Radioactive Substances Act Guidance (RASAG)
Chapter 4 - Generic Issues

Operational instruction **374_04** **Issued** 21/10/08

What's this document about?

This guidance provides information to support staff in carrying out non-nuclear regulatory duties under Radioactive Substances Act 1993 (RSA93).

This chapter deals with generic issues.

Who does this apply to?

RSR staff carrying out casework under RSA93

Document details

Related documents

Feedback

Contact for queries

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This guidance note is intended for internal Environment Agency use, to assist officers in interpreting and enforcing the relevant legislation. The explanatory note is based on information contained in the relevant legislation, and on current understanding. The note may be subject to change in the light of regulatory changes, future Government guidance or experience of applying the legislation. In the interests of transparency, this note is available to others. However, it has no status other than as internal Environment Agency guidance to its staff. Compliance with the law remains the user's responsibility. If users have concerns over compliance, they should seek professional advice, or contact their regulator or local authority.

1 GUIDANCE ON THE TRANSFRONTIER SHIPMENT OF RADIOACTIVE SUBSTANCES AND RADIOACTIVE WASTE

Note: the regulations on transfrontier shipment are expected to change from December 2008. Defra and the Agency will produce guidance on the new system – any additional queries should be made to RSR Process.

1 Introduction

The relevant management system documents EAQ/3/309 on the Transfrontier Shipment of Radioactive Waste and EAQ/3/306 on Transfrontier Shipment of Radioactive Substances are now out of date. They should be used cautiously in discussion with the Transfrontier Shipment National Service (details on Easinet).

2 Legislative Provisions

Three pieces of legislation may be relevant to the Agency, depending on the nature of the material/waste. BERR also implement the Export of Radioactive Sources (Control) Order 2006 (SI 2006/1846).

1.2 Council Regulation 1493/93/Euratom: on shipments of radioactive substances between Member States (TFSRS)

This Regulation applies solely to the transfrontier shipment of radioactive substances between EU Member States i.e. Shipments to and from Member States to third countries outside the EU is not covered. The provisions apply solely to sealed sources and other relevant sources (open sources) . Being an EU Regulation , it has the same direct effect in all Member States and no specific UK implementing regulations are required.

Sealed sources has the meaning given to it under Directive 80/836/Euratom (The 1980 Basic Safety Standards Directive)

Sealed source: a source consisting of radioactive substances firmly incorporated in solid and effectively inactive material, or sealed in an inactive container of sufficient strength to prevent, under normal conditions of use, any dispersion of radioactive substances

Other relevant source means any radioactive substance not being a sealed source intended for direct or indirect use of ionising radiation it emits for medical, veterinary, commercial, research or agricultural applications.

For shipments of sealed sources, the holder of sealed sources has to obtain a prior written declaration from the consignee to the effect that the consignee has complied, in the Member State of destination, with all applicable provisions implementing Article 3 of the Directive. The declaration must be noted and stamped by the competent authority of the Member State to which the shipment is being made prior to the declaration being sent to the holder of the sealed source.

For other relevant sources the suppliers are required to provide the competent authorities of member states of destination with a summary of deliveries.

An enforcement regime is not, **at present, in place for TFSRS therefore Agency staff should not try to enforce the Regulations. Neither is there yet a charging scheme for this work.**

The Environment Agency is a competent authority for England and Wales under Council Regulation 1493/93 Euratom on the Shipment of Radioactive Substances between EU Member States.

1.3 **SI 1993 No. 3031: The Transfrontier Shipment of Radioactive Waste Regulations 1993 (TFSRW).**

This implements European Council Directive 92/3/Euratom on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community. The Regulations provide for a system of prior authorisation and approval for the shipment of radioactive waste.

For the purposes of these regulations, radioactive waste mean any material which contains or is contaminated by radionuclides and for which no use is foreseen i.e. **this is not the same definition as in RSA93.** The TFSRW apply to shipments between Member States, and into and out of the Community other than -

(a) shipments where the quantities and concentration of the radioactive waste do not exceed the levels laid down in directive 80/836/Euratom (ie the 1980 BSS Directive).

(b) shipments where a sealed source (other than one containing fissile material) is returned by its user to the supplier of the source in another country.

The **TFSRW** provide for the issue by the competent authority of prior authorisations and prior approvals in respect of shipments (imports, exports and transhipments) of radioactive waste into/from and through the UK.

TFSRW makes provision for **Offences** and **Penalties** - these are concerned with the authorisation/ approval regime and **do not** contain specific powers for the seizure or direct control of inadvertent imports.

TFS National Service and RSR Policy deal with applications for the imports and exports of radioactive waste under TFSRW.

1.4 The Radioactive Substances Act 1993

RSA93 provides for the control in the UK of the keeping and use of radioactive material and the accumulation and disposal of radioactive waste. The Act principally involves the application of a prior permitting regime. However Section 30(1) of the Act gives the Agency powers **which may** be applicable to the discovery of radioactive materials/waste at ports or airports, i.e.

If there is radioactive waste on any premises, and the appropriate Agency is satisfied that -

(a) *the waste ought to be disposed of, but*

(b) *by reason that the premises are unoccupied, or that the occupier is absent, or is insolvent, or for any other reason, it is unlikely that the waste will be lawfully disposed of unless the Agency exercises its powers under this section,*

that Agency shall have power to dispose of that radioactive waste as that Agency may think fit, and to recover from the occupier of that premises, any expense reasonably incurred by that Agency in disposing of it.

The definitions of radioactive materials and radioactive waste under RSA93 **are different** from those contained within TFSRW and TFSRS. Advice should be sought from RSR Policy and Process before applying these powers under Section 30(1) of RSA93 to items also covered by either TFS provision.

2 NATURALLY OCCURRING RADIOACTIVE MATERIAL (NORM): WHEN DOES RSA93 APPLY?

1 Introduction

1.1 This note is intended to give guidance in the application of RSA93 in the regulation of NORM.

1.2 Nearly all materials contain trace amounts of natural radionuclides from, for example, the decay chains of U-238, U-235, Th-232. Where these materials are processed, concentration or enhancement of the levels of these radionuclides may occur. The products or wastes from these processes are described as Naturally Occurring Radioactive Material, NORM, or as Technically Enhanced NORM (TE NORM) in U.S. terminology.

2 Application of RSA 1993: Role of Schedule 1 to the Act and exemption orders.

2.1 Radioactive material and radioactive waste are defined in Sections 1 and 2 of RSA93. For NORM the relevant parts of the Act are sections 1(2) (a), 1(3) and Schedule 1 to the Act. For NORM the material or waste in question **must** contain at least one of the elements specified in Schedule 1 of the Act and the activity concentration must exceed the levels specified in Schedule 1 for that element not individual radionuclides. Only then will the material and any associated wastes be subject to regulation under RSA93.

2.2 RSA93 **does not** apply to naturally occurring radionuclides such as K-40, C-14, H-3, or Be-7 as these elements are not listed in Schedule 1. RSA93 does however apply to C-14 and H-3 if artificially formed.

2.3 When considering applications for the issue of registrations for the keeping or use of radioactive material or the grant of authorisations for the accumulation and or disposal of radioactive waste, care should be taken to establish whether the particular use of the material or accumulation or disposal of radioactive waste is covered by the current suite of Exemption Orders.

2.4 Some Exemption Orders (Phosphatic Substances, Lead, Exhibitions, Uranium and Thorium, Prepared Uranium and Thorium Compounds, Geological Specimens and Precipitated Phosphate) apply to NORM. Guidance on the Exemption Orders is contained in Chapter 3 of RASAG.

2.5 See also guidance in this chapter of RASAG on the interaction of RSA93 and other waste legislation.

3 SINGLE REGISTRATION AND AUTHORISATION OF MULTI- TENANT OR MULTI-OCCUPIER SITES

1 Introduction

At some premises, notably hospitals and universities, two or more legal entities may use radioactive substances or dispose of radioactive waste at the same time. For example at a teaching hospital, the facilities may be used by university and hospital staff or a charity may carry out work within a hospital.

Current Agency practice is to normally issue separate registrations and authorisations for such organisations, representing a change from previous practice.

The Agency and predecessor bodies have previously allowed one legal entity on a site to hold a registration and or an authorisation covering the activities of another legal entity. This arrangement has been allowed where a satisfactory written agreement is produced by both parties that the holder of the permissions takes responsibility for all registered/authorised activities.

This note provides guidance on dealing with this issue, but it needs to emphasised that normal practice is to issue separate certificates and the use of a single registration/authorisation to cover the activities of more than one legal entity must be considered exceptional.

In no circumstances will a registration and/or authorisation be issued to be more than one organisation.

2 General Position

2.1 **The presumption is that a separate registration and/or authorisation are required.**

2.2 However, this position may lead to difficulties where radioactive material frequently passes between occupants, staff fulfil roles in both organisations, or where there is interaction in use of the facilities. Therefore, in these **exceptional** circumstances, and only rarely, a single registration and/or authorisation can be issued when all the following criteria are met:

- One party takes full responsibility under the Act in the form of a written agreement between all parties (see section 4 for guidance).

and

- The disposal routes are common and using the same contractors and sewers.

and

- The Agency is content with the management arrangements and degree of control that will be exercised by the holder of the registration/authorisation.

Compliance with these criteria must be recorded in the technical trial required by the QMS procedure for authorisations.

In general terms “exceptional circumstances” are those where there is a regulatory **disadvantage** in granting separate authorisations/registrations. This could occur where the relationship between two organisations on a site is so close and complex that they are inseparable for the purposes of effective regulation and enforcement. For example, this could occur where it would not be possible to establish liability in the event of a breach of a disposal limit.

“Exceptional circumstances” may also be considered to exist where there is a “de minimis” situation, in which it could be argued that a separate authorisation/registration would amount to disproportionate regulation and be of no regulatory advantage. For example, one legal entity, perhaps a charitable organisation, may be represented by a single person on the premises of another legal entity, such as a hospital or university.

3 Application of this position to existing arrangements

3.1 The aim is to bring all existing arrangements with single registration/authorisation on multi-user sites up to the following standard:

- One party has taken full responsibility under the Act in the form of a written agreement between all parties. (see section 4 for guidance)

and

- The inspector is content with the management arrangements and degree of control that is exercised by the holder of the registration/authorisation.

3.2 Where the above position cannot be achieved then separate registration and/or authorisation should be put into place. If any party refuses to co-operate, legal advice should be sought.

4 Guidance on the main issues to be addressed in a Written Agreement

Where an inspector has concluded that “exceptional circumstances” exist and that a single authorisation/registration will therefore be granted, a written agreement between the various legal entities **must** be put into place. The agreement **must**:

- Include acceptance by the holder of the single registration/authorisation of legal liability for any breach of conditions in the permit(s) by any other legal entity on the premises (i.e. the other parties to the written agreement)

- Include arrangements for management of the holder of the permit (s) of the “tenant” organisation’s activities to the inspector’s satisfaction. For example, this would include record keeping arrangements for disposal and acquisition of sources and access to premises so that the holder can demonstrate that it has a reasonable degree of control of all the activities it has agreed to be responsible for.

4 GUIDANCE ON ADMINISTERING CHANGES TO AUTHORISATIONS AND REGISTRATIONS

1 For information on Agency charges see;

Current Agency charging scheme
Operational Instruction on application handling
Non-nuclear tariff typing guidance

Otherwise consult RSR Process Management.

5 INTERACTION BETWEEN THE RADIOACTIVE SUBSTANCES ACT AND OTHER LEGISLATIVE REQUIREMENTS DURING THE TRANSPORT OF RADIOACTIVE MATERIAL

1 Introduction

In England, Wales and Scotland the regulatory authority for the transportation of radioactive material is the Department for Transport (DfT).

2 Transport Legislation

2.1 The main legislation covering the safe transport of radioactive material is The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2007 (which superseded the Radioactive Material (Road Transport) Regulations 2002). These regulations implement regulations made by the International Atomic Energy Agency (IAEA) in its safety standards series for the Safe Transport of Radioactive Material (TS-R-1) and additional requirements contained in the European Agreement concerning the international carriage of dangerous goods by road (ADR). The Regulations also implement provisions of Council Directive 96/29/EURATOM and Commission Directive 2001/7/EC. The emphasis of the regulations is for the package design to provide the main element of safety, such that any possible risk of radioactive contamination or external radioactive hazard is kept to a minimum even in accident situations. The regulations also cover security of radioactive material in transit.

