

Order no. 356/2005

of 21/11/2005

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approving the Norms on orphan sources and control of high activity sealed radioactive sources

According to the provisions of the Law no. 111/1996 on safe deployment of nuclear activities, republished in the Official Bulletin, Part I, no. 78 of 18 February 1998, with subsequent completions and modifications, and the Government Decision no. 1.627/2003 approving the CNCAN Internal Rules, published in the Official Bulletin, Part I, no. 69 of 27 January 2004,

the President of the National Commission for Nuclear Activities Control issues the following Order:

Art. 1. – There are approved the Norms on orphan sources and control of high activity sealed radioactive sources, provided in the Annex which is integral part to this Order.

Art. 2. – This Order will be published in the Official Bulletin, Part I.

Art. 3. – The Division of International Affairs shall notify to the European Commission any modifications related to the art 28 of the Norms on orphan sources and control of high activity sealed radioactive sources.

This Order transposes the Directive 2003/122/EURATOM of 22 December 2003 on the control of high activity sealed radioactive sources and orphan sources, adopted by the Council of the European Union and published in the Official Journal on 31 December 2003.

President of the National Commission for Nuclear Activities Control
Vilmos Zsombori

Bucharest, 21 November 2005
No. 356

NORMS
on orphan sources and control of high activity sealed radioactive sources

CHAPTER I

Scope and applicability field

Art. 1. – The scope of these norms is to prevent the exposure of workers and population to the radiation generated by the orphan sources and resulted from an inadequate control of high activity sealed radioactive sources and to harmonize the existing control with that one from the European Union's Member States, by defining some specific requirements ensuring that each high activity sealed radioactive source is kept under control.

Art. 2. - (1) These norms shall be applied for the high activity sealed radioactive sources as they are defined in the Annex no. 1.

(2) The sealed radioactive sources whose activity is less than the exemption levels provided in the Fundamental Norms for Radiological Safety are excepted from the application of the provisions of these norms.

Art. 3. – These norms complete the requirements established within the Fundamental Norms for Radiological Safety

CHAPTER II

Definitions

Art. 4. – Terms and expressions used in the present norms are defined in the Annex no. 1.

CHAPTER III

Authorisation

Art. 5. – The development of any activity involving a high activity sealed radioactive source, including taking its in possession, requires a prior authorization from CNCAN, in accordance with the provisions of the Law no. 111/1996, republished, with subsequent completions and modifications

Art. 6. – Prior to issue the authorization, CNCAN shall ensure that:

a) conditions for the safe development of practices involving high activity sealed radioactive sources and those for their disposal as radioactive waste, including for the situations when they shall be disused, are established;

b) viable arrangements related to the transfer of high activity sealed radioactive sources to the supplier or to authorized units for storage or disposal exist or the producer's or supplier's commitment for their taking over exist;

c) necessary material and financial arrangements or equivalent, in the situation where these are disused and/or the holder is bankrupt or is ceasing its activity exist and are provided by the law

Art. 7. – During the authorization process of practices involving high activity sealed radioactive sources, CNCAN shall verify if the applicant fulfills, at least the requirements concerning:

a) the allocation and definition of responsibilities;

b) the training and licensing of the personnel involved in the practice development;

c) the high activity sealed radioactive source, the container and auxiliary equipment, in accordance with the applicable technical norms;

d) the existence of an intervention plan in case of radiological emergency and of necessary communication links;

e) the existence of working procedures;

f) the capability to carry-out the maintenance of the equipment, of the high activity sealed radioactive source and of the container, through authorized units in accordance with the provisions of the Law no. 111/1996 republished with subsequent modifications and completions;

g) the existence of a program for the situation when a high activity sealed radioactive source shall be disused, including of some arrangements concerning the transfer to the supplier, other authorization holder or authorized units for treatment, storage or disposal.

CHAPTER IV

Transfer

Art. 8. - CNCAN shall organize a national system for the operational evidence capable to record the movements of high activity sealed radioactive sources, including their transfer.

CHAPTER V

Records

Art. 9. – The authorization holder shall keep records on all high activity sealed radioactive sources that he/she possesses, the possession place and their transfer. The records shall include the information provided in Annex no. 3 of the present norms. The information shall be registered on the form provided in Annex no. 3 of the present norms.

Art. 10. - (1) The authorization holder shall place at CNCAN's disposal the records specified at art. 9 of the present norms, both in written and electronic format:

- a)** without undue delay a high activity sealed radioactive source has been acquired;
- b)** during month of January of each year, for the previous year;
- c)** whenever changes given the already reported situation have been occurred;
- d)** without undue delay a high activity sealed radioactive source has been disused; in this case, the identification data of the new holder or of the authorized unit for storage or disposal shall be transmitted;
- e)** immediately, at the ceasing of the activity, in accordance with the Norms on Radiological Safety – Authorization Procedures;
- f)** whenever so requested by CNCAN.

