

## SCHEDULE 8

### RADIOACTIVE SUBSTANCES ACTIVITIES

#### PART 2

##### Amendments to common framework provisions

###### **General Binding Rules – disapplication**

**13.** A person carrying on a regulated activity specified in column 1 of Part 1 of schedule 9 in compliance with the general binding rules specified for that activity is not authorised under these Regulations where—

- (a) the radioactive substance involved has been deliberately diluted to meet a value specified in schedule 9; or
- (b) the person who generated the radioactive waste did not take all practicable measures available to minimise the quantity of radionuclides generated as waste.

###### **Authorisation by permit or registration**

**14.**—(1) SEPA may only authorise the activities to which sub-paragraph (2) applies by granting a permit.

(2) This sub-paragraph applies to—

- (a) the deliberate administration of radioactive substances to an animal for the purpose of veterinary diagnosis, treatment or research (in so far as the radiation protection of the public is concerned);
- (b) the management of radioactive waste on a nuclear site;
- (c) the management of radioactive waste at a uranium mine;
- (d) any activity involving a high-activity sealed source;
- (e) the operation, decommissioning and closure of a facility for the long term storage or disposal of radioactive waste;
- (f) the management of radioactive waste for the purpose of long term storage or disposal; and
- (g) the discharge of significant amounts of radioactive waste into the environment.

###### **Applications**

**15.**—(1) SEPA must ensure that information to be included in an application for a permit or registration for a radioactive substances activity is—

- (a) relevant to radiation protection; and
- (b) commensurate with the nature of the activity and the radiological risks involved.

(2) In determining the information to be included in an application for a permit for a radioactive substances activity, SEPA must take into account the following for the purposes of ensuring adequate protection against public exposure—

- (a) responsibility and organisational arrangements for protection and safety;
- (b) staff competency, including information and training;
- (c) design features of the premises and of radiation sources;
- (d) anticipated public exposures in normal operation;

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- (e) safety assessment of the activity and the premises in order to—
  - (i) estimate, to the extent practicable, the probability and magnitude of a potential exposure;
  - (ii) assess the quality and extent of protection and safety provisions, including engineering features, as well as administrative procedures; and
  - (iii) define the operational limits and conditions of operation;
- (f) emergency procedure;
- (g) maintenance, testing, inspection and servicing so as to ensure that the radiation source and the premises continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime;
- (h) management of radioactive waste and arrangements for the disposal of such waste; and
- (i) quality assurance.

**Consultation: local authorities and relevant water authorities**

16. Where it appears to SEPA that the disposal of radioactive waste is likely to involve the need for special precautions to be taken by a local authority or a relevant water authority, SEPA must consult the authority regarding the special precautions which may need to be taken before granting an authorisation.

**Consultation: security of sealed sources**

17.—(1) SEPA must, insofar as it is reasonably practicable and before carrying out any of its functions under regulation 18, 19, 23, 25, 27, 30 or 31 in relation to an authorisation for an activity to which sub-paragraph (3) applies, consult—

- (a) the police; and
- (b) such other persons as appear to it to be appropriate,

regarding the security of premises on which the activity is, or is proposed to be, carried on.

(2) Where sub-paragraph (3) applies, SEPA must have regard to any advice it receives within such time as SEPA believes is reasonable from the police or other persons before—

- (a) determining the authorisation or effecting any variation, surrender or revocation of the authorisation; or
- (b) imposing any limitations or conditions in the authorisation.

(3) This sub-paragraph applies to a radioactive substances activity involving sealed sources in IAEA categories 1 to 4.

**Refusal of applications**

18.—(1) SEPA must refuse to grant an application for a permit for a radioactive substances activity involving a high-activity sealed source unless it is satisfied that the applicant has made either

- (a) adequate arrangements for the safe management and control of the source, including arrangements for when it becomes waste; or
- (b) adequate provision, by way of a financial provision or any other appropriate equivalent means, for the safe management of a source where—
  - (i) it becomes waste;
  - (ii) the authorised person becomes insolvent; or

(iii) the authorised person ceases to carry on the radioactive substance activities.

