

# Radioactive Substances Act Guidance (RASAG)

## Chapter 1 - Registrations

Operational instruction 371\_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 registrations.



Document details

### Who does this apply to?

RSR staff carrying out casework under RSA93



Related documents

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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.**

## Registration of depleted uranium

All uses of depleted uranium should be covered by a registration unless such use or the quantities of material involved are exempted from registration either by RSA93 itself or by The Radioactive Substances (Uranium and Thorium) Exemption Order 1962 S.I. 2710.

The following are **some** of the typical uses of depleted uranium for which a registration (normally as a sealed source) should be issued: -

1. Counterbalance weights held in store for future use in aircraft or vessels. The weights should not be registered while installed on individual aircraft or vessels considered to be in the course of a journey – including periods of maintenance in which the work does not involve the depleted uranium and where the intention is to return the aircraft or vessel to operational duty (section 47(3) of RSA93 refers).
2. Shielding blocks, including shielding in linear accelerators.
3. Source containers used by radiographers.

Because its A1 value in the IAEA Transport Regulations is unlimited, depleted uranium can never be a HASS source. Depleted uranium sealed sources should always be treated as category 5 for security purposes. See HASS guidance for further details: [http://www.environment-agency.gov.uk/commondata/acrobat/369\\_05\\_v6\\_1843912.pdf](http://www.environment-agency.gov.uk/commondata/acrobat/369_05_v6_1843912.pdf)  
Depleted uranium in the form of fine powder or machine turnings should be registered as an open source.

The items should be itemised by weight and material rather than by activity on the certificate schedule e.g.

MAXIMUM NUMBER OF SOURCES	RADIONUCLIDES AND ASSOCIATED MATERIALS	MAXIMUM MASS OR ACTIVITY IN EACH SOURCE
10	Depleted Uranium Metal	18 kg

Depleted uranium which is part of another device, such as a radiography source holder and source(s) or shields in linear accelerators, must appear as separate items in the schedule of radioactive material in the certificate of registration. For example, registrations must not refer to a source of x in a depleted uranium source container as it is quite probable that the source and source holder will subsequently become separated.

The accumulation of **waste** depleted uranium requires an authorisation unless exempted by an Exemption Order such as the Waste Closed Sources Exemption Order

or The Radioactive Substances (Uranium and Thorium) Exemption Order referred to above. See RASAG Chapter 3 for further guidance on exemption orders:  
<http://publications.environment-agency.gov.uk/pdf/PMHO0405BKHQ-e-e.pdf>

Where an existing registration is to be varied to add depleted uranium holdings, the current charging scheme should be consulted to determine whether a variation fee is appropriate.

### **Euratom Safeguards**

Safeguards are measures to verify that States comply with their international obligations not to use nuclear materials (plutonium, uranium and thorium) for nuclear explosives purposes. The UK Safeguards Office (which is part of HSE) oversees the application of safeguards in the UK under the terms of Commission Regulation (Euratom) 302/2005.

This is not a matter for the Agency. Enquiries by Operators regarding safeguards reporting should be directed to HSE at: UK Safeguards Office, 7<sup>th</sup> Floor, Rose Court, 2 Southwark Bridge, London, SE1 9HS. E-mail: [UKSO@hse.gsi.gov.uk](mailto:UKSO@hse.gsi.gov.uk). Further safeguards information is available on the UK Safeguards Office website, including guidance for small holders of nuclear material.  
([www.hse.gov.uk/nuclear/safeguards/index.htm](http://www.hse.gov.uk/nuclear/safeguards/index.htm))

## **Registration of spent technetium-99m generators.**

### **1 Introduction**

Many hospitals routinely receive these “Open source” generators on a regular basis and spent ones are collected for re-use. Some hospitals have a delivery cycle which involves three generators, one in use, one two weeks old and one, one week old.

### **2 How to register**

Generators should be registered as molybdenum-99, the parent nuclide. The registration should list these as “molybdenum-99 technetium generator”.

The maximum potential holding should be registered including those awaiting return for re-activation. (NB Application Form RSA 1 (Open Sources) advises applicants to multiply the nominal activity of Mo-99 by a factor of five to cover early delivery and continued holding of decaying generators).

### **3 When is an authorisation required?**

If the spent generators are held for decay for a period in excess of three months, then an authorisation for accumulation of radioactive waste under Section 14 of RSA 93 is normally required.

## Industrial radiography

### 1 Introduction

Industrial radiography involves the use of ionising radiation to form an image on a photographic plate of a weld or certain parts of a metal structure. The radiation penetrates the metal and can reveal flaws or defects. It is quite common for radiography to take place on construction sites. Radiography is sometimes referred to as a non-destructive testing (NDT) technique.

### 2 Isotopes used for Radiography - HASS

The nature and size of the metal or component affect the type and strength of source used. Isotopes used are iridium 192, cobalt 60, selenium 75, ytterbium 169, caesium 137 and californium 252 (neutrons).

Iridium is used for steel section of thickness between 10 and 50 mm, cobalt is used for thicker sections up to 150 mm. Caesium 137 is used for thinner sections and in the aircraft industry for aluminium. However some very large sources exist for castings and pressure vessels; these sources are over 60TBq. New Ir-192 sources are often about 4 TBq.

Many radiography sources are HASS and consequently require security and other measures specified in registration conditions. See HASS guidance for further details:

[http://www.environment-agency.gov.uk/commondata/acrobat/369\\_05\\_v6\\_1843912.pdf](http://www.environment-agency.gov.uk/commondata/acrobat/369_05_v6_1843912.pdf)

In order to achieve efficient and compact shielding, depleted uranium is generally used for storage/transport containers. Most new Ir-192 sources are transported and stored in "Techops 660" containers; these contain approximately 17 kg of depleted uranium. However numerous other types of source containers are in existence.

Each depleted uranium (DU) container must be registered as a sealed source under RSA93 with the weight of each container included in the schedule.

### 3 Radiation Issues

Refer to the Agency's Health & Safety documentation on carrying out RAS inspections.

Exposed radiography sources represent a severe potential hazard with dose rates of 500 mSv/h being quite common at 1 metre (for a 4 TBq Ir-192 source). The dose rate from depleted uranium source containers (empty) can be in the order of 15 µSv/hr and up to 30 µSv/hr for Type B containers such as the "Techops 660" with an Ir-192 source loaded. Special care must be taken when inspecting Type A containers; dose rates of up to 2 mSv/hr may be present at the container's surface. This is particularly relevant for Co-60 containers.

#### 3.1 Source Security

Due to the source activities and portable nature of radiography sources, storage and use must be carried out with due attention to security, both while sources are on the main premises and when at a remote location. A CTSA will be consulted

to assess security during an application for registration and should additionally be consulted if an Environment Agency Officer has security concerns at any other point. The requirements of the NaCTSO Security Document should be met.

