

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

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31(2) and 32 thereof,

Having regard to the proposal from the Commission, drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States, in accordance with Article 31 of the Treaty,

After consulting the European Economic and Social Committee,

Having regard to the opinion of the European Parliament(1),

Whereas:

(1) Article 30 of the Treaty requires basic standards to be laid down within the Community for the protection of the health of workers and the general public against the dangers arising from ionising radiation.

(2) Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation(2), continues the line of directives laying down basic safety standards since 1959.

(3) Article 4(1)(e) of Directive 96/29/Euratom requires prior authorisation for, amongst other practices, the use of radioactive sources for industrial radiography or processing of products or research or the exposure of persons for medical treatment. It is appropriate to extend this requirement to all practices involving high-activity radioactive sources in order further to reduce the likelihood of accidents involving such sources.

(4) Prior to authorisation, adequate arrangements and provision for the safe management of sources should exist.

(5) The International Atomic Energy Agency (IAEA) issues regulations for the safe transport of radioactive material that include activity limits for the requirements of the regulations, which should provide an appropriate basis for defining high-activity sealed radioactive sources within the scope of this Directive(3).

(6) In Directive 96/29/Euratom exemption values were laid down for the reporting of a practice to the authorities. These values were defined in that Directive on the basis of a negligible level of risk. As the requirements of this Directive should not put an administrative burden on the holders of small sources that is not commensurate with the possible health detriment, the definition of high activity radioactive sources should not be extended to the exemption levels of Directive 96/29/Euratom.

(7) Shipments of sealed sources between Member States are subject to the procedure established by Council Regulation (Euratom) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States(4).

(8) Although the legal requirements deriving from existing legislation at Community and at national level ensure basic protection, high-activity sources still imply considerable potential risks for human health and for the environment and therefore need to be subject to a strict control from the time they are manufactured to the time they are placed in a recognised installation for their long-term storage or disposal.

(9) Prevention of radiological accidents and injuries requires the location of each high-activity source to be known, recorded and verified from the time the source is manufactured or imported into the Community to the time it is placed in a recognised installation for its long-term storage or disposal or

it is exported from the Community. Changes in the situation of a high-activity source, e.g. its location or use, should also be recorded and notified. Physical or financial obstacles should not hinder any appropriate reuse, recycling or disposal of such sources when disused under any reasonably foreseeable circumstances.

(10) Cases of unintentional exposure should be notified to the competent authority.

(11) Movements within the Community of high-activity sources make it necessary to harmonise the control of and information on such sources through the application of minimum criteria.

(12) Experience shows that, despite the existence of an appropriate regulatory framework, control of high-activity sources may nevertheless be lost. Furthermore, the existence of orphan sources resulting from past activities requires that specific initiatives be undertaken.

(13) Accordingly, it is necessary to provide for the identification, marking and recording of each high-activity source as well as for the specific training and informing of all those involved in activities relating to the use of sources. However, the marking of existing high-activity sources by engraving or stamping by persons other than the manufacturer could be problematic and should be avoided. It is also advisable to provide appropriate training and information for those who may deal accidentally with orphan sources.

(14) It is also necessary to provide for suitable means of dealing with orphan high-activity sources for international cooperation and exchange of information in this area, for inspection and, finally, for making financial provision for cases in which the original holder either cannot be identified or, even if identified, is found to be insolvent.

(15) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented; those penalties should be effective, proportionate and dissuasive,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

##### Purpose and scope

1. The purpose of this Directive is to prevent exposure of workers and the public to ionising radiation arising from inadequate control of high-activity sealed radioactive sources and orphan sources and to harmonise controls in place in the Member States by defining specific requirements ensuring that each such source is kept under control.

2. This Directive applies to high-activity sources as defined in Article 2. Member States may exclude sources from the scope of this Directive once their activity has fallen below the exemption levels specified in Directive 96/29/Euratom.

