

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 I*

#### ***Institutional infrastructure***

#### *Article 76*

#### **Competent authority**

- 1 Member States shall designate a competent authority to carry out tasks in accordance with this Directive. They shall ensure that the competent authority:
  - a is functionally separate from any other body or organisation concerned with the promotion or utilisation of practices under this Directive, in order to ensure effective independence from undue influence on its regulatory function;
  - b is given the legal powers and human and financial resources necessary to fulfil its obligations.
- 2 Where a Member State has more than one competent authority for a given area of competence, it shall designate one point of contact for communication with the competent authorities of other Member States. Where it is not reasonably practicable to list all such points of contact for different areas of competence, Member States may designate a single point of contact.
- 3 Member States shall forward to the Commission the name and address of the points of contact and their respective areas of competence to enable rapid communication, where appropriate, with their authorities.
- 4 Member States shall forward to the Commission any changes to the information referred to in paragraph 3.
- 5 The Commission shall communicate the information referred to in paragraphs 3 and 4 to all points of contact in a Member State and shall publish it periodically in the *Official Journal of the European Union*, at intervals of no more than two years.

#### *Article 77*

#### **Transparency**

Member States shall ensure that information in relation to the justification of classes or types of practices, the regulation of radiation sources and of radiation protection is

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made available to undertakings, workers, members of the public, as well as patients and other individuals subject to medical exposure. This obligation includes ensuring that the competent authority provides information within its fields of competence. Information shall be made available in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, security, recognised in national legislation or international obligations.

#### *Article 78*

### **Information on equipment**

1 Member States shall ensure that any undertaking acquiring equipment containing radioactive sources or a radiation generator is provided with adequate information about its potential radiological hazards and its proper use, testing and maintenance, and with a demonstration that the design permits to restrict exposures to a level which is as low as reasonably achievable.

2 Member States shall ensure that any undertaking acquiring medical radiological equipment is provided with adequate information on the risk assessment for patients, and on the available elements of the clinical evaluation.

#### *Article 79*

### **Recognition of services and experts**

1 Member States shall ensure that arrangements are in place for the recognition of:

- a occupational health services;
- b dosimetry services;
- c radiation protection experts;
- d medical physics experts.

Member States shall ensure that the necessary arrangements are in place to ensure the continuity of expertise of these services and experts.

If appropriate, Member States may establish the arrangements for the recognition of radiation protection officers.

2 Member States shall specify the recognition requirements and communicate them to the Commission.

3 The Commission shall make the information received in accordance with paragraph 2 available to the Member States.

#### *Article 80*

### **Occupational health services**

Member State shall ensure that occupational health services perform medical surveillance of exposed workers, in accordance with Chapter VI, with regard to their exposure to ionising radiation and their fitness for the tasks assigned to them involving work with ionising radiation.

## Article 81

### Dosimetry services

Member State shall ensure that dosimetry services determine internal or external doses to exposed workers subject to individual monitoring, in order to record the dose in cooperation with the undertaking and in the case of outside workers, the employer, and where relevant the occupational health service.

## Article 82

### Radiation protection expert

1 Member State shall ensure that the radiation protection expert gives competent advice to the undertaking on matters relating to compliance with applicable legal requirements, in respect of occupational and public exposure.

2 The advice of the radiation protection expert shall cover, where relevant, but not be limited to, the following:

- a optimisation and establishment of appropriate dose constraints;
- b plans for new installations and the acceptance into service of new or modified radiation sources in relation to any engineering controls, design features, safety features and warning devices relevant to radiation protection;
- c categorisation of controlled and supervised areas;
- d classification of workers;
- e workplace and individual monitoring programmes and related personal dosimetry;
- f appropriate radiation monitoring instrumentation;
- g quality assurance;
- h environmental monitoring programme;
- i arrangements for radioactive waste management;
- j arrangements for prevention of accidents and incidents;
- k preparedness and response in emergency exposure situations;
- l training and retraining programmes for exposed workers;
- m investigation and analysis of accidents and incidents and appropriate remedial actions;
- n employment conditions for pregnant and breastfeeding workers;
- o preparation of appropriate documentation such as prior risk assessments and written procedures;

3 The radiation protection expert shall, where appropriate, liaise with the medical physics expert.

4 The radiation protection expert may be assigned, if provided for in national legislation, the tasks of radiation protection of workers and members of the public.