Most radiographers have mobile source registrations and therefore must have suitable storage facilities available at the location where the source is being used. A condition in the mobile registration requires the Environment Agency to be informed if a source is used off-site for longer than 3 months.

Transportation of sources is covered under Radioactive Materials Transport Regulations. Sources must not be stored overnight in a vehicle unless the vehicle is itself further secured, eg in a locked compound.

### **3.2 Record Keeping**

Any audit of the inventory will be limited to detailed checks on the paperwork that is associated with the sources. It is impossible to check the serial numbers on sources that emit high dose rates; however each source container should have a metal tag giving the source number, type, strength and date of assay.

### **3.3 HSE**

The HSE views radiography as a high risk area and undertakes spot checks at remote sites where NDT is being carried out. This generally tends to be at night because large areas of a site need to be evacuated when the source is exposed. HSE must be informed before site radiography takes place. HSE may hold useful information about radiography companies. Inspectors should refer to internal Agency procedures on radiation safety to ensure that they are aware of any personal health and safety issues that might be encountered during an inspection.

## **Dealing with sealed source registrations when registered Holders and sources are untraceable**

### **1 Introduction**

Sometimes an Environment Agency Officer is unable to contact a registered holder of sources. Examples range from an attempt to inspect premises that are demolished to a garage which has closed down in the recent past.

### **2 Guidance for low radiological impact sources (security category 5)**

The inspector should use his/her professional judgement to instigate a limited exercise through e.g. contacting HSE, the registered holder's RPA/RPS if known, contacting neighbouring sites and with suppliers to attempt to establish the fate of the source(s) and locate the holder of the registration. Conduct a search through Companies House.

If neither the source nor the owner is found the registration should be cancelled after a period of 12 months has elapsed since the start of the investigation.

If the holder of the registration is found, and there is evidence of an offence, then action should be taken following the Agency's current enforcement and prosecution policy and guidance. (NB older certificates may not include the requirement to notify us of ceasing to keep registered sources, etc.)

### **3 Guidance for loss of sources where there is a potential risk of significant harm to the public (HASS or categories 1 to 4)**

The inspector should use his/her professional judgement to instigate a rigorous exercise to find the source and the registered holder. The search should include the HASS database. The CTSA should be asked if he/she has any knowledge of the companies or individuals involved. The same guidance as above applies if the registered holder is found and there is evidence of an offence.

However, if the registered holder is not found, then the inspector should ensure that all reasonable steps have been taken, in proportion to the perceived risk, to track down the source. This could involve pursuing ex-directors, contacting scrap metal merchants etc., those contacts mentioned in paragraph 2 including a Companies House search, the liquidator, receiver, potential receivers of waste sources, and manufacturers of similar sources.

Cancellation of the registration should only proceed when such a detailed investigation has failed to locate the source and no less than two years have elapsed after discovering the loss.

## Registration of mobile sources

### General requirements for registration as mobile radioactive apparatus

The 'notes on clauses' to the original Radioactive Substances Act 1960 make clear that, as a general principle, premises should be registered under section 7 (s1 in RSA60). The alternative of registration of 'mobile radioactive apparatus' under s10 (s3 in RSA60) is described as a 'special registration procedure' providing 'exception to the general principle'. It was introduced to cover those sources which rely for their usefulness on being carried from place to place (for example, industrial radiography sources) and where it would be unduly burdensome if every set of premises that the apparatus might visit had to be registered.

For a sealed source to be registered as mobile radioactive apparatus:

there should be a genuine intention to use it on more than one premises; it should meet the definition given in s3 of RSA93 ('constructed or adapted for being transported from place to place'); and it should be used only for the purposes specified in s9 of RSA93 ('testing, measuring or otherwise investigating any of the characteristics of substances or articles').

### S7 and s10 registrations required?

Section 6 of RSA93 relates to the need for registration of a person on any premises which are used for the purposes of an undertaking by him. Section 6(c) provides for exemption from registration under section 7 if the radioactive material in question consists of mobile radioactive apparatus in respect of which a person (it can be a different person) is registered under section 10 (or is exempted under that section). This means that users who have sources registered under section 10 do not need separate registration under section 7 covering use of those sources at their base location. However, they do need a separate registration for any other sources that are used only at the base location.

### 'Permitting mobile apparatus to be kept or used'

Both sections 6 and 9 provide for users registered under sections 7 or 10 respectively to cause or permit radioactive material/mobile apparatus to be kept or used. This practice may indeed occur on some large factory sites which employ 'labour-only' subcontractors for radiography work. In these cases the factory undertaking is registered and takes full responsibility under the Act.

### Lending or letting on hire

Where a user has registered mobile radioactive apparatus under section 10 and lends or lets it on hire to another person to use in their own name, that borrower or hirer also needs to be registered under section 10.

### Road construction sites

In determining whether a person needs to be registered under section 7 or 10, it should be noted that a complete road construction site (often a series of small pieces of road, possibly still in use by the public) is not regarded as a premises in accord with the legislation.

### Security

The current certificate templates require that users notify the Agency if any mobile source is likely to remain in one place for more than 3 months. If these are HASS or sources of similar potential hazard, then security at the remote site should be specifically considered.

### Foreign companies

Sometimes foreign companies wish to conduct activities using radioactive substances in the UK without having an address in the UK where sources will be stored when not in use and where relevant records will be kept. In the absence of a place of business in

the UK, we require that the foreign company's customer is registered under section 7 of the Act for the sources that are to be used on their site. The "customer" company will thus be responsible for the sources on their site and for compliance with the RSA 93 registration conditions. Any work that the foreign company does on its customer's site with the radioactive sources must be under the control of its customer. (This approach is taken because it would be virtually impossible to enforce a s10 registration issued to the foreign company.)

### **Multiple bases**

Sometimes, a user of mobile sources who operates from several bases, will apply for a single mobile source registration, covering all his sources, with the intention of reducing charges. We should insist on a separate application & registration for each base, covering the sources that are normally kept at that base. (This approach is taken to facilitate compliance checking and ensure adequate cost recovery.)

### **Certificates of registration and lists of customers**

Agency Policy is not to require manufacturers of sources to supply lists of their customers. Such lists may be requested on a case specific basis if there has been a history of problems. When requests are made, they will be done through Head Office. Should any inspector think that such a list is necessary, he should raise the matter with RSR Process Management.

It should be noted that details of HASS must be notified to the Agency.

[http://www.environment-agency.gov.uk/commondata/acrobat/369\\_05\\_v6\\_1843912.pdf](http://www.environment-agency.gov.uk/commondata/acrobat/369_05_v6_1843912.pdf)

And also guidance on source notification:

<http://publications.environment-agency.gov.uk/pdf/GEHO1205BKCW-e-e.pdf>

## **Combine harvesters: americium 241 sources in crop flow Meters**

- 1 Some types of combine harvester use radioactive sources to measure crop yield. When used on more than one farm it is necessary to register the sources as mobile radioactive apparatus. Registration under Section 7 is possible if the source is kept and used on a single registered premises (ie farm).

