



Exemption guidance

Small amounts of open radioactive sources

**September 2011
Version 1**

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

Open sources 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.

What is an out of scope open source?

Either solid open sources and relevant liquids which contain:

- artificial radionuclides; or
- naturally occurring radionuclides used for their radioactive, fertile or fissile properties;

(together these are known as “practices” in this guidance) and have concentrations which do not exceed the values in Table 2.3 of the Government Guidance are out of scope. Aqueous liquids and gases from practices are not out of scope, irrespective of concentration (but see below).

Where more than one radionuclide is present then the Table 2.3 summation rule must be applied. Where artificial radionuclides are not listed, the values at the end of the table apply. Naturally occurring radionuclides not listed are out of scope.

For example, the following items would be out of scope:

- unlimited amount of solid containing C-14 at 10 Bq/g; or
- unlimited amount of liquid scintillant containing H-3 at 100 Bq/g; or
- unlimited amount of solid containing Co-60 at 0.05 Bq/g plus Cs-137 at 0.5 Bq/g.

Or where concentrations of solids or relevant liquids are above the Table 2.3 values, or it is aqueous liquid or a gas, the substance is still out of scope if any of the following are met:

- all radionuclides in the substance have a half-life of less than 100 seconds; or
- its radioactivity is only due to artificial background radiation; or
- it has previously been lawfully disposed of as radioactive waste or contaminated by such waste; or

- it is contaminated material which remains on the premises where it was created.

Certain NORM is out of scope also (see separate guidance).

What is an exempt open source?

Radioactive substances in the form of open sources (sometimes called unsealed sources) which contain:

- artificial radionuclides; or
 - naturally occurring radionuclides (if listed in Table 3.1 of the Government Guidance) used for their radioactive, fertile or fissile properties
- may be kept or used on premises in amounts up to the activity in column 2 or the concentration in column 3 of Table 3.1 of the Government Guidance. Note that these limits apply to the total activity of open sources kept or used on any premises and accumulated as radioactive waste by a person or organisation.

Where more than one radionuclide is present then the relevant Table 3.1 summation rule (that is, for quantity or for concentration) must be applied. For the exemption to apply, either:

- the total holding on the premises of open sources kept or used and accumulated open source radioactive waste must be below the quantity limit; or
- the maximum concentration of all open sources and accumulated open source radioactive waste must be less than the relevant concentration limits (applying the concentration summation rule to any substance that contains more than one radionuclide).

Exemption cannot be determined against a mixture of activity and concentration limits. Where artificial radionuclides are not individually listed, the values at the end of the table apply.

For example exemptions apply to the keeping or use of:

- 1GBq of H-3 in any physical form or concentration; or
- unlimited quantity of substances containing only H-3 with a concentration below 1 MBq/g; or
- 500 MBq of H-3 plus 5 MBq of C-14 (in the same or separate substances); or
- unlimited quantity of different substance containing only H-3 with a concentration below 1.0 MBq/g plus an unlimited quantity of substance containing only C-14 at a concentration below 10 kBq/g; or
- unlimited quantity of one substance containing both H-3 at a concentration below 0.5 MBq/g and C-14 at a concentration below 5 kBq/g.

Also included within the definition of exempt open sources are the items listed in Table 1 which are covered in other guidance. These items may be held in addition to the substances described in the previous paragraphs and are not covered by this guidance.

