

The Swedish Radiation Protection Authority's Regulations on the Control of High-Activity Sealed Radioactive Sources;

issued on 8 June 2006

On the basis of § 7 of the Radiation Protection Ordinance (1988:293), the Swedish Radiation Protection Authority has issued the following regulations.¹

Application

1 § These regulations apply to high-activity sealed radioactive sources.

These regulations apply to the sources until their activity has decayed to or under the exemption levels specified in the annex to the Radiation Protection Ordinance (1988:293).

These regulations do not apply to radioactive sources that are subject to authorization according to the Act (1984:3) on Nuclear Activities.

Definitions

2 § In these regulations terms and concepts are used with the meanings specified here.

<i>Recognised installation:</i>	means an installation within the European Union that, according to the national laws respectively, is authorized for handling, interim storage, long-term storage, or final storage of sources,
<i>holder:</i>	means any natural or legal person who is authorized according to the Radiation Protection Act (1988:220), to possess or use a source,
<i>disused source:</i>	means a source which is no longer used or intended to be used for the practice for which authorization was granted,
<i>supplier:</i>	means any natural or legal person who supplies a source or otherwise makes it available for rent or loan,
<i>operational control:</i>	means that suitable tests of the integrity of a source and the condition of the device containing the source are undertaken in accordance with sections 7 and 8,

¹ Cf. Council Directive 2003/122/Euratom of December 22, 2003 on the control of high-activity sealed radioactive sources and orphan sources, OJ L 346, 31.12.2003, p. 57, (Celex 303L0122).

high-activity sealed radioactive source in these regulations referred to as source: means a sealed source containing one or more radio-nuclides, whose activity at the time of manufacture or, if this is not known, when it first arrived to the European Union is equal to or exceeds the relevant activity level specified in *Annex 1*,

sealed source: means a source, whose structure is such as to prevent dispersion of radioactive substances under normal conditions of use, and whose capsule, where applicable, is enclosing the radioactive substance as an integral part of the source,

source container: means the containment of one or more sealed sources not being an integral part of the source .

Authorization

3 § Anyone who intends to conduct a practice involving a source shall apply for an authorization in advance for each source. An application for authorization covering a certain practice may comprise several sources of the same type to be manufactured or obtained during a certain period of time.

An application for authorization shall be sent to the Radiation Protection Authority and include a description of the measures taken and planned to be taken to ensure safe management of the source and, when it becomes a disused source, how the source according to an agreement can be returned to the manufacturer or supplier, be transferred to another user or be sent to a recognised installation.

Furthermore the application shall contain

1. radionuclide and activity,
2. intended use of the source,
3. name of the manufacturer or supplier,
4. a documentation showing that the source and its equipment meets the safety and radiation protection requirements in relation to its intended use according to the standard ISO 2919, edition 2, 1999 "Radiation Protection – Sealed radioactive sources – General requirements and classification", or meets the corresponding degree of safety,
5. photographs or drawings of the design of the source and equipment,
6. description of the radiation protection organisation,
7. competences of the staff including its information and training of the safe handling of the source,
8. work procedures to be followed for the handling of the source,
9. routines for operational control and maintenance of the source, the source container and the equipment,
10. routines for reporting unforeseeable events of significance from a radiation protection point of view.

Recording

4 § The holder shall keep updated records of all sources under his responsibility. The records shall include the information set out in the standard record sheet shown in *Annex 2*.

Reporting

5 § The holder shall before the end of March each year send the information in the standard record sheets to the Radiation Protection Authority. The standard record sheets may be sent electronically.

In addition extracts from the records shall be sent to the Radiation Protection Authority as soon as possible and not later than one week after that

1. a new source has been acquired,
2. the conditions specified in a record sheet have changed,
3. the holder has transferred the source to a new holder or to a recognized installation, supplemented with information to whom the source has been transferred,
4. the holder no longer holds any sources.