The Agency will act on the presumption that crop flow meter sources should be registered under Section 10. However should a farmer wish to register the source for use on only one farm we will register it under Section 7. We should draw the legal position to the attention of the farmer in writing because he could be committing an offence if he takes it off (or allows it to be taken off) the farm.

- 2 A farm consisting of non-contiguous patches of land or fields separated by public roads can be considered to be a single premises (farm). We cannot specify a maximum distance between fields in the same premises.

- 3 Specific points are:

- a. If registered under Section 7 the combine/flow meter can only be used on the registered farm. Sources registered under section 7 cannot be hired or lent out unless the lender is registered.
- b. If registered under Section 10 the farmer or anyone acting as part of his undertaking can use it anywhere in England and Wales but he can only lend or let it on hire to another appropriately registered person.
- c. If a combine travels on public roads it is in the course of a journey and is subject to regulation by the Department for Transport.
- d. Arrangements are in place to respond to accidents; these include the NAIR scheme co-ordinated by HPA and which the Agency supports.
- e. If demonstrations are proposed on farmers' land the source will need to be registered under Section 10.
- f. The Act does not address the problems of liquidation. The overriding need is to ensure that proper care is taken of the source. Specific legal advice is likely to be needed if problems arise. The receiver or administrator has certain legal obligations, which they should be aware of when taking responsibility for assets and liabilities. See additional guidance on companies going into liquidation.

- 4 Sources with aluminium source holders, which are vulnerable to damage by fire, should by now have been withdrawn and replaced with stainless steel source holders. The Agency will not grant new registrations for sources with aluminium source holders. We will insist on replacement of aluminium source holders with stainless steel.

- 5 The Environment Agency has established Agriculture Teams to carry out integrated regulation of farms and notifications may be received that particular farms are holding radioactive sources. On receipt of such notifications, Officers should check that the farm is registered (or that a source is registered as mobile) and take appropriate action if necessary.

## **Stat-attack ionising gun**

### **1 Introduction**

The number of premises registered to use static eliminators has reduced significantly in recent years as electrical methods of static elimination have come into widespread use. Details of equipment are available via the manufacturer's web site. Sources may require security registrations, depending on the activity in use.

### **2 Registration**

Polonium-210 and other sealed sources used for static elimination are required to be registered under section 7 of the Radioactive Substances Act 1993.

### **3 Justification**

Static elimination is specified as an existing use on the Defra web site.

See:

<http://www.defra.gov.uk/environment/radioactivity/government/legislation/pdf/justification-guidance.pdf>

and: <http://publications.environment-agency.gov.uk/pdf/PMHO1205BKHR-e-e.pdf>

## **Regulation of RSA93- offshore and Scotland based mobile Sources being used in England and Wales**

The Agency's North West Region South Area office will continue to be responsible for the determination of applications for registrations under section 7 and authorisations under section 13 of RSA93 for the English offshore area. Where radioactive waste is to be transferred to land for disposal the inspector determining the application shall confirm that the premises receiving the radioactive waste are authorised under section 13 to dispose of it by liaising with the inspector responsible for that area.

Applications for registrations under section 10 of RSA93 to use mobile radioactive sources offshore will be handled by the region in which the premises used for the storage of the radioactive sources (when not in use) and movement records are located.

Any enforcement work needed for registrations or authorisations offshore will be carried out by the Area nearest to the source location, with North West Region South Area kept aware.

Because of the separate legal system in Scotland, RSA 93 requires people who use mobile radioactive sources in both England and Scotland to hold separate registrations under S10 for use in England and Scotland. There is a long-standing agreement with SEPA that this will be done. In the event of any enquiries about this the need for separate registrations should be made clear.

Application for such registrations in respect of England and Wales should be handled by NW Region South Area. The Area which covers the base location in England remains responsible for enforcement work on that registration.

In the case of mobile HASS based in Scotland, the non-nuclear determination work instruction 474\_05 specifies the detail of the liaison needed between the Environment Agency and SEPA before issue of permits.

## **Repeaters containing Ra-226 coated valves in submarine Telephone cable systems**

Integral parts of submarine telephone cable systems are the repeater stations which amplify the signal. These are sited at intervals of 1 to 20 km along the cable, dependent on the age and design of the system. Each repeater could contain up to 8 valves containing 150 kBq of Ra 226.

The Radioactive Substances Act 1993 (RSA 93) does not extend to activities carried out in the sea or on the sea bed. Section 47 (1) defines "premises" to include any land, including land covered by water. This applies however to land covered by pools, for instance and not the sea bed. For territorial waters to be included there must be express reference in the statute (for example EPA 90 section 6, which provided that "Great Britain" includes so much of the adjacent territorial sea as is, or is treated, as relevant territorial waters for the purposes of the Water Resources Act 91). There is no such express reference in RSA 93.

Thus the question of whether the repeater stations fall within the definition of "premises" does not have to be considered. Therefore radioactive devices on the sea bed do not have to be registered.

## Regulation of high-energy medical linear accelerators (linacs)

### 1 Summary of Regulatory Position

#### 1.1 Activation Products

Internal components of LINACs - essentially the target and the collimator - may become activated in use. The nature of the machines, and the quantity of induced activity, are such that they fall within the provisions of The Radioactive Substances (Testing Instruments)(England and Wales) Exemption Order 2006 (SI 2006 No 1500).

#### 1.2 Depleted Uranium Shielding

Some LINACs contain depleted uranium shielding. This requires registration under RSA93.

### 2 Induced Activity Causes and Levels

Electrons incident on a tungsten target suffer capture and there are a number of subsequent reactions (threshold energy 7.5 to 13 MeV) resulting in activation with neutron and gamma emission, viz a number of (e,n) reactions involving W, Cu, Fe, Mn and Re with  $t_{1/2}$  varying from a few minutes to 2.6y, and a (e,p) reaction involving W. The emission from these activation products is mostly  $\gamma$  but there are some energetic  $\beta$  s. (Aluminium door furniture in a LINAC room can be easily activated by a (e, n) reaction to  $^{26}\text{Al}$  - very active,  $t_{1/2} = 5.35\text{sec}$ , 3.2 MeV  $\beta^+$ . Some significant dose rates can thus arise if aluminium items are used within the room - although this is a matter for HSE, rather than the Agency).

Except for the door furniture (and other similar items in the LINAC room), the activity is totally enclosed within components within the machine and is not removed from the premises on which the LINAC is used.

