

L.N. 13 of 2006

**NATIONAL INTEREST (ENABLING POWERS) ACT
(CAP. 365)**

**Control and Security of High-Activity Radioactive and Orphan
Sources Regulations, 2006**

IN exercise of the powers conferred by article 3 of the National Interest (Enabling Powers) Act, the Prime Minister has made the following regulations:-

1. (1) The title of these regulations is the Control and Security of High-Activity Radioactive and Orphan Sources Regulations, 2006. Citation, scope and coming into force.

(2) These regulations shall, unless otherwise indicated, be construed and interpreted as one with the Nuclear Safety and Radiation Protection Regulations, 2003, herein referred to as “the 2003 Regulations”. L.N. 44 of 2003.

(3) These regulations implement the requirements of 2003/122/Euratom and the International Atomic Energy Agency’s Code of Conduct on the Safety and Security of Radioactive Sources.

(4) These regulations shall come into force on the 31st January, 2006 provided that with regard sources placed on the market before this date:

(a) regulations 8 to 11 shall come into force on the 31st December 2007; and

(b) regulation 12 shall not apply, with the exception of the following requirements which shall come into force on the 31st December, 2007:

– the holder shall ensure that, if practicable, each such source and the source container are accompanied by written information to identify the source and its nature,

– the holder shall ensure that, if practicable, each such source, and the source container are labelled with an appropriate sign to warn people of the radiation hazard.

2. The competent authority that shall have overall responsibility for the implementation of these regulations is the Radiation Protection Board, except as explicitly specified. Competent authority.

Scope.

3. (1) The scope of these regulations is to:

(i) prevent exposure of workers and the public to ionising radiation arising from inadequate control of high-activity radioactive and orphan sources;

(ii) defining specific requirements ensuring that each such source is kept under control;

(iii) achieve and maintain a high level of safety and security of radioactive sources;

(iv) prevent unauthorised access or damage to, and loss, theft or unauthorised transfer of, radioactive sources, so as to reduce the likelihood of accidental harmful exposure to such sources and malicious use of such sources to cause harm to individuals, society or the environment; and

(v) mitigate or minimise the radiological consequences of any accident or malicious act involving a radioactive source.

Application.

4. These regulations shall apply to high-activity sources as defined in regulation 6. Sources the activity of which has fallen below the exemption levels specified in the 2003 Regulations are excluded from the scope of these regulations .

Minimum obligations.

5. The minimum obligations resulting from these regulations supplement those set out in the 2003 Regulations.

Interpretation.

6. For the purpose of these regulations, the following definitions shall apply:

“high activity source authorisation” means authorisation granted in a document by the Board, on request, to carry out a practice involving a source;

“high activity source disposal” means the emplacement of radioactive sources in an appropriate recognised installation without the intention of retrieval;

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

“high-activity source”, means a radioactive 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 as specified in the Activity Level 3 column of Schedule I;

“holder” means any natural or legal person who is responsible under national law for a source, including manufacturers, suppliers and users of sources but excluding “recognised installations”;

“management” means the administrative and operational activities that are involved in the manufacture, supply, receipt, possession, storage, use, transfer, import, export, transport, maintenance, recycling or high activity source disposal of radioactive sources;

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

“orphan source” means a radioactive source, the activity level of which, at the time of its discovery, is above the exemption level referred to in Article 3(2)(a) of Directive 96/29/Euratom, 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;

“radioactive source” means a sealed source and any radioactive material released if the sealed source is leaking or broken, but does not mean material encapsulated for disposal, or nuclear material within the nuclear fuel cycles of research and power reactors;

“recognised installation” means a facility located in Malta authorised by the Board in accordance with national law for the long-term storage or high activity source disposal of sources or an installation duly authorised under national law for the interim storage of sources;

“safety” means the measures intended to minimise the likelihood of accidents involving radioactive sources and, should such an accident occur, the mitigation of its consequences;

“safety culture” means the assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance;

“security” means measures to prevent unauthorised access or damage to, and loss, theft or unauthorised transfer of, radioactive sources;

“security level” means the level of security that needs to be applied to sources above the activity levels as laid in the different columns of Schedule I;

“security culture” means characteristics and attitudes in organisations and of individuals which establish that security issues receive the attention warranted by their significance;

“source container” means the containment of a sealed source not being an integral part of the source, but meant for transport, handling, and similar activities;

“storage” means the holding of radioactive sources in a facility that provides for their containment with the intention of removal;

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

“transfer” of a source means a transfer of a source from one holder to another one.

Functions of the Board.

