

MINISTER OF HEALTH OF THE REPUBLIC OF LITHUANIA

TO O R D E R
ON THE ADOPTION OF RULES FOR THE CONTROL OF HIGH-ACTIVITY SEALED
SOURCES OF IONISING RADIATION AND ABANDONED SOURCES OF IONISING
RADIATION

No V-1020 of 23 December 2005

Vilnius

In implementing the provisions of Directive 2003/122/Euratom of the Council of Europe of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources:

1. Approved the rules for the control of high-activity closed sources of ionising radiation and abandoned sources of ionizing radiation (attached).

2. P r o v i d e s that:

2.1. compliance of high-activity closed sources of ionizing radiation imported into the Republic of Lithuania before 31 December 2005 with the requirements of Chapter III of the Rules approved by this Order, with the exception of paragraph 19, must be ensured by the holders of high-activity closed sources of ionizing radiation until 31 December 2007;

2.2. the compliance of high-activity closed sources of ionising radiation imported into the Republic of Lithuania from the Member States of the European Union after 31 December 2005 with the requirements of Chapter III of the Rules approved by this Order must be ensured by manufacturers of high-activity closed sources of ionizing radiation;

2.3. compliance with the requirements of Chapter III of the rules approved by this Order from high-activity closed sources of ionizing radiation, imported into the Republic of Lithuania from non-Member States of the European Union after 31 December 2005, must be ensured by suppliers of high-activity closed sources of ionizing radiation.

3. P a v e m e n t u:

3.1. To prepare and submit to the Centre for Radiation Protection, as an authorised body, draft notifications to the European Commission of the provisions of Council of Europe Directive 2003/122/E of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources:

3.1.1. until 31 December 2005, the address of the authorized authority, the Centre for Radiation Protection, as well as all the information necessary to contact it urgently;

3.1.2. before 1 November 2010 on the experience gained from the implementation of the requirements of the rules adopted by this Order in accordance with the provisions of Article 14 of Directive 2003/122/Euratom of the Europa Council of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources;

3.2. to the Secretary of the Ministry to control the execution of this order in accordance with the area administered.

MINISTER OF HEALTH OS PROTECTION

ŽILVINAS PADAIGA

APPROVED
Republic of Lithuania
Minister of Health
By Order No V-1020 of 23 December 2005

RULES FOR THE CONTROL OF HIGH-ACTIVITY SEALED SOURCES OF IONISING RADIATION AND ABANDONED SOURCES OF IONISING RADIATION

I. GENERAL PROVISIONS

1. Rules for the control of high-activity sealed sources of ionising radiation and orphan sources of ionising radiation (hereinafter referred to as the "Rules") shall establish procedures for the control of high-activity sealed sources of ionising radiation and abandoned sources of ionising radiation in order to protect workers and the population from the possible harmful effects of ionising radiation.

2. These rules are binding on natural, legal persons and branches of legal entities established in a state signatory to the Agreement on the European Economic Area in the Republic of Lithuania, planning to carry out and carry out activities with sources of high activity outside the next sources of ionizing radiation or whose activities are related to the detention or identification of abandoned sources of ionizing radiation, and to state and municipal authorities in accordance with the Competence.

3. These rules complement the requirements for radiation protection and physical safety of sources of ionizing radiation, which are established in the Lithuanian Hygiene Norm HN 73:2001 "Basic Norms of Radiation Safety" approved by Order No. 663 of the Minister of Health of the Republic of Lithuania of 21 December 2001 (Official Gazette, 2002, No. [11-388](#); 2003, No. 90-4080) (hereinafter referred to as "HN 73") and other legislation regulating radiation safety and the physical safety of sources of ionizing radiation, but does not replace them.

4. Natural, legal persons and branches of legal entities established in a state signatory to the Agreement on the European Economic Area in the Republic of Lithuania who plan to carry out activities with high-activity closed sources of ionizing radiation must obtain a license from the Radiation Protection Center in accordance with the procedure established by legal acts.

5. A license is issued and high-activity closed sources of ionizing radiation may be imported into the Republic of Lithuania only if the holder of high-activity closed sources of ionizing radiation is ready to carry out and carries out radiation protection and physical protection of high-activity closed sources of ionizing radiation undertakes to clean up the disused closed sources of ionising radiation of high activity and in accordance with the procedure laid down by law.

6. State supervision and control of radiation protection for the implementation of the requirements of these rules is carried out by the Center for Radiation Protection.

7. These rules shall not apply to high-activity sealed sources of ionising radiation whose activity during activity with them has become lower than the unregulated level of activity as determined in HN 73.