3. The minimum obligations resulting from this Directive supplement those set out in Directive 96/29/Euratom.

#### Article 2

##### Definitions

For the purpose of this Directive, the following definitions shall apply:

(a) "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 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;

(b) "high-activity source", hereinafter referred to as "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 Annex I;

(c) "practice" has the meaning given to it by Directive 96/29/Euratom;

(d) "authorisation" means permission granted in a document by competent authorities, on request, to carry out a practice involving a source;

- (e) "competent authority" means any authority designated by a Member State to carry out tasks in accordance with this Directive;
- (f) "disused source" means a source which is no longer used or intended to be used for the practice for which authorisation was granted;
- (g) "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";
- (h) "manufacturer" means any natural or legal person who manufactures a source;
- (i) "recognised installation" means a facility located in the territory of a Member State authorised by the competent authorities of that State in accordance with national law for the long-term storage or disposal of sources or an installation duly authorised under national law for the interim storage of sources;
- (j) "exposed worker" has the meaning given to it by Directive 96/29/Euratom;
- (k) "sealed source" has the meaning given to it by Directive 96/29/Euratom and includes the capsule, where applicable, enclosing the radioactive material as an integral part of the source;
- (l) "supplier" means any natural or legal person who supplies or makes available a source;
- (m) "transfer" of a source means a transfer of a source from one holder to another one;
- (n) "source container" means the containment of a sealed source not being an integral part of the source, but meant for transport, handling, etc.

#### Article 3

##### Authorisation

1. Member States shall require the holder to obtain prior authorisation for any practice involving a source, including taking possession of a source.
2. Member States shall ensure that, before issuing authorisation:
  - (a) adequate arrangements, including those arising from this Directive, have been made for the safe management of sources, including when they become disused sources. These latter arrangements 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;
  - (b) adequate provision, by way of a financial security 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. Member States shall ensure that the authorisation covers:
  - (a) responsibilities;
  - (b) minimum staff competencies, including information and training;
  - (c) minimum source, source container and additional equipment performance criteria;
  - (d) requirements for emergency procedures and communication links;
  - (e) work procedures to be followed;
  - (f) maintenance of equipment, sources and containers;
  - (g) 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.

#### Article 4

##### Transfers

Member States shall set up a system to enable them to be adequately informed of individual transfers of sources.

#### Article 5

##### Records

1. The holder shall keep records of all sources under his responsibility, their location and their transfer. The records shall include the information set out in Annex II. This information may be recorded on a standard record sheet pursuant to paragraph 5.
2. The holder shall provide the competent authority with an electronic or written copy of all or part of the records referred to in paragraph 1, as required by the Member State concerned,

- without undue delay, at the time of the establishment of such records, which should be as soon as possible after the source is acquired,
- at intervals, to be determined by Member States/competent authorities, of not more than 12 months thereafter,
- 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 competent authority.

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

3. The competent authorities 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 competent authorities shall keep the records up to date, taking transfers into account, among other factors.

5. The Commission shall make available in electronic format the standard record sheet for the records set out in Annex II.

6. The Commission may, in accordance with the procedure referred to in Article 17, update the required information set out in Annex II and the standard record sheet for the records set out in Annex II.

#### Article 6

##### Requirements for holders

Each holder of sources shall:

- (a) ensure that suitable tests, such as leak tests based on international standards, are undertaken regularly in order to check and maintain the integrity of each source;
- (b) regularly verify, at specific intervals which may be determined by Member States, 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 competent authority 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 competent authority 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 competent authority, 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 competent authority of any incident or accident resulting in unintentional exposure of a worker or a member of the public.

#### Article 7

##### Identification and marking

1. The manufacturer shall identify or, in the case of sources imported from outside the 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.

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.

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

2. The holder shall ensure that each source is accompanied by written information indicating that the source is identified and marked in compliance with paragraph 1 and that the markings and 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.

#### Article 8

##### Training and information

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.

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.

