



Exemption guidance

Medical and veterinary uses of radioactive sources

**September 2011
Version 1**

**Radioactive Substances Act 1993
The Environmental Permitting (England and Wales)
(Amendment) Regulations 2011**

Medical and veterinary GUIDANCE

Version 1.0
September 2011

1 General questions

What regulations apply to permitting radioactive substances in the UK?

The Environmental Permitting (England and Wales) (Amendment) Regulations 2011
Radioactive Substances Act 1993
The Radioactive Substances Exemption (Scotland) Order 2011
The Radioactive Substances Act 1993 Amendment (Scotland) Regulations 2011
The Radioactive Substances Exemption (Northern Ireland) Order 2011
The Radioactive Substances Act 1993 (Amendment) Regulations (Northern Ireland) 2011

What other guidance is available?

The UK Government and Devolved Administrations have issued guidance for environmental regulators and users of radioactive substances as follows:
Guidance on the Exemptions Framework under the Radioactive Substances Act 1993 and Schedule 23 to the Environmental Permitting (England and Wales) Regulations 2011.

This document is one of a series of guidance documents issued by the environmental regulators to assist users in complying with the above regulations. They are available on the Environment Agency and SEPA web sites. The guidance is intended to apply to all parts of the UK. Because the regulations are different though, reference is made here to the tables in the Government Guidance to keep the text simple.

Exemptions from EPR2010/RSA 93 applicable to medical/veterinary practice

Radioactive materials are used in the diagnosis and treatment of both humans and animals. Open source material can be administered, usually via injection, to diagnose or treat disease. Sealed sources can also be used in the treatment of disease or to calibrate equipment. Pathology laboratories sometimes use radioactive material help diagnose disease.

Most of the time organisations carrying out such work would require a permit under EPR2010 or RSA93 for the keeping or use of radioactive material or accumulation and disposal of radioactive waste. Under some circumstances the use of small amounts of radioactive material in the medical and veterinary sector is exempt from the requirement to have a permit provided certain conditions are met. Some exemptions apply specifically to the sector. Other exemptions are more general but will be useful to this sector. This guidance describes in detail the exemptions specific to this sector and highlights other relevant exemptions. The new provisions are compared with the old Hospitals Exemption Order¹.

Who is this guidance for?

This guidance is intended for professionals using radioactive materials in the medical and veterinary sector.

Does it apply in England, Wales, Scotland and Northern Ireland?

Yes. The requirements are the same across the UK.

Specific exemptions for the medical and veterinary sector

Exemption for keeping or use of radioactive material and the accumulation of radioactive waste

Small quantities of radioactive material (other than sealed sources) intended for use for medical or veterinary diagnosis or treatment or clinical or veterinary trials are exempt. The resulting waste that is accumulated is also exempt. The maximum activity (material and waste) that can be held is:

Up to 1 GBq of Tc-99m and

Up to 200 MBq of all other radionuclides (no more than 100MBq of which is contained in material intended for use).

Scope of exemption

A clinical trial means an investigation in human subjects to ascertain the safety or efficacy of medicinal products as defined in the "Medicines for Human Use (Clinical Trials) Regulations 2004"².

A veterinary trial means an investigation to ascertain the safety or efficacy of veterinary products conducted under conditions of day-to-day use of the product, in the species for which it is intended to be used.

Hospitals and other establishments that are already permitted for the keeping and use of open sources for this purpose cannot take advantage of this exemption for keeping or use of radioactivity or accumulation of radioactive waste. Establishments with sealed source permits may make use of it.

It is broader in scope than the old hospitals exemption order since any organisation using radioactive material or accumulating radioactive waste for the specified purposes can take advantage of it. The hospitals EO only exempted work with radioactive materials in institutions such as nursing homes and mental hospitals. The restrictions on alpha emitters and iodines in the old order are removed.

This exemption does not apply to households since these are outside the scope of EPR and RSA93, so would not require a permit.

There is no specific restriction on the time that open source radioactive waste can be accumulated before disposal but it must be disposed of as soon as reasonably practicable, usually within two weeks. Longer accumulation periods may be justified in some cases and decay storage so that the radioactive waste reaches concentration levels for exempt disposal is allowed but this should normally be for no longer than 26 weeks. Section 5.1 gives the limits on amounts of exempt waste that can be disposed of.

When deciding whether a permit is required for work with radioactive materials the user needs to consider whether exempt disposal following decay storage is practicable. Material must be decay stored in a dedicated location with adequate records.

Conditions

Keep an adequate record of any exempt radioactive material and accumulated waste held and its location within the premises.

Ensure that where reasonably practicable exempt radioactive substances or the container of such radioactive substances, is marked or labelled as radioactive.