8. For the purposes of these Rules, the terms used and their definitions shall be as follows:

8.1. **'high-activity sealed source of ionising radiation'** (hereinafter referred to as 'source') means a sealed source of ionising radiation in which the activity(s) of the radionuclide(s) present at the time of manufacture of the source or when the source first enters the market (if the date of manufacture of the source is not known) is equal to or exceeds the activity(s) of the radionuclide(s) set out in Annex 1 to these Regulations;

8.2. **'manufacturer of a high-activity sealed ionising radiation source'**, hereinafter referred to as 'the manufacturer', means any natural or legal person who produces high-activity sealed sources of ionising radiation;

8.3. **'authorised body'** means an institution which, by law or regulation, has itself been subject to management functions in the field of radiation protection (Centre for Radiation Protection);

8.4. **'defunct high-activity sealed source of ionising radiation'** (hereinafter referred to as

'disused source') means a high-activity sealed source of ionising radiation, the holder of which is licensed in accordance with the procedure laid down by law, but this high-activity sealed source of ionising radiation is not used or is not intended to be used in the future;

8.5. **'orphan source' of ionising radiation** (hereinafter referred to as 'orphan source') means a sealed source of ionising radiation, the level of activity of which at the time of detection is higher than the level of the non-regulated activity as determined in HN 73, and which is not an object of control because it has never been the subject of control, or because it has been abandoned, lost, stored out of place, stolen or transferred to another licensee without proper notification of the radiation safety centre and without informing the recipient of the source of the ionising radiation thereof;

8.6. **'temporary storage facility for radioactive waste' means a temporary storage facility** for radioactive waste and/or disused closed sources of ionising radiation licensed in accordance with the procedure laid down by law or regulation, where radioactive waste is temporarily stored or stored for long-term storage and/or closed sources of ionising radiation are no longer used;

8.7. **'radioactive waste repository' means a storage facility** for radioactive waste and/or disused closed sources of ionising radiation licensed in accordance with the procedure laid down by law or regulation, where radioactive waste is buried and/or closed sources of ionising radiation are no longer used;

8.8. **'sealed source of ionising radiation' means a container** of a sealed source of ionising radiation which is not an integral part of this source but is used for its transport and storage;

8.9. **'holder of a high-activity closed source of ionising radiation'** (hereinafter referred to as the holder of the source) means any natural, legal person and branch of a legal entity established in a state signatory to the Agreement on the European Economic Area in the Republic of Lithuania, legally responsible for the closed source of ionizing radiation of the activity, with the exception of operators of temporary storage or burial grounds for radioactive waste. include producers and suppliers of high-activity sealed sources of ionising radiation ;

8.10. **'transmission of a high-activity closed source of ionising radiation'** (hereinafter referred to as 'source transmission') means the act of transmitting it by one holder of a high-activity sealed ionising radiation source to another holder of a high-activity sealed ionising radiation source;

8.11. **'supplier of a high-activity closed source of ionizing radiation'** (hereinafter referred to as the supplier of the source) – any natural, legal person and branch of a legal entity established in a state signatory to the Agreement on the European Economic Area in the Republic of Lithuania, supplying or assisting in obtaining a high-activity closed source of ionizing radiation;

8.12. the other terms and definitions used in these Rules correspond to the concepts used in other legal acts regulating radiation protection and their definitions.

II. RECORDING OF SOURCES AND PROVISION OF INFORMATION

9. The holder of the source shall be obliged to register each source on the registration card of the high-activity sealed source of ionising radiation (hereinafter referred to as the 'registration card'), the form of which is given in Annex 2 to these Regulations.

10. The holder of the source must provide the Radiation Protection Centre with an electronic or written copy of the registration card, charged with the security of the information on this card:

10.1. after purchasing the source – no later than within 10 working days;

10.2. by 31 January of each calendar year;

10.3. in case of any change in any information on the registration card – no later than within 10 working days;

10.4. no later than 10 working days after the source holder has declared the source to be disused or (and) no longer has any source. In this case, the holder of the source to whom the source was transferred or the temporary storage facility or burial ground for radioactive waste to which the source was transferred must be entered on the registration card. The registration card shall be accompanied by a request to suspend, revoke or revise the licence;

10.5. The Radiation Protection Centre shall be required to do so.

11. Electronic and written copies of the registration card shall have equal legal force.

12. The holder of the source shall be responsible for the accuracy and safety of the information provided on the registration card in accordance with the procedure established by legal acts and must enable the officials of the Radiation Safety Centre to verify the information contained in the registration cards in accordance with the procedure established by legal acts.

