06
	S 35	6.00E-02	6.00E-04
	TOTAL		<0.01
Nuclear Site Licence not required			
Hospital	C 11	3.70E-01	Exempt 3
	F 18	4.00E-01	Exempt 3
	I 124	1.00E-02	Exempt 3
	N 13	4.00E-02	Exempt 3
	O 15	1.50E+11	Exempt 3
	Zn 62	7.40E-03	Exempt 3
	TOTAL		All Exempt
Nuclear Site Licence not required			

Quotient = Activity (Bq) / (REPIIR Sch 2*100)

Exempt 1 – these naturally occurring radioisotopes are exempted from consideration in not “being matter which has been produced or irradiated in the course of the production or use of nuclear fuel”

Exempt 2 – sealed sources.

Exempt 3 – these short lived isotopes are produced by accelerators. Hence they are exempted from consideration in not “being matter which has been produced or irradiated in the course of the production or use of nuclear fuel”

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Mick Bacon (HSE)
Fred Barker (NULEAF)
Roger May (AMEC)
Bob Major (AMEC)
Alistair King (GE Healthcare)
Nigel Lister (LLWR)
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Andrea Murray (RKCL Administrator)

Frans Boyden (HSE):

- Welcomed the participants to the meeting and thanked them for attending.
- Noted the HSE's responsibility for nuclear site licensing.
- Noted the need now for various reasons to define 'bulk quantities' more clearly than has been done to date, and to consider licensing of a geological disposal facility (GDF).
- Noted that the HSE had begun some earlier consultation work on this issue, but that this had stalled, partly because of organisational changes.
- Emphasised that the HSE is now very keen to progress the issue and wants to take full account of stakeholder's views.

- Stressed the importance of two-way communication and the hope that participants would take the opportunity to share their views with the HSE.

Professor Ray Kemp:

- Introduced the RKCL team and facilitated round table introductions for the benefit of all present.
- Outlined the agenda and stressed that the workshop was a pre-consultation meeting to share the HSE's early thinking and to identify key issues and concerns in advance of formal public and stakeholder consultation being undertaken.
- Noted that a brief summary report of the meeting would be made available for participants.

Mick Bacon (HSE) described the background to the issue and the scope of the current project in some more detail. Key points included:

- The Nuclear Installations Act 1965 (NIA65) requires that a Nuclear Site Licence is in force before a site may be used for the purpose of installing or operating any fixed nuclear reactor or any other installation that may be 'prescribed'.
- The installations currently prescribed are specified in the Nuclear Installations Regulations 1971 (NIR71). Amongst other things, the NIR71 prescribe the storage of 'bulk quantities' of materials.
- The range of organisations potentially storing bulk quantities of radioactive matter is increasing and there is now a need to define 'bulk quantities' more clearly.
- Disposal of radioactive matter is not currently prescribed, but Government Policy is that a geological disposal facility (GDF) should be a licensed facility. However, an issue with prescribing disposal is whether LLW disposal facilities would be brought into the licensing regime.
- Under this project, therefore, the HSE is considering the storage and disposal of 'bulk quantities' of radioactive wastes, and envisages amending the NIR71 to include 'disposal of bulk quantities' and issuing guidance on HSE's interpretation of 'bulk quantities'.
- Amending the regulations may take several months, and the process would involve formal consultation on draft regulations in 2010.
- It was noted that HSE's proposals will also need to be considered through the OECD Nuclear Energy Agency (NEA) led process on the Paris Convention to ensure that the proposals correctly implement the terms of the Convention.

Facilitated discussion around this presentation addressed the following points:

- It was suggested that there may be a need to amend NIA65 to deal with exemption of wastes, and that if NIA65 was to be amended, then that could also provide an opportunity to clarify or remove the term 'bulk quantities'. On the other hand, it was also suggested that amending NIA65 might be more onerous than prescribing disposal and issuing guidance on bulk quantities.

It was pointed out that there would be difficulty in obtaining the necessary Parliamentary time to amend primary legislation and this was a major constraint that had to be considered.

- There was discussion of the distinction between 'processing' (as used in NIA65) and storage, of whether there is a need to define processing more clearly, and of when radioactive matter that is being processed should be considered to be in storage. There was also some concern over whether facilities processing wastes for later transfer to the national Low Level Waste Repository (LLWR) would be affected by the proposed licensing regime.

It was explained that, in practice, storage overlaps processing, and that radioactive matter that is being processed is always considered to be in storage. Currently the HSE cannot see a need to prescribe processing and, for example, the Studsvik Metal Recycling facility at Lillyhall in Cumbria is licensed for storage, not processing.

- There was some concern over whether the current proposals might lead to unnecessary 'dual regulation' of disposed wastes under the Radioactive Substances Act 1993 (RSA93) and NIA65.

It was explained that there is close cooperation between the HSE and the environment agencies, and that the two regulatory regimes are complementary rather than overlapping. The HSE's interests lie in public and worker health and safety during facility operations and accident emergencies, while the environment agencies' interests are different and lie in environmental protection and protection of the public from releases to the environment (e.g., to groundwater).

- Several questions were raised concerning de-licensing of storage and disposal facilities. The HSE is planning to further work on de-licensing under a separate project. This work would need to consider if and how the HSE's existing guidance on 'no-danger' might be revised and applied to radioactive waste disposal facilities, the meaning/timing of repository closure, and the roles of institutional control. It was suggested that the HSE might consider more extensive revision of the primary legislation to address several issues, including de-licencing, exemption and bulk quantities, at the same time.

It was explained that currently, the HSE's approach is to try to resolve issues one at a time because this is more tractable than trying to solve all of the issues at once, but HSE is open to stakeholder's views, e.g., on whether the proposals should be cast in a more holistic way.

Mick Bacon (HSE) described possible ways of defining bulk quantities. Key points included:

- The term 'bulk quantities' was first used in ~1959 with the aim of excluding trivial risks.
- Legal interpretation, likely based on the Oxford English Dictionary, would be that 'bulk quantities' refers to a *volume*.
- However, defining bulk quantities in terms of volume alone would not reflect the hazard or risk posed by the materials. Similar problems would arise if bulk quantities were defined in terms of mass.
- Therefore, the HSE is proposing to define bulk quantities in terms of *activity*.
- The HSE is intending to make a link to potential dose by developing activity criteria on bulk quantities that are related to dose using figures that are already established in legislation. The HSE's suggestion is to define bulk quantities as being 100 times the figures given in Schedule 2 of the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPPIR), which correspond to a potential off-site effective dose of 5 mSv in the period of one year immediately following a reasonably foreseeable radiation emergency. The factor of 100 has been derived by considering the levels in NIA65 when site licensing could be expected.

Discussion around this presentation addressed the following points:

- It was asked if the HSE would be acting in proper accordance with the law if it were to define bulk quantities in terms of *activity*.

It was emphasised that the HSE is only proposing to put forward its own interpretation of bulk quantities, and that the HSE recognises that this could be challenged in court. Any judicial decision would overrule HSE guidance on the interpretation of bulk quantities, but the HSE considers that that if it arrives at its guidance by a good process of consultation, then that process would provide an element of legitimacy for its guidance.