Documentation and checks

6 § The holder shall ensure that there is a written documentation for each source. The documentation shall include

1. identification and marking of the source according to sections 13 – 15,
2. source type identification,
3. radionuclide,
4. activity at a specified point of time,
5. photographs of the type of source, of the source container and of the equipment.

The documentation (or a copy of it) shall be stored locked up at another location than the source.

7 § The holder shall regularly check that each source and the equipment containing the source are present and apparently in good condition at its place of use or storage and that the marking is legible.

The checks shall be performed at least once a month.

8 § The holder shall ensure that suitable tests of the integrity of the source and its equipment are undertaken. Such tests shall be performed at least once a year and when there are reasons to suspect that the source has been damaged.

A check of the source may be done by wipe test of accessible parts according to Standard ISO 9978, edition 1, 1992 "Radiation protection – Sealed radioactive sources – Leakage test methods", Annex A, or by some other corresponding method.

The result of each check shall be recorded in the standard record sheet according to *Annex 2*.

9 § The holder shall establish documented routines and make arrangements to prevent unauthorised access to the source, theft or loss, damage through external impacts or fire.

Routines shall be available to arrange for a check of the source after a fire or any other event that may have damaged the source. If the source is damaged the Radiation Protection Authority shall be informed together with information what measures has been taken.

A damaged source must not be used. This also applies if the device is damaged in a way that has impaired the radiation protection properties.

10 § The holder shall immediately report to the Radiation Protection Authority if a source is missing or if there are reasons to suspect that it has been used in an unauthorised way.

11 § When a source has become a disused source the holder shall transfer it to the manufacturer or the supplier, to another user or a recognised installation without undue delay and not later than within six months, if the Radiation Protection Authority does not admit others.

Prior to the transfer of a source the holder shall make sure that the new holder possesses the relevant licence.

12 § The requirements in sections 3 – 8 and 11 do not apply to a recognised installation. At such an installation an up to date record on the stored items shall be kept.

Requirements for the manufacturer

13 § The manufacturer shall identify and mark each source and source container. The marking shall include a unique number that is engraved or stamped on the container and, where practicable, on the source. At transfer the source shall be accompanied with written documentation concerning its identification and marking.

If the source container is a reusable transport container, the source container shall at least be marked with information on the nature of the source.

14 § The manufacturer shall ensure that the source container and, where practicable, the source is permanently marked with a symbol for ionising radiation.

The symbol is shown in the standard ISO 7010, edition 1, 2003.

15 § The manufacturer shall provide photographs of each type of source and source container. At transfer the photographs shall accompany the source.

Manufacturing outside the European Union

16 § If a source has been manufactured outside the European Union, the manufacturer's obligations shall instead be the responsibility of the natural or legal person who imports the source into Sweden.

Training

17 § The holder shall ensure that the personnel of concern is informed and trained. Such information and training shall include locally established rules for the safe handling of the source and specific information on possible consequences if the source is lost or damaged. The information and training shall be documented and regularly repeated.

Further regulations on information and training are included in several regulations on various practices in the code of statutes of the Swedish Radiation Protection Authority.

Exemptions

18 § If special grounds exist, the Swedish Radiation Protection Authority may grant exemptions from these regulations.

Coming into force and provisional regulations

1. These regulations enter into force on 1 October 2006

2. A holder who possesses sources, whose activities at the date when these regulations enter into force are equal to or exceed the values stated in *Annex 1* shall before 1 September 2007

1. apply for an authorization according to section 3 regarding his possession,

2. set up a document for each source that includes a description of the properties of the source and information that makes it possible to identify the source and the source container and

3. mark each source container and the outside of the device with a symbol for ionising radiation.

Photographs and marking of the source itself are not required.

On behalf of the board of the Swedish Radiation Protection Authority

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Activity levels of sealed sources to which these regulations apply

For radio nuclides that are not included in the table below one hundredth (1/100) of the A_1 -values² included in IAEA Safety Standards Series No. TS-R-1 (ST-1, Revised), Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised) Vienna, 2000 apply.