One manufacturer has estimated that the maximum quantity of induced activity which might be present in a W/Re target (weighing 1.4g) is 1.5 kBq - this would be due predominantly to the radionuclide  $^{185}\text{W}$  ( $t_{1/2} = 75\text{ d}$ ). The actual quantity of activity present will depend on the service duty of a machine - in terms of the energies and duration of operating cycles - but it seems clear that the total induced activity in the target and tungsten collimator will not exceed 0.4 MBq.

## **Use of the section 10 'environmental studies' certificate for Medical administration of radioactive materials at GP's Surgeries, hospices, etc, and in patients' homes**

### **1 Administration in GPs' Surgeries, Hospices, etc**

Small amounts of a C-14 labelled pharmaceutical (185 kBq per test) are used in *in vivo* diagnostic tests for the detection of *Helicobacter pylori* (indicative of stomach ulcer). The tests involve oral administration of the pharmaceutical followed by collection of exhaled breath over a set period of time. Residual C-14 is lost by normal bodily means, partly on the premises and partly elsewhere.

In the interests of efficiency and patient care and comfort, these tests are usually carried out during special sessions at GPs' surgeries, under the supervision of a hospital physicist. Traditionally we would have asked for registration of the premises and authorised an aerial discharge (via patients' breath). In view of the users' concerns about the charges associated with this approach, and the relatively small quantities and risks involved, an alternative solution was found.

The Agency's Current position is that:

Administration of such tests at GPs' surgeries should be regulated by means of sections 9(2)(b) and 10, and charges made accordingly. Applications should be made using form RSA2 (Environmental Studies).

Certificates should be drafted using template S10E(h)A (or subsequent revisions of this). This template is effectively the standard Environmental Studies template with an alteration to the "Certificate" page and a set of "modifications" paragraphs added – reference 474\_05 SD60.

Any variation which adds a new location to modification section 5(a), will be regarded as a minor change and hence not chargeable (but users should be urged to minimise the number of such variations).

In the event of similar circumstances arising for other types of tests, the above approach to regulation may be used (amending references to carbon-14 in the certificate as appropriate), subject to the Applicant demonstrating that suitable controls are in place.

### **2 Administration in Patients' Homes**

The possibility exists of the need to administer radiopharmaceuticals to patients at home. (A real example of this was a request to administer I-131 therapy capsules for treatment of thyrotoxicosis in cases where it would cause undue distress for the patient to attend the hospital for therapy; in one case because the patient was disabled, and in another because the patient had another medical condition.) Department of Health have indicated that they would only approve such action in exceptional circumstances and under strict controls, including checks of the home environment prior to the administration.

In the event that a case meeting DoH's criteria does arise, the approach to regulation described in section 1 above should be used (amending references to carbon-14 in the certificate as appropriate). Note that there can be no question of registration under s7 in these circumstances, since a patient's home is not "premises which are used for the purposes of an undertaking ...".

## **Regulation of mobile PET scanners**

### **1 background**

Positron Emission Tomography (PET) is a non-invasive, diagnostic imaging technique for measuring the metabolic activity of cells in the human body. It is useful clinically in certain conditions affecting the brain and the heart and certain types of cancer. PET produces images of the body's basic biochemistry or function as opposed to most traditional diagnostic techniques which produce images of the body's anatomy or structure (x-ray, CT scans, MRI). Since the alteration of biochemical processes with disease often occurs before there is a change in gross anatomy, PET may lead to earlier diagnosis. PET is also able to show a biochemical change in some diseases where there is no gross structural change, such as Alzheimer's.

There is a clinically recognised need for additional PET scanning facilities in the UK. A number of companies are planning to rollout mobile PET scanners which will visit various hospital premises for periods of one or a few days at a time. Use of the mobile units is intended to assist hospitals subscribing to the service in establishing a business case for a permanent installation.

### **2 policy objective**

RSR Policy have indicated that use of mobile PET scanners should be supported because of their clinical benefits; and that, since the environmental impact will be low, they should be regulated with a 'light touch'.

### **3 mode of operation**

Each mobile unit will carry a number of closed sources for calibration purposes. These will stay with the unit and effectively remain under the control of the PET operator.

Open radioactive material (principally F-18 as fluorodeoxyglucose, FDG)(F-18 decays by electron capture with a 110 minute half-life) will be supplied to the hospital/mobile unit at the start of the day. The patient is injected (typically 400 MBq F-18 per administration), after ~1 hour uses the toilet, and is then scanned. It is expected that 6-10 patients per day will be treated. These may be in- or out-patients.

In most cases, it is expected that the patient will be injected, wait and use the toilet within the hospital, transferring to the mobile unit only for the scan. However, at least one mobile unit design incorporates a patient preparation room for injections & waiting, although use of the hospital toilet is still required. The possibility of an on-board toilet and associated storage tanks has been mooted, but this is to be discouraged.

Potential waste streams are thus:

- patient excreta discharged via the hospital drains system;
- unused FDG (eg if a patient fails to show), used sharps, contaminated swabs, tissues, etc. This could be returned to the FDG supplier, decay stored at the hospital and then disposed as non-active clinical waste, or decay stored on the mobile unit and disposed at a hospital further down the line as non-active clinical waste;
- solid wastes produced on the ward following scanning of in-patients.

### **4 normal regulatory approach**

Normal regulatory practice would be to:

- register the PET operator to hold the closed sources under a s10 mobile certificate;

- register each hospital to be visited to hold F-18 under a s7 open certificate;
- authorise each hospital to be visited to accumulate solid waste (unused material, sharps etc, and ward waste), to dispose of this waste following decay, and to dispose of aqueous waste to drain (excreta), under a s13/14 certificate.

This assumes that:

- decay storage of any waste on the mobile unit is to be discouraged;
- return of wastes to the FDG supplier is likely to be impracticable;
- there will be close co-operation between the hospital and the PET Operator, such that the hospital is effectively in control of the radioactive material & waste.

If the PET unit were to operate in a more autonomous mode (eg injections carried out on unit, decay store on hospital site assigned to PET Operator) the PET Operator could be considered as a 'tenant' on the hospital site and hold the open registration and authorisation, for each site, himself.

Following normal regulatory practice could be considered as regulation with a 'heavy hand' for the following reasons:

- effort and costs of acquiring major variations/new permissions for an activity that may only occur a few times per year;
- time to obtain permissions limits flexibility. Once a hospital has identified a need to use the mobile unit, it is likely to want to do so quickly.

Registration/authorisation of the hospital might also be considered inappropriate in some cases, in that, although the hospital's facilities are being used, the radioactive material remains under the control of the PET Operator (this is particularly likely to be the case in hospitals which do not have existing nuclear medicine departments).

## **5 alternative regulatory approach**

The following approach has been agreed and should be offered to Mobile PET Operators as an alternative. The normal regulatory regime is still available should any individual hospital prefer it (this may well be the case for those hospitals with existing nuclear medicine departments, since they may wish to take control of all radioactive materials used on their premises).

The Mobile PET Operator should be issued with a standard s10 mobile registration for the closed calibration sources.