- There was discussion of whether the form of the waste should be considered when defining bulk quantities (e.g., powders versus cemented wastes)? There was also discussion of whether the concentration of activity in the wastes should be the basis for the definition of bulk quantities.

- It was noted that activity is not equivalent to dose or risk. Participants asked if it would not be better to assess the requirement for licensing on a site-by-site basis. It was suggested that REPPiR type emergency doses could be calculated for each site and the need for licensing then determined case-by-case.

The HSE suggested that it would be clearer to use a directly measurable quantity (such as activity) to determine the need for licensing, rather than a derived (calculated) quantity such as dose or risk. Some participants suggested that a 'sufficient' assessment of dose or risk could be required and that this would mean that dose or risk could be used instead of activity. Other participants noted that although measurable in principle, there are uncertainties and limitations associated with the ability to measure activity. There was also discussion of whether dose or risk criteria could be used successfully in court and whether arguments over the assessment of dose or risk might cause delay in the licensing process.

- Questions were raised over when it would become necessary for a site that was gradually accepting more radioactive matter to have a license. Participants asked how a 'site' would be defined, whether neighbouring sites could be licensed, and whether sites could be divided to avoid licensing.
- It was noted that REPPiR may not endure and participants suggested, therefore, that the new regulations or HSE guidance should include an explicit table of the activity levels at which licensing would be required.

Mick Bacon (HSE) described some recent work to identify which facilities the proposed licensing scheme might impact.

- The HSE prefers an approach in which all industrial sectors would be treated in the same way, rather than singling out the nuclear industry for special consideration.
- The HSE does not want to license sites where it is not necessary and is aiming for better and proportionate regulation. HSE is, therefore, proposing to exclude all LLW disposal from the licensing under NIA65.
- Based on an initial survey of users of radioactive substances, and using the proposed 100 times REPPiR Schedule 2 values, some hospitals with large radiotherapy departments that hold large sealed sources might appear to need licensing. However, sealed sources are regulated under other legislation (e.g., the Ionising Radiations Regulations 1999 (IRR99) and the High-activity Sealed Radioactive

Sources and Orphan Sources Regulations 2005 (HASS)), and so the HSE is proposing to exclude all sealed sources from licensing. This would be consistent with the Paris Convention, which also excludes sealed sources.

Discussion around these points included:

- There was general support for an approach that would apply to all industrial sectors in the same way. The difficulty in defining the 'nuclear sector' as distinct from other sectors was pointed out.
- There was general agreement with the suggestion to exclude sealed sources, but a question as to whether orphan sources would need to be licenced.
- It was noted that if radioactivity content was used as the criterion, then the LLWR would become licensable because of its inventory.
- The HSE's initial survey of registered/authorised users/disposers of radioactive substances would not have identified any *proposed* LLW disposal facilities. It is unclear, therefore, whether these facilities would require a license if LLW disposal was not excluded.
- It was unclear whether any landfills not registered/authorised under RSA93 might need licensing, for example, due to their content of exempt wastes.
- HSE is proposing to exclude the disposal of LLW from licensing, because it believes that licensing of LLW disposal would be disproportionate to the risks involved. This belief is not based on a rigorous scientific assessment, but HSE cannot envisage how large off-site risks could arise from a LLW disposal site (even from a fire) if the wastes are sensibly packaged. It was noted, however, that not all LLW will be packaged or conditioned prior to disposal, and the issue of an aircraft crash as a possible though remote release scenario was mentioned.
- The advantages and disadvantages of licensing LLW disposal sites were discussed. It was unclear whether licensing of a LLW disposal site would build public confidence that strict regulation was in place, or raise public concern because the need for a licence could imply significant risks.
- It was suggested that the GE Healthcare site at Amersham would probably continue to need to be licensed under the

100 times REPIR Schedule 2 values, but that the GE Cardiff site would probably not.

- It was questioned whether some holders of NORM would probably need to be licensed using the 100 times REPIR Schedule 2 values. However, it was pointed out that NORM is excluded from the provisions of NIA65.
- Participants asked if the current proposals include enough 'headroom' to allow for future increases in the storage / disposal of radioactive materials (e.g., at hospitals and other facilities). It was considered that further work would be necessary to consider the potential impacts of the proposals, and to take account of possible future trends.
- There was a suggestion that all radioactive waste disposal sites could be licensed but that the degree of licence could be varied according to the facility and risks in question.
- The potential for the disposal of short-lived intermediate-level waste (ILW) to near-surface disposal facilities was identified, and it was asked whether this would require a license. It was pointed out that under the current proposals this would require a license.

In a facilitated discussion, the meeting participants identified the following key issues:

- Should the term 'bulk quantities' remain in legislation at all?
- The justification for the 100 times REPPIR Schedule 2 values needs to be clear; presently the justification is not completely clear, and it is not directly apparent how those values relate to risk. Can the proposals be linked more clearly to the Basic Safety Standards?
- Should the 100 times REPPIR Schedule 2 values be put in legislation rather than in guidance?
- There is a need to consider more carefully the implications of the proposals. It may not be enough only to look at the environment Agencies' databases of RSA93 registrations and disposals, because these may not be reliable or broad enough in scope.
- How would a GDF be de-licensed?
- There needs to be consistency between these HSE proposals and UK inputs to the Paris Convention development process. The requirement in the Paris Convention for liability insurance for all disposal sites has not yet been ratified and implemented in member states. There is a question of whether the UK Government should already be ensuring that LLW disposal sites have sufficient liability insurance in place.
- It was suggested that incineration of LLW and ILW were processing, not disposal and as such should be outside the licensing regime.
- There was some concern that the accidental contamination of soil could lead to the formation of 'bulk quantities' of waste that would require licensing.
- MOD sites and wastes are currently excluded from licensing under NIA65 in accordance with Government policy. If policy were to change in the future, would these sites then be covered by the licensing regime?
- Should the formal consultation document describe the process of getting to a GDF and its licensing and de-licensing rather broadly – before focusing in on the 'bulk quantities' issue in particular?
- Are there scenarios potentially leading to off-site risks from storage or disposal sites that are different from those scenarios considered when the REPPIR Schedule 2 values were derived?

- Is 'storage incidental to transport' adequately defined?
- Is there a need for flexibility for the HSE to consider each site on a case-by-case basis and, for example, take account of the form of the waste, and site-specific off-site release scenarios.
- It will be important to state clearly that just because a particular site is deemed not to require a license, that would not mean that the site is unregulated. There are layers of regulation that apply and these need to be made absolutely clear to all concerned.
- How would the proposed changes and licensing regime work in practice?
- Could some conceptual case studies be presented to show how the proposals would work in practice?

Prior to the meeting a list of questions for consideration had been provided to the participants. The meeting discussed their views on the most relevant questions:

1. *Do you agree with the proposed exclusion from licensing under NIA65 of sites for the storage of (i) sealed sources, (ii) naturally-occurring radioactive materials, and (iii) radioactive materials incidental to carriage?*

There was agreement with these proposed exclusions.