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

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

2. Member States shall provide encouragement to ensure that the management and workers in installations where orphan sources are most likely to be found or processed (e.g. large metal scrap yards and major metal scrap recycling plants), and the management and workers in significant nodal transit points (e.g. customs posts), are

- (a) informed of the possibility that they may be confronted with a source;
- (b) advised and trained in the visual detection of sources and of their containers;
- (c) informed of basic facts about ionising radiation and its effects;
- (d) informed of and trained in the action to be taken on site in the event of the detection or suspected detection of a source.

#### Article 9

##### Orphan sources

1. Member States shall ensure that the competent authorities are prepared, or have made provision, including assignment of responsibilities, to recover orphan sources and to deal with radiological emergencies due to orphan sources and have drawn up appropriate response plans and measures.

2. Member States shall ensure that specialised technical advice and assistance is promptly made available to the 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. Member States 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.

4. Member States shall ensure that campaigns are organised, as appropriate, to recover orphan sources left behind from past activities.

The campaigns may include the financial participation of Member States in the costs of recovering, managing and disposing of the sources and may also include surveys of historical records of

authorities, such as customs, and of holders, such as research institutes, material testing institutes or hospitals.

#### Article 10

##### Financial security for orphan sources

Member States shall ensure that, on the basis of arrangements to be decided by Member States, a system of financial security is established or any other equivalent means to cover intervention costs relating to the recovery of orphan sources and which may result from implementation of the requirements set out in Article 9.

#### Article 11

##### International cooperation and information exchange

Each Member State 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.

#### Article 12

##### Inspections

Member States shall establish or maintain a system of inspection to enforce the provisions introduced in compliance with this Directive.

#### Article 13

##### Competent authority

1. Member States shall designate the competent authority to carry out tasks in accordance with this Directive.
2. Member States shall forward to the Commission the name and the address of the competent authority and all necessary information for rapidly communicating with such authorities.
3. Where Member States have more than one competent authority, they shall designate one point of contact to act as an interface with correspondents in other Member States.
4. Member States shall forward to the Commission any changes to the data referred to in paragraphs 2 and 3.
5. The Commission shall communicate the information referred to in paragraphs 2, 3 and 4 to all competent authorities in the Community and shall publish it periodically in the Official Journal of the European Union, at intervals of no more than two years.

#### Article 14

##### Report on experience

By 31 December 2010, Member States shall report to the Commission on the experience gained in the implementation of this Directive, including consideration of any effect which Article 1(2) may have had.

On that basis, the Commission shall submit a report to the European Parliament, the Council and the European Economic and Social Committee.

#### Article 15

##### Penalties

Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive. The penalties shall be effective, proportionate and dissuasive.

#### Article 16

##### Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 31 December 2005.

Member States may provide, as regards sources placed on the market before the date referred to in the first subparagraph, that:

- (a) Articles 3 to 6 shall not apply until 31 December 2007;

(b) Article 7 shall not apply, with the exception of the following requirements which shall apply by 31 December 2007 at the latest:

- 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, if practicable, and the source container are labelled with an appropriate sign to warn people of the radiation hazard.

Where these measures are adopted by the Member States, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive, together with a table showing how the provisions of this Directive correspond to the national provisions adopted.

#### Article 17

##### Committee

The Commission shall be assisted in performing the tasks laid down in Article 5(6) by an Advisory Committee composed of the representatives of the Member States and chaired by the representative of the Commission.

The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion of the Committee shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the manner in which its opinion has been taken into account.

#### Article 18

##### Entry into force

This Directive shall enter into force on the day of its publication in the Official Journal of the European Union.

#### Article 19

This Directive is addressed to the Member States.

Done at Brussels, 22 December 2003.

For the Council

The President

A. Matteoli

(1) Opinion of 18 November 2003 (not yet published in the Official Journal).

(2) OJ L 159, 29.6.1996, p. 1.

(3) IAEA Safety Standards Series No TS-R-1 (ST, Revised), Vienna, 2000.

(4) OJ L 148, 19.6.1993, p. 1.

#### ANNEX 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(1).

>TABLE>

(1) No TS-R-1 (ST-1, revised) - International Atomic Energy Agency, Vienna 2000.

#### ANNEX II

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