The Mobile PET Operator should also be issued with a s10 environmental studies registration for the open sources (F-18), allowing operation at a number of hospital sites. This equates the injection of patients with 'introducing radioactive material into organisms', and follows the model previously used for C-14 helicobacter tests at GP surgeries.

Use of s10(env studies) negates the need for authorisation for disposal of wastes produced from the patient post-injection (ie excreta and ward wastes). The potential environmental impact of such disposals has to be assessed when applying for registration. Limitation is achieved by only registering for the maximum activity needed for one day's work.

The Mobile PET Operator should also be issued with an authorisation under s13(2) to dispose of waste (unused materials, sharps, etc) by transfer to each hospital. Conditions on final disposal (and accumulation prior to) can be included, so that the

hospitals can take advantage of s13(4) – ie no further authorisation required for final disposal.

Applications should be made using forms RSA2m (Mobile Sealed Sources), RSA2esy (Environmental Studies) and RSA3. Certificates shall be drafted using the current versions of templates S10S, S10E(mobPET) and S13(mobPET). All hospitals that the Mobile PET Operator has indicated are likely to be visited shall be listed on the certificates. The templates allow for further hospitals to be visited subject to prior notification to the Agency. As for any other 'disposal by transfer', the agreement of the proposed waste recipient (ie the named hospital(s)) to accept the waste should be provided with the application or notification. A form is included with the covering letter for issue of certificates to the mobile PET Operator, to ensure that he provides appropriate information with a notification.

Note that, as there are no 'premises where sources are normally kept' for the F-18, schedule 2 of S10E(mobPET) has been modified to specify the premises where **records** are kept. This will need to be agreed with the Operator (likely to be the Company's registered office, or the storage location of the mobile unit) and should be treated as the 'premises address' for the IPCIS records for both the environmental studies registration and authorisation. This address will also determine which Agency Area Office should deal with the application and 'own' the permissions.

In order to comply with s10(3), s10(5)(b), s16(6) and s16(9)(b)(i), the Environmental Studies and Authorisation applications and certificates shall be copied to the local authorities for each of the named hospitals as per normal procedures and copied to the relevant local authorities each time a new notification is received.

The relevant PIR/RSR Area teams for the named hospitals shall, where practicable, be consulted prior to issue of certificates and on receipt of new notifications, and be sent copies of certificates and notifications.

The Environmental Studies authorisations should be treated for charging purposes as a standard 'Band 3' authorisation (not 3A or 3B). Each hospital should be listed on the IPCIS 'RAS details' page as a 'disposal by transfer' route.

Where several notifications have been received (5 or more), it may be advisable to reissue the permissions to show the full list of premises, but this will have to be done as a non-chargeable variation. Notified premises can also be added when permissions are being varied for some other reason.

## **6 review**

Successful operation of this more flexible approach will rely on good co-operation between the Mobile PET Operator and the hospitals visited, and the use of good practice in aspects where regulatory control is reduced compared to the normal regime (eg disposal of ward wastes). If persistent failures in these areas arise, the facility to use this alternative regime may be withdrawn.

Regulatory Officers should inform RSR Process Management of all relevant occurrences of non-compliance or 'bad practice' that come to their attention.

## **7 references**

Relevant template permissions and letters can be found via the non-nuclear determination work instruction.

## Guidance on Requirements for Cancellation of RSA93 Registrations

When a user requests the Environment Agency to cancel a registration we need assurance that all sources, apart from those that may be exempt, have been removed from the premises.

An applicant for cancellation of a registration certificate should address the following matters:

The applicant should give 21 days notice in writing of the intention to cease to hold registered sources in accordance with the condition of the registration certificate.

An audit should be carried out of the sources that have been brought on to the site against those that have been disposed of or transferred to other premises. Records should be made available for sources that have been transferred to other persons. Such records might include consignment notes made under the Road Transport Regulations, where the sources, activities, and destinations are described. The consignee should assess the suitability of the recipient of the sources.

In the case of sealed sources which are of no further use to the organisation, the *Radioactive Substances (Waste Closed Sources) Exemption Order (SI/1963/1831)* will usually cover the accumulation of the sources for up to 12 weeks before disposal.

In the case of open sources, disposal will normally be possible via the routes already authorised unless this is not possible without variation. It is likely that cancellation of an open source registration will be progressed in parallel with revocation of the associated authorisation, for which separate guidance is provided.

Records should be retained within the document management system of the organisation for a period and at a place agreed with the local inspector. Under section 20 of the Radioactive Substances Act 1993, the Environment Agency may impose requirements on the holders of registrations to retain records for a specified period after activities on the site have ceased. This may also require copies of certain records to be furnished to the Environment Agency after the registration has been cancelled. It is generally advisable to retain records of the site history in view of possible future redevelopment or land sales.

If any sources covered by an Exemption Order are to remain on the premises, for example in smoke detectors or in testing instruments, then these should be clearly identified both in the documentation and to the new owner of the premises.

## **Guidance for Registration of Storage in Transit ("SiT")**

The introduction of the High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005 ("the Regulations"), HASS (England) Directions 2005 and HASS (Wales) Directions 2005 ("the Directions") has prompted the Environment Agency to review its regulation of radioactive substances stored in the course of a journey. We have developed a specific, pragmatic approach to the regulation of SiT, taking account of the transitory nature of the business. This approach is documented by an application form for registration of storage in transit, supported by this guidance and a revised registration template covering all types of packages containing radioactive material.

SiT registrations should be issued only:

- 1 for storage of packages (which must remain unopened) whilst in the course of a journey (in transit), and
- 2 where the Radioactive Substances (Storage in Transit) Exemption Order 1962 (the "Exemption Order") cannot be used

SiT registration will be required for companies such as those providing commercial services as shippers or transporters of packages containing radioactive material, who are unable to meet the terms of the Exemption Order. In these cases many registered holders will have little advance information regarding the receipt or contents of packages containing radioactive materials and will not retain them for long periods, before dispatching them unopened. The current template registration for SiT has been designed to take account of this set of circumstances.

The revised standard SiT registration contains no limits on holdings of radioactivity since in many cases the holder will be unable to specify maximum holdings. If, in exceptional circumstances, limits are appropriate then additional guidance should be sought.

The standard conditions of the revised SiT registration template incorporate the requirements of the Radioactive Substances Act 1993 ("RSA 93"), the Regulations and the Directions. The conditions therefore include those requirements in respect of high activity sealed sources ("HASS") and sources of similar level of potential hazard which are considered practicable for storage in transit. There is only one template for SiT – the same conditions apply to any package subject to SiT registration.

Holders of storage in transit registrations to the new template, must have management systems to implement the registration conditions. The management system must cover routine working arrangements and the actions to be taken in the event of packages being damaged or undeliverable for any reason, including refusal by the consignee. This is especially important for imported radioactive packages, which may contain large sources or be difficult to return to the sender. The Holder must have plans in place for dealing with packages containing radioactive material, which are not delivered to the consignee (see below).

