UNOFFICIAL ENGLISH TRANSLATION

The Protection from Ionizing Radiation Law of 2002

Regulations made under Section 40

The Protection from Ionising Radiation (Control of High Activity Sealed Radioactive Sources and Orphan Sources) Regulations of 2006

Arrangements of Regulations

The Protection from Ionising Radiation (Control of High Activity Sealed Radioactive Sources and Orphan Sources) Regulations of 2006, which have been made by the Council of Ministers under Section 40 of the Protection from Ionising Radiation Law, after been submitted to and approved by the House of Representatives, are published in the Official Journal of the Republic, according to paragraph (3) of the Section 3 of the Deposit in the House of Representatives of Regulations made under a Law, Law (L.99 of 1989, and as modified with L.227 of 1990).

THE PROTECTION FROM IONISING RADIATION LAW

Regulations made under Section 40

For the purpose of harmonization with the European Community Act with title:

Official Journal E.U. L.346 of 31.12.2003, p. 57

"Council Directive 2003/122/EU of the 22nd December 2003 on the control of high-activity radioactive sources and orphan sources",

115(I) of 2002

The Council of Ministers, in exercise of the power conferred on it by Section 40 of the Protection from Ionizing Radiation Law, hereby makes the following Regulations.

Short title

1. These Regulations may be cited as the Protection from Ionizing Radiation (Control of High Activity Sealed Radioactive Sources and Orphan Sources) Regulations of 2006.

Interpretation

2. (1) In these Regulations, unless the context otherwise requires:

"recognised installation" means a facility located in the territory of the Republic authorised in accordance with the Law for the long-term storage or disposal of sources or an installation duly authorised under the Law for the interim storage of sources;

"source container" means the containment of a sealed source not being an integral part of the source, but meant for transport, handling, etc.

"orphan source" means a sealed source, the activity level of which, at the time of its discovery, is above the exemption level referred to in Section 9 (1)(i) of the Law, and which is not under regulatory control, either because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen or transferred, without proper notification of

the competent authority, to a new holder or without informing the recipient;

"disused source" means a source which is no longer used or intended to be used for the practice for which authorisation was granted;

"manufacturer" means any natural or legal person who manufactures a source;

"holder" means any natural or legal person who is responsible under the Law for a source, including manufacturers, suppliers and users of sources, but excluding recognised installations;

"sealed source" has the meaning given to it by the Law and, where applicable, includes the capsule enclosing the radioactive material as an integral part of the source;

"transfer of a source" means a transfer of a source from one holder to another one;

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"Law" means the Protection from Ionising Radiation Law;

"high-activity source" or **"source"**, means a sealed source containing a radionuclide whose activity at the time of manufacture or, if this is not known, of the first placing on the market is equal to or exceeds the relevant activity level specified in Schedule I;

"supplier" means any natural or legal person who supplies or makes available a source;

"third countries" means countries which are not members of the European Union;

"Control Service" means the Radiation Inspection and Control Service established under Section 4 of the Law.

(2) All terms used in these Regulations, unless the context otherwise requires, shall have the meaning assigned to them by the Law.

Scope of the Regulations

3. The scope of these Regulations is:

a) to prevent the exposure of workers and the public to ionising radiation arising from inadequate control of high-activity sealed radioactive sources and orphan sources, and

b) to harmonise the controls in place in the Republic with those in other member states of the European union by prescribing specific requirements ensuring that each such source is kept under control.

Application of the Regulations

4. (1) These Regulations shall apply to high-activity radioactive sources.

(2) The minimum obligations resulting from the application of these Regulations supplement any other obligations set out in the Law and any other Regulations made under the Law.

Authorisation

5. (1) Subject to the provisions of Sections 8 and 13 of the Law, no person can perform any practice where a source is used or is involved, including taking possession of a source, without obtaining a prior authorisation.

(2) Before issuing authorisation, the persons who apply for authorization shall ensure that:

a) Adequate measures, including those required by these Regulations, are taken for the safe management of sources, including when they become disused sources, and

b) Adequate arrangements, by the way of an insurance of the source or any other equivalent means appropriate to the source in question, have been made for the safe management of sources when they become disused sources, including the case where the holder becomes insolvent or goes out of business.

(3) Subject to the provisions of Section 8 of the Law, the arrangements made under the subparagraph (a) of paragraph (2) may provide for the transfer of these sources to the supplier or their placement in a recognised installation or an obligation for the manufacturer or the supplier to receive these sources.

Conditions of the License

6. Notwithstanding the obligations of Section 12 (4) of the Law, the license shall, amongst other prescribe:
   a) The responsibilities of the licensee;
   b) The minimum competencies of the personnel, including information and training the personnel shall receive;
   c) The minimum source, source container and additional equipment performance criteria;
   d) The requirements for emergency procedures and communication links;

e) The work procedures to be followed;
f) The maintenance of equipment, sources and containers;
g) The adequate management of disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a supplier, to another authorised holder or to a recognised installation.