(2) The records shall be placed at CNCAN's representative disposal during the control.

Art. 11. - CNCAN shall keep the evidence of authorisation holders and of high activity sealed radioactive sources that they possess. This evidence shall include information on:

- a)** the activity of the high activity sealed radioactive source, at the date of its manufacturing or in case this is unknown, the activity at the time of its placing on the market or at the date of its acquisition;
- b)** the radionuclide, the physical and chemical form, the high activity sealed radioactive source's classification and the capsule identification, as they are defined in the form in Annex no. 3 of the present norms.

Art. 12. – The evidence provided under Art. 11 shall take into account the transfer of high activity sealed radioactive sources and shall be kept up-to-date.

Art. 13. - CNCAN places at the authorization holders disposal the electronic version of the form provided in Annex no. 3 of the present norms.

Art. 14. – At the European Commission request, CNCAN shall review the content of the form provided in Annex no. 3 of the present norms.

CHAPTER VI

Obligations of the authorisation holders

Art. 15. – Each high activity sealed radioactive source's holder shall:

- a)** ensure the conditions for carrying-out the necessary periodical tests (surface unfixed contamination based on international standards) in order to check and maintain the integrity of each high activity sealed radioactive source that he possesses;

- b)** ensure daily verification that high activity sealed radioactive sources and, where relevant, the equipment containing such sources at their place of use or of storage, as well as adequate preservation conditions are present;
- c)** establish, by case, a physical protection system in order to prevent the unauthorized access to, damage by fire, loss or theft of any high activity sealed radioactive source, or equipment having high activity sealed radioactive source, by case;
- d)** promptly notify CNCAN of any loss, theft or unauthorised use of high activity sealed radioactive sources and ensure their checking after any event that could affect their integrity, including after fire and inform on the measures taken;
- e)** ensure the return of any disused high activity sealed radioactive source to the supplier or transfer it to authorized units for storage or disposal without undue delay after termination of the use
- f)** ascertain that, before a transfer is made, the recipient is authorized in accordance with the provisions of Law no. 111/1996 republished, with subsequent modifications and completions;
- g)** notify, without undue delay, CNCAN of any incident or accident resulting in unintentional exposure of workers or public.

CHAPTER VII

Identification and marking

Art. 16. - (1) In case of imported high activity sealed radioactive sources, manufacturers or suppliers shall ensure that each kind of source is identified by a unique number. This number shall be engraved or stamped on the high activity sealed radioactive source, where practicable.

(2) The number shall also be engraved or stamped on the high activity sealed radioactive source container. If this is not feasible or in the case reusable transport containers, the container shall, at least, have information on the nature of the high activity sealed radioactive source.

(3) The manufacturers or the suppliers, by case, shall ensure that the containers and, where practicable, the high activity sealed radioactive sources are marked and labeled with the symbol "Radiation danger"

(4) The manufacturers shall provide a photograph of each type of high activity sealed radioactive source and of its type of container.

Art. 17. – The holders shall ensure that each high activity sealed radioactive source that he/she possesses is accompanied by written information indicating that the source is identified and marked in compliance with the provisions of Art. 16 that the labels remain legible.

Art. 18. – The information shall include photographs of the high activity sealed radioactive source, of the source container, transport packaging, device and equipment, as appropriate.

CHAPTER VIII

Training and information

Art. 19. - (1) The high activity sealed radioactive source holder shall ensure that information and training of the occupational exposed workers, as provided in the Fundamental Norms on Radiological Safety, include specific requirements for the field "Sealed sources" from the Norms on issuing the exercising permits of nuclear activities and designation of qualified experts radiation protection.

(2) The information and training shall place particular emphasis on description of radiological safety requirements and shall contain specific information on the possible consequences of the loss of control of high activity sealed radioactive sources.

(3) The information and training shall be repeated at regular intervals, in accordance with the provisions of the Fundamental Norms on Radiological Safety and shall contain the necessary information for the adequate training of occupational exposed workers, in case of an incident occurs.

(4) The authorisation holder shall ensure the participation of all occupational exposed workers in the training programme for radiation protection and radiological safety.

Art. 20. –CNCAN shall take the necessary measures so that the management and the workers in installations where orphan sources are most likely to be found or processed (e.g. metal scrap yards and metal scrap recycling plants), as well as the management and workers in significant custom transit points to be:

- a) informed of the possibility that they may be confronted with the situation of a high activity sealed radioactive source existence;
- b) informed of the necessity of the visual control for detecting the high activity sealed radioactive sources and their containers;
- c) informed of the basic notions about ionizing radiation and its effects;
- d) informed and trained on the actions to be taken on-site in the event of the detection or suspected detection of a high activity sealed radioactive source existence.