2.2 The transport regulations cover such issues as:

- the maximum permitted dose rates at the surface and 1 metre from the package (which may be significantly higher than normally acceptable for storage conditions)
- the maximum permitted dose rates on the surface and at 2 metres for conveyances
- the testing, categorising and certification of packaging types e.g. Type C, Type B, Type A, Industrial or Excepted packages
- the labelling of the package
- the placarding of the vehicle
- the provision of a fire-proof information plate in the cabin of the vehicle
- documentation and record keeping.
- consignment certificate detailing the radioactive load.

2.3 The Ionising Radiations Regulations (IRRs) also include a regulation on the transport and movement of radioactive material. 'Transport' of radioactive material relates to the transfer of material through the public domain, including when carried or propelled by hand. 'Movement' of radioactive material is normal taken to be internal to a building or site. The standards required by the IRRs regarding transport and movement are not as detailed or restrictive as that required by transport legislation. However the use of the terms 'so far as is reasonably practical' and 'suitable' lead a user towards the requirements of the IAEA regulations.

3 Incidents

3.1 There are two main situations where the Agency may become involved with the DfT:

4 Loss, theft or damage of radioactive material during transport

4.1 The lead enforcing authority is the DfT as the incident occurs during transport. However the user will have to notify without delay the Agency (and the HSE) of the loss, theft or damage of mobile sources. Written notification of the incident should follow.

4.2 Notification of a contamination incident during on-site movement of radioactive material will be to the Agency and the HSE.

6 INTERPRETATION OF REGISTRATION AND AUTHORISATION CONDITIONS CONCERNING SPILLAGE OF RADIOACTIVE SUBSTANCES

1 Standard conditions

The relevant standard condition in the certificate of registration for open sources (S7OD) is as follows:-

`If the user believes or has reasonable grounds for believing that a registered material is escaping or has escaped from any container or location in which it is kept or used he shall

a. without delay inform the Environment Agency
b. …
c. …
d. as soon as is practicable report the circumstances in writing to the Environment Agency.'

A similar condition is included in certificates for the disposal and accumulation of waste.

2 Principles

While only a judicial decision can give a precise interpretation there is a need for general guidelines for both inspectors and users to assist in a consistent and practicable approach. The major issues to be considered are

i. the radioactive waste management implications;
ii. apparent failure of the user's management and control systems;
iii. possible involvement of the public; and
iv. the likelihood that the event may lead to public or media interest.

3 Examples

The user and particularly the person supervising the use of radioactive substances will have to exercise his or her own judgement in each case. The following examples are given to assist in interpretation of certificate conditions.

Users should inform the Environment Agency of the following broad categories of events:-

I. Events involving radioactivity which lead to the closure for all work, even if temporarily, of any working area (e.g. a laboratory) unless monitoring of the area conducted promptly afterwards shows that no contamination has occurred.

ii. Spillages in any area where radioactivity is not normally used. In particular any areas to which the public has access (e.g. a hospital or university corridor).

iii. Spillage which results in the creation of a waste stream for which the user has no authorised disposal route or for which an abnormal decay period is required prior to disposal.

iv. Spillage which results in the creation of a quantity of radioactive waste which is substantially in excess of the normal amount of waste created.

v. Spillage which results in any abnormal or special precautionary measure being taken e.g. removal of workers clothing (other than protective overalls, gloves etc) for decontamination, need for extensive decontamination of personnel or laboratory fittings etc or removal of laboratory furniture for disposal.

vi. Losses of effluent from leaking or blocked drain systems where the consequences are as described in (I) to (iv) above.

vii. Any fire or explosion involving radioactive material.

viii. Any relevant event reported to any other authority (e.g. HSE) or made public.

The following events are regarded as ones which would <u>not</u> normally require notification.

i. Spillage of small amounts of radioactive liquid in a laboratory bench tray designed to contain the liquid, where the disposal of any waste created takes place either as liquid to drain or as solid waste (tissues etc) within the normal authorised limits.

ii. Minor contamination of toilet facilities in nuclear medicine departments where this does not lead to closure of facilities on the day following the event.

iii. Minor contamination of laboratory surfaces, e.g. sink areas, where contamination can reasonably be expected and it is easily removed.

NOTE

Inspectors may wish to draw the attention of users to the possible need to inform other regulatory bodies (e.g. HSE, DfT) of relevant events.

7 GUIDANCE ON RETENTION OF RECORDS REQUIRED BY RSA93 CERTIFICATES OF REGISTRATION AND AUTHORISATION

1 Introduction

1.1 The following is guidance to inspectors on the length of time for which users should be required to retain records. It is not prescriptive. Users may keep such records as hard copy or in electronic form.

1.2 Certificates of registration and authorisation issued by the Agency under RSA93 require the user to keep records of receipts, holdings and removals of radioactive materials, and records of accumulations and disposals of radioactive wastes. No limit is set on the period for which these records must be retained - the certificates require that they be kept until the user is notified in writing by an authorised person [i.e. an Agency inspector authorised under s.108 of the Environment Act 1995] that they can be destroyed.

1.3 When an existing certificate for premises is revised (by cancelling or revoking the old certificate and issuing a new certificate), a standard condition in the new certificate requires the user to retain the records that were required under the old certificate. A notice under s20 of RSA93 may be served on any person to whom a registration relates or who holds an authorisation requiring him to provide or retain copies of records after he ceases to carry on the relevant activities, or to furnish the Agency with copies of records in the event of the registration or authorisation being cancelled or revoked. It is not believed that s20 enables the Agency to request the (former) user to retain records after final cancellation or revocation. If we want long-term retention after final cancellation/revocation we should require copies of the records before we cancel certificates and retain them ourselves.

1.4 It is at the **inspectors discretion** whether to allow destruction of records, and the inspector should only do this if he is satisfied with the information they contain, and that there is no longer a requirement for that information. In accordance with the standard certificate conditions, **the user** must not destroy records except with the Agency's written agreement.

1.5 The following guidelines are considered to represent a pragmatic approach, taking account of the following principles:

i. records should be retained, for audit purposes, for the entire period from one inspection visit to the next;
ii. where records relate to contaminated land, including potentially contaminative disposals of longer-lived radionuclides to drain, records need to be retained permanently. (Contamination on a site is often associated with a use of radioactive material many years in the past. In those circumstances, the Agency has found that investigatory work is greatly assisted where relevant records are available).
iii. records for landfill disposal of radioactive waste should be kept for long periods; and
iv. there should be no need to keep large volumes of minor documentation indefinitely.

2 Retention Guidelines

2.1 It is re-emphasised that the guidance is not prescriptive. Inspectors may decide that other retention periods are warranted in the circumstances of specific cases. **In particular**, small disposals (such as those from the use of a few radioimmunoassay kits) and/or radionuclides of low radiotoxicity (e.g. carbon-14, tritium) or short half-life (e.g. technetium-99m, gallium-67, thallium-201) may not warrant indefinite retention of records.

2.2 Records of the use of radioactive substances in **environmental tracer tests** registered under s.10 of RSA93: to be retained indefinitely.

2.3 **All other records** of **source acquisitions, holdings and removals** kept in accordance with certificates of registration under sections 7 and 10 of RSA93: 4 years after the date at which the radioactive substances was removed from the premises or became radioactive waste.

2.4 Records, required by certificates of authorisation issued under ss.14 and 13 of RSA93, for **accumulations and disposals** of radioactive waste:

Type of record	Retention Period
Accumulation	4 years from the date on which the waste was disposed of.
Disposal of long-lived radionuclides, except carbon-14 and tritium, in liquid waste to drain	Indefinite
Disposal of low-level waste to landfill for burial at a specified location	Indefinite
Disposals of small quantities and/or disposals of radionuclides of low radiotoxicity or short half-life.	4 years from the date on which the waste was disposed of.
All other disposals	4 years from the date on which the waste was disposed of.

2.5 **Records of radiation and contamination surveys.** While these are not prescribed by certificates of registration or authorisation issued under RSA93, they can help to demonstrate that there has been no unauthorised accumulation or disposal of radioactive waste. Survey records may therefore be requested during an inspection of a premises. Normally, an inspector would expect to see records of the most recent survey (representing the current state of the premises) together with records of surveys during the preceding year (representing any trends, and demonstrating that any necessary decontamination work had been carried out).

2.6 **Records of Incidents.** Users should be expected to retain these for an indefinite period, as these may prove to be particularly important in terms of reassurance at a future stage.

8 USE OF GROUPS OF RADIONUCLIDES IN REGISTRATIONS AND AUTHORISATIONS

1 Introduction

This guidance concerns the extent to which radionuclides should be expressed in terms of groups in certificates. Specifically it gives the groups to be used in most hospital authorisations.

When deciding the degree of specificity for radionuclides in certificates, consideration should be given by the Agency to:

(1) what the applicant applies for;

(2) the relative hazard of the radionuclides involved;

(3) the need for the operator to have conditions and limits within which he can straightforwardly conduct his operation and against which the inspector can check compliance;

(4) operational flexibility such that we do not involve ourselves in changing certificates at frequent intervals to cater for the introduction of new (often relatively less hazardous) radionuclides (e.g. phosphorus 33, iodine 123);

(5) a total aggregate discharge limit which is not excessive e.g. by not specifying a large number of radionuclides with individual limits with contingency for each;

(6) the needs of the Pollution Inventory for the reporting of releases.

2 Registrations – open sources

Where a single or a few radionuclides dominate the usage they should be individually specified. All alpha emitting radionuclides should be individually specified. Where small amounts e.g. a few megabecquerels of similar radionuclides are used for convenience and to give flexibility, it is possible to register these as a group. For example, where up to 10MBq sulphur-35, 5 MBq iodine-125 and 15 MBq phosphorus-32 are to be used, the application could refer to these as "beta/gamma emitting radionuclides, maximum activity 30 MBq". However, whilst a registration may be granted in the terms of groups that you suggest, it is helpful to obtain full information about the proposed level of use and individual radionuclides.

3 Registrations – closed sources

If users intend to hold several sources of the same radionuclide with approximately the same activity they can be described together as a group, referring to the maximum activity of an individual source. (For example, Caesium-137, three sources, maximum activity for each 100 megabecquerels would cover sources of 75, 85, and 95 megabecquerels activity.)
There is no need to include radionuclides which are present as a result of radioactive decay of the listed radionuclides.

It is appropriate to consider the maximum number of sources that users reasonably expect to hold in the foreseeable future (ie the next 1-2 years). If users want to hold large numbers of relatively small sources, you can opt to register them as a group. (For example, beta/gamma emitting radionuclides, alpha emitting radionuclides.) However, it is often helpful to obtain as much information as possible about the proposed individual radionuclides intended to be used. The maximum activity of any single source in a group must not exceed the HASS threshold (see Environment Agency HASS guidance annex) for that radionuclide.

4 Authorisations

For authorisations the groups could be different for each of the disposal routes.

Specifically for most hospital authorisations, liquid discharge limits should normally be expressed in terms of the following groups:

(i) **Technetium-99m;**

(ii) **Iodine radionuclides** i.e. I-123, I-125, I-131 (where there is significant relevant diagnostic or therapy work);

(iii) **Tritium and carbon 14** (rarely referred to separately for hospitals - only used if the activity is significantly larger than the remainder included in (iv) below);

(iv) **Other radionuclides except alpha-emitters (in total)**

In any radiological assessment, operators should be expected to justify their proposals in terms of the most hazardous radionuclides likely to be present in these groups.

It is considered this advice will best satisfy the various requirements mentioned above, enable the Environment Agency both to regulate properly the operators' activities, and give an equitable basis for charging. It will not overly penalise an operator for introducing a new radionuclide which has similar or less hazardous properties to the one which he has already considered in his assessment.

9 **RSA 93 RECORDS OF CONVICTION**

SI 1992 No 1685 (The Radioactive Substances (Records of Convictions) Regulations 1992) specifies records to be made available to the public, for the purposes of section 13A(1)(d) of RSA60. These regulations continue in force as if they were issued under section 39(1)(d) of RSA93.

The records specified in relation to each conviction are the offence, the name of the offender, the date of conviction, the penalty imposed and the name of the Court.