2. *What is your view of whether 'bulk quantities' should be defined in terms of volume (m³), activity (Bq), dose (Sv), risk of death (y⁻¹), or some other measure? Would it be appropriate to apply the HSE concept of 'no danger' as part of the definition of bulk quantities?*

Most participants were in agreement that it would not be sensible to define bulk quantities in terms of volume or mass alone. Most participants agreed that using activity would be sensible, but there was some concern that this might be challenged in court, and that the link between activity and risk was not completely clear.

3. *What is your view (e.g., from practical experience) as to what constitutes a bulk quantity of radioactive materials?*

This question was not addressed.

4. *Should all sectors be treated equally or could special treatment of the nuclear industry be justified in this instance? Is the distinction between the nuclear and non-nuclear sectors sufficiently clear?*

There was agreement that all industrial sectors should be treated equally and that the licensing regime should reflect the risk associated with the different facility types. It was considered that the definition of 'nuclear sector' is not sufficiently clear.

5. *Is the basis for using values derived from the Nuclear Installations (Prescribed Sites) Regulations 1983 and REPPiR to help determine the requirement for licensing under NIA65 clear? Would the use of such values be an acceptable approach?*

There was general support for the proposed approach based on the use of values derived from REPPiR, but comments that as yet the derivation of the proposed criteria is not completely clear.

6. *Have we set out the options sufficiently clearly?*
7. *Are there other options that should be considered – if so what are they?*

Questions 6 and 7 were taken together. It was recognised that there is more work to do to describe the options for the consultation document. It was suggested that the consultation document should include the option of more fundamental legislative revision to NIA65, and another option of licensing all disposal sites (rather than excluding LLW disposal).

8. *What is your preferred option?*

It was not felt to be appropriate to deal with this question at this pre-consultation stage.

9. *Do you agree with the proposed exclusion from licensing under NIA65 of sites used for near-surface (i.e., non-geological) disposal of LLW?*

See response to Questions 6 and 7.

10. *What do you consider to be the key impacts of the proposed changes? Do you have any comments?*

Participants noted that it is important that the proposals do not have a negative effect on the drive for greater flexibility in radioactive waste management introduced by the recent LLW Policy document.

11. *Do you have any comments on the proposed approach to consultation?*

It was noted that the HSE is not proposing further consultation meetings – just a formal consultation document package in 2010. The timing of the consultation will depend on the Paris Convention process. There were no suggestions that the process should be revised.

12. *Do you have any other comments?*

There were no further comments.

Frans Boyden thanked all of the participants for their contributions and was pleased with the dynamic and constructive nature of the discussions.

Annex 2

HSE Nuclear Directorate

Bulk Quantities Pre-Consultation Stakeholder Workshops: Summary Report

16th June, Radisson Hotel, Manchester Airport

Participants

Mick Bacon (HSE Nuclear Directorate)
Bruce Cairns (DECC)
Ray Kemp (RKCL Facilitator)
Simon Morgan (NDA)
Michael Calloway (NDA)
Steve Daish (AMEC)
Stuart Cripps (AMEC)
Simon Moyle (Augean)
Alistair King (GE)
David Ferguson (Energy Solutions)
Andrew Drom (Magnox North Sites)
Phil Holland (SITA)

Apologies

Roh Hathlia (DECC)
Rob Allott (EA)
Fred Barker (NULEAF)

1 Introductions

Mick Bacon (HSE)

- Welcomed the participants to the meeting and thanked them for attending.
- Explained how the HSE would no longer be addressing the issue of *disposal* of Bulk Quantities of radioactive waste in its consultation process but would instead be focusing on the definition of Bulk Quantities for storage.
- Informed those present that DECC would be taking the issue of disposal of Bulk Quantities forward in a separate consultation which will involve issues related to the Paris and Brussels Conventions.
- Emphasised that the HSE is now very keen to progress the issue and wants to take full account of stakeholder's views.
- Stressed the importance of two-way communication and the hope that participants would take the opportunity to share their views with the HSE.

Professor Ray Kemp:

- Facilitated round table introductions for the benefit of all present.
- Outlined the agenda and stressed that the workshop was a pre-consultation meeting to share the HSE's thinking following the pre-consultation meetings held last November and subsequent discussions

with DECC and to identify key issues and concerns in advance of formal consultation being undertaken this summer.

- Noted that a brief summary report of the meeting would be made available for participants.

2 Presentation and Discussion of Draft HSE Proposals

2.1 Background and Scope

Mick Bacon (HSE) described the background to the issue and the scope of the current project in some more detail. Key points included:

- The Nuclear Installations Act 1965 (NIA65) requires that a Nuclear Site Licence is in force before a site may be used for the purpose of installing or operating any fixed nuclear reactor or any other installation that may be 'prescribed'.
- The installations currently prescribed are specified in the Nuclear Installations Regulations 1971 (NIR71). Amongst other things, the NIR71 prescribe the storage of 'bulk quantities' of materials.
- Disposal of radioactive matter is not currently prescribed, but Government Policy is that a geological disposal facility (GDF) should be a licensed facility. However, an issue with prescribing disposal is whether LLW disposal facilities would be brought into the licensing regime.
- The Paris Convention requires operating nuclear facilities to carry substantial amounts of no-fault insurance for off-site damage. The UK Government is required to ratify the 2004 Protocol on the Paris Convention which defines "damage" and specifies levels of insurance. This ratification also needs to bring "disposal" (with no de-minimis) within the scope of the application of the Convention. However, in the UK, the application of the Paris Convention is linked to the issuing of a nuclear site licence with the possible implication of licensing ALL disposal sites.. This is not the case in other countries.
- In order to resolve this anomaly, DECC will take the lead for re-consideration of arrangements for disposal through the OECD Nuclear Energy Agency (NEA) led process on the Paris Convention to ensure that proposed UK arrangements for licensing and disposal correctly implement the terms of the Convention. Stakeholders with an interest in disposal issues should ensure that they engage with the DECC consultation process which HSE understands is likely be held in the near future.

- In the meantime, the range of organisations potentially storing bulk quantities of radioactive matter is increasing and there is now a need to define 'bulk quantities' more clearly.
- Under this project, the HSE is only considering the **storage** of 'bulk quantities' of radioactive wastes, and envisages issuing guidance on HSE's interpretation of 'bulk quantities'.