Transfers

7. Subject to the provisions of Section 13 of the Law, no person can transfer any source to other person or recognised installation, except if a prior authorisation is granted from the Minister.

Records kept by the holder

8. (1) Each holder shall keep records of all sources under his responsibility, their location of placement or storage and their transfer.

(2) The records referred to in paragraph (1) shall include the information set out in Schedule Two. This information may also be recorded in electronic form.

(3) Each holder shall provide the Control Service with an electronic or written copy of all or part of the records referred to in paragraph (1), as required by the Control Service, in the following cases:

a) without undue delay, at the time of the establishment of such records, which should be as soon as possible after the source is acquired,
b) after the first transfer, at intervals of 3 months or at intervals, to be specified by the Control Service, of not more than 12 months thereafter,
c) if the situation indicated on the information sheet has changed,
d) without undue delay on the closure of the records for a specific source when the holder no longer holds this source; in this case the name of the holder or recognised installation to which the source is transferred shall be included,
e) without undue delay on the closure of such records when the holder no longer holds any sources, and
f) whenever so requested by the Control Service.

Records kept by the Control Service

(4) The holder's records referred to the paragraph (1) shall be available in any case for inspection by the Control Service.

9. (1) The Control Service shall keep record of authorised

holders and of the sources they hold.

(2) The record referred to the paragraph (1) shall include the relevant radionuclide of the source, the activity at the time of manufacture, or if this activity is not known, the activity at the time of the first placing on the market or at the time the holder acquired the source, and the type of source.

(3) The Control Service shall keep the records up to date, taking, among other factors, transfers into account.

Obligations of holders

10. Each holder of a source shall:
    a) Ensure that suitable tests, such as leak tests based on standards approved by the Control Service, are undertaken regularly in order to check and maintain the integrity of each source;
    b) Regularly verify or at regular intervals which may be specified by the Control Service, that each source and, where relevant, the equipment containing the source, is still present and in apparently good condition at its place of use or of storage;
    c) Ensure that each fixed and mobile 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;
    d) Promptly notify the Control Service of any loss, theft or unauthorised use of a source, arrange for a check on the integrity of each source after any event, including fire, that may have damaged the source and, if appropriate, inform the Control Service thereof and of the measures taken;
    e) Return each disused source to the supplier or place it in a recognised installation or transfer it to another authorised holder unless otherwise agreed by the Control Service, without undue delay after termination of the use;
    f) Ascertain that, before a transfer is made, the recipient holds appropriate authorisation;
    g) Promptly notify the Control Service of any incident or accident resulting in unintentional exposure of a worker or a member of the public to ionising radiation.

Identification and labeling

11. (1) The manufacturer shall identify each source or, in the case of sources imported from third countries, the supplier shall ensure that each source is identified by a unique number. This number shall be engraved or stamped on the source, where practicable.

(2) The number referred to in paragraph (1) shall also be engraved or stamped on the source container. If this is

not feasible or in the case of reusable transport containers, the source container shall at least have information on the nature of the source.

(3) The manufacturer or the supplier shall ensure that the source container and, where practicable, the sources are marked and labeled with an appropriate sign to warn people of the radiation hazard.

(4) The manufacturer shall provide a photograph of each manufactured source design type and of the typical source container.

(5) The holder shall ensure that each source is accompanied by written information indicating that the source is identified and labeled in compliance with paragraph (1) and that the labels referred to in paragraph (1) remain legible. The information shall include photographs of the source, source container, transport packaging, device and equipment as appropriate.

Training and information

12. (1) When arranging information and training in the field of radiation protection in compliance with the Law, the holder shall ensure that such training includes specific requirements for the safe management of sources.

(2) The information and training referred to in paragraph (1) shall:

a) Give particular emphasis on the necessary safety requirements and shall contain specific information on possible consequences of the loss of adequate control of sources.

b) Be repeated at regular intervals and documented, with a view to preparing the relevant workers adequately for such events.

c) Be addressed to exposed workers.

(3) Each employer or licensee and the workers in installations where orphan sources are most likely to be found or processed, such as large metal scrap yards and major metal scrap recycling plants, and the manager and the workers in significant nodal transit points, such as customs, with the responsibility of the employer or the licensee shall:

a) be informed of the possibility that they may be confronted with a source;

b) receive special guidance and training for the visual detection of sources and of their containers;

c) be informed of basic facts about ionising radiation and its effects on health and the environment;

d) be informed of and trained about the action to be taken on site in the event of the detection or suspected detection of a source.

Orphan sources

Insurance of orphan sources

13. The Control Service, whenever it may deems appropriate, may request the establishment or use of systems, devices or instruments aimed at detecting orphan sources in places such as large metal scrap yards and major metal scrap recycling installations where orphan sources may generally be encountered, or at significant nodal transit points, wherever appropriate, such as customs posts.