The Agency has received directions made under section 25(1) of RSA93 which state that all information contained in or relating to applications/registrations in relation to sealed sources under sections 7 and 10 of RSA 93 is to be withheld from public registers. There is a separate direction which provides that all information contained in or relating to applications/authorisations made by/issued to HM Revenue and Customs under sections 13 or 14 is to be withheld from public registers . The information prescribed under the Radioactive Substances (Records of Convictions) Regulations 1992 is information relating to such registrations/authorisations, and should therefore be withheld.

Current Agency policy is for the information relating to sealed sources and sections 13/14 of RSA93 to be withheld also. A direction is being sought from Defra – if relevant seek additional guidance from RSR Process.

While neither RSA93 nor the Records of Convictions Regulations require that the records are given to the local authorities, paragraph 11 of DoE Circular 22/92 (Welsh Office Circular 43/92 for Wales) states that the records will be sent by the Agency to those local authorities who were (or should have been) provided with a copy of the certificate (of registration or authorisation) connected with the infringement.

When sending the records to the relevant local authorities reference should be made in the covering letter to the DOE/ Welsh Office Circular especially paragraphs 11 and 12 and confirm (where appropriate) that no convictions relate to individuals and thus that the complete records are requested to be kept available for public inspection.

10 GUIDANCE ON STANDARDS FOR RADIOCHEMICAL LABORATORIES IN NON- NUCLEAR PREMISES

1 Introduction

1.1 This section provides guidance to Inspectors on the key considerations, from the Agency's perspective, for laboratory facilities on premises where open radioactive sources are kept and used.

1.2 This guidance focuses on radioactive waste management implications. It does not specifically cover radiation safety and the protection of workers on a premises, which may give rise to additional requirements such as radiation shielding. However, nothing in this guidance should conflict with any occupational safety considerations, e.g. those in the Ionising Radiations Regulations 1999. As the matters dealt with in this note are of common interest to the Agency and HSE, Inspectors should consider liaising with colleagues in HSE on specific cases.

1.3 By its very nature, any use of open sources is dispersive to some extent, and there will inevitably be arisings of radioactive wastes which will need to be managed. There is a general expectation that any radioactive waste which is generated is of such a type and quantity that it can be disposed of by an available route. Specifically authorisations contain conditions covering:

a. minimisation of creation of radioactive waste,
b. prevention of loss or escape of radioactive waste,
c. prevention of unauthorised access,
d. prevention of contamination of the premises, and
e. easy decontamination of the premises

1.4 This guidance is neither prescriptive nor exclusive, and there may be other appropriate means of compliance in specific circumstances. It is not a detailed design guide, and users should be expected to consult relevant publications on laboratory design and to take appropriate advice before constructing a new radiochemical laboratory. BS4247 on surface materials for use in radioactive areas may be a useful source of additional information.

1.5 The benchmark for the standards given in this guidance is a new radiochemical laboratory. **Inspectors should always have regard to the criterion of reasonable practicability/best practicable means where relevant; therefore additional flexibility may be appropriate where any of the following are involved:**

- existing facilities; or holdings only of less radiotoxic nuclides such as tritium, carbon-14 or technetium-99m; or
- minor usage, such as a few radioimmunoassay kits; or
- one-off (as opposed to continuing) uses.

2 Floors

2.1 The floor should be covered with an impervious surface such as a **continuous** sheet of PVC or linoleum at least 2.5 mm thick. The covering should be coved to the walls to a height of about 15 cm contiguous with the floor surface. All edges at the walls should be sealed or welded to prevent seepage of spilled materials. Coving should be used to prevent contamination from seeping into floor level service voids behind false walls. If service voids are likely to become contaminated then they will also need impervious services.

2.2 Joints between flooring sheets are not recommended, but may be permitted if the joints are welded and inspected to ensure the absence of a seepage path for contamination.

2.3 Any special requirements of the flooring should be taken into account when deciding what to install. For example: Use of liquefied gases may require special floorings able to withstand cold. Non-slip material is difficult to decontaminate, but when considering its installation a number of factors should be taken into account; the vulnerability of the site to slips, whether or not large quantities of long-lived radionuclides are to be used, and the potential doses that could arise from an area of fixed contamination. Epoxy resin coatings are likely to be suitable for facilities subject to heavy loads and low risk of contamination.

3 Walls and Ceilings

3.1 The walls and ceilings should generally be smooth and painted with a hard gloss or high quality waterproof vinyl emulsion to facilitate cleaning. (BS 4247 Part 2). The use of stippled surfaces or a paint finish applied to unplastered concrete blocks is undesirable.

3.2 A note of caution: many paints undergo chemical or physical reactions with certain radionuclides. A more important criterion may therefore be the ease with which the paint can be stripped off again rather than its cleaning properties. A known problem occurs with chloride ions which may bind irremovably with painted surfaces.

3.3 Suspended ceilings may potentially cause problems due to penetration of contamination.

3.4 Joints should be sealed or filled with silicone type materials to facilitate cleaning (or removal in the event that decontamination cannot be achieved). Service penetrations in walls and ceilings should be sealed and coved.

4 Doors and Windows

4.1 Wooden surfaces should be covered with plastic laminate material or painted with a good quality polyurethane gloss paint or varnish. See 3.1 and 3.2 above.

4.2 Security of keeping radioactive materials is essential - see the Agency guidance on HASS (relevant to sealed sources) and the NaCTSO Security

Requirements Book (available from CTSAs and relevant to open and sealed sources).

4.3 Where opening windows are fitted, care should be taken that no persons will be affected by any release of radioactivity immediately outside. Open windows should not be used as intentional discharge routes.

5 Benches

5.1 Working surfaces should be smooth, hard and non-absorbent and have appropriate heat and chemical resistant properties. All gaps and joints should be sealed with a silicone type material. Account may need to be taken of the problems involved in decontaminating certain materials used for bench surfaces. For example: Corrian apparently binds iodine (e.g. I-125) in several chemical forms; Melamine fixes sodium ions (e.g. Na-22) under some conditions; stainless steels may bind phosphate (e.g. P-32) or chromium (e.g. Cr-51) firmly and may be very difficult to decontaminate).

5.2 The bench tops should be coved (up stand) at the rear against walls. Gaps should be sealed with a silicone type material. Bench tops may also have rounded front edges (lipped) so as to give fewer entry points for contamination - although some users feel this increases the likelihood of spills on to the floor, as the operator may misjudge where the flat surface of the bench finishes. Some bench top designs have a raised front lip which can help prevent a spillage running off the bench on to the floor.

5.3 Exposed wood, including under benches and under bench cupboards, must be painted with a good quality hard gloss paint or polyurethane varnish or laminated. The use of wood surfaces should be avoided on all laboratory designs.

5.4 Users should carry out inspections to ensure that cracked surfaces are repaired or painted as appropriate.

5.5 Dedicated areas of bench should be set aside for radioactive work and be clearly delineated. It is good working practice to work in plastic or metal trays on bench tops - and, especially, in dispensing / preparation cabinets where larger quantities of activity are involved - to minimise spills and spread of contamination. Disposable absorbent coverings such as Benchkote may similarly be useful - but as a supplement to, rather than instead of, proper bench surfaces.

6 Waste Disposal Sinks and Drainage Pipes

6.1 Sinks for the disposal of radioactively contaminated aqueous liquid waste should be constructed of suitable material: for most applications, stainless steel is preferred. Where possible, combined sinks and draining boards should be used, with rounded front edges and coved (up stand) at the rear against walls. Ideally an easily decontaminable rear splash plate should extend a reasonable distance up the wall behind the sink. Side splash guards may also be useful.

6.2 Drainage system materials should take into account the possible build up of contamination on surfaces. **NB.** All drainpipe materials may retain specific

radionuclides. Vulcathene and PVC fix iodine very strongly - which may be significant where the radioiodines have to be disposed of through drains of this material. Phosphate ions may bind strongly on to stainless steel, and this may cause problems in laboratories where P-32 is used in quantity. Borosilicate pipework may be appropriate in some circumstances.

6.3 Small diameter U-shaped or bottle traps should be used, instead of large traps or catch pots, so as to avoid accumulations of radioactive sediments.

6.4 The drain should be connected as directly as possible to the main foul water sewer leaving the premises. Holding tanks are generally undesirable in terms of sedimentation, but may be used by some industries for other reasons - such as confirming compliance with chemical discharge consent conditions. The discharge route should be mapped and recorded for future reference in case of maintenance on the system.

6.5 Drainage pipes for radioactive effluent should be labelled with the ionising radiation symbol up to a point at which their contents are diluted substantially with frequently-flowing, non-radioactive effluents. This is to alert maintenance staff and thus prevent unauthorised disposal of any contaminated pipes removed during maintenance work. Pipes should be well-supported along a suspended run, should be down-sloped to prevent accumulations of radioactivity, and, where reasonably practicable, should be made accessible - for example by the use of demountable panels - and subject to periodic inspection so as to assure their integrity.

6.6 The possible need for decay storage of liquid waste before discharge may need to be considered in some cases. See the Agency guidance on BPM in RASAG.

7 Ventilation and Containment

7.1 Most dispensing or preparation of radioactive materials is unlikely to cause airborne contamination. If that is a risk, such work should be carried out under conditions to prevent dispersal of the substances. In particular, volatile radioactive materials should never be used in the open laboratory, only in appropriate containment such as a fume cupboard. Recirculating ventilation systems may be inappropriate for volatile radioactive materials.

7.2 General dilution ventilation (air circulation) should be provided in all radioactive laboratories. Where small quantities of radioactive materials are used, this may be provided using an extractor fan mounted in a window or a wall.

7.3 Where larger quantities of radioactive materials are used, a guiding principle for effective control of contamination is that air movement should be maintained from less-contaminated areas to more-contaminated areas. This may be achieved for example by extracting from a general laboratory area through a fume cupboard to a discharge stack.

7.4 Inspectors should note that the balancing of an extract ventilation system having a number of ducts, dampers and inlet points, so as to achieve design airflow rates, requires considerable skill and expertise. Alterations to damper settings by unskilled operators are therefore generally to be deprecated.

7.5 A contained work station (microbiological safety cabinet or fume cupboard) should be used for dispensing or manipulation of large quantities of radioactive materials. Adequate ventilation by continuous movement of air into the work station should be checked regularly, preferably by measurement with an anemometer. Airflow criteria for fume cupboards are specified in BS 7258.

7.6 Fume cupboard internal and external surfaces should be smooth, hard and non-absorbent and have the necessary heat and chemical resistant properties.

8 Radioactive Storage Facilities (Including Waste)

8.1 Adequate storage space should be available to keep essential equipment in order to minimise the cluttering of equipment near working areas, and reduce the risk of spreading contamination. It may be desirable to have an area set aside for the storage of equipment awaiting decontamination.

8.2 All refrigerators / freezers, and radioactive materials within them, should be easily identified (labelled) and should be lockable and should be kept locked unless they are under surveillance, especially in large general laboratories. Refrigerators / freezers should be regularly defrosted. It should be noted that volatile radionuclides, in particular tritium, may accumulate in the ice: it is good practice for the user to check this periodically.

8.3 Waste disposal bins in the laboratory (used for storing solid waste awaiting disposal) should be constructed of a material which is robust, and preferably should be foot-operated. The lid should be closed when not in use and the contents in the bag sealed or secured before removing them from the bin. All sharps, bottles, tubes, etc should be placed in sharps containers to ensure safe handling of the materials. Bins located outside the control of the user must be secure to prevent misuse of the contents.

8.4 Adequate storage space (e.g. a bunker or store room) should be available for radioactive waste either inside or outside the laboratory. Consideration should be given to the security of storage. The storage space must be kept locked and may need to be under surveillance. See also guidance on waste accumulation in RASAG chapter 2.

9 Other Facilities

9.1 Adequate **decontamination facilities**, including decontamination solutions, should be available. Decon (and Radiacwash etc.) is principally useful where heavy metal contamination is present, as its special properties are in solubilising poorly soluble metals. In other circumstances, its performance may be similar to other phosphate free detergents. For most labs only the ordinary detergent used for washing up and liquid soap for hand washing should be needed, although certain other more specialist cleaning agents may be used for special purposes. It is important that some of the old-fashioned laboratory cleaning agents such as chromic acid and permanganic acid are never used in radioactive areas (risks of fire, explosion and volatilisation of radioactive materials). More aggressive decontamination

agents should normally be held centrally as they require specialised knowledge to use them properly and safely.