2.2 Defining Bulk Quantities

Mick Bacon (HSE) described possible ways of defining bulk quantities. Key points included:

- The term 'bulk quantities' was first used in ~1959 with the aim of excluding trivial risks.
- Legal interpretation, likely based on the Oxford English Dictionary, would be that 'bulk quantities' refers to a *volume*.
- However, defining bulk quantities in terms of volume alone would not reflect the hazard or risk posed by the materials. Similar problems would arise if bulk quantities were defined in terms of mass.
- Therefore, the HSE is proposing to define bulk quantities in terms of *activity*.
- The HSE's suggestion is to define bulk quantities as being 100 times the figures given in Schedule 2 of the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPPIR), which correspond to a potential off-site effective dose of 5 mSv in the period of one year immediately following a reasonably foreseeable radiation emergency. The factor of 100 has been derived by considering the levels in NIA65 when site licensing could be expected.
- A "reality check" against the Environment Agency's data base of current sites in the UK appears to indicate that the suggested multiplier of 100 times REPPPIR is reasonable.
- The HSE prefers an approach in which all industrial sectors would be treated in the same way, rather than singling out the nuclear industry for special consideration.
- The HSE does not want to license sites where it is not necessary and is aiming for better and proportionate regulation.
- Based on an initial survey of users of radioactive substances, and using the proposed 100 times REPPPIR Schedule 2 values, some hospitals

with large radiotherapy departments that hold large sealed sources might appear to need licensing. However, sealed sources are regulated under other legislation (e.g., the Ionising Radiations Regulations 1999 (IRR99) and the High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005 (HASS)), consistent with the Paris Convention, which also excludes sealed sources. This would be addressed in the DECC consultation process.

2.3 Discussion

Facilitated discussion around this presentation addressed the following points:

- **Processing.** There was discussion of the distinction between 'processing' (as used in NIA65) and storage, of whether there is a need to define processing more clearly, and of when radioactive matter that is being processed should be considered to be in storage. There was also some concern over whether facilities processing wastes for later transfer to the national Low Level Waste Repository (LLWR) would be affected by the proposed licensing regime.

It was explained that, in practice, storage overlaps processing, and that radioactive matter that is being processed is always considered to be in storage. Currently the HSE cannot see a need to prescribe processing and, for example, the Studsvik Metal Recycling facility at Lillyhall in Cumbria is licensed for storage, not processing.

- **Dual regulation.** There was some concern over whether the current proposals might lead to unnecessary 'dual regulation' of disposed wastes under the Radioactive Substances Act 1993 (RSA93) and NIA65.

It was explained that there is close cooperation between the HSE and the environment agencies, and that the two regulatory regimes are complementary rather than overlapping. The HSE's interests lie in public and worker health and safety during facility operations and accident emergencies, while the environment agencies' interests are different and lie in environmental protection and protection of the public from releases to the environment (e.g., to groundwater).

- **De-licensing.** Several questions were raised concerning de-licensing of facilities. The HSE is planning to further work on de-licensing under a separate project.

It was explained that currently, the HSE's approach is to try to resolve issues one at a time because this is more tractable than trying to solve all of the issues at once, but HSE is open to stakeholder's views, e.g., on whether the proposals should be cast in a more holistic way.

- **Due Process.** It was asked if the HSE would be acting in proper

guidance should include an explicit table of the activity levels at which licensing would be required.

- **Treating all sectors equally.** There was general support for an approach that would apply to all industrial sectors in the same way. The difficulty in defining the 'nuclear sector' as distinct from other sectors was pointed out.
- **Sealed sources.** There was general agreement with the suggestion to exclude sealed sources, but a question as to whether orphan sources would need to be licenced.
- **Amersham.** It was suggested that the GE Healthcare site at Amersham would probably continue to need to be licensed under the 100 times REPIR Schedule 2 values, but that the GE Cardiff site would probably not.
- **Naturally-Occurring Radioactive Matter (NORM).** It was questioned whether some holders of NORM would probably need to be licensed using the 100 times REPIR Schedule 2 values. However, it was pointed out that NORM is excluded from the provisions of NIA65.
- **Headroom and future-proofing.** Participants asked if the current proposals include enough 'headroom' to allow for future increases in the storage of radioactive materials (e.g., at hospitals and other facilities). It was considered that further work would be necessary to consider the potential impacts of the proposals, and to take account of possible future trends.
- **Degrees of licensing.** There was a suggestion that the degree of licensing could be varied according to the facility and risks in question. It was pointed out that licensing is a high impact form of regulation most appropriate for High Hazard industries. It is intrusive and costly.

3 Plenary Discussion of Key Issues

In a final facilitated discussion, the meeting participants identified the following key issues for HSE to consider:

- Should the term 'bulk quantities' remain in legislation at all?
- The justification for the 100 times REPPiR Schedule 2 values needs to be clear; presently the justification is not entirely clear, and it is not directly apparent how those values relate to risk. Can the proposals be linked more clearly to the Basic Safety Standards?
- Would a simple threshold level would be to implement? If so, set this at a higher rather than lower level and emphasise that this does not mean exemption from regulation. The fact that a nuclear site licence is not required does not mean that a site is not properly regulated.
- There is a need to consider more carefully the implications of the proposals. It may not be enough only to look at the environment Agencies' databases of RSA93 registrations and disposals, because these may not be reliable or broad enough in scope.
- There needs to be consistency between these HSE proposals and UK inputs to the Paris Convention development process. The requirement in the Paris Convention for liability insurance for all disposal sites has not yet been ratified and implemented in member states. There is a question of whether the UK Government should already be ensuring that LLW disposal sites have sufficient liability insurance in place.
- Is there a need for flexibility for the HSE to consider each site on a case-by-case basis and, for example, take account of the form of the waste, and site-specific off-site release scenarios?
- It will be important to state clearly that just because a particular site is deemed not to require a license that would not mean that the site is unregulated. There are layers of regulation that apply which need to be made absolutely clear to all concerned.
- How would the proposed changes work in practice? Could some conceptual case studies be presented to show how the proposals would work in practice?

4 Meeting Summary and Close

A summary discussion of the key points included the following:

1. The HSE will be consulting on its proposed approach to defining Bulk Quantities of radioactive material in relation to storage this summer – probably from the end of July onwards.
2. The intention is to release a Policy Statement with a clear method identifying a single threshold defining what constitutes Bulk Quantities for the storage of radioactive material.
3. DECC will be consulting separately the proposed approach to disposal, exemptions from licensing and ratification of the Paris Convention. HSE recommended that everyone should watch carefully for further information from DECC.
4. The method being proposed by the HSE is intended to be proportionate to the issues and to be helpful to all concerned.
5. Delicensing is an important consideration since once a licence is issued, the operator will need to demonstrate “no danger” at the end of its period of responsibility and that is a difficult test required by Primary Legislation.
6. There remain uncertainties but the building blocks towards resolving the issues are slowly coming into place.
7. The output of HSE’s approach is not dependent on the DECC discussions with the NEA Steering Committee and will be a policy statement by the HSE.
8. However it is important that there is co-ordination between the two strands of work and HSE will provide technical support to DECC. Meetings of the NEA Steering Committee only occur bi-annually.
9. It is recognised that there is an urgent need to set out the issues for stakeholders and the general public; to clarify what is meant by “Bulk Quantities” and what that implies in terms of the need for any liability insurance for off-site risks.
10. HSE is keen to maintain open lines of communication on these issues and encourages everyone to suggest others who may wish to be included. HSE is happy to attend additional meetings to discuss the issues and listen to people’s views.

Mick Bacon thanked all of the participants for their contributions and was pleased with the dynamic and constructive nature of the discussions.