Table 1

Radioactive material or accumulated radioactive waste type	Maximum quantity of radionuclides for each item of material or waste	Maximum quantity of radionuclides: - on any premises in items of the material or waste which satisfy the limit in column 2; or -in mobile radioactive apparatus held by a person
A luminised article (open source).	8×10^7 Bq Pm-147 or 4×10^9 Bq H-3	4×10^{10} Bq Pm-147 or 2×10^{11} Bq H-3
A tritium foil source.	2×10^{10} Bq	5×10^{12} Bq
An electrodeposited source.	6×10^8 Bq Ni-63 or 2×10^8 Bq Fe-55	6×10^{11} Bq
A Ba-137m eluting source.	4×10^4 Bq Cs-137+	4×10^5 Bq Cs-137+
A substance or article which is or contains magnesium alloy or thoriated tungsten in which the thorium concentration does not exceed 4% by mass.	No limit	No limit
A uranium or thorium compound.	Up to a total of 5 kg of uranium and thorium.	Up to a total of 5 kg of uranium and thorium.
A substance or article (other than a sealed source) which is intended for use for medical or veterinary diagnosis or treatment or clinical or veterinary trials.	1×10^9 Bq Tc-99m and in respect of the total for all other radionuclides— (i) 1×10^8 Bq if the substance or article is radioactive material; or (ii) 2×10^8 Bq if the substance or article is radioactive waste.	1×10^9 Bq Tc-99m and 2×10^8 Bq of all other radionuclides, (no more than 1×10^8 Bq of which is contained in radioactive material).

Who is this guidance for?

This guidance is for businesses and other organisations that:

- use small amounts of open sources,
- supply small amounts of open sources,
- receive waste small amounts of open sources.

This guidance is not aimed at manufacturers of small amounts of open sources.

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

Yes.

What do exemption and out of scope of regulation mean?

Out of scope of regulation means that there are no restrictions under EPR or RSA93 to keep or use such radioactive sources, or accumulate and dispose of such radioactive waste.

Exempt means that no permit is required under EPR or RSA93 to keep or use such radioactive sources, or accumulate and dispose of such radioactive waste, provided that the conditions specified are met.

Who is responsible for deciding if my sources are out of scope or exempt?

The person or organisation responsible for the sources, eg company or university.

Do I need to tell anyone I believe my small amounts of open sources are out of scope or exempt?

No.

Where can I get more advice?

From an appropriate adviser, eg suitable Radiation Protection Adviser or Radioactive Waste Adviser. Or from the environment agency which regulates your premises.

2 Keeping and using small amounts of open sources

Note: the rest of this guidance does not relate to items listed in Table 1 in this guidance – these are addressed in other guidance.

What quantity of open sources may I hold as exempt?

With respect to artificial radionuclides and natural radionuclides used for their radioactive, fertile or fissile properties, either:

- the total holdings of open sources (including any accumulated as waste) held by a person on the premises must not exceed the quantity limit given in Table 3.1 in the Government Guidance (applying the summation rule if more than one radionuclide is held); or
- an unlimited quantity can be held if the concentration of radionuclides in every open source including any accumulated as waste, on the premises is below the concentration limit given in Table 3.1 in the Government Guidance (applying the summation rule to any substance that contains more than one radionuclide).

What premises are exempt from the need for a permit?

All types of premises may be exempt providing that the limits specified above are met.

The regulations do not apply to homes and no permit is needed for them.

Can I use the small amounts of open sources on more than one premises?

The exemption for open sources does not apply to mobile radioactive apparatus. However, as any person carrying out an undertaking can be exempt for the specified use on any premises, exemption on multiple premises is possible in practice.

What do I need to do if I use more or stop using exempt open sources?

If you need more than the limit then you must inform the relevant environment agency promptly, who will ask you to apply for a permit. You do not need to tell anyone if you stop using exempt open sources, but you must dispose of them in accordance with the exemption.

I already have a permit to use some radioactive sources, can I be exempt for others?

If you have a permit to keep or use open sources (other than those of a type described in the first column of Table 1 in this guidance), you cannot use this exemption; your permit must cover all of your open sources. If your permit is for other types of sources, eg sealed sources, then you can use this exemption. See later for accumulation of waste and disposal.

3 Exempt waste open sources

How much waste can I hold?