CHAPTER IX

Orphan sources

Art. 21. - (1) CNCAN establishes responsibilities to recover orphan sources and to draw-up an intervention plan in case of radiological emergency, adequate measures and resources plan for their recovery.

(2) CNCAN shall establish to put the recovered orphan sources under the safeguards control system, as the case may be.

Art. 22. - CNCAN shall take all necessary measures that technical and specialized assistance to be granted for that people which normally is not involved in actions subject to radiation protection requirements and that suspect the presence of an orphan source. The main purpose of the technical and specialized assistance shall be the protection of workers and population against ionizing radiation and security of high activity sealed radioactive sources.

Art. 23. – CNCAN shall establish a measures plan aimed at detecting orphan sources in places where they are encountered, generally unknown (metal scrap yards and metal scrap recycling installations or in custom transit **offices**).

Art. 24. - (1) CNCAN decides actions to recover orphan sources left behind from past activities.

(2) The decided actions may include measures on the participation, according to legal provisions, to the financing of necessary costs for recovering, managing, storing and disposing of recovered sources and may include the verification of historical records of the authorities (i.e. customs) and of holders (i.e. research institutes, material testing institutes or hospitals).

CHAPTER X

Financial security for orphan sources

Art. 25. – The financing manner and other means necessary to cover the activities for recovery of orphan sources and the activities necessary to implement the requirements set-out in Chapter IX from the present norms shall be ensured in accordance with the legal provisions

CHAPTER XI

International cooperation and information exchange

Art. 26. - CNCAN shall exchange information and cooperate with the EU Member States, with third countries and with international organizations as regards loss, abandonment, theft or discovery of high activity sealed radioactive sources and as regards related further investigations and actions without prejudice to confidentiality requirements and national regulations.

CHAPTER XII

Inspections

Art. 27. - CNCAN shall establish and maintain a system of inspection to enforce the application of the provisions of the present norms.

CHAPTER XIII
Competent authority

Art. 28. - (1) CNCAN is the national competent authority with attributions for applying the provisions of the present norms.

(2) CNCAN shall forward to the European Commission all necessary information for rapidly communication with other authorities.

(3) CNCAN shall ensure the interface with other authorities with attributions for applying the provision sof the present norms and is the point of contact acting as interface with other Member States and the European Commission.

CHAPTER XIV
Reports

Art. 29. – On December 31st, 2010, CNCAN shall report to the European Commission the results of the implementation of the present norms, including consideration of effects which the provisions of Chapter 1, art. 2 have had.

CHAPTER XV
Penalties

Art. 30. – For breaching the provisions of the present norms, the penalties provided by the Law no. 111/1996 republished with subsequent modifications and completions shall be applied.

CHAPTER XVI
Final and transitory provisions

Art. 31. - (1) The provisions of the present norms shall entry into force at the date of its publishing in the Romanian Official Bulletin.

(2) As regards the high activity sealed radioactive sources placed on the marked before December 31st, 2005:

(a) the provisions of chapters III, IV, V and VI shall be applied starting on December 31st, 2007;

(b) the provisions of chapter VII did not apply, with the exception of the following requirements that should be fulfilled by December 31st, 2007 at the latest;

(i) the holder shall ensure that each high activity sealed radioactive source and each container are accompanied by written information on the nature of the source and its identification;

(ii) the holder shall ensure that each high activity sealed radioactive source and its container are labeled with the symbol "Radiation danger"

DEFINITIONS

National competent authority in the field is the authority, established by law, having the legal competence to issue authorizations and to regulate the siting, design, construction, commissioning, operation or decommissioning of nuclear and radiological facilities.

Authorisation means the document issued by the national competent authority in the field for developing a nuclear activity, on the basis of a control and nuclear safety evaluation, to a *person set-up* in compliance with the provisions of the Law no. 111/1996 republished with subsequent modifications and completions at his/her request.

The high activity sealed radioactive source's container means the container the source is included in, but not being an integral part of the source and being used in its transport and handling.

The intermediate or final repository means the installation authorized by CNCAN, in accordance with the provisions of the Law no. 111/1996 republished with subsequent modifications and completions, for the storage or disposal of high activity sealed radioactive sources.

Holder means any natural or legal person set-up up in accordance with the provisions of the Law no. 111/1996 republished with subsequent modifications and completions, having responsibilities for high activity sealed radioactive sources according to legal provisions in force. In this category are included the manufacturers, suppliers and users excluding the storage or disposal facilities of waste.