Annex 3

HSE Nuclear Directorate

Bulk Quantities Pre-Consultation Stakeholder Workshops: Summary Report

17th June, Hilton Hotel, Edinburgh Airport

Participants

Mick Bacon (HSE)
Ray Kemp (RKCL Facilitator)
Stuart Hudson (Scottish Government/SEPA)
Ewan Young (Scottish Government)
Rita Holmes (Hunterston SSG)
Kenny MacDougall (Hunterston SSG)

Apologies

Roh Hathlia (DECC)
Jim Cochrane (SEPA)
June Love (Dounreay SSG)
Alan Mowatt (DSRL)
David Orr (Magnox North, Chaplecross)

1 Introductions

Mick Bacon (HSE)

- Welcomed the participants to the meeting and thanked them for attending.
- Explained how the HSE would no longer be addressing the issue of *disposal* of Bulk Quantities of radioactive waste in its consultation process but would instead be focusing on the definition of Bulk Quantities for storage.
- Informed those present that DECC would be taking the issue of disposal of Bulk Quantities forward in a separate consultation which will involve issues related to the Paris and Brussels Conventions.
- Emphasised that the HSE is now very keen to progress the issue and wants to take full account of stakeholder's views.
- Stressed the importance of two-way communication and the hope that participants would take the opportunity to share their views with the HSE.

Professor Ray Kemp:

- Facilitated round table introductions for the benefit of all present.
- Outlined the agenda and stressed that the workshop was a pre-consultation meeting to share the HSE's thinking following the pre-consultation meetings held last November and subsequent discussions with DECC and to identify key issues and concerns in advance of formal consultation being undertaken this summer.

- Noted that a brief summary report of the meeting would be made available for participants.

2 Presentation and Discussion of Draft HSE Proposals

2.1 Background and Scope

Mick Bacon (HSE) described the background to the issue and the scope of the current project in some more detail. Key points included:

- The Nuclear Installations Act 1965 (NIA65) requires that a Nuclear Site Licence is in force before a site may be used for the purpose of installing or operating any fixed nuclear reactor or any other installation that may be 'prescribed'.
- The installations currently prescribed are specified in the Nuclear Installations Regulations 1971 (NIR71). Amongst other things, the NIR71 prescribe the storage of 'bulk quantities' of materials.
- Disposal of radioactive matter is not currently prescribed, but Government Policy is that a geological disposal facility (GDF) should be a licensed facility. However, an issue with prescribing disposal is whether LLW disposal facilities would be brought into the licensing regime.
- The Paris Convention requires operating nuclear facilities to carry substantial amounts of no-fault insurance for off-site damage. The UK Government is required to ratify the 2004 Protocol on the Paris Convention which defines "damage" and specifies levels of insurance. This ratification also needs to bring "disposal" (with no de-minimis) within the scope of the application of the Convention. However, in the UK, the application of the Paris Convention is linked to the issuing of a nuclear site licence with the possible implication of licensing ALL disposal sites.. This is not the case in other countries.
- In order to resolve this anomaly, DECC will take the lead for re-consideration of arrangements for disposal through the OECD Nuclear Energy Agency (NEA) led process on the Paris Convention to ensure that proposed UK arrangements for licensing and disposal correctly implement the terms of the Convention. Stakeholders with an interest in disposal issues should ensure that they engage with the DECC consultation process which HSE understands is likely be held in the near future.
- In the meantime, the range of organisations potentially storing bulk quantities of radioactive matter is increasing and there is now a need to define 'bulk quantities' more clearly.

- Under this project, the HSE is only considering the **storage** of 'bulk quantities' of radioactive wastes, and envisages issuing guidance on HSE's interpretation of 'bulk quantities'.

2.2 Defining Bulk Quantities

Mick Bacon (HSE) described possible ways of defining bulk quantities. Key points included:

- The term 'bulk quantities' was first used in ~1959 with the aim of excluding trivial risks.
- Legal interpretation, likely based on the Oxford English Dictionary, would be that 'bulk quantities' refers to a *volume*.
- However, defining bulk quantities in terms of volume alone would not reflect the hazard or risk posed by the materials. Similar problems would arise if bulk quantities were defined in terms of mass.
- Therefore, the HSE is proposing to define bulk quantities in terms of *activity*.
- The HSE's suggestion is to define bulk quantities as being 100 times the figures given in Schedule 2 of the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPPIR), which correspond to a potential off-site effective dose of 5 mSv in the period of one year immediately following a reasonably foreseeable radiation emergency. The factor of 100 has been derived by considering the levels in NIA65 when site licensing could be expected.
- A "reality check" against the Environment Agency's data base of current sites in the UK appears to indicate that the suggested multiplier of 100 times REPPPIR is reasonable.
- The HSE prefers an approach in which all industrial sectors would be treated in the same way, rather than singling out the nuclear industry for special consideration.
- The HSE does not want to license sites where it is not necessary and is aiming for better and proportionate regulation.
- Based on an initial survey of users of radioactive substances, and using the proposed 100 times REPPPIR Schedule 2 values, some hospitals with large radiotherapy departments that hold large sealed sources might appear to need licensing. However, sealed sources are regulated under other legislation (e.g., the Ionising Radiations Regulations 1999 (IRR99) and the High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005 (HASS)), consistent

with the Paris Convention, which also excludes sealed sources. This would be addressed in the DECC consultation process.

2.3 Discussion

Facilitated discussion around this presentation addressed the following points:

- **Legitimate Consultation.** The HSE were asked how they intended to run the public consultation process since attendance at this meeting was so low and it was essential that the public were properly informed.

The HSE apologised that unavoidable short notice for the meeting was a chief reason why several could not attend. However the HSE was keen to receive ideas on how to conduct the consultation, and who else might be contacted. HSE was also willing to meet further with interested parties as part of the on-going process.

- HSE were invited to attend the September meeting of the Hunterston SSG and Mick Bacon indicated that he would be pleased to attend the meeting.
- Proper consultation meant such things as involving Community Councillors, newspaper publicity, mass emails, journal articles, and so on – and engagement with a variety of views and opinions – not just industry interests. SCCORS represents 32 Local Authorities in Scotland for instance.
- People's time shouldn't be wasted and there should be a 2-way process with feedback being given to those who respond. Consultation must and must be seen to have an effect on the outcome.
- It was suggested that as simple language as possible should be employed and the use of obscure ACRONYMS avoided at all costs.

These comments were welcomed by the HSE. RKCL was advising on the consultation process which also had to be put into perspective in terms of the nature of the issues being addressed. It was acknowledged that more should be done to ensure those in Scotland understood they had the opportunity to engage.

- **Impact of the Proposals.** It was advised that it is important to explain what the impact of the proposals will be so as to avoid confusion. The main concern of most people will be whether a site is to be regulated by the NII or SEPA. There may be confusion that there could be long-term health implications as a result of the proposed approach and these concerns need to be addressed.

Mick Bacon acknowledged that it used to be clear what should be licensed by the NII but now some sites were "in the middle" – they were not trivial risks but "Bulk Quantities" implies a potential off-site risk. The implications for sites being licenced are not are not trivial: the insurance requirements jump to between £70 million and £170 million; NII

charges can be £50,000 - £100,000 per annum; and a more onerous inspection regime is imposed.

- **What should be Licensed?** It was suggested that a clear approach was needed to retain confidence in the NII.