You can hold up to the quantity allowed by Table 3.1 of the Government Guidance in the form of open sources and open source waste, in total. If the concentration limits in that Table are not exceeded by either the waste or the open sources, you can hold an unlimited amount.

Can I store exempt waste open sources?

Yes but all waste should be disposed of as soon as reasonably practicable.

Decay storage is an acceptable method of initially managing radioactive waste if the subsequent management is made easier by such a process, i.e. the waste becomes more manageable. The storage must be well managed and in a dedicated location with adequate records being kept.

The activity of aqueous liquid waste created must be minimised.

How should I dispose of exempt solid waste open sources?

Solid radioactive waste up to the quantities specified in Table 2 (extracted from Table 3.3 of Government Guidance) can be disposed of to a person who disposes of substantial quantities of non-radioactive waste by burial in landfill, incineration or recovery. Such a person does not need a permit to receive the exempt waste. The wastes in Table 2 are commonly known as very low level waste (VLLW). VLLW can also be disposed of by transferring it to a person who holds a permit to accumulate or dispose of such radioactive waste.

Table 2

<i>Radioactive waste</i>	<i>Maximum concentration of radionuclides</i>	<i>Maximum quantity of waste to be disposed of in the period stated</i>
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

There is more detailed guidance available on disposal of VLLW.

How should I dispose of aqueous radioactive waste?

Exempt aqueous waste can be disposed of:

- directly into a river or the sea;
- to a sewer; or
- to a waste permitted person;

subject to the restrictions set out below. You cannot take advantage of this exemption if you hold a permit for the disposal of aqueous radioactive waste on or from your premises.

Restrictions on disposals to a river or the sea

- The river must have a flow-rate of not less than 1 m³s⁻¹.
- Disposals must not be made to a sewer in the same calendar year as disposals to river/sea.
- The concentration of radioactivity must not exceed the value in column 2 of Table 3.4 in the Government Guidance (applying the summation rule where more than one radionuclide is present). The concentration limit applies to the waste as produced – that is, prior to any dilution.
- The total quantity of radioactivity disposed of in a calendar year (including any disposed of to a waste permitted person) must not exceed the value in column 4 of Table 3.4 in the Government Guidance (applying the summation rule where more than one radionuclide is disposed of).

Restrictions on disposals to a sewer

- Disposals must only be made to:
 - a public sewer; or
 - a disposal main leading to a sewage disposal works that can handle at least 100 m³ of effluent per day and discharges treated effluent either to the sea, or to a river with a flow rate of at least 1 m³s⁻¹.
- Disposals must not be made directly to a river or the sea in the same calendar year as disposals to a sewer.
- The total concentration of radioactivity must not exceed 100 Bq/ml (100 kBq/l). The concentration limit applies to the waste as produced – that is, prior to any dilution.
- Where any of the waste has a concentration of radioactivity that exceeds the value in column 2 of Table 3.4 in the Government Guidance (applying the summation rule where more than one radionuclide is present), the total quantity of radioactivity disposed of in a calendar year (including any disposed of to a waste permitted person) must not exceed:

- 100 MBq 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.
- Where none of the waste has a concentration of radioactivity that exceeds the value in column 2 of Table 3.4 in the Government Guidance (applying the summation rule where more than one radionuclide is present), the total quantity of radioactivity disposed of in a calendar year (including any disposed of to a waste permitted person) must not exceed the least restrictive of:
 - the values given in the previous bullet point; or
 - the value in column 3 of Table 3.4 in the Government Guidance (applying the summation rule where more than one radionuclide is disposed of).

Restrictions on disposals to a waste permitted person

- Where any of the waste is disposed of to river/sea in the same calendar year, the concentration and quantity limits given above for disposals to river/sea apply. (The total activity of waste disposed of to river/sea and to a waste permitted person must not exceed the quantity limit.)
- Where:
 - any of the waste is disposed of to sewer; or
 - aqueous waste is only disposed of to a waste permitted person;
 the concentration and quantity limits given above for disposals to sewer apply. (The total activity of waste disposed of to sewer and to a waste permitted person must not exceed the quantity limit.)