9.2 A **contamination monitor** should be available and it must be appropriate for the type of radionuclides used in the laboratory. Indirect monitoring (by liquid scintillation counting of swabs taken from surfaces) may be needed for soft beta emitters such as carbon-14 and (almost always) tritium. Records demonstrating that instruments are checked before use and are calibrated are required. A log book should be available to show that the laboratory is regularly monitored (benches, sinks, floors, drainage traps and equipment), that the results are recorded, and that any necessary decontamination is carried out.

9.3 **Tacky mats** may usefully be installed in laboratory doorways, to prevent the spread of contamination. Monitoring of these mats may give early warning of a contamination problem.

9.4 A designated **hand wash basin** should be provided: it must never be used for the disposal of radioactive substances (other than traces from the washing of hands).

9.5 **Warning signs**, clearly and legibly marked with the word “Radioactive”, with the Ionising Radiation symbol conforming with BS3510: 1968 or ISO 361, and any other information necessary (contact person, telephone number, etc), should be placed on doors, cupboards, equipment, refrigerators, working areas, drainage pipes, sinks, storage facilities, sewers, exhausts as appropriate. An indication of the maximum holdings in the laboratory may usefully be included on the sign placed on the door. Warning signs should only be used when there is a real possibility of contamination: in particular, indiscriminate use of radioactive warning tape should be avoided. Generally, ancillary items such as pens and books should not be used where there is a possibility of contamination and therefore should not require warning signs.

9.6 Adequate **lighting** should be provided throughout the laboratory, particularly to enable operators to see spillages easily.

9.7 Particular considerations apply to users who handle **tritium in quantity**. Although this is a rather specialised field affecting relatively few users, nevertheless Inspectors may find it useful to be aware that tritium may be readily converted to tritiated water, which when allowed into the working environment moves with atmospheric water vapour. It is taken up by most common materials - wood, paper, clothing - and this can make them impossible to decontaminate. It is the usual practice for a facility handling large amounts of tritium to be separate from other buildings to prevent the spread of radioactivity beyond the controlled area, and to allow any escape to be diluted by the outside atmosphere. Particular attention should be given to the design of the equipment and facilities, with specialist advice sought where necessary.

11 RADIOACTIVE MATERIAL IN SCRAP METAL

1 Introduction

1.1 This section provides guidance on dealing with incidents involving the discovery of radioactivity in the scrap metal reclamation industry. It is directed at Managers, Team Leaders and PPC/RSR Officers enforcing the Radioactive Substances Act 1993 (RSA93) and who have the necessary competences to do so. Separate guidance is available on the Easinet for Environment Officers in the form of a quick guide and e-learning package.

1.2 There is international concern over the incidence of radioactive material being detected in the scrap metal industry.

1.3 The industry has reacted to this - they have no wish to have contaminated feedstock. Some bigger operators have fitted lorry monitors which will detect very small amounts of activity in consignments arriving at their yards; others have equipped themselves with portable monitors. In parallel with these developments, a poster was distributed some years ago throughout the industry with the assistance of the British Metals Federation (now the British Metals Recycling Association (BMRA)) and this warned operators of what to look out for and the action to take. A follow-up campaign is being planned.

1.4 **We do not attend the scene of a radiation incident in a scrap yard. A change from this position requires the agreement of the RSR-Duty Tactical Manager.** We contribute to the response through strategic advice. Additional information on the Agency's Radiation Incident Management system is available on the Easinet. In practice the Agency may be contacted when an item bearing the radiation trefoil is located, or radiation is detected by a fixed or hand-held monitor. Reporting can be made via the Agency's hot-line number 0800 807060. The Agency cannot provide an emergency service in the context of making safe, recovering sources or remediating contaminated facilities/land, and this should be made clear to any enquirer. BMRA has issued guidance to operators through its Health and Safety Manual and has made arrangements for RPA advice to be available to operators.

1.5 Annex A provides a description of types of incident which have been encountered and the consequences.

1.6 It is important that each incident is reported to the RSR DTM.

2 Statutory requirements

2.1 The Agency is responsible for enforcing the provisions of RSA93. Inspectors should note that there are other statutory requirements enforced by separate regulatory authorities, which may need to be observed - in particular the Ionising Radiations Regulations 1999 (enforced by HSE) and The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2007 (which superseded the Radioactive Material (Road Transport) Regulations 2002) (enforced by DfT). Those regulatory authorities should be informed and consulted during the progress of an incident, as appropriate.

2.2 An authorisation is required to accumulate (s14) and to dispose of (s13) any radioactive waste (unless this is exempted under an exemption order - see below). However, when a scrap yard operator inadvertently and unexpectedly acquires a radioactive source and is prepared to dispose of it promptly in the proper way, it is often not practicable or reasonable to issue an authorisation. To insist on authorisation in these circumstances carries the risk that the Agency would not be informed when such sources are found and that they would be disposed of irresponsibly. In such circumstances no authorisation should be issued (unless specifically applied for). Instead, the letter at Annex B should be used and there will be no charge to the operator.

2.3 Where an operator does apply for authorisation it should be determined in the usual way. Authorisation should certainly be required where an operator conducts his business so that there is a probability of him recovering a radioactive source, for example where an operator offers a service to other scrap yards for storage and /or disposal of sources.

2.4 Unless there is clear evidence to the contrary, registration under s7 of the Act is not deemed necessary since the operator is construed to not be using or keeping radioactive material in the course of an undertaking, and any items should be regarded as radioactive waste (as opposed to material) in view of their prior disposal.

2.5 **Exemption Orders – see also separate guidance on exemption orders in RASAG**

Waste in the form of a sealed source

Under the terms of the Radioactive Substances (Waste Closed Sources) Exemption Order 1963 (SI 1963 No 1831), radioactive waste consisting of a sealed radioactive source may be disposed of without the need for an authorisation to be issued under RSA93 - either to a manufacturer or supplier of sources or to a person who is authorised under section 13(3) of RSA93 to receive such waste.

Solid waste not in the form of a sealed source

In this instance, two exemption orders are relevant:-

(i) The Radioactive Substances (Substances of Low Activity) Exemption Order 1986 (SI 1986 No. 1002) sets an exempted limit of 0.4 Bq/g for the sum total of all man-made radionuclides taken together.

(ii) The Radioactive Substances (Phosphatic Substances, Rare Earths etc) Exemption Order 1962 (SI 1962 No. 2648) provides an exempted limit of up to 15 Bq/g for each of the following natural radioactive elements - that is, in each case, for the sum total activity of all radioactive isotopes of that element that may be present: actinium, lead, polonium, protactinium, radium, thorium and uranium.

It should be noted that both of these Exemption Orders require the waste to be substantially insoluble in water. Also, they do not specify the quantity of waste over which the activity concentrations are to be averaged; this is

something on which an Inspector will have to form a judgement in the circumstances of the specific incident, so as to agree appropriate averaging criteria which will provide assurance that no hazardous hot spots are present.

3 Action by Inspector

3.1 **Operators must not be discouraged - indeed, just the opposite - from reporting any occurrence to the Agency. Inspectors should be sympathetic to scrap metal industry operators who discover radioactive material in consignments and should see this primarily as an opportunity to (a) secure proper disposal and, (b), if possible, identify the culpable person and apply the Agency's Enforcement and Prosecution Policy.**

3.2 When the Agency is informed of a discovery at a scrap yard, the Inspector should determine as much detail as possible over the phone regarding

- the physical nature of the item,
- the results of any measurements taken,
- the location of the item at that moment,
- the condition of the item if known,
- any plans the scrap yard has for dealing with the item (eg returning it to the originator),
- from where the material has come.

3.3 In respect of danger to the public and workers, he should advise the operator to seek advice from an RPA. The BMRA has made arrangements with its RPA service to provide advice. **In <u>extreme circumstances</u> where the general public may be at risk, Inspectors may advise the police to summon assistance through the NAIR (National Arrangements for Incidents involving Radioactivity) arrangements. Details are given in the NAIR handbook published by HPA and available on the HPA web site.** If the Inspector is in any doubt about this, advice should be sought either locally or from the RSR Duty Tactical Manager.

3.4 The Inspector should immediately inform the relevant Health and Safety Executive office in accordance with the EA/HSE MoU, and provide the details as at paragraph 3.2 above.

3.5 The site should not be visited during the incident stage except with the agreement of the DTM. A subsequent visit to conduct an investigation into the circumstances would normally be appropriate.

3.6 The duty of assessing the radiological situation rests solely with the site operator. If the Inspector does undertake any monitoring, it is purely to confirm the operator's initial findings and no more. If initial monitoring reveals that gamma-emitting radioactive material is present <u>in a load of scrap which is still on a vehicle at the receiving premises</u>, the operator should be advised that an examination should be undertaken in accordance with the following guidance.

(a) The vehicle should be taken immediately to a secure location at the receiving premises;

(b) Once the vehicle is secured, the load should be investigated by a competent person to determine the exact location of the activity and the physical condition, particularly regarding the integrity of the containment, of any radioactive material which may be present;

(c) If the containment of any sealed source is undamaged, it may be removed from the load in accordance with procedures complying with the Ionising Radiations Regulations 1999 (IRR99) and the remaining part of the load may be processed as normal, provided it has been shown to be uncontaminated. If the source is damaged, it should not be moved except in accordance with the advice of an RPA.

3.7 The favoured course of action is to retain the source or contaminated material within a system of control, either by way of authorised disposal or, in the interim, by storage in a suitable secure location until disposal is arranged - and advice should be given to this effect. If, however, the operator decides to return the item(s) to the consignee, he should be advised that :

(a) transport of the item (either to a store located at other premises or by return to the consignee) must be in accordance with the relevant road transport Regulations and the advice of a competent person (or DfT) must be sought by the operator, and

(b) the Agency should be informed of the address to which it has been returned.

3.8 In both the cases described in paragraphs 3.6 and 3.7, the onus is on the person(s) in control of the premises and/or the load, and not the Agency, to:

(a) arrange for a competent person to survey any suspect load,

(b) determine the address for the return of any radioactive material and/or, where necessary, a suitable site for the disposal of any radioactive waste.

3.9 The Inspector should write to the operator to confirm that he has noted the occurrence, the nature of the contamination, and the action taken by the operator (e.g. stored pending disposal - in which case send letter at Annex B, return to a (named) site, etc).

3.10 Where the load, or item, has been returned to another location, the Inspector should contact an Inspector in that Area in order to make enquiries so that proper disposal is ensured. If that particular consignor returns it to a previous customer, then enquiries will need to be made down the line - with letters as at paragraph 3.9 being sent as appropriate.

3.11 Inspectors involved in an incident should promptly notify the RSR DTM of the nature of the offending material, any analyses or measurements made, and the fate of the material. When detailed information is available, the Inspector should submit a completed form giving the required details for the Agency's HASS database (where relevant) and the HPA/HSE/Agency

Ionising Radiations Incident Database (IRID) (Contact RSR Process over IRID).

3.12 Inspectors should investigate any incident as thoroughly as possible to determine (a) the origins of the material/source and (b) who may be culpable. Areas have Environmental Crime Teams who may be able to assist in investigations.

ANNEX A

(para 1.5)

TYPES OF INCIDENTS

A.1 Sealed Sources

Sealed radioactive sources have been used for many years in industrial applications and subject to registration under the Radioactive Substances Act 1993 (RSA93).

Despite rigorous systems of regulation, there is a possibility that the control over such a source may break down. This has come to the fore when an industrial plant has been closed down and is being demolished, and a radioactive source may be included inadvertently in the scrap metal arisings. Examples known to us are as follows:

a. A caesium-137 source was inadvertently processed at a steelworks in Europe and the baghouse dust pellets, being rich in heavy metals, were sent to a lead-zinc smelter for recycling. Routine monitoring at the smelter revealed that the dust was contaminated with caesium-137. Considerable effort was required to decontaminate the site and dispose of the waste; it is estimated that the total cost was in the region of £0.5 million.

b. A demolition contractor found two level gauges containing radioactive sources at an iron foundry.

c. There have been a number of occasions when mobile radiography source holders containing depleted uranium (but empty of the iridium-192 source) have been reported to us by scrap yard operators. There have also been some incidents where thorium-hardened magnesium alloys have been found in scrap.

d. Old artifacts containing radium-226 are detected at scrap yards; these may be luminised items, valves, etc of mainly military origin, or dating back to the historic marketing of health-aids.