The HSE view is that a risk based approach is sensible but difficult to implement. The justification for nuclear licensing should be that there is potentially an exceptional off-site risk. A judgement based on radioactivity – Becquerels – should be explored. It makes sense to have upper and lower bounds of activity such that above a certain level a licence is required, below a certain level one isn't required, and judgement is needed in between. Initial thoughts are that the upper bar should be 1800 x REPPiR (Schedule 2) and the lower bar should be 100 x REPPiR.

The need for a clear approach is that a number of new sites are coming forward. The issue of Sealed Sources will be addressed by DECC in its response to the Paris Convention and Transportation of Sealed Sources is already regulated.

The HSE is not seeking to exempt anything from regulation, but it is saying that certain sites with high hazard require additional NII regulation. Determining where to set the additional bar for NII regulation is the issue to be addressed.

- **The issue of Dounreay.** It was stated forcefully that any approach that means that the new Dounreay Low Level Waste Disposal Facility would not require an NII licence would be condemned as “sneaky” by the community. Any document that supports such an approach should be widely disseminated in the public domain.

The discussion pointed out that the Scottish Government doesn't believe the new Dounreay disposal facility should be licensed by the NII. HSE pointed out that DECC is preparing a consultation document on the prescription of disposal as part of the UK's obligation to ratify the Paris Convention.

The HSE made clear that DSRL is progressing on the basis that it will require a Nuclear Site License. In addition, the Dounreay facility would be captured by HSE's proposed screening method because on first examination the design criteria is approximately 300 x REPPiR.

3 Meeting Summary and Close

A summary discussion of the key points included the following:

1. The HSE will be consulting on its proposed approach to defining Bulk Quantities of radioactive material in relation to storage this summer – probably from the end of July onwards.
2. The intention is to release a Policy Statement with a clear method identifying a single threshold defining what constitutes Bulk Quantities for the storage of radioactive material.
3. DECC will be consulting separately the proposed approach to disposal, exemptions from licensing and ratification of the Paris Convention. HSE recommended that everyone should watch carefully for further information from DECC.
4. The method being proposed by the HSE is intended to be proportionate to the issues and to be helpful to all concerned.
5. Delicensing is an important consideration since once a licence is issued, the operator will need to demonstrate “no danger” at the end of its period of responsibility and that is a difficult test required by Primary Legislation.
6. There remain uncertainties but the building blocks towards resolving the issues are slowly coming into place.
7. The output of HSE’s approach is not dependent on the DECC discussions with the NEA Steering Committee and will be a policy statement by the HSE.
8. However it is important that there is co-ordination between the two strands of work and HSE will provide technical support to DECC. Meetings of the NEA Steering Committee only occur bi-annually.
9. It is recognised that there is an urgent need to set out the issues for stakeholders and the general public; to clarify what is meant by “Bulk Quantities” and what that implies in terms of the need for any liability insurance for off-site risks.
10. HSE is keen to maintain open lines of communication on these issues and encourages everyone to suggest others who may wish to be included. HSE is happy to attend additional meetings to discuss the issues and listen to people’s views.

Mick Bacon thanked all of the participants for their contributions and was pleased with the dynamic and constructive nature of the discussions.

Annex 4

HSE Nuclear Directorate Bulk Quantities Pre-Consultation Stakeholder Workshop: Summary Report

2 December 2009, Hilton Hotel, Edinburgh Airport

Participants

Mick Bacon (HSE)
John Lamb (Hunterston Site Stakeholder Group)
Kenny MacDougall (Hunterston Site Stakeholder Group)
Bob Earnshaw (Dounreay Site Stakeholder Group)
Jim Cochrane (SEPA)
David Orr (Magnox North, Chaplecross)
Alec Anderson (DSRL)
Alan Mowat (DSRL)
Stuart Hudson (Scottish Government)
John Convey (Scottish Government)
Ray Kemp (RKCL Facilitator)
David Bennett (TerraSalus Limited / RKCL Rapporteur)
Andrea Murray (RKCL Administrator)

1 Introductions

Mick Bacon (HSE):

- Welcomed the participants to the meeting and thanked them for attending.
- Noted the HSE's responsibility for nuclear site licensing.
- Noted the need now for various reasons to define 'bulk quantities' more clearly than has been done to date, and to consider licensing of a geological disposal facility (GDF).
- Noted that the HSE had begun some earlier consultation work on this issue, but that this had stalled, partly because of organisational changes.
- Emphasised that the HSE is now very keen to progress the issue and wants to take full account of stakeholder's views.

Professor Ray Kemp:

- Introduced the RKCL team and facilitated round table introductions for the benefit of all present.
- Outlined the agenda and stressed that the workshop was a pre-consultation meeting to share the HSE's early thinking and to identify key issues and concerns in advance of formal public and stakeholder consultation being undertaken.
- Noted that a brief summary report of the meeting would be made available for participants.

2 Presentation and Discussion of Draft HSE Proposals

2.1 Background and Scope

Mick Bacon (HSE) described the background to the issue and the scope of the current project in some more detail. Key points included:

- The Nuclear Installations Act 1965 (NIA65) requires that a Nuclear Site Licence is in force before a site may be used for the purpose of installing or operating any fixed nuclear reactor or any other installation that may be 'prescribed'.
- The installations currently prescribed are specified in the Nuclear Installations Regulations 1971 (NIR71). Amongst other things, the NIR71 prescribe the storage of 'bulk quantities' of materials.
- The range of organisations potentially storing bulk quantities of radioactive matter is increasing and there is now a need to define 'bulk quantities' more clearly.
- Disposal of radioactive matter is not currently prescribed, but Government Policy is that a geological disposal facility (GDF) should be a licensed facility. However, an issue with prescribing disposal is whether LLW disposal facilities would be brought into the licensing regime.
- Under this project, therefore, the HSE is considering the storage and disposal of 'bulk quantities' of radioactive wastes, and envisages amending the NIR71 to include 'disposal of bulk quantities' and issuing guidance on its interpretation of 'bulk quantities'.
- Amending the regulations may take several months, and the process would involve formal consultation on draft regulations in 2010.
- Formal consultation on the proposals and draft regulations was planned for early 2010, but this may now be delayed due to legal implications associated with the Paris Convention.

Facilitated discussion around this presentation addressed the following points:

- **Amending primary legislation.** Several participants noted that they would welcome increased clarity on the definition / interpretation of bulk quantities, but asked if it would not be better to amend primary legislation on bulk quantities (i.e., NIA65) rather than issuing guidance. It was noted that the Paris Convention does not use the term bulk quantities but, rather, speaks only of storage, and it was suggested that UK legislation could do the same.

However, it was pointed out that there would be difficulty in obtaining the necessary Parliamentary time to amend primary legislation and this was a major constraint that had to be considered.

- **Precedent.** Participants asked if the HSE's recent decision to license the Studsvik Metal Recycling Facility (MRF) at Lillyhall in Cumbria was based on consideration of bulk quantities, and whether any precedent had been established.