Supplier means any natural or legal person set-up up in accordance with the provisions of the Law no. 111/1996 republished with subsequent modifications and completions, who supplies or makes available a high activity sealed radioactive source.

Occupational exposed worker has the meaning given to it by the Fundamental Norms on Radiological Safety.

Practice has the meaning given to it by the Fundamental Norms on Radiological Safety.

Manufacturer means any natural or legal person set-up up in accordance with the provisions of the Law no. 111/1996 republished with subsequent modifications and completions, who manufactures high activity sealed radioactive sources.

Sealed source has the meaning given to it by the Fundamental Norms on Radiological Safety and includes, where applicable, the capsule enclosing the radioactive material as an integral part of the sealed source.

High-activity sealed radioactive source means a sealed source containing a radionuclide whose activity at the time of manufacture or, if this is unknown, at the first placing on the market, is equal to or exceeds the activity levels specified in Annex no. 2 of the present norms.

Orphan source means the sealed source, whose activity at the time of its discovery is above the exemption level referred to in the Fundamental Norms on Radiological Safety, 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 the high activity sealed radioactive source which is no longer used or intended to be used for the practice for which authorisation was granted.

Transfer means the transfer of a high activity sealed radioactive source from one holder to another one.

THE ACTIVITY LEVELS FOR THE HIGH ACTIVITY SEALED RADIOACTIVE SOURCES

For radionuclide not included in the below table, but that are included in the Fundamental Norms on Radiological Safety, it shall be considered the value of activity to be 1/100 from the value A1 specified in the IAEA regulations for the safe transport of radioactive materials.

The element (Atomic No.)	Radionuclide	Activity (Bq)
Fier (26)	Fe-55	4×10^{11}
Cobalt (27)	Co-60	4×10^9
Seleniu (34)	Se-75	3×10^{10}
Krypton (36)	Kr-85	1×10^{11}
Stronțiu (38)	Sr-90 ¹	3×10^9
Paladium (46)	Pd-103 ¹	4×10^{11}
Iod (53)	I-125	2×10^{11}
Cesiu (55)	Cs-137 ¹)	2×10^{10}
Prometiū (61)	Pm-147	4×10^{11}
Gadolinu (64)	Gd-153	1×10^{11}
Taliu (69)	Tm-170	3×10^{10}
Iridiu (77)	Ir-192	1×10^{10}
Taliu (81)	Tl-204	1×10^{11}
Radiu (88)	Ra-226 ²)	2×10^9
Plutoniū (94)	Pu-238 ¹)	1×10^{11}
Americiu (95)	Am-241 ²)	1×10^{11}
Californiu (98)	Cf-252	5×10^8

¹) – The activity includes the contributions from the daughter nuclides with half-life time less than 10 days

²) – Includes radioactive sources containing beriliu and emit neutrons

FORM ON RECORDING THE HIGH ACTIVITY SEALED RADIOACTIVE SOURCES

1. Identification number of the high activity sealed radioactive source	2. Identification of the authorized holder Name: Address: Country: Manufacturer [] Supplier [] User []	3. Location of the high activity sealed radioactive source (use or possession), if there is different from the information under point 2 Name Address: Using place [] Storage []
4. Recording:	5. Authorization:	6. Operational control of the high activity sealed radioactive source (dd/mm/yy):
7. Characteristics of the high activity sealed radioactive source Radionuclide: Activity at the date of manufacturing or at the time of its first placing on the market: Manufacturer / Supplier: ¹⁾ Name: Address: Country: Physical and chemical characteristics: Identification of source type: Identification of capsule: ISO Classification: ANSI Classification: Other specifications of the certificate: (Special form material certificate)	8. Delivery of the high activity sealed radioactive source: Date of receiving: Received from: Name: Address: Country: Manufacturer [] Supplier [] User []	Date: <hr/> Date: <hr/> Date: <hr/> Date: <hr/> Date: <hr/> Date: <hr/> Date: <hr/> Date: <hr/> Date: <hr/> Date: <hr/> Date: <hr/>
	9. Transfer of the high activity sealed radioactive source:	10. Other information: Loss [] Date of loss: Theft [] Date of theft: <div style="text-align: right;">Yes [] No []</div> Recovery: Date: Place: Other information:
	Date of transfer:	
	Transferred to:	
	Name:	
	Address:	
	Country:	
	Manufacturer [] Supplier [] User []	
	Intermediate or final repository []	

¹⁾ Where the manufacturer is from the outside of European Union, the identification data of the importer or supplier shall be specified.

at the date of its manufacturing or in case this is unknown, the activity at the time of its placing on the market or at the date of its acquisition

¹⁾ În cazul în care producătorul este din exteriorul Uniunii Europene, trebuie precizate datele de identificare ale importatorului sau furnizorului.