

2005 No. 2686

ATOMIC ENERGY AND RADIOACTIVE SUBSTANCES

**The High-activity Sealed Radioactive Sources and Orphan
Sources Regulations 2005**

<i>Made</i> - - - -	<i>24th September 2005</i>
<i>Laid before Parliament</i>	<i>28th September 2005</i>
<i>Coming into force</i> - -	<i>20th October 2005</i>

The Secretary of State, being a Minister designated(a) for the purposes of section 2(2) of the European Communities Act 1972(b) in relation to the making of measures relating to basic safety standards for health protection of the general public and workers against the dangers of ionising radiation, in exercise of the powers conferred upon her by that section(c), makes the following Regulations:

Citation, commencement and extent

1.—(1) These Regulations may be cited as the High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005.

(2) These Regulations shall come into force on 20th October 2005.

(3) These Regulations extend to the United Kingdom except regulation 5 which extends to England, Wales and Scotland.

Interpretation

2.—(1) In these Regulations—

“the 1993 Act” means the Radioactive Substances Act 1993(d);

“authorisation” means an authorisation granted under section 13 or 14 of the 1993 Act;

“the Basic Safety Standards Directive” means Council Directive 96/29/EURATOM(e) laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation;

“existing high-activity source” means a high-activity source first placed on the market on or before 31st December 2005;

“the HASS Directive” means Council Directive 2003/122/EURATOM(f) on the control of high-activity sealed radioactive sources and orphan sources;

(a) S.I. 1991/2289.

(b) 1972 c.68.

(c) As regards Scotland, the Secretary of State’s power to act under that section is preserved by section 57(1) of the Scotland Act 1998 (c.46).

(d) 1993 c.12.

(e) OJ L 159, 29.6.1996, p.1.

(f) OJ L 346, 31.12.2003, p.57.

“high-activity source” has the same meaning as it has in the HASS Directive but excluding any such source once its activity level has fallen below the exemption levels specified in column 2 of Table A to Annex I to the Basic Safety Standards Directive;

“registration” means a registration made under section 7 or 10 of the 1993 Act.

(2) Unless otherwise stated, expressions used that appear in the 1993 Act or the HASS Directive have the same meaning in these Regulations as they do in that Act or, as the case may be, that Directive.

Variation of registrations

3.—(1) Subject to paragraph (2), where a person holds a registration in respect of any high-activity source and either—

- (a) intends to keep or use a high-activity source (other than an existing high-activity source) on or after 1st January 2006; or
- (b) intends to keep or use an existing high-activity source on or after 1st January 2008;

that person shall apply to the appropriate Agency or the chief inspector under section 12 of the 1993 Act to vary his registration to enable the appropriate Agency or the chief inspector to ensure that the registration complies with the relevant provisions of the HASS Directive and that person shall make that application in accordance with paragraph (3).

(2) The appropriate Agency or the chief inspector may notify a person to whom paragraph (1) applies—

- (a) that such person is not required to make an application under paragraph (1); or
- (b) if it, or he, is satisfied that in its, or his, opinion exceptional circumstances apply to that person, that such person may make an application within a period shorter than that provided for under paragraph (3).

(3) Except where notification is given under subparagraph (2)(b), the application under paragraph (1) shall be made—

- (a) at least four months before the date the source is intended to be kept or used; or
- (b) in the case of a high-activity source (other than an existing high-activity source) which is intended to be kept or used within four months of these Regulations coming into force, as soon as practicable and in any event at least two months before the date of intended keeping or use of the source.

(4) If a person fails to make an application in accordance with paragraph (3), his registration shall be cancelled by the appropriate Agency or the chief inspector, so far as it relates to the high-activity source in question.

Variation of authorisations

4.—(1) Subject to paragraph (2), where a person holds an authorisation in respect of any high-activity source and either—

- (a) intends to dispose of or accumulate a high-activity source (other than an existing high-activity source) on or after 1st January 2006; or
- (b) intends to dispose of or accumulate an existing high-activity source on or after 1st January 2008;

that person shall apply to the appropriate Agency or the chief inspector under section 17 of the 1993 Act to vary his authorisation to enable the appropriate Agency or the chief inspector to ensure that the authorisation complies with the relevant provisions of the HASS Directive and that person shall make that application in accordance with paragraph (3).