A.2 Mining, oil and natural gas industry waste

Radioactive material may be present in scrap metal associated with the mining, oil and natural gas industries, where natural radionuclides from the uranium, actinium and thorium radioactive decay series may deposit preferentially in mine drainage pipes and in parts of the processing and distribution systems for oil and gas. This problem is well known in the North Sea oil industry, regarding contaminated tubulars, and in the natural gas distribution industry regarding filters, where steps are routinely taken in both cases to control disposal. The main contaminant in

these instances is radium and daughters. While the total activity present may not be large, the material may be dusty and give rise to a potential problem of loose contamination.

A.3 Imported scrap

Recipients of imported scrap metal need to take care in regard to consignments originating from developing countries and Eastern Europe - where standards of control may not be as rigorous as those in the UK. This may involve both natural and man-made radionuclides, either as sealed sources or as contamination. Serious incidents involving the loss of large sources are known to have occurred in the past, e.g. at Juarez (Mexico) and Goiania (Brazil) in the 1980s: the former incident resulted in the smelting of a cobalt-60 source and export of contaminated steel to the United States.

A consignment of copper-nickel heat exchanger tube scrap was been imported from Eastern Europe by a non-ferrous metal company, and was suspected to be contaminated. The cut and crimped tube had already been melted and cast into ingots which were in transit to foreign customers. The dross from the melting operation was awaiting resmelting; although these were contaminated, they had already been diluted in a larger stockpile, and it was agreed that this could be resmelted. Metallurgical samples, which the company routinely retained from ingots despatched to customers, were free of contamination. Of note in this instance was the contamination of the furnace lining and on the floor area where the scrap had been stored. There has been a similar occurrence, more recently, where copper dross with caesium-137 and cobalt-60 contamination was detected and returned to the foreign exporter.

A.4 Fate of radionuclides

An appreciation of the fate of radionuclides in the re-processing of contaminated waste is important. The steel industry have a good knowledge of this in respect of steelmaking and have offered advice on request; RSR Process can facilitate this.

In the examples given above, two outcomes are likely depending on the radionuclide involved, whether it is volatile, and/or whether it alloys with other materials. In the case of the Mexican cobalt-60 incident, the cobalt alloyed well with the steel; conversely, radium-226 does not and partitions, but not totally, into the slags and drosses. Caesium is volatile (BP = 690^{0}C) and condenses out in off-gases onto particulates; baghouse dust has been found to contain 200 Bq/g whereas the raw scrap contained only 20 Bq/g.

ANNEX B – see para 2.2

LETTER TO OPERATOR

Arrangements for Disposal of *[describe source]*

Thank you for letting us know that *[...describe circumstances e.g. you have taken delivery of (describe source) from (recipient), in order to secure its safe disposal, or radioactive material has arrived at your site as part of an incoming load and you are storing it in order to secure its safe disposal]*.

We note that you are proposing to dispose of the source by way of *[describe disposal route]*, pending which you are storing the source *[describe interim storage arrangements, if relevant]*.

We agree that these are appropriate *[storage and]* disposal arrangements, and that in the circumstances of this case, no *[authorisation / registration / variation of your existing authorisation / registration]* under the Radioactive Substances Act 1993 is called for.

You expect to pass on the source to *[recipient]* by *[date]*. Could you please write to me then, confirming for our records when you passed on the source. If in the event you need to hold on to it for longer, we may need to ask you to apply for a *[authorisation / registration / variation of your present authorisation / registration]*.

Thank you for being prepared to arrange for the safe disposal of this source.

12 GUIDANCE ON THE INTERACTION BETWEEN RSA93 AND OTHER WASTE LEGISLATION

Radioactive waste which is the subject of an authorisation under RSA93 does not fall within other, conventional waste legislation. We can include conditions about those other non-radioactive characteristics and their environmental management in RSA93 authorisations - especially if we thought that problem owners were using a waste's nominal radioactive content to avoid their other obligations.

However, waste disposed of under an exemption order does not escape regulation under other regimes. Neither does waste which is not, by definition, radioactive.

Waste which is radioactive should not be designated as hazardous merely because of that radioactivity - but its other characteristics might make it so.

13 GUIDANCE ON USE OF BEST PRACTICABLE MEANS FOR NON-NUCLEAR RADIOACTIVE WASTE

1 Summary

1.0 This guidance covers circumstances where the objective is to minimise radioactive waste creation and disposal resulting from work activities which intentionally and necessarily use radioactivity as a part of the process. Cases will arise when the issues are not so clear cut, for example during decommissioning of premises previously contaminated with radioactivity and in the incineration of radioactive waste. However, in these cases the same general principles should be used to decide between the various process options available.

1.1 Objectives of BPM

BPM is a way of comparing options for process design and operation, which is intended to arrive at the lowest radiation dose to the public whilst taking account of a wide range of factors. The costs of applying BPM to a particular process should not be grossly disproportionate to the benefits derived from the process. This requires a balance of detriments in terms of radiation exposure and others, including time, trouble and money, against the benefits of carrying out some action. The hierarchy for implementation of this is for prevention of public radiation exposure due to radioactive waste to come first followed by minimisation of the impact of waste unavoidably created.

1.2 Implementation

All existing users are expected to have available for inspection, written assessments showing the considerations taken into account in reaching decisions on disposal of radioactive waste and how that constitutes the use of BPM. Any applications for new or revised authorisation under RSA 93, should confirm that BPM is being applied by the submission of a BPM Assessment with their application.

1.3 Culture

1.3.1 In order to give due consideration to BPM, it is necessary for the application of BPM to become embedded within the management and operational culture of the organisation. The consideration of BPM needs to become as much part of the way of planning and using radioactivity as is the consideration of worker dose restriction by ALARP. Ideally, both considerations should be carried out together so as to arrive at the best overall decisions, but it is recognised that this will not always be possible.

1.3.2 BPM will therefore need to be considered at many stages of the planning for and use of radioactive substances by non-nuclear users. This will often require consideration by many different people within organisations, not just those used to advising on radiation matters.

1.3.3 BPM is not a consideration restricted to a short period of time, such as when making an application under the Radioactive Substances Act 1993.

1.4 BPM/ALARA

1.4.1 BPM is intended to apply the principle of ALARA to radiation exposure of the public from creation and disposal of radioactive waste. This is not intended to encroach upon the work of HSE. The Agency will continue to work with HSE to minimise the regulatory impact on users where the interests of the two bodies overlap. In the meantime, it should be emphasised that the focus of the Agency's interests and needs is on radioactive waste management.

1.4.2 Potential conflict can arise between restriction of public exposure by use of BPM and worker exposure by ALARP. This can be avoided by the consideration of both principles simultaneously at each stage of process consideration, whenever practicable, to arrive at the process and management options which are best overall. Users should ensure that reduction of dose to the public is not at the expense of excessive doses to workers.

1.5 Judgement on BPM

1.5.1 How the final judgement on which option is BPM is arrived at is not amenable to detailed guidance at this stage. Similar decision processes are used in consideration of health and safety and industrial pollution to arrive at reasoned decisions. The costs of implementing the BPM process itself should be proportionate to the scale of production and disposal of the radioactive waste. The Agency does not propose to use any low threshold of dose below which no further consideration of BPM is required by users. However, at low levels of predicted public dose, the resources applied to BPM Assessments should be proportionately low. It is unlikely that other than very simple assessments will be necessary at very low doses, that is, those below 20 μSv per year.

2 Requirements

2.0.1 The accumulation and disposal of radioactive waste in England and Wales is controlled in accordance with the provisions of the Radioactive Substances Act 1993 (RSA93). Under RSA 93, anyone intending to accumulate and dispose of radioactive waste on premises used for the purposes of an undertaking in England and Wales requires an authorisation from the Environment Agency (the Agency).

2.0.2 Since November 2003, all Agency RSA93 authorisations have included a set of standard conditions requiring the user to use Best Practicable Means (BPM) to:

- minimise the activity in all disposals of radioactive waste;
- where authorised, minimise the volume of radioactive waste disposed of by transfer to other premises;
- dispose of radioactive waste at times, in a form, and in a manner so as to minimise the radiological effects on the environment and members of the public.

2.0.3 Further conditions require the user:

- to have a management system, organisational structure and resources to achieve compliance with the BPM conditions, including provision for consultation on BPM with suitable RPAs, or other qualified experts;

- to maintain in good repair the systems and equipment provided as part of BPM;
- to check and review at an appropriate frequency that systems remain effective in achieving BPM.

2.0.4 The use of open radioactive substances often produces radioactive waste and certificates of registration covering such work require users to minimise so far as reasonably practicable, the amount of radioactive waste which arises from the keeping and use of the radioactivity. Thus, judgements balancing costs and benefits are required to be made in the methods of use of the radioactivity, which are equivalent to the judgements required for BPM.

3 Principles of Best Practicable Means

3.0.1 The purpose of this document is to explain the concept of BPM, and how to work with it. It is intended for Agency Regulators but is also being made available to users who are authorised to accumulate and dispose of radioactive waste under RSA93. It is not intended to be detailed technical guidance about how to design or equip facilities or to be prescriptive, as the application of BPM should be proportionate to the potential environmental risk. The user is best placed to assess how to apply BPM to his or her circumstances provided that the appropriate principles are in use.

3.0.2 BPM requires operators to take all reasonably practicable measures in the design and operational management of their facilities to minimise the volume and activity of discharges and disposals of radioactive waste, so as to achieve a high standard of protection for the public and the environment. BPM is applied to such aspects as minimising waste creation, abating discharges, and monitoring plant, discharges and the environment. It takes account of a range of factors including the availability and cost of relevant measures, operator safety and the benefits of reduced discharges and disposals. If the operator is using BPM, radiation risks to the public and the environment will be ALARA. The hierarchy for implementation of this is for prevention of public radiation exposure due to radioactive waste to come first followed by minimisation of the impact of waste unavoidably created.

3.0.3 The Agency considers that many organisations that generate radioactive wastes are already using techniques of good management practice that are directly relevant to BPM. By addressing the issues of BPM, the Agency expects that the user will find that BPM is not only a tool for the regulator to use, but one which the user will find is useful in managing their radioactive wastes, and minimising their costs and liabilities.

In a non-nuclear context the Agency sees the following key issues in relation to BPM:

3.1 **Culture** – it is important that users understand the extent to which BPM should influence every decision involving production and disposal of radioactive waste, from the earliest design or planning stages to the final disposal. The principle of reducing disposals to the maximum extent without incurring excessive costs should be adopted as a way of considering all processes involving disposal of radioactive waste.

3.2 **Proportionality** – The overall costs in applying BPM to a particular process should not be grossly disproportionate to the benefits derived from the process. It is recognised that there are two aspects of this. In the first

instance the scope and process of applying BPM should be in line with the risk. The Agency would not expect to see the high levels of time, money and trouble put into identifying and applying BPM for the generation of wastes arising from the use of very small quantities of radioactivity. Secondly the technical and managerial measures which constitute BPM should also be in line with the risk.

3.3 **Decisions between options** – Organisations producing radioactive waste will need to use BPM to compare options for all aspects of process design and operation with the intention of achieving the lowest radiation dose to the public whilst taking account of a wide range of factors, including overall benefit to the public balanced against the costs and other detriments of application.

3.4 **Review** – Processes and management arrangements which represent BPM at one point in time need to be considered periodically to ensure they remain BPM in the light of developing process and abatement options.

3.5 **No threshold** - There is no "*de minimis*" level below which BPM does not apply. However, proportionality is a key principle of the application of BPM, and so at lower levels of radiological risk to the environment, the Agency would be content to see a less developed demonstration that BPM is being applied, compared to circumstances in which the risks are much higher. The primary requirement for a fully developed consideration of BPM relates to situations where the realistic dose to the critical group is between 20 μSv/y and 300 μSv/y. Operations giving rise to doses above 300 μSv will not be authorised and at doses below 20 μSv, a simpler consideration of BPM should be used to keep doses as low as reasonably achievable.

3.6 **Worker dose** - Potential conflict can arise between restriction of public exposure by use of BPM and worker exposure by ALARP. The Agency recognises that certain health and safety aspects of keeping and using radioactive materials are subject to regulation by HSE. BPM should not require reduction of dose to the public at the expense of excessive doses to workers.