7. The functions of the Board with respect to these regulations shall be to:

(a) propose rules and issue guidance relating to the safety and security of radioactive sources;

(b) require those who intend to manage radioactive sources to seek an high activity source authorisation, and to submit:

(i) a risk assessment; and

(ii) a security plan or assessment as appropriate ;

(c) obtain all relevant information from an applicant for an authorisation;

(d) issue, amend, suspend or revoke, as necessary, authorisations for the management of radioactive sources;

(e) attach clear and unambiguous conditions to the authorisations issued by it;

(f) obtain any relevant and necessary information from a person with an authorisation, in particular if that is warranted by revised safety or security assessments;

(g) require those supplying or transferring radioactive sources or devices incorporating radioactive sources to provide the recipient with all relevant technical information to permit their safe and secure management;

(h) enter premises in order to undertake inspections for the verification of compliance with regulatory requirements;

(i) monitor, or request other authorised bodies to monitor, at appropriate checkpoints for the purpose of detecting orphan sources;

(j) ensure that corrective actions are taken when a radioactive source is in an unsafe or non-secure condition;

(k) provide, on a case-by-case basis, to a person with a high activity source authorisation and the public any information that is deemed necessary in order to protect individuals, society and the environment;

(l) liaise and co-ordinate with other governmental bodies and with relevant non-governmental bodies in all areas relating to the safety and security of radioactive sources;

(m) liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information;

(n) establish criteria for intervention in emergency situations;

(o) ensure that radioactive sources are stored in facilities appropriate for the purpose of such storage;

(p) ensure that, where disused sources are stored for extended periods of time, the facilities in which they are stored are fit for such purpose; and

(q) issue guidelines on all aspects of the different security levels.

8. (1) The Board requires the holder to obtain prior high activity source authorisation for any practice involving a source, including taking possession of a source.

(2) Before issuing high activity source authorisation, it shall be ensured that the potential holder of the source shall have provided for:

(a) adequate arrangements, including those arising from these regulations, have been made for:

(i) the safe and secure management of sources;

(ii) disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a supplier, another authorised holder or a recognised installation;

(iii) the supplier to receive disused sources;

(b) adequate provision, by way of a financial security or any other equivalent means appropriate to the source in question, having 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;

(c) assignment of responsibilities within the practice;

(d) minimum staff competencies, including information and training;

(e) minimum source, source container and additional equipment performance criteria;

(f) for emergency procedures and communication links;

(g) work procedures to be followed;

(h) maintenance of equipment, sources and containers;

(i) adequate management of disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a supplier, another authorised holder or a recognised installation;

(j) security plan or assessment including measures to detect and delay the unauthorised access to, or the theft, loss or unauthorised use or removal of radioactive sources during all stages

of management. The degree of security required, shall be dependent on the source activity level as laid out in the three columns of Schedule I. Security measures for the different activity levels are given in Table 1 in Schedule III. The security plan or assessment shall be periodically reviewed and records of such reviews kept;

(k) minimum performance criteria and maintenance requirements for equipment and systems used to ensure the safety and security of radioactive sources;

(l) measures to determine, as appropriate, the trustworthiness of individuals involved in the management of radioactive sources; and

(m) the confidentiality of information relating to the security of sources.

(3) The holder has the prime responsibility for the safe management of, and the security of, radioactive sources.

9. Holders shall notify and get approval in writing from the Board Transfers. prior to any transfer of any source.

10. (1) The holder shall keep records of all sources under his Records. responsibility, their location and their transfer. The records shall include the information set out in Schedule II. This information may be recorded on a standard record as set out in Schedule II.

(2) The holder shall provide the Board with an electronic or written copy of all relevant parts of the records referred to in sub-regulation (1) of this regulation:

- without undue delay, at the time of the establishment of such records, which should be as soon as possible after the source is acquired,

- by the 31st of January of every year,

- if the situation indicated on the information sheet has changed,

- 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,

- without undue delay on the closure of such records when the holder no longer holds any sources, and
- whenever so requested by the Board.

The holder's records shall be available for inspection by the Board.

(3) The Board shall keep records of authorised holders and of the sources they hold. These records shall include the radionuclide involved, 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.

(4) The Board shall keep the records up to date, taking transfers into account, among other factors.

Requirements for holders.

11. Each holder of sources shall:

(a) ensure that suitable tests, such as leak tests based on international standards, are undertaken every 14 months in order to check and maintain the integrity of each source;

(b) carry out verification 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. Verification frequency shall be as listed in Table 2 in Schedule III;

(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 Board 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 Board 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 Board, without undue delay after termination of the use;

(f) ascertain that, before a transfer is made, the recipient holds appropriate high activity source authorisation;

(g) promptly notify the Board of any incident or accident resulting in unintentional exposure of a worker or a member of the public.

12. (1) The manufacturer shall identify or, in the case of sources imported from outside the European Community, 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. Identification and marking.