(2) The appropriate Agency or the chief inspector may notify a person to whom paragraph (1) applies—

- (a) that such person is not required to make an application under paragraph (1); or

- (b) if it, or he, is satisfied that in its, or his, opinion exceptional circumstances apply to that person, that such person may make an application within a period shorter than that provided for under paragraph (3).

(3) Except where notification is given under subparagraph (2)(b), the application under paragraph (1) shall be made—

- (a) at least four months before the date the source is intended to be disposed of or accumulated; or
- (b) in the case of a high-activity source (other than an existing high-activity source) which is intended to be disposed of or accumulated within four months of these Regulations coming into force, as soon as practicable and in any event at least two months before the date of intended disposal or accumulation of the source.

(4) If a person fails to make an application in accordance with paragraph (3), his authorisation shall be revoked by the appropriate Agency or the chief inspector, so far as it relates to the high-activity source in question.

Exercise of powers of the appropriate Agency

5.—(1) Paragraph (2) applies with regard to the exercise of the powers of the appropriate Agency concerning the prevention of unauthorised access to, or loss or theft of—

- (a) high-activity sources; or
- (b) other sealed sources which, in the opinion of the appropriate Agency, are of a similar level of potential hazard to high-activity sources;

including matters relating to the security of sites where such material is held.

(2) The appropriate Agency may exercise its powers under any enactment in relation to the matters referred to in paragraph (1) notwithstanding that the control of pollution is not the primary or only purpose for which the powers are exercised.

(3) For the purposes of paragraph (2), “any enactment” includes any Act of the Scottish Parliament or any subordinate legislation made under such an Act.

Site security

6.—(1) Subject to paragraph (2), in performing its, or his, functions under sections 7, 10, 12, 13, 14 or 17 of the 1993 Act, the appropriate Agency or chief inspector shall comply with paragraphs (3) and (4) where the following material is, or will be, kept, used, disposed of or accumulated on any premises—

- (a) high-activity sources; or
- (b) other sealed sources which, in the opinion of the appropriate Agency or the chief inspector, are of a similar level of potential hazard to high-activity sources.

(2) Paragraph (1) shall not apply where the premises are, or are part of, a nuclear site.

(3) Where paragraph (1) applies, the appropriate Agency or chief inspector, in considering if the measures taken, or to be taken, by the applicant or person granted the registration or authorisation ensure the adequate security of any premises, shall where it, or he, considers it appropriate—

- (a) inspect those premises; and
- (b) consult with the police and such other persons as it, or he, considers appropriate concerning the measures.

(4) Where paragraph (1) applies, the appropriate Agency or chief inspector shall have regard to any advice it, or he, receives from the police or other persons within such time as the appropriate Agency or chief inspector believes is reasonable before—

- (a) determining the registration or authorisation or effecting any variation or cancellation of the registration or authorisation; or
- (b) imposing any limitations and conditions on the registration or authorisation.

(5) Where the appropriate Agency or chief inspector inspect any premises under paragraph (3), it, or he, may be accompanied by such other persons as are appropriate to assist it, or him, in assessing the measures.

(6) An applicant or person holding a registration or authorisation shall permit the appropriate Agency or chief inspector (and any person accompanying them) reasonable access to any premises it, or he, wishes to inspect under paragraph (3).

(7) If an applicant or person holding a registration or authorisation fails to comply with paragraph (6), the appropriate Agency or chief inspector may refuse the application or cancel the registration or revoke the authorisation insofar as it relates to the sources referred to in paragraph (1).

Records and inspections

7. The appropriate Agency and the chief inspector shall—

- (a) keep records of those matters—
 - (i) required by Articles 5(3) and (4) of the HASS Directive; and
 - (ii) notified to it, him or them under Article 6 of that Directive;and
- (b) establish or maintain a system of inspections to enforce the provisions of Articles 3, 4, 5 and 6, and 7 (subject to 16(1)(b)) of the HASS Directive which must be complied with by persons holding registrations or authorisations.

Advice and assistance in respect of orphan sources

8.—(1) The relevant person referred to in paragraph (2) shall ensure that—

- (a) in relation to the public and workers, specialised technical advice and assistance is promptly made available to such persons who are not normally involved in operations subject to radiation protection requirements and who suspect the presence of an orphan source; and
- (b) the primary aim of such advice and assistance is—
 - (i) the safety of the source; and
 - (ii) the protection of the public and workers from radiation.

