

Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

## CHAPTER IX

### **GENERAL RESPONSIBILITIES OF MEMBER STATES AND COMPETENT AUTHORITIES AND OTHER REQUIREMENTS FOR REGULATORY CONTROL**

#### *SECTION 2*

#### *Control of radioactive sources*

##### *Article 85*

#### **General requirements for unsealed sources**

- 1 Member States shall ensure that arrangements are made for keeping control of unsealed sources with regard to their location, use and, when no longer required, their recycling or disposal.
- 2 Member States shall require the undertaking, as appropriate and to the extent possible, to keep records of unsealed sources under its responsibility, including location, transfer and disposal or discharge.
- 3 Member States shall require each undertaking holding an unsealed radioactive source to notify the competent authority promptly of any loss, theft, significant spill, or unauthorised use or release.

##### *Article 86*

#### **General requirements for sealed sources**

- 1 Member States shall ensure that arrangements are made for keeping control of sealed sources with regard to their location, use and, when no longer required, their recycling or disposal.
- 2 Member States shall require the undertaking to keep records of all sealed sources under its responsibility, including location, transfer and disposal.
- 3 Member States shall establish a system to enable them to be adequately informed of any transfer of high activity sealed sources and where necessary individual transfers of sealed sources.
- 4 Member States shall require each undertaking holding a sealed source to notify the competent authority promptly of any loss, significant leakage, theft or unauthorised use of a sealed source.

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### *Article 87*

#### **Requirements for control of high-activity sealed sources**

Member States shall ensure that, before issuing authorisation for practices involving a high-activity sealed source:

- (a) adequate arrangements have been made for the safe management and control of sources, including when they become disused sources. Such arrangements may provide for the transfer of disused sources to the supplier or their placement in a disposal or storage facility or an obligation for the manufacturer or the supplier to receive them;
- (b) adequate provision, by way of a financial security or any other equivalent means appropriate for the source in question, has been made for the safe management of sources when they become disused sources, including the case where the undertaking becomes insolvent or ceases its activities.

### *Article 88*

#### **Specific requirements for licensing of high-activity sealed sources**

In addition to the general licensing requirements set out in Chapter V, Member States shall ensure that the licence for a practice involving a high-activity sealed source includes, but does not have to be limited to:

- (a) responsibilities;
- (b) minimum staff competencies, including information and training;
- (c) minimum performance criteria for the source, source container and additional equipment;
- (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 manufacturer, a supplier, another authorised undertaking or a waste disposal or storage facility.

### *Article 89*

#### **Record keeping by the undertaking**

Member States shall require that the records for high-activity sealed sources include the information set out in Annex XIV and that the undertaking provides the competent authority with an electronic or written copy of all or part of these records upon request and at least under the following conditions:

- (a) without undue delay, at the time of the establishment of such records, which shall be as soon as is reasonably practicable after the source is acquired;

- (b) at intervals to be determined by Member States;
- (c) if the situation indicated on the information sheet has changed;
- (d) without undue delay upon the closure of the records for a specific source when the undertaking no longer holds this source, whereby the name of the undertaking or waste disposal or storage facility to which the source is transferred shall be included;
- (e) without undue delay upon the closure of such records when the undertaking no longer holds any sources.

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

#### *Article 90*

### **Record keeping by the competent authority**

Member States shall ensure that the competent authority keeps records of any undertaking authorised to perform practices with high-activity sealed sources and of the high-activity sealed sources held. 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 undertaking acquired the source, and the type of source. The competent authority shall keep the records up to date, taking transfers of the sources and other factors into account.

#### *Article 91*

### **Control of high-activity sealed sources**

1 Member States shall require that the undertaking carrying out activities involving high activity sealed sources complies with requirements set out in Annex XV.

2 Member States shall require that the manufacturer, the supplier, and each undertaking ensures that high-activity sealed sources and containers comply with the requirements for identification and marking as set out in Annex XVI.