### **1 Scope of user's responsibilities**

The template registration addresses the management and security of packages containing radioactive material but does not address some aspects of HASS regulation (financial provision, arrangements for disused sources, requirement for checking that recipients are registered under RSA 93 or record keeping) as we do not consider that these requirements are appropriate for storage in transit of packages containing radioactive material.

### **2 Recipients of HASS and Similar Sources**

Regulatory Officers dealing with sites where packages are known to contain large sources (ie HASS and sources of similar potential hazard), should review the Holder's records for such packages and confirm that consignees are registered to receive them when necessary.

### **3 Length of Storage**

Packages may only be held for a maximum of 4 weeks - any longer than 4 weeks is not normally considered to be in transit. This is to prevent packages being held for long periods if they are not deliverable initially. If packages are retained for longer than 4 weeks, the Holder should discuss with the Environment Agency what course of action is most appropriate in the circumstances in accordance with their plan for such eventuality. Priority should be given in these cases to the safe and secure transfer of the packages to an appropriate recipient.

### **4 Security for Packages containing Radioactive Material**

Premises subject to a SiT registration are assumed to be Category 2/Security Group B (as defined in the document entitled Security Requirements for Radioactive Sources published by NaCTSO in May 2008 – available from police Counter Terrorism Security Advisers (CTSAs)), unless this is clearly not appropriate on the basis of knowledge of the types of packages received. Advice should be sought from CTSAs in the normal manner. Premises in use 24 hours a day may not need alarm systems if the packages are effectively under continuous supervision. Improvements in security may be required if necessary, by conditions imposed in an improvement programme.

Schedule 1 of the certificate will specify the security group appropriate to the site, as defined in the NaCTSO Document. Security measures appropriate to the security group specified must be in place. During inspection visits, Regulatory Officers should examine records of storage in transit and check that only sources appropriate to the security group specified have been received.

### **5 Conditions of storage**

Holders are expected to store packages in such a manner as to prevent damage. They should be checked (usually visually) to confirm their location and apparent good condition on at least a daily basis. In deciding when to carry out such checks, the Holder should take account of the time for which packages are held, the hazard they represent and the frequency of access to the store. Tests for leakage or contamination are not normally expected unless a package has been visibly damaged or subjected to extreme conditions.

### **6 Loss or Damage**

In the event of a package being lost or damaged, the Holder's arrangements for such an eventuality must be put into action. Authorisation may be required for accumulation and disposal of radioactive waste from such an incident.

### **7 Transport Regulations**

Radioactive packages held during storage in transit may be subject to the relevant transport regulations, in addition to RSA 93, the Directions and the Regulations. Routine liaison with the Department for Transport will not normally be required for regulation since the registration meets the Agency's requirements. If, however, liaison is required then the normal contact arrangements for DfT should be followed. Liaison may be appropriate following an incident.

## **8 Premises which are already registered**

Cases may arise where SiT is carried on as part of a Holder's operation involving radioactive materials, eg a hospital may store packages for a period on their way to another hospital. In these cases where the work can be satisfactorily regulated under an open or closed registration required for other purposes, that should be done. Where the work is not amenable to regulation in this way (eg package contents are too unpredictable), then a separate SiT registration should be issued.

## **Inclusion of sealed source Radium-226 luminous articles in museums in open source registrations**

Regulation of museums can be improved and made more risk based by the simplification of the registration system shown below. Development of a single registration template which covers both sealed (category 5) and open sources is considered impractical at this stage because the RSR regime is expected to be included in a future round of Environmental Permitting Regulations which would mean that the position would change again soon.

A new optional paragraph has been included in Operational Instruction 474\_05\_SD02 (additional paragraphs for specific purposes) to be used where relevant, ie when the total holding of radium in a museum is less than 400 MBq:

The open sources to which this registration applies (the registered material specified in the table in Schedule 2) may include sealed sources luminised with Ra-226.

A sealed source luminised with Ra-226 is an item which is an instrument, illuminant or indicator which is luminous and is radioactive material solely because it incorporates a luminescent substance sealed within it by a glass or acrylic cover.

### **Notes:**

This paragraph is only to be used for museums.

The total activity of Ra-226 in open and sealed sources should be specified in one entry in the table.

There is no need for a fixed condition registration for these cases.

## **Background**

In recent years the Agency's approach to registration of items luminised with radium-226 has been:

- If the radium paint is covered with glass or other solid robust covering and the item is intact then registration as a closed/sealed source is appropriate as the radium is likely to be contained.
- If the item is damaged so that the radium is not enclosed or was never enclosed (eg spots of luminous paint on sights etc), then the radium is vulnerable to damage and deterioration and can spread contamination. Such items have been considered as open/unsealed sources.

Museums frequently hold aircraft instruments, compasses and other luminised items some of which are open and some sealed sources. They therefore need both open and sealed source registrations. Users would be encouraged to dispose of open source items which are causing contamination. Disposal of open sources as waste would require authorisation.

Control of radioactive substances in museums can be poor unless we have inspected and required improvements. Museums sometimes do not know the activity of items and estimates need to be made based on radiation dose rates. In general the risk from museums is directions apply to sealed sources; security for open sources (beyond that of the standard RSA and IRR requirements) is voluntary. The security category for sealed source luminised items is determined by A/D calculation as the use is not covered by the descriptions in the NaCTSO Security Book. CTSA's advise on the extent to which

collections of smaller sources are vulnerable to a single threat and should be aggregated to determine security category. In many cases the total holding of radium luminised items will be small (category 5) and also dispersed throughout a museum and so formal security requirements are unlikely to be appropriate. However, in a few cases there may be very large holdings of sealed sources (eg national museums) gathered together for storage or display. In these circumstances, if the security category is 4, the user needs to meet regulatory security requirements through a 4S certificate.

At a few sites the luminised items may be in airworthy planes which are flown from time to time, perhaps to other museums or displays. Such sources are generally considered to be "in the course of a journey" and so may be considered in the same manner as that for depleted uranium in aircraft balance weights, ie excluded from RSA on the basis of section 47.

At a few sites there may be more than one user user-organisation in reasonable proximity, eg sharing an aircraft hanger. The interactions between these organisations can be complex and will generally require each to be separately registered and keep records for their own holdings. Regulatory Officers need to be clear about responsibilities in these cases. For the reasons given above, aggregation of the different source holdings for security purposes is unlikely to be needed.

### **Additional matters**

We are directed not to include information on sealed sources onto public registers. PSC should not send these applications covering both open and sealed sources to Local Authorities or public registers. Areas should not send certificates. Authorisations would continue to be sent unless they cover sealed sources also.