4 Background to Best Practicable Means

4.0.1 In 2000 a Ministerial Direction (Radioactive Substances (Basic Safety Standards) (England and Wales) Direction 2000) was issued under the provisions of the Environment Act 1995. The Direction implements part of the EU Basic Safety Standards Directive (96/29 EURATOM).

4.0.2 One of the key issues of the Direction is the requirement that:

"the Environment Agency shall….ensure that all exposures to ionising radiation of any member of the public and of the population as a whole resulting from the disposal of radioactive waste are kept as low as reasonably achievable, economic, and social factors being taken into account".

4.0.3 The Agency believes that the requirement for "as low as reasonably achievable" (ALARA) is achieved by including BPM conditions in waste disposal authorisations that it grants.

4.0.4 The Direction provides that the Agency shall wherever practicable ensure that the sum of the radiation doses resulting from the exposure of any member of the public to ionising radiation shall not exceed the dose limits set out in Article 13. The principal dose limit in Article 13 is 1 mSv per year.

Additionally the Agency shall have regard to the following maximum doses to individuals which may result from a defined source, for use at the planning stage in radiation protection-

0.3 millisieverts per year from any source from which radioactive discharges are first made on or after 13th May 2000; or

0.5 millisieverts per year from the discharges from any single site.

4.0.5 The Agency must follow the requirements of the Direction, and no authorisations will be granted that result in breaches of these constraints due to authorised discharges.

5 Definition of Best Practicable Means

5.0.1 The definition contained within Command 2919 is as follows:

"Within a particular waste option, the BPM is that level of management and engineering control that minimises, as far as practicable, the release of radioactivity to the environment whilst taking account of a wider range of factors, including cost-effectiveness, technological status, operational safety, and social and environmental factors".

5.0.2 It goes on to say:

"In determining whether a particular aspect of the proposal (for waste disposal) represents BPM, the Agency will not require the applicant to incur expenditure, whether in time, money or trouble, which is disproportionate to the benefits likely to be derived".

5.0.3 The non-nuclear certificate of authorisation contains the following on and about BPM:

(a) In determining whether particular means are the "best practicable" for the purposes of this authorisation, the user shall not be required to incur expenditure whether in money, time or trouble which is, or is likely to be, grossly disproportionate to the benefits to be derived from, or likely to be derived from, or the efficacy of, or likely efficacy of, employing them, the benefits or results produced being, or likely to be, insignificant in relation to the expenditure;

(b) Where reference is made to the use of "best practicable means" in this Certificate of Authorisation, the means to be employed shall include:

(i) the provision, maintenance and manner of operation of any relevant plant, machinery or equipment;

(ii) the supervision of any relevant operation.

5.0.4 Appropriate management systems will need to be in place to ensure that authorisation conditions are being complied with, proportionate to the work being undertaken.

6 General Guidance

6.0.1 The application of BPM requires the consideration of options for the management, selection and operation of plant and processes and applies at all stages and in all uses of radioactivity which result in the production and disposal of radioactive waste. In particular, it is a significant contributor at the key stages at which decisions are needed on:

- Planning new, refurbished, modified or enlarged production or processes,
- The way in which the production or process is to be carried out,
- The minimisation of the quantities of radioactivity in use,
- The waste minimisation techniques to be employed,
- The choice of discharge route (e.g. use of fume cupboards),
- The method for minimising contamination,
- The possible need for abatement of discharges,
- Maintenance requirements and methods,
- The prevention of fugitive emissions by process and plant improvement,
- Implementation of a policy of continuous improvement to reduce disposals and discharges, including regular review,
- Waste sampling, measurement or estimation and on radiological assessment requirements,

6.0.2 The above list is not exhaustive but is intended to cover the key stages at which judgement is needed about the balance of detriments in terms of radiation exposure and others, including time, trouble and money, against the benefits of carrying out (or choosing not to carry out) some action. In order for this to be done by a user, it is necessary for the application of BPM to become embedded within the management and operational culture of the organisation. The consideration of BPM needs to become as much part of the way of planning and using radioactivity as is the consideration of worker dose restriction by ALARP. Ideally, both considerations should be carried out together so as to arrive at the best overall decisions, but it is recognised that this will not always be possible.

6.0.3 BPM is ultimately a way of comparing options for process design and operation, which is intended to arrive at the lowest radiation dose to the public whilst taking account of a wide range of factors discussed in this guidance. The costs of applying BPM to a particular process should not be grossly disproportionate to the benefits derived from the process. Such judgements will need to be made on a case by case basis -initially by users of radioactivity and for compliance checking by Regulators. In making such decisions, account may be taken of the generally applicable standards in use within other relevant processes and practices.

6.0.4 How the final judgement on which option is BPM is arrived at is not amenable to detailed guidance at this stage. Similar decision processes are used in

consideration of health and safety and industrial pollution to arrive at reasoned decisions. The costs of implementing the BPM process itself should be proportionate to the scale of production and disposal of the radioactive waste. The Agency does not propose to use any low threshold of dose below which no further consideration of BPM is required by users. However, at low levels of predicted public dose, the resources applied to BPM Assessments should be proportionately low. It is unlikely that other than very simple assessments will be necessary at very low doses, that is, those below 20 μSv per year.

6.0.5 An internationally accepted approach to the protection of non-human species continues to be developed. The protection of non-human species is not itself subject to control by a mechanism equivalent to BPM, but exposure of non-human species may in some cases be considered as a detriment to be included in the overall balance of costs and benefits.

6.0.6 Any applications for new or revised authorisation under RSA 93, should confirm that BPM is being applied by the submission of a BPM Assessment with their application. For users who are already under the regulatory regime of the Agency, it is expected that evidence that BPM is being applied, will be available for review by the Agency Inspector on request.

6.0.7 The amount of time and effort that goes into an assessment of BPM, and any consequential process improvements required, will depend on the predicted level of environmental impact, balanced with the cost in time, money and trouble required both to do the review, and to implement the options selected. The Agency cannot provide definitive guidance on the level required, but does recognise that the circumstances could be very different for say, a new department in the planning stage compared to a well established department in a densely built urban area with limited scope for new facilities to be built.

6.0.8 The use of BPM clearly requires a commitment from managers of organisations to minimise and then continue to seek further reductions where they are possible, in the quantities and activity content of wastes requiring disposal, without incurring disproportionate cost. Agency authorisations require that organisations have suitable management systems in place to achieve compliance with all conditions. We intend to issue further regulatory guidance in this area in due course. Users and applicants to dispose of radioactive waste should be able to satisfy themselves and Regulators, that suitable management arrangements are in place to implement BPM. Users are expected to apply consistent, clear and transparent decision making to all of these areas. In the case of BPM, the Agency expects the user to provide a description of the systems used for ensuring that BPM is being used along with alternative options which have been considered, data on each option and underlying criteria for decision making as a “BPM Assessment”. This will form the organisation’s overall statement of how it is using BPM to manage and control radioactive waste in accordance with the authorisation conditions. BPM Assessments are expected to be kept up to date, supplied to the Agency as support for applications for new or revised authorisations and should be available for inspection at all times.

6.0.9 The purpose of the BPM Assessment is to clearly reveal those measures that the organisation has taken and will take to apply BPM. It should contain sufficient, transparent, detail to enable Regulators to judge whether all necessary steps have been and continue to be taken to minimise the public

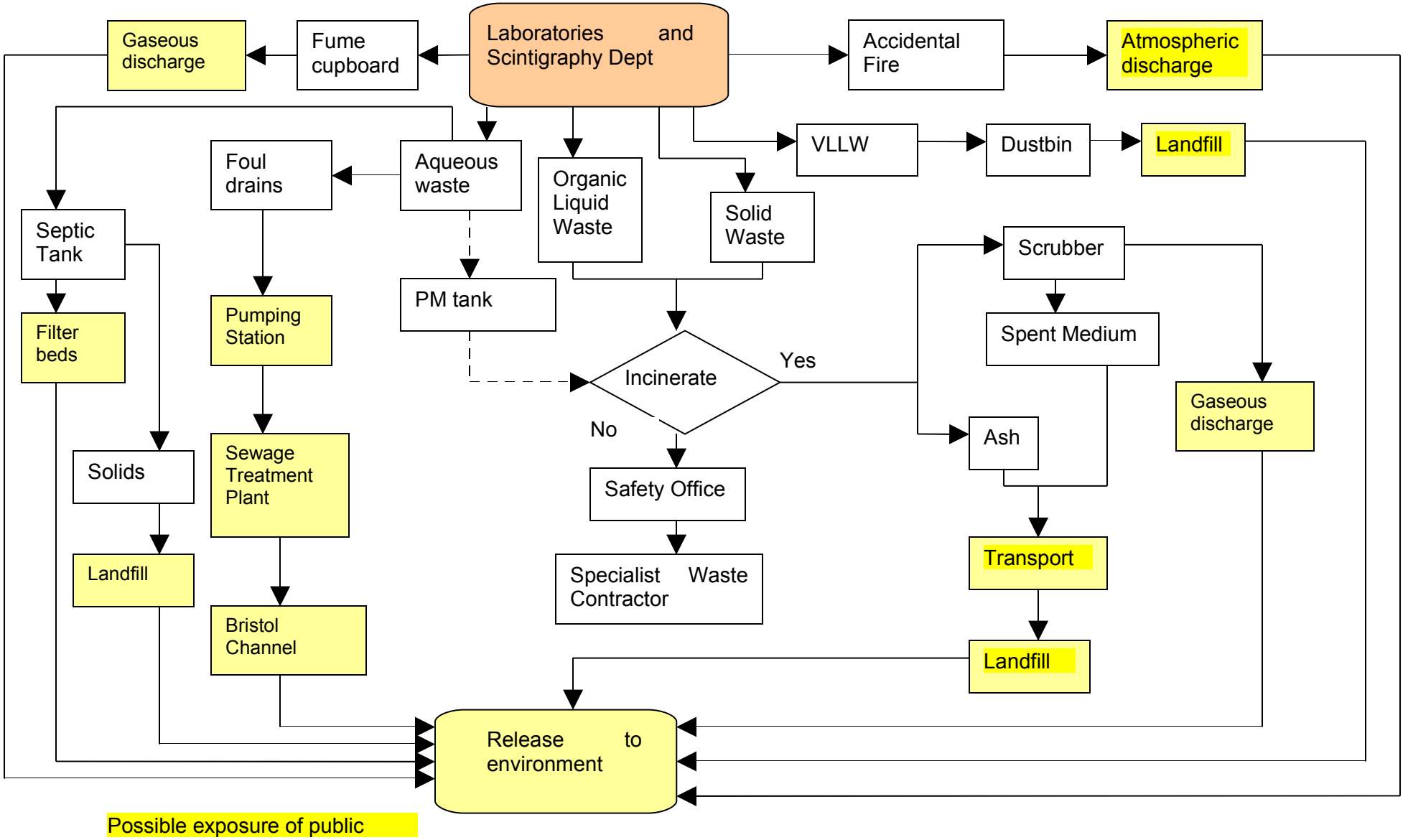
health impact of radioactive waste creation and disposal. It should also specify the options available for each waste stream and set out clear, transparent and consistent analyses of each and so reveal the process by which BPM decisions have been made. Only where a BPM Assessment achieves this objective can it be considered adequate, otherwise an operator cannot be considered to have demonstrated that they have used BPM, and the Regulator should require further work of the user.

6.0.10 For new applicants, regulators will need to be satisfied that users' proposals reflect sound BPM analyses representing the best practice for the options available. New or substantially refurbished processes will always be expected to achieve the highest standards available without incurring disproportionate cost.

6.0.11 As part of a BPM Assessment, it is important that the user has sufficiently detailed knowledge of the mechanisms for creation, handling and disposal of radioactive waste to enable the options to be considered properly. This may be expressed in the form of a flowsheet to aid clarity of analysis. An example of such a flowsheet is given below, as presented in an actual BPM Assessment (Figure 1).