(2) For the purposes of paragraph (1)—

- (a) in relation to England and Wales and Scotland and the protection of workers and in relation to England and the protection of the public (except workers), the relevant person means the Secretary of State;
- (b) in relation to Wales and the protection of the public (except workers), the relevant person means the National Assembly for Wales,
- (c) in relation to Scotland and the protection of the public (except workers), the relevant person means the Scottish Ministers, and
- (d) in relation to Northern Ireland and the protection of the public (except workers), the relevant person means the Department of the Environment and in relation to the protection of workers the relevant person means the Department of Enterprise, Trade and Investment.

Amendment of section 7 of the 1993 Act

9. Section 7 of the 1993 Act (registration of users of radioactive material) shall be amended as follows—

- (a) in subsection (7), omit from “,except in” to “subsection (6),”;
- (b) after subsection (7) insert—

“(7A) Subsection (7) does not apply—

- (a) in relation to high-activity sources and to other sealed sources which, in the opinion of the appropriate Agency or the chief inspector, are of a similar level of potential hazard to high-activity sources, or
- (b) in determining whether to impose any conditions falling within paragraph (b) or (c) of subsection (6).”;

and

(c) in subsection (8), for paragraph (a) substitute—

“(a) shall furnish him with a certificate which contains all material particulars of the registration or gives sufficient information as to the particulars to enable them to be ascertained, and”.

Amendment of section 10 of the 1993 Act

10. In subsection (5) of section 10 of the 1993 Act (registration of mobile radioactive apparatus), for paragraph (a) substitute—

“(a) shall furnish him with a certificate which contains all material particulars of the registration or gives sufficient information as to the particulars to enable them to be ascertained, and”.

Amendment of section 12 of the 1993 Act

11. After subsection (1) of section 12 of the 1993 Act (cancellation or variation of registration) insert—

“(1A) The powers of the appropriate Agency and of the chief inspector under this section are exercisable with or without the making of an application by the person holding the registration.”.

Amendment of section 16 of the 1993 Act

12. In subsection (9) of section 16 of the 1993 Act (grant of authorisations), for paragraph (a) substitute—

“(a) shall furnish the person to whom the authorisation is granted with a certificate which contains all material particulars of the authorisation or gives sufficient information as to the particulars to enable them to be ascertained, and”.

Amendment of section 16A of the 1993 Act

13. In subsection (8) of section 16A of the 1993 Act (transfer of authorisations), for paragraph (b) substitute—

“(b) furnish the transferee with a certificate which contains all material particulars of the authorisation he holds as a result of the transfer or gives sufficient information as to the particulars to enable them to be ascertained;”.

Amendment of section 20 of the 1993 Act

14. Section 20 of the 1993 Act (retention and production of site or disposal records) shall be amended as follows—

(a) in subsection (1) after the word “site” add “, source transfer”; and

(b) in subsection (4), in the definition of “records” after the words “of any place where the apparatus is kept” insert—

““source transfer records” means records relating to the transfer of control of high-activity sources”.

Amendment of section 23 of the 1993 Act

15. After subsection (5) of section 23 of the 1993 Act (power of Secretary of State to give directions to the appropriate agency and chief inspector) insert—

“(6) In Northern Ireland, where the Department of the Environment gives directions to the chief inspector under this section for the purpose of implementing provisions of the HASS Directive the following requirements apply—

- (a) any direction shall be published in such manner as the Department considers appropriate for the purpose of bringing the matters to which it relates to the attention of persons likely to be affected by it;
- (b) copies of a direction shall be made available to the public;
- (c) notice of a direction and of where a copy may be obtained shall be given in the Belfast Gazette;
- (d) a direction shall be given only after consultation with the chief inspector; and
- (e) no direction shall be varied or revoked unless, notwithstanding the variation or revocation, the provisions of the HASS Directive as they have effect for the time being which were implemented by that direction, continue to be implemented, whether by directions or any other instrument or by any enactment.”.

Section 30A of the 1993 Act

16. After section 30 of the 1993 Act (power of the appropriate Agency to dispose of radioactive waste) insert the following—

“Recovery and disposal of orphan sources

30A.—(1) The appropriate Agency shall be prepared or have made provision, including assignment of responsibilities, to recover any orphan source and shall have drawn up appropriate response plans and measures.