13. The Centre for Radiation Protection shall keep a record of the holders of the sources and the sources available to them and shall update the registration records and shall ensure the confidentiality of the information stored on the registration cards in accordance with the procedure laid down by law.

14. At the reasoned request of the authorised authorities of the Member States of the European Union and of other Member States, the Centre for Radiation Protection shall provide information on the transmission of sources in order to ensure data security.

III. IDENTIFICATION AND LABELLING OF SOURCES

15. Each source shall be assigned a unique identification number which, where technically possible, shall be engraved or embossed on the surface of the source. The same identification number must also be engraved or embossed on the container in which the source is stored. Where, for technical reasons, this is not possible or, in the case of reusable carriers of the source, the source container must otherwise contain information on the source identification number, the name of the radio-nuclide, the activity of the source on the day of manufacture and the date of manufacture of the source.

16. The source, if technically feasible, and the container(a) in which the source is stored must bear a basic sign of ionising radiation giving warning of the danger posed by the source.

17. The source number and marking details shall be legible and shall remain legible throughout the lifetime of the source.

18. Written information must be drawn up in a language understandable to the holder of the source that the source and the container in which the source is stored are identified and marked in accordance with the requirements of paragraphs 15 to 17 of these Rules.

19. Written information must be accompanied by:

19.1. source certificate (technical passport) or a copy thereof;

19.2. photographs of a representative source, where technically feasible, of the receptacle of the source, of the packaging of the transport, of the device or of the device in which the source is located.

IV. REQUIREMENTS FOR THE HOLDER OF THE SOURCE

20. The holder of the source must:

20.1. before acquiring a source, require the manufacturer or supplier of the source from the source or before transferring (selling) the source to another source holder to ensure that the source and the receptacle of the source in which the source is stored are identified and labelled in accordance with the requirements of paragraphs 15 to 17 of these Rules and that written information is provided in accordance with the requirements of paragraphs 18 to 19;

20.2. to carry out physical control and inventory of sources in accordance with the procedure established by legal acts, to make sure that each source and (or) device in which the source is located is intact, and to make appropriate entries in a free-form journal;

20.3. ensure that each source is used in accordance with the procedures for using the source;

20.4. provide in the description of the physical safety of sources for measures to prevent unauthorized use of sources, their loss, theft or damage in the event of fire;

20.5. immediately notify the Radiation Protection Center of any loss, theft or unauthorized use of the source;

20.6. to carry out an inspection of the tightness of each source in accordance with the

procedure and periodicity established by legal acts. This inspection must also be carried out after any event, including a fire, which may have damaged the tightness of the source, and the radiation protection centre shall be informed immediately of this and of the measures taken to remedy the identified deficiencies;

20.7. in accordance with the procedure established by legal acts, return the disused source to the supplier, transfer it to a radioactive waste storage or burial ground or transfer it to another recipient of the source, having previously made sure that the recipient has a license issued in accordance with the procedure established by legal acts;

20.8. immediately inform the Radiation Protection Center about any incidents or accidents that may have caused or caused exposure of workers and /or residents ;

20.9. ensure that workers are periodically trained and instructed on radiation protection, the safe use of sources and their physical safety. Training and instruction must address the specific issues of safe source management and the possible consequences of losing source control;

20.10. to ensure the physical safety of sources in accordance with the procedure established by legal acts.

V. ABANDONED SOURCES

21. Scrap metal purchasing establishments, scrap metal processing plants and border checkpoints in non-Member States of the European Union and, where possible, border checkpoints of member states of the European Union must have portable and stationary equipment for detecting orphan sources. Portable equipment for the detection of abandoned sources must be possessed both by the customs mobile groups of the Customs Department under the Ministry of Finance of the Republic of Lithuania, which carry out controls in the territory of the Republic of Lithuania, during which orphan sources may be detained or identified, and by employees of scrap metal purchase sites. detection must make aware of what ionising radiation is, what its effects are, be able to identify the sources and their receptacles and take the necessary action in the event of detection or suspicion of the source.

22. The training of employees, officials and representatives and managers of the administration, whose work (activities) are related to the detection of abandoned sources, in accordance with the program approved by the Center for Radiation Protection, is organized by the administration of enterprises, state institutions in accordance with the procedure established by legal acts.

23. The Centre for Radiation Protection and other state authorities must, within the limits of their competence, organise and carry out searches for abandoned sources in the spheres where activities with them have previously been carried out.