International cooperation and information exchange

14. (1) The Control Service may request from any employer who has responsibility of a place or premise where orphan sources are most likely to be found or processed, such as large metal scrap yards and major metal scrap recycling plants, to have insurance or any other equivalent means to cover intervention costs relating to the recovery of orphan sources.

(2) When the last source holder is known, before the source become orphan because of his neglect or fault or in the case of an orphan source is found in installations, place, container or other place where a person is responsible, the Control Service may require from these persons to pay the whole or part of the intervention costs relating to the recovery of the orphan source.

15. In the case of loss, theft or discovery of sources, the holder or the person who has responsibility of the premises for the installation where the source was lost or discovered shall immediately inform the Radiation Inspection and Control Service. The Control Service exchange information and cooperates with other relevant Member States or third countries and with relevant international organisations as regards such incidents with prejudice to relevant confidentiality requirements laid down in the Law.

SCHEDULE ONE
(Regulation 2(1))

Radioactivity levels

For radionuclides not listed in the Schedule below, but referred to Annex II, Schedule II of the Law, the relevant activity level is one hundredth of the corresponding A1 value given in the IAEA Regulations for the Safe Transport of Radioactive Materials[1].

Element (Atomic number)	Radionuclide	Activity level (Bq)
Iron (26)	Fe-55	4×10^{11}
Cobalt (27)	Co-60	4×10^{9}
Selenium (34)	Se-75	3×10^{10}
Krypton (36)	Kr-85	1×10^{11}
Strontium (38)	Sr-90[(a)]	3×10^{9}
Palladium (46)	Pd-103 [(a)]	4×10^{11}
Iodine (53)	I-125	2×10^{11}
Cesium (55)	Cs-137 [(a)]	2×10^{10}
Promethium (61)	Pm-147	4×10^{11}
Gadolinium (64)	Gd-153	1×10^{11}
Thulium (69)	Tm-170	3×10^{10}
Iridium (77)	Ir-192	1×10^{10}
Thallium (81)	Tl-204	1×10^{11}
Radium (88)	Ra-226 [(b)]	2×10^{9}
Plutonium (94)	Pu-238 [(a)]	1×10^{11}
Americium (95)	Am-241 [(b)]	1×10^{11}
Californium (98)	Cf-252	5×10^{8}

[(a)] The activity level includes contributions from daughter nuclides with half-lives less than 10 days.
[(b)] Includes neutron sources with beryllium.

[1] TS-R-1: IAEA, Vienna, Ed. 2005 or newer edition.

SCHEDULE TWO
(Regulation 8(2))

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

<table>
<tr><td>1. HASS identification number:</td><td>2. Identification of authorised holder

Name:
Address:
Country:
Manufacturer □ Supplier □ User □</td><td>3. Location of HASS (Use or storage)
If not the same as in 2.
Name:
Address:

Fixed use □ Storage (mobile) □</td></tr>
<tr><td rowspan="2">4. Registration
Date of start or registration:
Date of transfer of registration to historic file:</td><td rowspan="2">5. Authorisation
Number:
Date of issue:
Date of expiry:</td><td>6. Operational control of HASS</td></tr>
<tr><td>Date:</td></tr>
<tr><td rowspan="2">7. HASS characteristics</td><td rowspan="2">8. Receipt of HASS</td><td>Date:</td></tr>
<tr><td>Date:</td></tr>
<tr><td>Radionuclide:</td><td></td><td>Date:</td></tr>
<tr><td>Activity at the date of manufacturing or the first placing on the market:</td><td>Date of receipt:</td><td>Date:</td></tr>
<tr><td></td><td></td><td>Date:</td></tr>
<tr><td>Date of manufacturing:</td><td>Receipt from:</td><td>Date:</td></tr>
<tr><td>Manufacturer/Supplier[1]:</td><td>Name:</td><td>Date:</td></tr>
<tr><td>Name:</td><td>Address:</td><td>Date:</td></tr>
<tr><td>Address:</td><td>Country:</td><td>Date:</td></tr>
<tr><td>Country:</td><td>Manufacturer □ Supplier □ Another user □</td><td>Date:</td></tr>
<tr><td>Physical and chemical characteristics:</td><td>9. Transfer of HASS</td><td>10. Further information</td></tr>
<tr><td>Source type identification:</td><td>Date of transfer:</td><td>Loss □ Date of loss:</td></tr>
<tr><td>Capsule identification:</td><td>Transfer to:</td><td>Theft □</td></tr>
<tr><td>ISO classification:</td><td>Name:</td><td>yes□ no □</td></tr>
<tr><td>ANSI classification:</td><td>Address:</td><td>Finding: date:</td></tr>
<tr><td>Special form certificate:</td><td>Country:</td><td>Place:</td></tr>
<tr><td></td><td>Manufacturer □ Supplier □ Another user □</td><td>Other information:</td></tr>
<tr><td></td><td>Recognised installation:</td><td></td></tr>
</table>

[1] Where the manufacturer of the sources is established outside the Community, the name and address of the importer-supplier may be provided instead.