(2) This number 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 source are marked and labelled 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 marked in compliance with sub-regulation (1) and that the markings and labels referred to in sub-regulation (1) remain legible. The information shall include photographs of the source, source container, transport packaging, device and equipment as appropriate.

13. (1) When arranging information and training in the field of radiation protection in compliance with Article 22 of Directive 96/29/Euratom, the holder shall ensure that such training includes specific requirements for the safe management of sources. Training and information.

(2) The information and training shall place particular emphasis on the necessary safety requirements and shall contain specific information on possible consequences of the loss of adequate control of sources.

(3) The information and training shall be repeated at regular intervals and documented, with a view to preparing the relevant workers adequately for such events.

(4) The relevant information and training shall be addressed to exposed workers.

Orphan sources.

14. (1) The Civil Protection Department is the agency responsible to recover orphan sources and to deal with radiological emergencies due to orphan sources and the department shall draw up appropriate response plans and measures.

(2) The Board will give specialised technical advice and assistance to persons, not normally involved in operations subject to radiation protection requirements, who suspect the presence of an orphan source. The primary aim of advice and assistance shall be the protection of workers and members of the public from radiation and the safety of the source.

(3) Scrap metal dealers shall have access to an appropriate radiation monitor in order to ascertain that no orphan sources are present within the scarp metal.

(4) The Board shall encourage the establishment of systems 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.

(5) The Board shall organise, as appropriate, the recovery of orphan sources left behind from past activities.

International cooperation and information exchange.

15. The Board shall promptly exchange information and cooperate with other relevant Member States or third countries and with relevant international organisations as regards loss, removal, theft or discovery of sources and as regards related follow-up or investigations, without prejudice to relevant confidentiality requirements and relevant national regulations.

Enforcement.

16. (1) The enforcing regulatory authority acting on behalf of the Board, for any breach of these regulations shall be the Occupational Health and Safety Authority.

(2) Occupational Health and Safety Authority Officers, authorised in writing by the Radiation Protection Board, shall carry out inspections to enforce the provisions of these regulations.

(3) Any breach of any of these regulations or of the Schedules to these regulations shall be deemed an offence.

(4) In any proceedings for an offence under these regulations consisting of a failure to comply with a duty or requirement to do something, it shall be for the accused to prove, as the case may be, that

it was not practicable to do more than was in fact done to satisfy the requirement or duty, or that there was no better practicable means than was in fact used to satisfy the duty or requirement.

SCHEDULE I

Activity levels

For radionuclides not listed in the table below, but referred to in Annex I, Table A, of Directive 96/29/Euratom, the relevant activity level is one hundredth of the corresponding A1 value given in the IAEA Regulations for the safe transport of radioactive materials.

Table 1

Element (Atomic Number)	Radionuclide	Activity Level 3	Activity Level 2	Activity Level 1
		Bq	Bq	Bq
Americium (95)	Am-241 ^(a)	1×10^{11}	6×10^{11}	2×10^{15}
Californium (98)	Cf-252	5×10^8	5×10^{11}	2×10^{13}
Curium (96)	Cm-244	2×10^{11}	5×10^{11}	5×10^{13}
Cobalt (27)	Co-60	4×10^9	3×10^{11}	3×10^{13}
Caesium (55)	Cs-137	2×10^{10}	1×10^{12}	1×10^{14}
Gadolinium (64)	Gd-153	1×10^{11}	1×10^{13}	1×10^{15}
Iridium (77)	Ir-192	1×10^{10}	8×10^{11}	8×10^{13}
Promethium (61)	Pm-147	4×10^{11}	4×10^{14}	4×10^{16}
Plutonium (94)	Pu-238	1×10^{11}	6×10^{11}	6×10^{13}
Plutonium (94)	Pu-239 ^(a)	1×10^{11}	6×10^{11}	6×10^{11}
Radium (88)	Ra-226 ^(a)	9×10^{19}	4×10^{11}	4×10^{13}
Selenium (34)	Se-75	3×10^{10}	2×10^{12}	2×10^{14}
Strontium (38)	Sr-90	3×10^9	1×10^{13}	1×10^{15}
Thulium (69)	Tm-170	3×10^{10}	2×10^{14}	2×10^{16}
Ytterbium (70)	Yb-169	4×10^{10}	3×10^{12}	3×10^{14}
Gold (79)	Au-198	1×10^{10}	2×10^{12}	2×10^{14}
Cadmium (48)	Cd-109	3×10^{11}	2×10^{14}	2×10^{16}
Cobalt (27)	Co-57	1×10^{11}	7×10^{12}	7×10^{14}
Iron (26)	Fe-55	4×10^{11}	8×10^{15}	8×10^{17}
Germanium (32)	Ge-68	5×10^9	7×10^{12}	7×10^{14}
Nickel (28)	Ni-63	4×10^{11}	6×10^{12}	6×10^{14}
Krypton (36)	Kr-85	1×10^{11}	3×10^{14}	3×10^{16}
Iodine (53)	I-125	2×10^{11}	2×10^{12}	2×10^{14}
Palladium (46)	Pd-103	4×10^{11}	9×10^{14}	9×10^{16}
Pollonium (84)	Po-210	4×10^{11}	6×10^{12}	6×10^{14}
Ruthenium (44)	Ru-106	2×10^9	3×10^{12}	3×10^{14}
Thallium (81)	Tl-204	1×10^{11}	2×10^{12}	2×10^{14}