Mick Bacon (HSE) acknowledged that an interpretation of bulk quantities had been made in coming to that decision, but the HSE considers that its opinion on the Studsvik case does not set a precedent for future applications. It was noted that implementation of the current proposals would not mean that the Studsvik MRF would no longer need to be licensed. However, given that the Studsvik MRF has been licensed, some participants found it odd that proposed LLW disposal facility at Dounreay might not need to be licensed.

2.2 Defining Bulk Quantities

Mick Bacon (HSE) described possible ways of defining bulk quantities. Key points included:

- The term 'bulk quantities' was first used in ~1959 with the aim of excluding trivial risks.
- Legal interpretation would be that bulk quantities referred to a *volume*.
- However, defining bulk quantities in terms of volume alone would not reflect the hazard or risk posed by the materials. Similar problems would arise if bulk quantities were defined in terms of mass.
- Therefore, the HSE is proposing to define bulk quantities in terms of *activity*.
- The HSE is intending to make a link to potential dose by developing activity criteria on bulk quantities that are related to dose using figures that are already established in legislation. The HSE's suggestion is to define bulk quantities as being 100 times the figures given in Schedule 2 of the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPPIR), which correspond to a potential off-site effective dose of 5 mSv in the period of one year immediately following a reasonably foreseeable radiation emergency. The factor of 100 has been derived by considering the levels in NIA65 when site licensing could be expected.

Discussion around this presentation addressed the following points:

- **Use of dose or risk-based criteria.** It was noted that activity is not equivalent to dose, and some participants suggested that dose would be a better indicator to use when considering the need for licensing. The HSE suggested that it would be clearer to use a directly measurable quantity (such as activity) to determine the need for licensing, rather than a derived (calculated) quantity such as dose or risk. Other participants noted that although measurable in principle, there are uncertainties and limitations associated with the ability to measure activity. There was also discussion of whether dose or risk criteria could be used successfully in court and whether arguments over the assessment of dose or risk might cause delay in the licensing process.
- **Non-radiological hazards.** It was noted that non-radiological hazards at landfill sites are regulated based on their concentration, rather than on their total amount. It was suggested, therefore, that this argues in favour of the use of a licensing criterion for radioactive wastes based on activity concentration (specific activity), rather than total activity.

2.3 Potential Impacts

Mick Bacon (HSE) described some recent work to identify which facilities the proposed licensing scheme might impact.

- The HSE prefers an approach in which all industrial sectors would be treated in the same way, rather than singling out the nuclear industry for special consideration.
- The HSE does not want to license sites where it is not necessary and is aiming for better and proportionate regulation. HSE is, therefore, proposing to exclude all LLW disposal from the licensing under NIA65.
- Based on an initial survey of users of radioactive substances, and using the proposed 100 times REPPiR Schedule 2 values, some hospitals with large radiotherapy departments that hold large sealed sources might appear to need licensing. However, sealed sources are regulated under other legislation (e.g., the Ionising Radiations Regulations 1999 (IRR99) and the High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005 (HASS)), and so the HSE is proposing to exclude all sealed sources from licensing. This would be consistent with the Paris Convention, which also excludes sealed sources.

Discussion around these points included:

- **Proposed LLW disposal facilities.** Participants asked what the relationship would be between the proposed 100 times REPPiR Schedule 2 values and the waste acceptance criteria for the proposed LLW disposal facility at Dounreay. It was explained that the HSE is proposing to exclude all LLW disposal facilities from licensing, because

it believes that licensing of LLW disposal would be disproportionate to the risks involved.

There was discussion of when a decision may be reached as to whether the proposed LLW disposal facility at Dounreay would need a license. This will depend on the outcome of the bulk quantities consultation, and developments on the Paris Convention. It was emphasised that if a license is required, it is required for facility *installation* (including construction) as well as for facility operation. DRSL indicated that it has included provision in its work programme to apply for a licence.

- **VLLW disposal.** There was discussion of whether disposal sites for VLLW should be licensed. It was suggested that licensing might bring better record keeping, and that this might help when it came to the later re-use of landfilled areas for housing. It was noted that currently no operating landfill sites in Scotland are authorised for VLLW disposal, although VLLW has been disposed of to Scottish landfills in the past and could be again in future. This led to discussion of how waste management routes may change in future, and it was agreed that this needs to be considered further when assessing the potential impacts of the proposals.
- **NORM wastes.** There were questions as to whether the disposal of wastes from oil fields would need to be licensed. It was explained that NORM is excluded from the provisions of NIA65 and so sites for the disposal of NORM wastes would not need to be licensed.
- **How would licensing work in practice?** Questions were raised as to how the proposed licensing arrangements would work in practice. It was explained that organisations wishing to register the use, or disposal of radioactive materials would apply to the relevant Environment Agency for an RSA93 authorisation in the usual way, and that the Environment Agency would then be expected to notify the HSE of applications relating to large (i.e., bulk) quantities.
- **Case Studies.** Participants suggested that it would be useful to include in the consultation package some case studies of hypothetical sites to show how the proposals would work.
- **Alternative licensing arrangements.** It was noted that currently, the Environment Agencies can comment on the packaging of ILW through agreements with the HSE. Participants suggested that in a similar way, the HSE could comment on the disposal of wastes authorised under RSA93 and, in this way, would not necessarily have to take a lead role in the regulation and licensing of radioactive waste disposal. This would allow the HSE to remain focussed on the major nuclear installations.

- **Graded licensing.** There was discussion of whether a form of graded licensing might be applied. The HSE already takes account of the level of hazard and risk associated with licensed sites, and this is reflected in, for example, the frequency of inspections. However, the requirement for liability insurance derives from the Paris Convention and for licensed sites, is required at either an upper or

3 Plenary Discussion of Key Issues

During a facilitated discussion the meeting participants identified the following issues:

- LLW Disposal
 - The regulators and Government should provide clear and consistent messages on what the requirements are for LLW disposal.
 - The benefits of licensing LLW disposal should be more clearly identified.
 - Any exclusions from licensing (e.g., LLW disposal) must be well justified and readily explainable to the public.
 - The consultation document will need to explain the issues assuming a low level of stakeholder understanding – otherwise there is a risk that the proposed changes will not be properly understood.
 - It was felt that the regulations concerning LLW disposal should be applied equally to all sites. There was, therefore, some concern that any decision on the proposed LLW disposal facility at Dounreay would set a precedent.
- Regulatory Burden
 - There is some concern that the imposition of licensing might de-incentivise the radioactive waste management market, and work against moves to increase flexibility and implement the waste hierarchy.
 - It would be better if there was only one regulator (the relevant Environment Agency) for LLW disposal.
- Insurance Burden
 - It would be helpful if the consultation package could provide further information on the levels of insurance that would be required, the required duration of the insurance cover, and the possible costs of obtaining such insurance.
 - The liability insurance required under NIA65 is meant to be sustained for 30 years after site closure; what would be the requirements for a disposal site, where risks may arise much further into the future?

- Links between the Paris Convention, NIA65 and other legislation.
 - Legislative solutions other than just NIA65 should be considered for implementing the requirements of the Paris Convention. For example, RSA93 or other environmental legislation might be used to ensure that the need for insurance is complied with.
 - Stakeholders would rather see new clear documents than compilations of slightly modified old text – i.e., more root and branch change to address the issues and really improve and clarify things.