(2) SEPA must refuse to grant an application for a permit for a radioactive substances activity involving a sealed source in IAEA Categories 1 to 4 unless it is satisfied that the applicant has made adequate arrangements for the security of the source.

(3) Sub-paragraph (2) does not apply to an application involving a high-activity sealed source which is proposed to be managed only on a nuclear site.

**19.** SEPA must refuse to grant an authorisation for a radioactive substances activity unless the activity has been found to be justified within the meaning of the phrase “found to be justified” given in regulation 4(4) of the Justification of Practices Involving Ionising Radiation Regulations 2004<sup>(1)</sup>.

#### **Authorisation conditions: general**

**20.** SEPA must ensure that a permit or registration for a radioactive substances activity includes such conditions as it considers appropriate to—

- (a) prevent the deliberate dilution of radioactive waste for the purpose of being released from regulatory control unless the dilution takes place in normal operations where radioactivity is not a concern or the dilution is a result of mixing radioactive waste with a non-radioactive material for the purposes of re-use or recycling;
- (b) ensure adequate protection against any public exposure or contamination liable to extend—
  - (i) beyond the authorised place; or
  - (ii) to the ground beneath the authorised place;
- (c) ensure that the authorised person—
  - (i) optimises the level of radiation protection for members of the public;
  - (ii) uses adequate equipment and procedures for measuring and assessing exposure of members of the public and radioactive contamination of the environment;
  - (iii) checks that equipment used for measuring and assessing exposure of members of the public and radioactive contamination of the environment is effective and is adequately maintained and calibrated;
- (d) ensure that the authorised person seeks appropriate advice from a radiation protection expert in relation to—
  - (i) the matters set out in sub-paragraph (c); and
  - (ii) such other matters as SEPA thinks fit,
- (e) ensure that the authorised person makes arrangements for keeping control of radioactive material with regard to its location, use and, when it becomes radioactive waste, its management;
- (f) ensure, as appropriate and to the extent possible, that the authorised person keeps records of an unsealed source which the authorised person is authorised to hold, including records of location, transfer and disposal or discharge;
- (g) ensure that the authorised person keeps records of all sealed sources which the authorised person is authorised to hold, including records of location, transfer and disposal;
- (h) ensure that the authorised person informs SEPA promptly of any loss, theft, significant spill, or unauthorised use or release of radioactive material in the form of an unsealed source;

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- (i) ensure that the authorised person informs SEPA promptly of a transfer of a high-activity sealed source;
- (j) ensure that the authorised person informs SEPA promptly of the loss, significant leakage, theft or unauthorised use of a sealed source;
- (k) ensure that the authorised person implements a recording and analysis system of significant events involving or potentially involving accidental or unintended public exposure to radioactivity;
- (l) ensure that in the event of the public exposure to radioactivity otherwise than in accordance with an authorisation, the authorised person—
  - (i) informs SEPA without delay;
  - (ii) carries out a full investigation into the event, and provides SEPA with the results of the investigation, without delay; and
  - (iii) takes corrective measures to avoid the recurrence of similar events; and
- (m) ensure that the authorised person makes adequate arrangements for the security of sealed sources.

#### **Authorisation conditions: discharge limits**

**21.**—(1) SEPA must ensure that a permit or registration for a radioactive substances activity includes such conditions as it considers appropriate to apply limits for—

- (a) the discharge of radioactive waste; and
  - (b) the introduction of radioactive material into the environment.
- (2) SEPA must for the purposes of setting conditions required by sub-paragraph (1)—
- (a) take into account the results of any optimisation of radiation protection;
  - (b) reflect good practice in the operation of similar facilities; and
  - (c) take into account, where appropriate, the results of a generic screening assessment based on internationally recognised scientific guidance to demonstrate that environmental criteria for long-term human health protection are met.

#### **Authorisation conditions: monitoring**

**22.**—(1) SEPA must ensure that a permit or registration for a radioactive substances activity to which sub-paragraph (3) applies includes such conditions as it considers appropriate to ensure—

- (a) the authorised person carries out appropriate monitoring and evaluation of radioactive discharges into the environment in normal operation of the activity; and
- (b) the results of the monitoring and evaluation are reported to SEPA.