24. Orphaned sources found, detained or identified shall be handled in accordance with the procedure established by law.

25. Orphan sources found, identified, detained, stolen or lost shall be immediately communicated to the authorities and international organizations of the other States concerned and shall be informed and exchanged information on the further progress and results of the investigation in accordance with the procedure laid down by law and without prejudice to confidentiality.

VI. FINAL PROVISIONS

26. Natural, legal persons and branches of companies established in the States of the European Economic Area established in the Republic of Lithuania shall be liable for violations of the requirements of these Rules in accordance with the procedure established by laws and other legal acts.

High activity of closed ionizations in the
 radiation sources and abandoned
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 control rules
 Annex 1

LEVELS OF ACTIVITY OF HIGH-ACTIVITY SEALED SOURCES OF IONISING RADIATION⁽¹⁾

Radionuclide	Activity, Bq
⁵⁵ Fe	4×10 ¹¹
⁶⁰ Co.,	4×10 ⁹
⁷⁵ Se	3×10 ¹⁰
⁸⁵ Kr ⁽²⁾	1×10 ¹¹
⁹⁰ Sr ⁽²⁾	3×10 ⁹
¹⁰³ Pd	4×10 ¹¹
¹²⁵ I	2×10 ¹¹
¹³⁷ Cs ⁽²⁾	2×10 ¹⁰
¹⁴⁷ Pm	4×10 ¹¹
¹⁵³ Gd	1×10 ¹¹
¹⁷⁰ Tm	3×10 ¹⁰
¹⁹² Am	1×10 ¹⁰
²⁰⁴ Pb	1×10 ¹¹
²²⁶ Ra ⁽³⁾	2×10 ⁹
²³⁸ Pu ⁽²⁾	1×10 ¹¹
²⁴¹ Am ⁽³⁾	1×10 ¹¹
²⁵² Cf	5×10 ⁸

⁽¹⁾ The activity of radionuclides not listed in this Annex but given in Annex HN 73 A.1 is equal to 1/100 A₁ (special forms of radioactive substances). The values of A₁ are set out in technical annexes A and B to the European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Official Gazette, 2004, No. [91-3349](#));

⁽²⁾ including radionuclides daughters with a half-life of less than 10 days;

⁽³⁾ including neutron sources with beryllium.

High-activity closed ionizing agents
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Annex 2

HIGH-ACTIVITY SEALED SOURCE OF IONISING RADIATION REGISTRATION CARD FORM

(High-activity sealed source of ionising radiation in the form of a registration card)

1. Source identification number:		2.Data of the licensee of the ve iklos with sources of ionising radiation		3. Place of use or storage of the source (if different from the information on p. 2)	
		Title:		Title:	
		Address:		Address	
		Side:		Stationary <input type="checkbox"/> * Portable <input type="checkbox"/> *	
		Manufacturer <input type="checkbox"/> * Supplier <input type="checkbox"/> *		Used in <input type="checkbox"/> * Protected <input type="checkbox"/> *	
		User <input type="checkbox"/> *			
4. Registration		5. License data for activities with sources of ionizing radiation		6. Technical verification marks of the source	
Start of registration (date)		License number:		Date:	
End of registration (date)		Date of issue of the licence:		Date:	
				Signature	
				Signature	
7. Source properties		8. Source receipt data		Date:	
Radionuclide(s):		Date of receipt:		Date:	
Activity on the day of manufacture:		Derived from:		Date:	
				Signature	
Activity on the date of placing on the market of the source: (to be filled in if the date of manufacture is unknown)		Title:		Date:	
				Signature	
Date of manufacture:		Address:		Date:	
Expiration date:		Side:		Date:	
Manufacturer/supplier (importer) (to be filled in if the source is produced in a Member State other than the European Union):				Signature	
Title:		Manufacturer <input type="checkbox"/> * Supplier <input type="checkbox"/> *		Date:	
		User <input type="checkbox"/> *		Signature	
Address:		9. Source transmission data		10. Other information	
Side:		Date of transmission:		Lost <input type="checkbox"/>	
				Date:	
Physical and chemical properties:		Passed:		Stolen <input type="checkbox"/>	
		Title:		Date:	
Source type:		Address:		Found <input type="checkbox"/>	
Type of protective shell of the source:		Side:		Date:	
Classification according to ISO:		Manufacturer <input type="checkbox"/> * Supplier <input type="checkbox"/> *		Place:	
Classification according to ANSI:		Other user <input type="checkbox"/> *		11. The card was filled in by:	
Source certificate (technical passport):		Radioactive waste temporary storage <input type="checkbox"/> *		Position, first name, last name:	
		Burial ground <input type="checkbox"/> *		Date:	

* notes what is needed