Nuclide	Activity (Bq)	Nuclide	Activity (Bq)
H-3	$4 \cdot 10^{11}$	Pm-147	$4 \cdot 10^{11}$
Fe-55	$4 \cdot 10^{11}$	Gd-153	$1 \cdot 10^{11}$
Co-57	$1 \cdot 10^{11}$	Yb-169	$4 \cdot 10^{10}$
Co-60	$4 \cdot 10^9$	Tm-170	$3 \cdot 10^{10}$
Ni-63	$4 \cdot 10^{11}$	Ir-192	$1 \cdot 10^{10}$
Se-75	$3 \cdot 10^{10}$	Au-198	$1 \cdot 10^{10}$
Kr-85	$1 \cdot 10^{11}$	Tl-204	$1 \cdot 10^{11}$
Sr-90 ^a	$3 \cdot 10^9$	Ra-226 ^{a,b}	$2 \cdot 10^9$
Pd-103 ^a	$4 \cdot 10^{11}$	Po-210	$4 \cdot 10^{11}$
Ru-106 ^a	$2 \cdot 10^9$	Pu-238	$1 \cdot 10^{11}$
Cd-109	$3 \cdot 10^{11}$	Am-241 ^b	$1 \cdot 10^{11}$
I-125	$2 \cdot 10^{11}$	Cm-244	$2 \cdot 10^{11}$
Cs-137 ^a	$2 \cdot 10^{10}$	Cf-252	$5 \cdot 10^8$

a) The activity level includes contributions from daughter nuclides with half-lives less than ten days.

b) Includes neutron sources with beryllium.

A sealed source that contains more than one radio-nuclide shall be considered a high activity source if

$$\sum_k A_k/L_k \geq 1$$

where A_k is the actual activity of the nuclide k and L_k is the activity according to the table for the nuclide k.

² The A_1 -values correspond, in most cases, to the activity which gives rise to a dose rate of 100 mSv/h at a distance of 1 meter.

STANDARD RECORD SHEET FOR HIGH-ACTIVITY SEALED SOURCES (HASS) (optional in italics)

1. HASS identification number:	2. Identification of authorised holder Name: Address: Country: Manufacturer <input type="checkbox"/> Supplier <input type="checkbox"/> User <input type="checkbox"/>	3. Location of HASS (Use or storage) if not the same as in 2. Name: Address: Fixed use <input type="checkbox"/> Storage (mobile) <input type="checkbox"/>
4. Registration Date of start of registration: Date of transfer of registration to historic file:	5. Authorisation (licence) Number: Date of issue: Date of expiry:	6. Operational control of HASS Date:..... Date:..... Date:..... Date:..... Date:..... Date:..... Date:..... Date:.....
7. HASS characteristic Radio nuclide: Activity at the date of manufacturing or the first placing on the market:..... Date of manufacturing:..... Manufacturer/Supplier ⁽³⁾ Name:..... Address:..... Country:.....	8. Receipt of HASS Date of receipt:..... Receipt from Name: Address: Country: Manufacturer <input type="checkbox"/> Supplier <input type="checkbox"/> Another user <input type="checkbox"/>	Date:..... Date:..... Date:..... Date:..... Date:..... Date:..... Date:..... Date:.....
Physical and chemical characteristics: <i>Source type identification:</i> <i>Capsule identification:</i> <i>ISO classification:</i> <i>ANSI classification:</i> <i>Special form certificate:</i>	9. Transfer of HASS Date of transfer: Transfer to Name: Address: Country: Manufacturer <input type="checkbox"/> Supplier <input type="checkbox"/> Another user <input type="checkbox"/> Recognised installation <input type="checkbox"/>	10. Further information Loss <input type="checkbox"/> Date of loss:..... Theft <input type="checkbox"/> Date of theft:..... Finding: yes <input type="checkbox"/> no <input type="checkbox"/> Date: Place: Other information:

⁽³⁾ Where the manufacturer of the source is established outside the Community, the name and address of the importer/supplier may be provided instead.

The standard record sheet can be downloaded from the SSI's web site www.ssi.se