Users still need to understand the distinction between sealed and open sources because waste sealed sources may be disposed of under the Waste Closed Sources Exemption Order while waste open sources need authorisation. This would need to be clear in guidance and liaison with the sector.

Charging is by Band 4F or 4A (depending on whether or not an authorisation is also held). Closed source registrations could be cancelled after inclusion of the sealed sources onto open source certificates. Most casework could be done with discretionary waiver of the application charge, depending on the circumstances.

## Regulation of Cyclotrons

### Introduction

Several cyclotrons are being constructed and used to manufacture short-lived positron-emitting radionuclides for PET/CT scanning. This work can be either for medical diagnosis or research into new drugs or treatments. The box below explains PET/CT scanners. The building housing the cyclotron also has an automated manufacturing pharmacy to convert the cyclotron's product into the chemical form used in treatment. Some sites are located next to a hospital that uses their product. Some scanners are up to two hours away by road and the radioactive material is transported in heavily shielded transport containers. Guidance on regulation of mobile PET scanners is given in RASAG Chapter 1.

PET/CT consists of two machines that permit the near simultaneous scanning of a human being. The CT creates a three dimensional X-ray image of the patients bones and organs. The PET scan images the tissue that has cancer. It identifies many cancers but not all and there is a limit to the size that can be visualised. By combining positron emission tomography with a low detail CT imaging machine the clinician can locate the cancer better to a particular organ and the colour representation on the display makes the location of primary and secondary cancers easier. This scanner also gives a far clearer picture with less uncertainty than MRI or CT machines, which provide an image of greys of different density.

Most of the newer cyclotrons are dedicated to  $^{18}\text{F}$ FDG (fluorodeoxyglucose labelled with F-18) production for screening on PET/CT machines. A few cyclotrons are designed and used to make a wider variety of positron emitting radionuclide.

Information on the commonly used radionuclides is as follows:

Radio nuclide	Approx Half life, minutes	Purpose of radionuclide
F-18	110	FDG in aqueous solution is injected into the blood. Many centres now coming on line run by a few companies and a few research/hospitals centres
N-13	10	Nuisance by-product of sample irradiation. Created from the small fraction of O-16 in the sample when making F-18.
C-11	20	Research material. Production limited to about four centres in E&W: Hammersmith, Manchester, Birmingham and Cambridge.
O-15	2	Used for medical scanning by injection into the blood, especially for neurological screening.

The radioactive material is produced by high-energy irradiation of suitable material in a cyclotron where they undergo a nuclear reaction. They then undergo chemical processing in a shielded hot cell to produce the product material in the physical and chemical form needed. The materials are held in a liquid or gaseous phase in a vessel (target), which is connected via tubing to the hot cell where processing takes place. Because of the short half lives of the nuclides and the time taken for chemical processing and other delays before use, the initial activities produced are very high.

The targets are usually an aqueous solution enriched with the nuclide which on irradiation forms the required radionuclide, eg F-18 is produced from O-18.

The transfer of the radionuclides from the target to cells where the finished product is produced is carried out remotely by automated systems to reduce radiation exposure of staff. The various systems are served by a controlled ventilation system which is fitted with abatement to reduce gaseous discharges and monitors to measure them. The

various stages produce solid, aqueous and organic liquid wastes. Inspectors needing further details of cyclotron operations are advised to contact RSR Process Management.

### **Design**

The design of cyclotrons, their facilities and ancillary equipment should be subject to advice at an early stage from a suitable Radiation Protection Adviser/Qualified Expert (RPA/QE) experienced in PET/CT work. A substantial amount of information about production of radioactivity and radioactive waste will be needed at this stage from the supplier of the equipment, which should be based on previous operating experience of the same or similar equipment.

The cyclotron is likely to be replaced within a decade and a way of removing the machine should be included in the design. Good access to important features should be built into the design. Services should avoid high flux areas where possible.

There are three types of design at present, "fully" self-shielded, partially shielded and not shielded at all. As fast neutrons are an inevitable by-product of the bombardment, the equipment and walls may become activated. This is particularly noticeable with non-shielded cyclotrons. Walls can be built with a strippable layer and consideration should be given to moderating and adsorbing the fast neutron radiation in the surface layers to cut costs and future disposal problems. Cyclotron vaults can have a layered floor so that the activation is effectively located in the upper layer, which can be removed easily. Consideration should be given to use of non-metal reinforcement in place of the usual rebar in concrete.

The materials in the cyclotron and the layout of its design can reduce the activation of the cyclotron's materials. Test pieces of the materials of fabrication should be located at the maximum flux so that the activation of the cyclotron's components can be evaluated easily. Alternatively, measurements of the same materials in a predecessor cyclotron can be used, if the energy cycles match.

### **BPM**

One principle objective is the consideration of options for minimising the production and disposal of radioactive waste using Best Practicable Means (BPM)(see RASAG guidance on BPM). The Environment Agency will require it to be clear that BPM will be used in design, operation, maintenance and plans for decommissioning of cyclotrons, before they are authorised for use. In order to do this, users will need to supply written assessments of BPM for the site to be authorised, with their application for authorisation.

Some specific issues that the BPM assessment should address are:

- The operating procedures used can have a significant effect on the reliability of HAVAR windows, eg damage can be caused by beams focused too tightly.
- The tube bundles connecting the cyclotron to the chemistry cell have to be replaced and it is important that the connections are re-made and tested every time that this operation is done.
- A maintenance programme is an essential for achieving BPM.
- A substantial proportion of discharges is commonly in the form of peaks or spikes and the BPM assessment must show that this has been taken into account and address how to prevent and minimise such discharges.
- Awareness of possible impurity and secondary radionuclides.
- Response to monitoring data.

## Ventilation system

The potential for the discharge of highly active radionuclides makes it very likely that abatement equipment will be needed in ventilation systems serving the active plant. This can take several forms depending on the radionuclides to be produced and other factors. Features of the different types which have been installed at operating facilities are discussed below:

Radio nuclide	Abatement techniques currently known or used.
F-18	Carbon impregnated filters achieve a significant reduction. N13 spike can occur at the same time as F18 and need separate abatement.
N-13	Stored in a bladder in the hot cell prior to discharge duct. Discharged to hot cell ventilation after decay.
C-11	Should be accumulated into pressurised bottles, subject to long delay path (see O-15) or chemically adsorbed to reduce local doses, when significant amounts are made. Bottles are discharged to stack via ventilation ducts after decay.
O-15	Can be piped for decay into a very long plastic pipe, which is open to the cyclotron's ventilation system.

The design intention of abatement equipment should be made with reference to operating experience at similar cyclotrons. Ventilation and abatement equipment should be designed to be readily maintained in accordance with the manufacturer's instructions. Filters should be safely accessible at floor level whenever possible.