(a) Includes neutron sources with beryllium

SCHEDULE II

Table 2

<p>1 High Activity Source Identification Number</p>	<p>2 Identification of authorised holder</p> <p>Name: Address Country</p> <p>Manufacturer <input type="checkbox"/> Supplier <input type="checkbox"/> User <input type="checkbox"/></p>	<p>3 Location of High Activity Source (Use or storage) If not the same as in 2</p> <p>Name: Address</p> <p>Fixed use <input type="checkbox"/> Storage <input type="checkbox"/></p>
<p>4 Registration</p> <p>Date of start of registration: Date of transfer of registration to historic file:</p>	<p>5 High activity source authorisation</p> <p>Number Date of issue: Date of expiry:</p>	<p>6 Operational control of High Activity Source</p> <p>Date: Date: Date: Date: Date: Date: Date: Date:</p>
<p>7 High Activity Source characteristic</p> <p>Radionuclide Activity at the date of manufacturing or of the first Placing on the market: Date of manufacture: Manufacturer/Supplier Name: Address: Country: Physical and chemical characteristics:</p> <p><i>Source type identification</i> <i>Capsule identification</i> <i>ISO classification</i> <i>ANSI classification</i> <i>Special form certificate:</i></p>	<p>8 Receipt of High Activity Source</p> <p>Date of receipt:</p> <p>Receipt from Name: Address: Country: Manufacturer <input type="checkbox"/> Supplier <input type="checkbox"/> Another User <input type="checkbox"/></p>	<p>9 Transfer of High Activity Source</p> <p>Date of transfer:</p> <p>Transfer to: Name: Address: Country: Manufacturer <input type="checkbox"/> Supplier <input type="checkbox"/> Another User <input type="checkbox"/> Recognised installation</p>
		<p>10 Further information</p> <p><i>Loss</i> <input type="checkbox"/> <i>Date of Loss</i> <i>Theft</i> <input type="checkbox"/> <i>Date of Theft</i></p> <p style="text-align: right;"><i>yes</i> <input type="checkbox"/> <i>no</i> <input type="checkbox"/></p> <p><i>Finding</i> <i>date:</i></p> <p style="text-align: right;"><i>place</i></p> <p><i>Other information</i></p>

SCHEDULE III

Security measures

Table1 Security requirements for the different Activity Levels

	Activity Level 3 Sources	Activity Level 2 Sources	Activity Level 1 Sources
Type of security measures required	Safe management and protect as an asset		
	Deter unauthorised access		
		Timely detection of unauthorised access	
		Timely detection of unauthorised acquisition	
			Delay acquisition until response is possible

Specific Security Measures

Administrative Measures

Holders should have the following administrative procedures in order to comply with these regulations

- access control procedures;
- key control procedures;
- adequate surveillance for activity levels 1 & 2;
- records related to management of sources;
- inventories;
- reliability and trustworthiness of personnel;
- information security for activity levels 1 & 2;
- quality assurance measures; and
- establishment of a safety and security cultures.

Technical Measures

Technical measures pose a physical barrier to a source, device or facility in order to separate it from unauthorised personnel and to deter, or to prevent, inadvertent or unauthorised access to, or removal of, a radioactive source.

Technical measures are generally hardware or security devices and include

- fences;
- walls;
- cages;
- transport packages;
- locks and interlocks for doors;
- locked shielded containers;
- intrusion-resistant source holding devices;
- access points with alarm;

Table 2 Recommended measures

	Activity Level 3 Sources	Activity Level 2 Sources	Activity Level 1 Sources	
General administrative measures	Semi-annual accounting	Weekly accounting	Daily accounting	
	Access control to source location	Access control to source location allowing timely detection of unauthorised access		
Deterrence measures		Two measures (one technical) separating the source from unauthorised personnel	Two technical measures separating the source from unauthorised personnel	
	Generic emergency plan	Specific emergency response plan		
		Background check		
		Security plan		
		Information security		
		Upgrade security for increased threat		
		Timely detection by local alarm	Timely detection by remotely monitored intruder alarm	
			Timely response to an alarm	