Allow the regulator access to records or premises if required.

Store the exempt radioactive substances (when not in use) safely and securely to prevent, so far as practicable the accidental removal, loss or theft from the premises where it is held, or loss of containment.

Do not modify or mutilate that container housing the exempt material or waste or allow any uncontrolled or unintended release of radioactive material or radioactive waste from the container. (the purpose of unsealed radioactive material usually requires that it is dispensed from the container – this is allowed but unintended or uncontrolled release should be prevented).

Report loss or theft (or suspected loss or theft) of exempt radioactive substances to the regulator as soon as practicable. Include in that notification the details of any other incidents of loss or theft (or suspected loss or theft) of any radioactive substances over the 12 months preceding the incident being notified. Notification to the regulator only needs to be made if the quantity of material lost or stolen (or suspected to have been lost or stolen) in the 12 month period exceeds 10 times the amount shown in column 2 of Table 3.1 of the government guidance. (e.g. 100MBq of Tc-99m).

Exemption for disposal of human excreta in aqueous solution

Radioactive waste in the form of human excreta in aqueous solution can be disposed of to the foul sewer³. The maximum quantities that can be disposed annually are:

10GBq of Tc-99m;

5GBq of other radionuclides

Scope

This exemption does not apply to households since these are outside the scope of EPR and RSA93 so would not require a permit.

Conditions

Ensure that adequate records are kept to demonstrate compliance with the annual limits for disposal.

Allow the regulator access to the premises and records if required.

Other relevant exemptions and exclusions not specific to the medical and veterinary sector

Very Low Level Waste (VLLW)

Small amounts of solid waste (very low level waste) can be disposed by mixing with substantial quantities of non-radioactive waste provided certain limits and conditions are met. The maximum activities and concentrations are given in the Table below. See also separate guidance.

Radioactive waste	Maximum concentration of radionuclides	Maximum quantity of waste to be disposed
Solid radioactive waste, with no single item > 4 x 10 ⁴ Bq	4 x 10 ⁵ Bq for the sum of all radionuclides per 0.1m ³	2 x 10 ⁸ Bq/year
Solid radioactive waste containing tritium and C-14 only, with no single item > 4 x 10 ⁵ Bq	4 x 10 ⁶ Bq of tritium and C-14 per 0.1m ³	2 x 10 ⁹ Bq/year

Note that insignificant amounts of liquid waste, such as vials containing radiopharmaceutical residues, that are disposed of with the solid waste can also be regarded as VLLW.

Labels and markings indicating that the material is radioactive must be inaccessible or removed before disposal with inactive waste. There is no need to remove labels from waste that is disposed of in a sealed “sharps bin”.

This exemption is similar to the exemption for solid waste in the old Hospitals Exemption order but now includes alpha emitters and disposal by incineration is allowed.

Exemption for disposal of aqueous liquid wastes other than human excreta

Aqueous radioactive waste with a radionuclide concentration less than 100 Bq/ml can be disposed to the foul sewer. The maximum annual activity that can be disposed is

100MBq for the sum of: H-3, C-11, C-14, F-18, P-32, P-33, S-35, Ca-45, Cr-51, Fe-55, Ga-67, Sr-89, Y-90, Tc-99m, In-111, I-123, I-125, I-131, Sm-153, Tl-201; and

1 MBq for the sum of all other radionuclides.

Many users will find this comparable to the provision in the old hospitals exemption order (disposal of 50MBq month to sewer for non alpha emitters).

This does not apply to organic liquids such as scintillant that cannot be disposed of to the sewer and are normally incinerated. Instead this material can be considered a “relevant liquid” and is not subject to regulation if the concentration is below that given in table 2.3 of the government guidance.

More detailed guidance on exemption of open sources is available.

Small sealed sources

There is provision for a number of small sealed sources to be held without a permit. Separate guidance is available. Sealed sources up to 4MBq can be held without a permit provided that the total activity on the premises of these exempt sources is less than 200MBq (includes keeping, use and waste accumulation)

Very small sealed sources (up to 200kBq) can be disposed of with ordinary refuse provided that certain conditions are met. Separate guidance is available.

Waste sealed sources

No permit is required for the accumulation and disposal of intact waste sealed sources provided that this is by transfer to a suitably permitted organisation. 26 weeks accumulation is allowed. Separate guidance is available.

Gaseous Waste

Gaseous radioactive waste which is released from within a container at the time that the container is opened, where that gas has been emitted by solid or liquid radioactive material within the container, is exempt from regulation. This would include Xe-131m that can be released when I-131 containers are opened. Precautions such as the use of a fume cupboard to ensure compliance with IRR99 should be followed.