The design of ventilation systems should:

Ensure the efficient removal of contaminated air from the intended space	The system should extract efficiently and not leak into the area extracted or any other area
Ensure abatement of radioactivity concentrations	By design, maintenance and operation Requires information about the expected activity in terms of which radionuclides and their pattern of production
Ensure discharge into the atmosphere in a manner to minimise the radiation exposure of people nearby	Needs to be supported by suitable modelling (computer or wind tunnel)

Assessment of the potential radiation exposures from discharges should be made using computer models. However, in exceptional circumstances when nearby buildings or other features are likely to significantly affect dispersion, other methods (such as wind tunnel modelling) may be necessary also.

## Wastes and Decommissioning

In designing cyclotron facilities, provision should be made for the handling and storage of other wastes which are likely to arise during operation and maintenance of the equipment.

The need to decommission the facilities in due course should be taken into account during the initial design. This should include sufficient access and space for working

and removal of equipment, the potential for activation of construction materials (especially steel reinforcing bars) by irradiation, inclusion of removable test plugs in concrete and the potential for provision of sacrificial layers in floors. The intention is to minimise the amount of radioactive waste needing to be disposed of when decommissioning, so only longer-lived radionuclides need be taken into account in this aspect.

### Monitoring

It will be necessary to install monitoring equipment in the ventilation system to measure and control the amount of radioactivity being discharged. Additionally, monitors provided in the working environment primarily for health and safety purposes may have a useful secondary purpose of warning of failure of the ventilation system (leakage into the work space).

There are two main types of ventilation system monitors in use: gamma monitors and co-incidence counters. All instruments should be installed so that they can be readily maintained and calibrated and in areas where the background radiation level allows them to operate with sufficient sensitivity. It is difficult to distinguish by direct monitoring between different positron emitters and emission monitors are not required to achieve this. Manufacturers of the different types of monitors are shown below:

Type	Manufacturer
Gamma	Lab Impex Berthold
Co-incidence	Thermo

In practice it has been found that a substantial proportion of the gaseous discharges from cyclotron operation arise from peaks or spikes in the activity discharged. Monitoring systems should be designed to measure and record these for trend analysis to assist BPM consideration.

### Operation

The operation of the cyclotron needs to be in accordance with the conditions of the authorisation issued by the Environment Agency. Attention is drawn to the conditions of the authorisation which require the operator of the facility to have management systems and to use BPM to minimise waste disposals. The Environment Agency has issued separate guidance on both of these subjects.

The operator should carry out analysis of monitoring data at suitable intervals to see that the pattern of discharges is as expected and to see if any actions are possible which could reduce discharges, in the context of continuing application of BPM. These may be triggered by reporting thresholds given in additional conditions (see below).

Discharges which breach authorised limits or failure to accumulate waste in accordance with authorisation conditions need to be reported to the Agency as specified in the authorisation.

The Environment Agency will set discharge limits to restrict discharges to those that are necessary for the proper operation of the equipment, within reasonable operational fluctuations. We will not authorise incidents or accidental releases.

## Registration/Authorisations conditions

This section deals with the way we will regulate cyclotrons in England and Wales.

### Open and Sealed Registrations Conditions

The activated radionuclides arising from the bombardment of the shielding or cyclotron should not be accounted for in the registration while the components are part of the operating cyclotron or its shielding, but must be identified and their activity known at the end of life of the component when they are declared as waste. Only routinely produced items that are removed from the cyclotron or associated equipment need to be treated as waste in the authorisation. This will include target windows/foils and other items which become activated with long-lived activity. Usually the window of the target is made of HAVAR and these are routinely replaced after a period of use. Their regular failure is not to be seen as an accident but as a routine consequence of material wear out, provided suitable maintenance has been carried out in accordance with the manufacturer's recommendations. An additional condition in the authorisation can exclude the listing of the activity of short half-life items.

The useful radionuclides that are being produced are to be included in the table in the schedule of radioactive material in the open registration. Targets usually contain liquids, but may be gases.

### Authorisation Conditions

Radioactive waste is listed in the authorisation. The adventitiously produced gases like A-41 and H-3 produced in the cyclotron should be identified in the application documents and an estimate of their likely rate of production made. They will be covered by a general term in the authorisation... "all other radionuclides"... and the Modification section should have a condition which exempts their listing in records and the Pollution Inventory.

The intention is to have a condition in the authorisation to cover decommissioning, in particular to record how the machine was actually built and the composition of significant materials of construction. Drawings of the as-built machine and the building housing it should be stored in a safe but known place. Photographs should be taken during construction. Analyses of significant materials of construction should identify the quantity of trace elements in the materials since this may well dominate the induced activity. A report containing all these sources of information, a plan of how decommissioning would be done and an analysis of likely disposal options for the cyclotron and the vault concrete should be made.

The decommissioning condition is essential also to bring home to designers that reasonable access and ease of dismantling must be built into the facility.

Other improvement conditions that may be included are intended to reflect the special nature of a machine designed to produce radionuclides. One condition requires the reporting of spike releases that are above specified thresholds without delay and in an annual report to the Agency.

The authorisation does not require that the induced radioactivity in the materials of construction be recorded through the life of the machine. Components that are removed as waste items must be recorded and segregated by material type, half-life and date produced so that the material can be stored and disposed of appropriately. Plastic and rubber components produced may be suitable, after a short decay period, for incineration. Concrete waste can be separated into active parts and relatively inactive. Long lived metal components may need storage for 10 years decay.

Surplus/reject radioactive material of short half-life retained for decay does not need to be included in long-term records.

## Schedule – cyclotron conditions

### FURTHER CONDITIONS

1. The user shall submit to the Environment Agency in writing a decommissioning plan within six months of the start of operation of the cyclotron or the coming into force of this authorisation, whichever is later. The plan shall include a record of how the plant was constructed, including drawings, photographs and material specifications. Details of any sacrificial layers or test pieces, used to determine the long term induced activity, shall be identified with their locations. The plan shall include an estimate of the types and quantities of radioactive waste likely to arise at the end of life of the cyclotron. The methods of production, accumulation and disposal of the waste shall be included.

The user shall review the decommissioning plan at least every five years and an updated plan submitted to the Environment Agency within one month of the review.

2. The user shall submit to the Agency in writing by 31 January each year, a report for the previous calendar year on the releases in 1 minute of greater than 1 GBq of positron emitting radionuclides from the authorised disposal routes specified in Table 1 of Schedule 3b. The report shall include an analysis of the trends in discharges.

The user shall notify the Agency without delay of any releases in less than 1 minute of greater than 10 GBq of positron emitting radionuclides from the authorised gaseous disposal routes specified in Table 1 of Schedule 3b. Details of the releases shall be included in the report submitted to the Agency by 31 January each year.

3. The user is exempt from the requirement in Conditions 12 and 13 of Schedule 1 to make records of the accumulation of radioactive waste containing only positron emitting radionuclides with a half life of less than 2 hours.