Can I dispose of gaseous radioactive waste?

Disposals of gaseous radioactive waste are exempt only in two specific situations.

- 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. (This exemption does not apply if the gas arises because a process (for example, deliberate heating) has been applied to the contained material. It does not cover any loss of gas or vapour after the liquid or solid has been dispensed.)
- Gaseous radioactive waste containing only Kr-85, up to an annual total activity released of 1×10^{11} Bq.

In both cases you must use good practice to minimise the quantity of radionuclides generated as waste. If the waste is produced outdoors, you must prevent, as far as is reasonably practicable, its entry into a building. If the waste is produced in a building, you must, where reasonably practicable, use an extraction system to vent it to atmosphere, and prevent its re-entry into a building.

General Conditions on exemption for waste open source disposal.

- Ensure that where reasonably practicable any marking or labelling of the waste or its container is removed before the person disposes of that waste.
- Dispose of radioactive waste as soon as reasonably practicable after it has become waste
- Maintain records of all waste disposed of to the environment.
- The exemption does not apply if there has been a process of dilution intended to ensure that the waste has a concentration of radioactivity which is below

the relevant values. The normal use of a quantity of water to aid safe and effective disposal of aqueous waste is not a process of dilution in this context.

- Good practice should be used to minimise the overall activity generated for discharge.
- Allow the environmental regulator access to such records or such premises as he/she may request in order to determine that the conditions in respect of that exemption are complied with.

There is further guidance on the conditions for exemption in the Government Guidance.

How much exempt open source waste can I receive and how should I handle it?

If you receive exempt open source waste (that is, VLLW), as part of your business of managing, treating or disposing of substantial quantities of waste which is not radioactive waste, then you are exempt from the need for a permit.

Organisations which receive VLLW as part of substantial quantities of non-radioactive waste for disposal etc, should dispose of it in accordance with their permits for the non-radioactive waste as soon as reasonably practicable and dispersed in the non-radioactive waste. The radioactive waste should not be separated from other waste.

Waste in the form of VLLW is subject to conventional waste legislation and the same standards and controls apply.

I am a sewerage undertaker and people are discharging exempt aqueous waste to my sewer – do I need to do anything?

Not if they are going to a sewage disposal works with a capacity of $>100\text{m}^3$ of effluent per day. If you are aware of discharges being made under this exemption to sewage works smaller than this, then you should inform the person making the discharges and the relevant environment agency.

Tritium example

Tritium labelled small molecule drugs, ordering 37 MBq three times per annum, used for studying drug binding in living target cells. 2.5 MBq/exp. 90% of waste is aqueous 10% is solid/scintillant waste.

Exempt stockholding up to 1GBq on the premises. All stock, labelled material and waste must be accounted for and counts towards the total 1GBq permitted activity on the premises.

Accumulated waste – contaminated gloves, benchkote, plastic vials, pipettes and scintillant in mini-vials. Waste removed on a monthly basis. Disposed of as VLLW, maximum solid waste generated is 3.7MBq/month (if all of one 37MBq batch used in one month). Can be disposed of all in one 0.1cu metre bin (no single item $>400\text{kBq}$, total $<4\text{MBq}$, annual disposal less than 200MBq)

Disposals – Up to 33 MBq/month aqueous waste generated and 99 MBq/year. Waste comes from washings and separation of labelled material. Up to

2.4 MBq produced from each experiment. Allowed disposals under the exemption order are up to 100kBq/litre with a maximum disposal in a year of 100MBq. Concentration of activity in waste stream could prohibit use of exemption order, but volume of water used in act of disposal (flushing with 10L of water) can be taken into account when assessing activity concentration (i.e. limit is effectively 1MBq/10L flush). Using more water than this would constitute dilution and is not allowed.