(2) The appropriate Agency shall have the power to recover any expenses reasonably incurred by it (or by a person on its behalf) in the recovery and disposal of an orphan source from the holder of that source or from the occupier or owner of the premises where the source is located.

(3) For the purposes of paragraph (2), “holder” means the person who is or is required to be registered or authorised under this Act in relation to that orphan source.

(4) If the relevant person thinks fit, the relevant person may make available to the appropriate Agency a sum or sums of money in respect of costs and expenses incurred or to be incurred by the appropriate Agency (or by a person on its behalf) in relation to the recovery and disposal of orphan sources where—

- (a) the amount of such costs and expenses exceeds or is expected to exceed any reasonable provision for such costs and expenses made by the appropriate Agency, and
- (b) the making available of such sum or sums is necessary to enable the recovery and disposal of any orphan source.

(5) In subsection (4), “relevant person” means—

- (a) in relation to England, the Secretary of State,
- (b) in relation to Wales, the National Assembly for Wales,
- (c) in relation to Scotland, the Scottish Ministers, and
- (d) in relation to Northern Ireland, the Department of the Environment.

(6) In the application of this section to Northern Ireland a reference to the appropriate Agency must be taken to be a reference to the chief inspector.”.

Amendment of section 47 of the 1993 Act

17.—(1) In subsection (1) of section 47 of the 1993 Act (general interpretation provisions) the following definitions shall apply—

- (a) after the definition of “disposal” insert the following—
 - “the HASS Directive” means Council Directive 2003/122/EURATOM(a) on the control of high-activity sealed radioactive sources and orphan sources;
 - “high-activity source” has the same meaning as it has in the HASS Directive but excluding any such source once its activity level has fallen below the exemption levels specified in column 2 of Table A to Annex I to Council Directive 96/29/EURATOM(b) laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation,”; and
- (b) after the definition of “nuclear site licence” insert the following—
 - ““orphan source” has the same meaning as it has in the HASS Directive,”.

(2) After subsection (5) of section 47 insert—

“(5A) A reference in this Act to the keeping or use of radioactive material means, in relation to a high-activity source, any practice in relation to that source except the disposal or accumulation of the source: and “practice” must be construed in accordance with Council Directive 96/29/EURATOM laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.”.

Amendment of section 48 of the 1993 Act

18. In section 48 of the 1993 Act (index of defined expressions) the following shall apply—

- (a) after the reference to “disposal” insert—

“the HASS Directive	section 47(1)
high-activity source	section 47(1);
and	
- (b) after the reference to “nuclear site licence” insert—

“orphan source	section 47(1)”.
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The Ionising Radiations Regulations 1999 and 2000

19.—(1) Paragraph (2) applies to—

- (a) paragraphs (a) and (b) of regulation 14 of the Ionising Radiations Regulations 1999(c); and
- (b) paragraphs (a) and (b) of regulation 14 of the Ionising Radiations Regulations (Northern Ireland) 2000(d),

referred to in this regulation as the “ionising radiations provisions”.

(2) In relation to a high-activity source, the appropriate training and adequate information required by the ionising radiations provisions shall include—

- (a) specific requirements for the safe management of such a source;
- (b) particular emphasis on the necessary safety requirements in relation to such a source; and
- (c) specific information on possible consequences of the loss of adequate control of such a source,

(a) OJ L 346, 31.12.2003, p.57.
(b) OJ L 159, 29.6.1996, p.1.
(c) S.I. 1999/3232.
(d) S.R. 2000/375.

and such training and information shall be repeated at regular intervals and documented, with a view to preparing the employees and other persons referred to in the ionising radiations provisions for such matters.

24th September 2005

Elliot Morley
Minister of State
Department for Environment, Food and Rural Affairs

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision in connection with the implementation of Council Directive 2003/122/EURATOM (OJ L 346, 31.12.2003, p.57) on the control of high-activity sealed radioactive sources and orphan sources (the HASS Directive) and make relevant amendments to the Radioactive Substances Act 1993 (c.12) (the 1993 Act). They apply to the whole of the United Kingdom save regulation 5 that applies to England, Wales and Scotland.