- De-licensing.
 - What are the implications for the End States of existing nuclear sites of licensing near-surface LLW disposal on or near those sites? How will the End States change and be updated?
 - Could the operator of a storage or disposal facility ask for the site to be de-licensed as soon as the activity of the waste present reduces (e.g., as a result of radioactive decay) to levels below the licensing criteria?
 - For disposal facilities, the meanings of repository closure, of site closure, and of the end of institutional control should be clarified, and their relationships to the licensing and insurance regimes made clear.

4 Trial Answers to Questions

Prior to the meeting a list of questions for consideration had been provided to the participants. The meeting discussed their views on the most relevant questions:

1. *Do you agree with the proposed exclusion from licensing under NIA65 of sites for the storage of (i) sealed sources, (ii) naturally-occurring radioactive materials, and (iii) radioactive materials incidental to carriage?*

There was agreement with these proposed exclusions, but some participants felt that the justification for excluding NORM should be made clearer.

2. *What is your view of whether 'bulk quantities' should be defined in terms of volume (m^3), activity (Bq), dose (Sv), risk of death (y^{-1}), or some other measure? Would it be appropriate to apply the HSE concept of 'no danger' as part of the definition of bulk quantities?*

There was general support for the use of radionuclide-specific activity values based on REPIR Schedule 2, even though activity is not a direct analogue for dose or risk. It was noted that the physical form of the waste can be important, and that this may argue for the establishment of ranges of values that take account of the form of the waste. There were also suggestions to use activity concentrations rather than just activity.

3. *What is your view (e.g., from practical experience) as to what constitutes a bulk quantity of radioactive materials?*

This question was not addressed.

4. *Should all sectors be treated equally or could special treatment of the nuclear industry be justified in this instance? Is the distinction between the nuclear and non-nuclear sectors sufficiently clear?*

There was agreement that all industrial sectors should be treated equally. It was considered that the definition of 'nuclear sector' is not sufficiently clear. It was felt that the arrangements for the regulation of Ministry of Defence (MOD) wastes should be clearer, particularly if MOD wastes are to be managed by the NDA together with 'civilian wastes'.

5. *Is the basis for using values derived from the Nuclear Installations (Prescribed Sites) Regulations 1983 and REPIR to help determine the requirement for licensing under NIA65 clear? Would the use of such values be an acceptable approach?*

There was general support for the proposed approach based on the use of values derived from REPPiR. There were comments that the derivation of the proposed criteria is not completely clear.

6. *Have we set out the options sufficiently clearly?*
7. *Are there other options that should be considered – if so what are they?*

Questions 6 and 7 were taken together. It was suggested that there is more work to do to identify and describe a suitable range of options for the consultation document.

8. *What is your preferred option?*

It was not felt to be appropriate to deal with this question at this pre-consultation stage.

9. *Do you agree with the proposed exclusion from licensing under NIA65 of sites used for near-surface (i.e., non-geological) disposal of LLW?*

It was felt that further information would be required to properly answer this question. The potential benefits of licensing LLW disposal should be more clearly identified, and the possible exclusions from licensing of LLW disposal would have to be well justified and readily explainable to the public.

10. *What do you consider to be the key impacts of the proposed changes? Do you have any comments?*

There was keen interest in the potential impacts of the proposals, but it was felt that further information would be required to properly answer this question.

11. *Do you have any comments on the proposed approach to consultation?*

It was felt that more face to face meetings than are currently proposed would be helpful. The consultation also needs to access a wide audience. It was suggested that the HSE should consider writing to the site stakeholder groups, to Nuleaf and to the Scottish Councils Committee on Radioactive Substances (SCCORS), for their views on how the consultation should go ahead. It was also suggested that there will be a need to consult with local authorities and potential companies in the supply chain that could be affected.

12. *Do you have any other comments?*

There were no further comments.

5 Meeting Close

Mick Bacon (HSE) thanked all of the participants for their contributions and noted the desire for further face-to-face engagement on this subject in the future.

Health and Safety Executive

Public consultation on ONR's interpretation of 'bulk quantities' of radioactive matter

Completing this questionnaire

You can move between questions by pressing the 'Tab' / 'Shift-Tab' or 'Page Up' / 'Page Down' keys or by clicking on the grey boxes with a mouse. Please type your replies within the rectangular grey boxes or click on the square grey boxes to select an answer (eg 'Yes' or 'No').

Respondent's details:

Name:

Job title:

Organisation:

Email:

Street:

Town:

Postcode:

Telephone:

Fax:

Size of organisation:

Choose one option:

Not applicable

1 to 9 employees

10 to 49 employees

50 to 249 employees

250 to 1000 employees

1000+ employees

Self-employed

Confidentiality

Please put a cross in the box if you do not wish details of your comments to be available to the public. (NB if you do not put a cross in the box they will be made public. This takes precedence over any automatic notes on e-mails that indicate that the contents are confidential.)

What is your type of organisation:

Choose one option

- | | | | |
|------------------------------|--------------------------|-------------------------------|--------------------------|
| Industry | <input type="checkbox"/> | Local government | <input type="checkbox"/> |
| National government | <input type="checkbox"/> | Non-governmental organisation | <input type="checkbox"/> |
| Non-departmental public body | <input type="checkbox"/> | Trade union | <input type="checkbox"/> |
| Charity | <input type="checkbox"/> | Trade association | <input type="checkbox"/> |
| Academic | <input type="checkbox"/> | Consultancy | <input type="checkbox"/> |
| Member of the public | <input type="checkbox"/> | Pressure group | <input type="checkbox"/> |
| Other | <input type="checkbox"/> | | |

If 'Other' please specify:

In what capacity are you responding:

Choose one option:

An employer

An employee

Trade union official

Health and safety
professional/Safety representative

Training provider

1. Is “activity” the correct criterion for HSE to use when determining whether bulk quantities of radioactive material are being stored?

Yes

No

Please provide some comments to support your answer.

2. If you do not agree with HSE’s proposed criterion, what alternative criterion should be used and why?

3. Do you agree with the proposal to disregard “sealed sources” for the purposes of determining whether a bulk quantity of material is being stored?

Yes

No

Please provide some comments to support your answer.

4. Do you agree with HSE’s view that a bulk quantity will be a quantity of radioactive materials that has an activity level of [at or above] 100 times REPPIR values?

Yes

No

5. If you do not agree with the proposal in Q4, what value should HSE use to determine whether a bulk quantity of materials is being stored?

6. Do you agree with our assessment of the impact of proposed interpretation of “bulk quantities”?

Yes

No

Please provide some comments to support your answer.

Are there any further comments you would like to make on the issues raised in this consultation document that you have not already responded to in this questionnaire?

Is there anything you particularly liked or disliked about this consultation?

Please send your response by 12 December 2011 to:

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Senior Account Manager
ONR - Communications Team
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Merseyside L20 7HS

Tel: 0151 951 4482
Fax: 0151 951 4004

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Thank you for taking the time to complete this questionnaire