6.0.12 The responsibility for demonstrating that BPM is being properly and proportionately applied rests with the user.

Figure 1


Laboratories and Scintigraphy Dept
Gaseous discharge
Fume cupboard
Accidental Fire
Atmospheric discharge
VLLW
Dustbin
Landfill
Foul drains
Aqueous waste
Organic Liquid Waste
Solid Waste
Septic Tank
Filter beds
Pumping Station
PM tank
Scrubber
Spent Medium
Incinerate
Yes
No
Gaseous discharge
Ash
Solids
Sewage Treatment Plant
Safety Office
Landfill
Transport
Specialist Waste Contractor
Bristol Channel
Landfill
Release to environment
Possible exposure of public

7 Detailed Guidance

7.0.1 Every application for authorisation should include a BPM Assessment, highlighting the options considered and the stages of the process adopted in identifying and implementing BPM. The complexity and depth of the case should be proportionate to the complexity of the operations proposed and need be only brief for simple cases. Reference may be made to other documents, which should be available on demand but need not be supplied with the application.

7.1 Issues for BPM

7.1.1 The following issues should be addressed in a BPM Assessment and thus be presented as part of an application for authorisation. Reference should be made to any other documents relied upon for the BPM Assessment.

7.1.2 The reasons for the choice of particular radionuclides should be explained. If it is associated with a generally accepted technique or process, for example the use of I-131 in radiotherapy, then the issues can be stated briefly, subject to suitable consideration of alternatives as below. The Agency does not seek to challenge the basis for clinical judgements but does expect the most appropriate procedures to be used, taking all relevant factors into account. The possible use of alternatives should always be considered and should include the effectiveness of those alternatives in securing the purpose of the procedure and the consequences in respect of wastes produced, doses, costs and other detriments. If the user believes there are no alternatives available then this should be stated in the BPM Assessment so that the Regulator is aware.

7.2 Techniques for handling the radionuclides

7.2.1 The range of possible techniques available for handling the radionuclides should be considered. These should be directed at carrying out the work necessary with minimum environmental effect, with due regard to the doses received by staff, and the potential for accidents. The best overall approach to these issues is likely to be a strong candidate for selection as the BPM in addition to meeting the obligation to keep worker doses ALARP.

7.2.2 The Agency does not regulate doses to workers or doses which would result from accidental release of radionuclides. Nevertheless, Regulators may be presented with BPM Assessments which propose as BPM, techniques which do not give the lowest doses to the public but which have important advantages in respect of estimated worker doses. Regulators will need to give careful attention to the methods used and to the results of worker dose calculations in these circumstances and may need to discuss them with HSE.

7.2.3 In many situations, especially in universities and other research work, systems will be in place to require experimenters proposing to carry out work, to submit their proposals for review by an RPA or other competent person. Such reviews should include the existence of suitable disposal routes for the wastes produced, the environmental impact of the proposal, including the use of BPM, and should form part of the BPM Assessment, and should therefore be available for inspection.

7.2.4 The operator should be able to demonstrate that the storage on, and disposal of radioactive waste from, the premises has been well planned and that those plans have been effectively and routinely implemented. Staff handling radioactive materials and waste should demonstrably be competent, adequately trained and supervised and should be familiar with the relevant procedures and work instructions.

7.2.5 The systems used for the storage and disposal of radioactive waste, including fume cupboards, ventilation ducts, drains, pipework, filters, scrubbers and other abatement equipment, should where practicable be designed and constructed for those applications, but should in any event be fit for purpose. They should be regularly inspected and well maintained, where installed.

7.2.6 The minimum quantities of radioactive material needed for successful completion of the work should be used.

7.2.7 Quality control measures in use of radioactive materials are a valuable contributor to minimisation of waste creation by, for example, prevention of repeat experiments or procedures.

7.2.8 Unused radioactive material should be returned to the supplier for reuse whenever reasonably practicable to do so to avoid the creation of unnecessary radioactive waste.

7.2.9 A statement confirming that all purchase orders of radioactive substances are co-ordinated (often best achieved by a person holding a central position in the organisation), will be important in demonstrating good practice. Similarly, a statement confirming that a management system for the disposal of radioactive waste is in place or a timetable for achievement may be seen as a significant contribution to maintaining high standards.(formal ISO 14001 arrangements or, with relevant details, locally developed systems).

7.2.10 In some cases, consideration of the concentration of work with radioactivity into fewer facilities may be an option which should be considered. The ability to better equip a smaller number of facilities would need to be balanced against the disadvantages. Issues of management of radioactivity and radioactive waste both as benefits and detriments would need be taken into account.

7.3 Techniques for minimising the production of waste

7.3.1 The range of techniques available for minimising waste production is very broad and applies at all stages of processes. Some of the most important techniques used in individual decisions on minimising wastes are introduced below. How these issues have been addressed in considering BPM should be documented in the BPM Assessment, where they are relevant.

- planning work to fully take account of environmental issues,
- ordering and using minimum quantities of radionuclides consistent with the task,
- selection of the form of the materials handled (e.g. aqueous, liquid, powder),
- avoidance of the creation of secondary wastes by contamination,
- careful planning of experiments (including dry runs) and work activities - including the segregation of waste streams,
- planned maintenance of plant and equipment,
- expert assessment of experimental proposals.

7.3.2 The minimum amount of radioactive material should be purchased but minimum order quantities mean that even this is sometimes more than an individual experimenter or department requires. In these cases suitable efforts should be made to agree to share vials between departments, provided safety is maintained

7.3.3 The avoidance of creation of secondary wastes as far as possible is especially important. Measures should include the design and condition of the facilities being used, the planning of the work and the method of working by the individual operator. Procedures should be in place for dealing promptly with any spillage of radioactive materials. Periodic review of secondary waste generation should be undertaken.

7.3.4 Waste generated should be segregated at source when there are benefits to be achieved, to ensure the most appropriate disposal is made of each waste type.

7.3.5 It may be appropriate to filter discharges at the entrance to ventilation ducts rather than contaminate ductwork that will be expensive to dispose of. The filters can then be managed as solid radioactive waste. This is particularly important when long-lived radionuclides are employed.

7.3.6 Consideration of the design features of laboratories handling radioactive materials can be very effective in reducing the production of radioactive waste.

7.4 Release routes

7.4.1 In larger (i.e. nuclear) installations the choice of disposal route would normally be determined by the outcome of a separate Best Practicable Environmental Option study and as an integral part of a waste management strategy. Such complexity of process will seldom be warranted in non-nuclear cases, and in these cases the choice of the most appropriate disposal route should be made as part of the BPM Assessment. This should be done by ensuring that the options considered as part of the BPM Assessment include alternative disposal arrangements. Separate BPEO studies are not required for non-nuclear premises.

7.5 Abatement

7.5.1 The key issues here are;

- the existence of appropriate abatement plant for the radioactive waste arising,
- the benefits achievable from the use of such plant,
- the costs of installation, use and maintenance of such plant,
- the alternative and secondary waste streams created by the use of such plant.

7.5.2 Abatement should be used where discharges can be effectively reduced without requiring the expenditure of time, money or trouble disproportionate to the benefits likely to be derived.

7.6 Decay Storage

7.6.1 Decay storage of both solid and liquid radioactive wastes may be an option to be considered as a potential component of the BPM. Decay storage of short-lived solid waste is likely to be BPM in many cases. Storage of organic liquid waste is often likely to be needed on the grounds of the practicality of arrangements with external contractors for collection of waste. Decay storage of aqueous liquid waste should be considered as a potential BPM when significant doses can arise to the public from discharges of short lived radionuclides, or which give rise to significant concentrations of radionuclides in environmental media. Suitable materials and engineering solutions are required to make it acceptable.

7.6.2 The circumstances will need to be judged on a case by case basis with decay storage much more likely to be BPM in cases of construction of new facilities or major expansion or refurbishment programmes. Costs are more likely to be disproportionately high when considering the backfitting of decay facilities to existing infrastructures. Consideration of decay storage of aqueous liquids should be carried out alongside a careful consideration of other options, including the use of other radionuclides and segregation of waste streams, otherwise the costs of decay storage can, in isolation, appear excessive. Operator doses will need careful attention in such cases.

7.6.3 Accumulated radioactive waste should be kept in suitable stores according to agreed procedures. During storage, waste should be regularly checked for losses, theft or leakage. The frequency of checks will be determined by the user, balancing the risk of losses to the environment with the radiation protection needs of the staff doing the check.

7.7 Measurement or assessment of disposals

7.7.1 Unless information is available on the actual or proposed quantities and forms of radioactive waste created, it will not be possible to sensibly compare the various options appropriately. Information is needed at a level of detail commensurate with the decision making process. If, for example, the costs of an option are excessively high then there will be little need for detailed assessment of disposals as this option is unlikely to represent BPM. The cost of carrying out the measurements or assessments of disposals themselves is a relevant issue in the BPM consideration and should not be disproportionate.

7.8 Radiological consequences

7.8.1 Realistic dose assessments are needed to enable clear transparent comparison between options. The Agency has issued separate guidance on this subject (Radiological Assessment - Initial Prospective Source Assessment, 1/10/2004).

7.8.2 It is clearly not acceptable for an environmental option to be selected as BPM which gives rise to unacceptably high doses to the workers. On the other hand worker dose should not be permitted to dominate the consideration of BPM. Other decision making mechanisms (outside of the Agency's regulatory remit) are used to control worker doses and specific consideration of measures to protect workers may be required in certain cases, for example, cleaning or shielding to reduce doses from operations and during the maintenance of iodine delay tanks.

7.9 Potential for unintentional release

7.9.1 The potential for accidents should not normally be dominant in the decision making process on BPM. Where a proposal suggests significant environmental consequences as a result of techniques to avoid accidents, liaison between both parties and HSE will be especially important. Records of such liaison should be part of the BPM Assessment.

7.10 Review

7.10.1 Regulators should check that BPM has been adopted into the culture of organisations by seeking evidence that procedures and operations remain under consideration with a view to achieving consequent reduction in disposals and their environmental consequences. Users should keep BPM under review and should demonstrate awareness of developments in relevant process and abatement options. The overall objective is to maintain the BPM Assessment as a sound and contemporary summary of the relevant factors and the conclusions which have been implemented as a result of that analysis. The process of reviewing procedures is part of the BPM Assessment.

7.11 Maintenance

7.11.1 The following facilities should be subject to appropriate maintenance, judged on a risk basis:

- facilities in which radioactive wastes are produced, processed or stored, e.g. fume cupboards, laboratory equipment or waste stores;
- abatement plant, e.g. tanks or filters;
- discharge plant and equipment, e.g. drains.

7.11.2 Maintenance may include inspection, preventative maintenance and repair of plant and equipment. Inspection and preventative maintenance should be planned and carried out on a risk basis; equipment which is essential to the provision of BPM may need to be subject to inspection or routine maintenance to ensure adequate reliability.

7.11.3 The provision of backup plant may be needed in exceptional cases to maintain an essential service.

7.11.4 When considering the risk basis for planning maintenance, consideration should include both the likelihood and consequences of equipment failure.

7.11.5 Appropriate records should be kept of inspection and maintenance of high-risk equipment.

8 Example of Considerations

8.0.1 It is the current Agency view that backfitting of iodine delay tanks is not generally indicated for existing facilities. The time, money and trouble involved in backfitting them is likely, in most cases, to prove to be disproportionate to the environmental benefit. The possibility remains, however, that cases could exist or arise where installation may be needed, e.g. an increase in workload or a particularly sensitive receiving environment.

8.0.2 In a few cases of construction of new facilities or substantially modified facilities, delay tanks may be found to constitute BPM. For example, a Nuclear Medicine department, intending to increase its throughput on construction of a new hospital facility, may find that, even after consideration of other discharge

reduction options, doses can be reduced by the use of delay tanks without disproportionate costs. For such a new build, a detailed study would be necessary, and even if tanks are not indicated immediately, it may be appropriate to leave the space available in case of future need. If discharges are not diluted promptly in the sewerage system, then special care will need to be taken in assessment of BPM.

8.0.3 The following issues may be significant in such an assessment:

- local habits in regard to the dose assessment,
- radionuclide concentrations in the environment with increased discharges,
- substitution of alternative radionuclides,
- costs of tanks and their maintenance,
- realistic worker doses for tank operation and maintenance,
- possible public relations aspects of radionuclide concentrations in the brook,
- the limiting of any future discharges to the level of the proposed authorisation if no delay tanks or alternative radionuclides are used.