High-activity sources as defined in Article 2 of the HASS Directive are radioactive material within section 1 of the 1993 Act and as such are regulated under that Act. High-activity sources for the purposes of these Regulations and the amendments made to the 1993 Act by these Regulations do not include such sources once their activity level has fallen below the exemption levels specified in column 2 of Table A to Annex I to Council Directive 96/29/EURATOM (OJ L 159, 29.6.1996, p.1) laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (the Basic Safety Standards Directive). High-activity sources first placed on the market on or before 31st December 2005 are referred to in these Regulations as existing high-activity sources.

Regulation 3 provides for applications for variation of registrations under the 1993 Act concerning high-activity sources. The Environment Agency, the Scottish Environment Protection Agency or the chief inspector will consider if any variation of the registration is required to comply with the HASS Directive. Failure to make an application as required shall mean the registration is revoked so far as it relates to the high-activity source in question.

Regulation 4 provides for variation of authorisations under the 1993 Act in a similar way to variations required in relation to registrations under regulation 3.

Regulation 5 applies to England, Wales and Scotland and provides that the Environment Agency or the Scottish Environment Protection Agency may exercise their powers under any enactment in connection with the prevention of unauthorised access to, or loss or theft of high-activity sources and other sources which, in their opinion, are of a similar level of potential hazard to high-activity sources, notwithstanding that the control of pollution is not the primary or only purpose for which the powers are exercised.

Regulation 6 imposes requirements in relation to premises where high-activity sources and other sources (which, in the opinion of the Environment Agency, the Scottish Environment Protection Agency or the chief inspector, are of a similar level of potential hazard to high-activity sources) will be kept, used, disposed of or accumulated.

Regulation 7 provides for the appropriate Agency and chief inspector to keep various records and to establish or maintain a system of inspections to enforce the provisions of the HASS Directive.

Regulation 8 provides for specialised technical advice and assistance to be made available in connection with the presence of orphan sources.

Regulations 9 to 14 make minor amendments to the 1993 Act in relation to the HASS Directive.

Regulation 15 inserts section 23(6) into the 1993 Act. It provides that in Northern Ireland, where the Department of the Environment makes directions under section 23 of the 1993 Act for the purpose of implementing provisions of the HASS Directive, the Department must follow certain procedural requirements in relation to those directions. It is intended that directions will be made as soon as possible after these Regulations come into force.

Regulation 16 inserts section 30A into the 1993 Act to provide for the Environment Agency, the Scottish Environment Protection Agency or the chief inspector to comply with Article 9(1) of the HASS Directive in relation to the recovery of orphan sources. It also provides that sums may be provided to them for the costs and expenses of recovery and disposal of orphan sources where the sums required to do so exceed the reasonable provision for such costs and expenses.

Regulation 17 inserts additional definitions in section 47 of the 1993 Act, including the insertion of subsection (5A). That subsection provides that in relation to the regulation of high-activity sources under sections 7 and 10 of the 1993 Act, the keeping or use of those sources shall mean any practice concerning those sources, except their disposal or accumulation. The disposal or accumulation of high-activity sources is a matter for authorisation under sections 13 or 14 of the 1993 Act. The expression “any practice” is defined in the Basic Safety Standards Directive.

Regulation 18 inserts “the HASS Directive”, “high-activity source” and “orphan source” into the index of defined expressions in section 48 of the 1993 Act.

Regulation 19 provides that the requirements for appropriate training of, and adequate information to be given to, employees and other persons concerning ionising radiation under regulation 14 of the Ionising Radiations Regulations 1999 (S.I.1999/3232) and regulation 14 of the Ionising Radiations Regulations (Northern Ireland) 2000 (S.R. 2000/375) shall include the training and information requirements in Article 8(1) of the HASS Directive. Notice of this regulation will be given on the websites of the Health & Safety Executive (www.hse.gov.uk) and the Health & Safety Executive for Northern Ireland (www.hseni.gov.uk).

A full Regulatory Impact Assessment of the effect that this instrument will have on the costs of business, and a transposition note, have been prepared and are available from Dr Martin Hum, Department for Environment, Food and Rural Affairs, Zone 3/H25, Ashdown House, 123 Victoria Street, London SW1E 6DE.

STATUTORY INSTRUMENTS

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