(2) For the purposes of sub-paragraph (1), where the radioactive substances activity is carried on a nuclear site, the permit or registration conditions imposed must require the monitoring of radioactive discharges and reporting to SEPA of such information on radioactive discharges as the Scottish Ministers direct.

(3) This sub-paragraph applies to radioactive substances activities which involve either or both the—

- (a) disposal of radioactive waste; or
- (b) introduction of radioactive material to the environment.

### **Authorisation conditions: high-activity sealed sources**

**23.** SEPA must ensure that a permit for a radioactive substances activity involving a high-activity sealed source includes such conditions as it considers appropriate to—

- (a) ensure that the authorised person ascertains that, before a high activity sealed source is transferred, the transferee is legally entitled to hold the source;
- (b) ensure the authorised person informs SEPA of the particulars (including the date, details of the source and identity and location of the transferee) of a transfer of a high-activity sealed source;
- (c) set out requirements specifying—
  - (i) responsibilities;
  - (ii) minimum staff competency, including information and training;
  - (iii) minimum performance criteria for the source, source container and additional equipment;
  - (iv) emergency procedures and communication links;
  - (v) work procedures to be followed;
  - (vi) maintenance of equipment, sources and containers; and
  - (vii) adequate management of waste sources, including agreements regarding the transfer, if appropriate, of waste sources to a manufacturer, a supplier, another authorised person or a waste disposal or storage facility;
- (d) require that the authorised person—
  - (i) undertakes suitable tests, such as leak tests based on international standards, regularly in order to check and maintain the integrity of a source;
  - (ii) regularly verifies at specific intervals that a source and, where relevant, the equipment containing the source, remain present and in apparently good condition at their place of use or storage;
  - (iii) ensures that a source is subject to adequate documented measures, such as written protocols and procedures, aimed at preventing unauthorised access to or loss or theft of the source or its damage by fire;
  - (iv) arranges for a check on the integrity of a source after any event, including fire, that may have damaged the source and notifies SEPA of the event and the measures taken;
  - (v) promptly after a source becomes radioactive waste—
    - (aa) returns the source to the supplier;
    - (bb) places the source in a facility for long term storage or disposal; or
    - (cc) transfers it to another person;
  - (vi) ensures that a source is accompanied by written information which—
    - (aa) confirms that the source is identified and marked with a unique number and that the number remains legible; and
    - (bb) includes photographs of the source, source container, transport packaging, device and equipment as appropriate; and
  - (vii) makes adequate arrangements (including financial provision) for the safe management and control of the high-activity source.

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**Authorisation conditions: manufacture and supply of high-activity sealed sources**

24. SEPA must ensure that a permit for a radioactive substances activity involving the manufacture or supply of a high-activity sealed source includes such conditions as it considers appropriate to—

- (a) ensure that a source is identified by a unique number which, where practicable, must be engraved or stamped on the source;
- (b) ensure either that a source container is engraved or stamped with the source's unique number or, if the container is a reusable transport container, that the container, at least, bears information on the nature of the source;
- (c) ensure a source container and, where practicable, the source are marked and labelled with an appropriate sign to warn people of the radiation hazard; and
- (d) require the manufacturer of the source to provide a photograph of each manufactured source design type and a photograph of the typical source container.

**Authorisation conditions: records of high-activity sealed sources**

25. SEPA must ensure that a permit for a radioactive substances activity involving a high-activity sealed source includes such conditions as it considers appropriate to require the authorised person—

- (a) to keep records which include as a minimum the information set out in Table 5;
- (b) to provide a copy of the records, or make a copy available, to SEPA on request;
- (c) to provide SEPA with a copy of the records—
  - (i) after acquisition of a source;
  - (ii) if the information indicated on the records has changed; and
  - (iii) if the authorised person is no longer holding the source; and
- (d) to provide SEPA with the details of any person or disposal or storage facility to which the source is transferred.