Contaminated apparatus and equipment still in use and remaining on the premises

Certain radioactive materials are “outside the scope” of, or not subject to, EPR2010/RSA93 requirements at all. Equipment or apparatus that has been incidentally contaminated during the course of its use is outside the scope of EPR2010/RSA93 provided that it is not waste and remains on the premises where it

was created. Contamination can include activation by high energy sub-atomic particles. Thus the activated components of a cyclotron, such as the target assembly, are not subject to regulation under EPR2010 or RSA93 whilst in use. Such items therefore do not need to be included on the permit as “radioactive material”. Once the item becomes waste it is subject to regulation – the activated target windows or foils for example, once no longer usable, are regarded as radioactive waste and need to be included on the appropriate permit. (Where a material is activated with the intention of using its radioactive properties, such as the PET emitting radiopharmaceuticals, it is radioactive material and subject to regulation). IRR consideration may be relevant.

The high energy photon beams generated by linear accelerators can cause the production of a small number of thermal neutrons which are then capable of causing activation of materials within the treatment room. These activation products are similarly outside the scope of regulation under EPR2010 or RSA93.

Short Lived Radionuclides

Radionuclides with half lives less than 100 seconds are outside the scope of EPR2010 and RSA93, and not subject to regulation. This would apply to Kr-81m.

Other notes

Human corpses are never regarded as “waste” – thus when a patient dies following the administration of a radioactive substance the corpse cannot be regarded as radioactive waste. Burial grounds and crematoria are therefore outside the scope of regulation. The Medical and Dental Guidance Notes⁴ give guidance on the precautions required following the death of these patients. This should be followed (to ensure that the public dose limits are met). Specific guidance on precautions after the implantation of I-125 seeds is expected to be published by the professional bodies.

Animal corpses containing radioactive material are radioactive waste.

Who is responsible for deciding if radioactive material or waste is exempt?

The user. Responsibility for the use of exemptions and compliance with the conditions rests with the person or organisation responsible. If the environment agencies become aware of failure to hold a permit when one is needed or to comply with exemption conditions, action will be taken to obtain compliance.

Do I need to tell anyone I believe radioactive material or waste I have is exempt?

No.

Where can I get more advice?

From an appropriate adviser, e.g. a suitable Radioactive Waste Adviser or Radiation Protection Adviser. Or from the environmental regulator

Common scenarios where exemptions apply

An in-patient in a hospital without a permit goes to a permitted hospital for a nuclear medicine test. They return later to the un-permitted hospital. Radioactive waste that is excreted and goes to the sewer is covered by the exemption for the disposal of human excreta outlined in section 4.1. Any solid waste (incontinence pads, dressings etc) can be accumulated and decayed to VLLW levels using the provision outlined in section 4.1. Assuming that the investigation is a bone scan and the ARSAC⁵ maximum activity (600MBq) has been administered, using the appropriate

excretion factor, 10% or 60MBq should be assumed to be excreted to the sewer at the un-permitted site. Since the hospital can dispose of 10GBq/year to the sewer 166 such patients could be accepted back each year under the exemption regime.

A hospital without a permit wants to carry out sentinel node investigations. 20MBq is injected into patients before they go for their operation. The hospital could operate under the exemption that allows up to 1GBq of Technetium-99m to be kept on the premises.

The tracer does not enter the systemic circulation so excretion to sewer does not need to be considered.

Tissue samples retained for analysis are radioactive material covered by the exemption.

Solid waste can be disposed as VLLW following decay storage if required.

Any liquid waste from instrument washing etc. is covered by the exemption described in section 5.2 above.

The small check sources sometimes supplied with the probe used to detect the radioactivity in the operating theatre are usually covered by the exemption for small sealed sources.

Notes

1. The Radioactive Substances (Hospitals) Exemption Order 1990 SI 2512 as amended by The Radioactive Substances (Hospitals) Exemption (Amendment) Order 1995 SI 2395

2. "Clinical trial" means any investigation in human subjects, other than a non-interventional trial, intended—

(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products,

(b) to identify any adverse reactions to one or more such products, or

(c) to study absorption, distribution, metabolism and excretion of one or more such products,

with the object of ascertaining the safety or efficacy of those products;

³ The foul sewer must connect to either

a public sewer; or

a disposal main leading to a sewage disposal works that can handle at least 100m³ of effluent per day and discharges treated effluent either to the sea, or to a river with a flow rate of at least 1m³s⁻¹.

⁴ Medical and Dental Guidance Notes: a Good Practice Guide on All Aspects of Ionising Radiation in the Clinical Environment, Institute of Physics and Engineering in Medicine, 2002.

⁵ The Administration of Radioactive Substances Advisory Committee