14 Guidance on the application of Justification to RSA 93

1 Introduction

Agency Officers dealing with applications for certificates under RSA93 will need to consider whether practices meet the requirements of the Justification of Practices Involving Ionising Radiation Regulations 2004 (SI 2004/1769). These regulations came into force in August 2004. This guidance derives from the Agency Policy Statement on Justification for Classes or Types of Practice

2 JUSTIFICATION

The ICRP principle of justification is that no practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals, or to society, to offset the radiation detriment it causes. The Regulations implement part of the Basic Safety Standard Directive (96/29/Euratom)(BSS) and part of Directive 97/43/Euratom on health protection of individuals against the dangers of ionising radiation in relation to medical exposure. Under these Directives and under the Regulations, what is required to be justified is a particular class or type of practice and not individual uses.

The BSS Directive defines a "practice" as: "a human activity that can increase the exposure of individuals to radiation from an artificial source, or from a natural radiation source where natural radionuclides are processed for their radioactive, fissile or fertile properties, except in the case of an emergency exposure."

An "existing class or type of practice" is defined in the Regulations as one in which a practice of that class or type was carried out in the United Kingdom before 13 May 2000.

Defra has issued guidance on the Regulations, available on its website at http://www.defra.gov.uk/environment/radioactivity/government/legislation/justification.htm. The guidance includes a list of existing classes or types of practice (on 13 May 2000). A justification register of applications and decisions made under the regulations is provided separately on the Defra website, where additional information can also be obtained.

Consideration of whether classes or types of practice are justified involves weighing both technical factors and wider social and economic issues. The Justifying Authority takes justification decisions under the Regulations and performs most of the functions. The Justifying Authority is the Scottish Ministers, National Assembly for Wales or a Northern Ireland Department (to the extent that devolution allows) and the Secretary of State in respect of England and for matters that are not devolved. The objective for the Environment Agency is to avoid issuing registrations and authorisations for practices which are not justified.

If applicants for registrations or authorisations express concerns, for example about non-determination of applications which are pending Government decisions on justification, Officers should refer them to the Justifying Authority.

3 The Environment Agency's role

The Environment Agency has two main roles in relation to the Regulations:

(i) Considering whether a particular use of radioactivity falls within the scope of an existing class or type of practice or appears as a justified practice on the

justification register. This role arises whenever an application for registration, authorisation or variation is received. If a practice is either an existing practice, or appears as a justified practice on the justification register, then the Environment Agency can proceed to determine the application.

(ii) Enforcement of justification decisions in any cases where enforcement powers are delegated to the Environment Agency. This is considered likely to be rarely, if ever, required and no guidance is being issued on it. In case of need, Officers are advised to seek guidance from RSR Helpdesk.

The following points are significant in the Environment Agency's role under (i) above:

With the exceptions given below, consideration under (i) above is required whenever any application under RSA 93, whether for registration or authorisation, is received from an operator of a site or premises undertaking, or intending to undertake, a practice at a premises or for a mobile practice, including nuclear sites.

The ECJ decision on the JASON case (C-61/03) has made it clear that the Euratom Treaty is not applicable to uses of nuclear energy for military purposes. Thus, practices carried out by MOD, and its contractors on its behalf, are not subject to consideration of justification. Hence, the Environment Agency will not give consideration under (i) above for such applications. The RSA 93 application forms seeks details to enable identification of MOD contractors.

Proposals concerning the management of radioactive wastes do not need a separate justification decision under the Regulations. Rather, it is the practice that gives rise to the wastes that requires the justification decision. (However, a proposal concerning the management of radioactive wastes is subject to the usual consideration by the Environment Agency of whether it is a suitable option for managing the wastes and whether best practicable means are employed.)

For applications limited to handling radioactive wastes from elsewhere (e.g. incinerators), no consideration under (i) above is required irrespective of the origin of the wastes. Rather, consideration under (i) above is given whenever the Environment Agency receives any application under RSA 93 from an operator creating radioactive wastes.

For applications relating to radioactive wastes arising from past practices (as during site decommissioning and clean-up), consideration under (i) above is required for the past practice. However, if comparison with the list of existing practices indicates an anomaly, it is anticipated that further consideration would be given to such cases. The RSR Helpdesk should be informed of any such case so that RSR Policy can inform Government.

Use of the non-radioactive properties of NORM does not need a justification decision since it is not included in the definition of practices in the BSS Directive because it has not been processed for its radioactive, fissile or fertile properties (see definition of "practice" in Section 2 above).

The intention of the Defra guidance (paragraphs 21-23) is that storage of radioactive materials falls within the scope of the practice for which the materials will be used. It is Environment Agency policy that all cases limited to storage of radioactive materials do not require consideration under (i) above. This is because storage should always be associated with transport of radioactivity to or from a justified practice or a practice /work activity not requiring justification.

The Regulations prohibit the addition of radioactive substances to personal ornaments and toys. The addition of radioactive substances to cosmetics is already prohibited by earlier legislation.

Medical exposure of an individual to radiation is permitted where, at the discretion of a clinician, it is considered medically justified for that individual even where the practice is not justified in general. We may occasionally become aware of such a case, which should be referred to the RSR Helpdesk for guidance.

The Environment Agency does not have to issue permissions for exempt sources and hence would not normally give consideration to them under (i) above. However, if a use of exempt sources comes to its attention that does not appear to comply with the Defra lists, the case should be referred to the RSR Helpdesk for consideration by RSR Policy.

Sources may be used for more than one practice. Each such practice should be checked against the Defra lists and details entered onto the standard file note as required by the Work Instruction In the event of one practice being justified but another one not, then discussions should be held with the applicant to decide whether they want the source to be registered in respect of the justified practice alone or the application refused.

The lists of existing and justified practices are located on the Defra web site. The inclusion of a separate list in the Environment Agency application forms is to enable the Environment Agency's numbering system to be used and to include uses which do not require justification but do require registration or authorisation.

The Environment Agency may be made aware of a decision on justification in the following ways: the introduction of new Regulations, publication in the London Gazette, the updating of the Defra web site or notification of the decision in writing.

The Regulations themselves do not provide any specific right of appeal against the Justifying Authority's decisions - although any such decision may be appealed by way of judicial review. However, a person may at any time apply to the Justifying Authority to review an existing class or type of practice if either new and important evidence about its efficacy or consequences is acquired, or there has been a justification decision that is not justified.

From time to time the Environment Agency may receive information which it considers to amount to new and potentially important evidence about the efficacy or consequences of an existing practice in relation to which registrations or authorisations have been issued under RSA 93. In this event the RSR Helpdesk should be informed so that RSR Policy can refer this information to the relevant Government department.

15 Management system conditions

Basic requirement

Holders of certificates under RSA93 covering open andfor the keeping and use of sealed radioactive sources including or the accumulation and disposal of radioactive waste are required to have a management system, organisational structure and resources that are sufficient to achieve compliance with the limitations and conditions of the registration.

Plan-do-check-act method

Management systems are often based on the methodology known as Plan-Do-Check-Act. We expect you to:
plan: establish the processes necessary to achieve compliance with the registration conditions;
do: implement those processes;
check: monitor those processes to ensure that compliance is being achieved;
act: take action to improve those processes where failures or weaknesses are identified.
We do not necessarily expect you to set up a stand-alone system. It may be integrated with any other management system that you already have in place.
The system must be documented and should be aligned to your work, ie the more complex the work the more the management system will need to be detailed.

Minimum requirements

We expect your management system, as a minimum, to cover:
definition of roles, responsibilities and authorities;
identification of resources required;
identification of training needs;
establishment of procedures for procurement, operation and maintenance of equipment and systems relating to the use of radioactive materials;
establishment of emergency procedures;
record-keeping arrangements;
arrangements for checking compliance;
consultation with a suitable RPA;
adequate supervision of keeping and use of radioactive sources and the management and disposal of radioactive waste.
Some of these aspects are specifically addressed by certificate conditions. Guidance on some aspects is given below; more is in our published guidance on high-activity sealed sources. Joint Agency/HSE publication IRP8 gives general guidance on control of radioactive substances.
Useful guidance on management systems generally is given in the ISO 9000 and ISO 14000 series of standards. HSE also publish guidance on safety management systems which may be relevant to environmental considerations (Managing Health and Safety - Five steps to success).

Operating instructions

You must provide written operating instructions to all staff involved in work affected by the requirements of certificates.
We expect the instructions:
a. to:
provide direction on how equipment and/or sources are to be used to achieve the work objective,
and to address the precautions to be taken as part of that work to ensure safe management of sources and waste.

Example: This might include instructions on booking sources out from, and returning sources to, the source store at the beginning and end of the work period and recording amounts of open radioactive sources used and waste disposed of.
b. to be provided both for:
work that directly involves the use of sources or management of waste;
and for work that does not directly involve the use of sources/management of waste but has the potential to impact on their safe management. For example, cleaning operations.

Definition of roles, responsibilities and authorities

We expect a diagram or description showing the roles of staff with responsibility for radioactive sources; it must specifically identify those responsibilities, not simply their general roles in the organisation. This should extend from the Chief Executive or equivalent downward throughout the organisation.

Appropriate authority should be given to those involved in securing compliance with certificate conditions.

Identification of resources required

It is important that organisations using radioactive sources allocate sufficient resources in terms of staff, facilities and equipment to achieve compliance with certificate conditions. How you identify what resources are required to meet your circumstances should be described and also how this is kept under review.

Identification of training needs

You must:
specify competency and training requirements for all staff involved in work affected by the certificate conditions;
provide that training;
and keep training and competency records.
We expect you to provide training for:
staff directly involved in the keeping and use of sources;
staff who are not directly involved but whose work has the potential to impact on the safe management of sources;
and other staff who may, for example, need to recognise warning signs, such as cleaners.
Note that 'staff' includes contractors.
Training should be appropriate to the nature of the work and the needs of the individual. It may be provided in conjunction with the training required by regulation 14 of IRR99. It must cover those requirements of the registration that are relevant to the work that individuals do, and what they need to do to comply with those requirements when carrying out that work. Staff should be aware of when they need to seek help and where to find it.

Maintenance

You will be required to ensure that all equipment associated with keeping and using sources, including sources and source containers, is maintained in good condition.
The purpose of this condition is to ensure that the likelihood of damage to, or loss of, a source is not increased because equipment is in a poor state. The extent and frequency of maintenance will depend on the nature of the equipment and the conditions in which it is used.

We expect you, as a minimum, to follow any advice on maintenance provided by the manufacturer, supplier or installer, or maintain to an equivalent standard.You should describe how you will maintain your equipment. Your arrangements should address:
a planned maintenance programme for any equipment that you need to avoid your sources/waste being damaged, lost or stolen. (You should use the manufacturer's recommended inspection and maintenance timescales, or explain in writing why you have used another schedule.)
provision of spare parts
whether in-house or external maintenance is appropriate

Establishment of emergency procedures

You should describe your arrangements for actions in the event of:
Loss or theft of, or escape ofdamage to, radioactive sources including or radioactive waste;,
non-compliance with certificate conditions.

See also Agency guidance on high-activity sealed sources.

Record-keeping arrangements

The way in which you collect, assess and retain records relating to the requirements of the certificate, should be described.

Arrangements for checking compliance

You should describe how you check that your arrangements are effective in achieving compliance with the certificates.

Consultation with a suitable RPA

You must specify in what circumstances you consult an RPA and how you ensure that this is done.

Adequate supervision of work with and disposal of radioactive sources

You must ensure that a person (or persons) who is competent and able to secure compliance with the limitations and conditions of certificates, is responsible for supervision of the radioactive sources, including wasteshould describe your arrangements for appointing the persons responsible for supervising the keeping and use of sources or the management and disposal of wastes.
We expect you to appoint a supervisor who:
a. knows and understands the requirements;
b. commands sufficient authority from the people doing the work to allow them to supervise the relevant aspects of that work;
c. understands the necessary precautions to be taken to ensure safe management of sources including waste;
d. knows what to do in the event of an incident or emergency.
They will usually be in a line management position, closely involved with the work being done, to allow them to exercise sufficient supervisory authority. A person appointed as a Radiation Protection Supervisor under IRR99 will often, subject to receiving appropriate training, be suitable for this role as well.
All staff involved in keeping and using sources should know who the competent supervisor is.
Although the competent supervisor has a crucial role to play in helping to ensure compliance with the certificate conditions, the legal responsibility remains with the registered or authorised user and cannot be delegated.