### Article 83

#### Medical physics expert

1 Member States shall require the medical physics expert to act or give specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements set out in Chapter VII and in point (c) of Article 22(4) of this Directive.

2 Member States shall ensure that depending on the medical radiological practice, the medical physics expert takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure, give advice on medical radiological equipment, and contribute in particular to the following:

- a optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;
- b the definition and performance of quality assurance of the medical radiological equipment;
- c acceptance testing of medical radiological equipment;
- d the preparation of technical specifications for medical radiological equipment and installation design;
- e the surveillance of the medical radiological installations;
- f the analysis of events involving, or potentially involving, accidental or unintended medical exposures;
- g the selection of equipment required to perform radiation protection measurements;
- h the training of practitioners and other staff in relevant aspects of radiation protection;

3 The medical physics expert shall, where appropriate, liaise with the radiation protection expert.

### Article 84

#### Radiation protection officer

1 Member States shall decide in which practices the designation of a radiation protection officer is necessary to supervise or to perform radiation protection tasks within an undertaking. Member States shall require undertakings to provide the radiation protection officers with the means necessary for them to carry out their tasks. The radiation protection officer shall report directly to the undertaking. Member States may require employers of outside workers to designate a radiation protection officer as necessary to supervise or perform relevant radiation protection tasks as they relate to the protection of their workers.

2 Depending on the nature of the practice, the tasks of the radiation protection officer in assisting the undertaking, may include the following:

- a ensuring that work with radiation is carried out in accordance with the requirements of any specified procedures or local rules;
- b supervise implementation of the programme for workplace monitoring;
- c maintaining adequate records of all radiation sources;
- d carrying out periodic assessments of the condition of the relevant safety and warning systems;
- e supervise implementation of the personal monitoring programme;

- f supervise implementation of the health surveillance programme;
  - g providing new workers with an appropriate introduction to local rules and procedures;
  - h giving advice and comments on work plans;
  - i establishing work plans;
  - j providing reports to the local management;
  - k participating in the arrangements for prevention, preparedness and response for emergency exposure situations;
  - l information and training of exposed workers;
  - m liaising with the radiation protection expert.
- 3 The task of the radiation protection officer may be carried out by a radiation protection unit established within an undertaking or by a radiation protection expert.

## 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.

## *SECTION 3*

### ***Orphan sources***

#### *Article 92*

### **Detection of orphan sources**

- 1 Member States shall ensure that arrangements are made for:
  - a raising general awareness of the possible occurrence of orphan sources and associated hazards; and
  - b issuing guidance for persons who suspect or have knowledge of the presence of an orphan source on informing the competent authority and on the actions to be taken.
- 2 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

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where orphan sources may generally be encountered, or at significant nodal transit points, wherever appropriate.

3 Member States shall ensure that specialised technical advice and assistance is promptly made available to persons who suspect the presence of an orphan source and who are not normally involved in operations subject to radiation protection requirements. 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.

#### *Article 93*

### **Metal contamination**

1 Member States shall encourage the establishment of systems to detect the presence of radioactive contamination in metal products imported from third countries, in places such as at major metal importing installations or at significant nodal transit points.

2 Member States shall require that the management of a metal scrap recycling installation promptly informs the competent authority if it suspects or has knowledge of any melting of or other metallurgical operation on an orphan source and shall require that the contaminated materials are not used, placed on the market or disposed of without the involvement of the competent authority.

#### *Article 94*

### **Recovery, management, control and disposal of orphan sources**

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

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

The campaigns may include the financial participation of Member States in the costs of recovering, managing, controlling and disposing of the sources and may also include surveys of historical records of authorities and of undertakings, such as research institutes, material testing institutes or hospitals.

#### *Article 95*

### **Financial security for orphan sources**

Member States shall ensure that a financial security system or other equivalent means is established to cover intervention costs relating to the recovery of orphan sources and which may result from implementation of Article 94.



## SECTION 4

### **Significant events**

#### Article 96

#### **Notification and recording of significant events**

Member States shall require the undertaking to:

- (a) implement, as appropriate, a recording and analysis system of significant events involving or potentially involving accidental or unintended exposures;
- (b) promptly notify the competent authority of the occurrence of any significant event resulting or liable to result in the exposure of an individual beyond the operational limits or conditions of operation specified in authorising requirements with regard to occupational or public exposure or as defined by the competent authority for medical exposure, including the results of the investigation and the corrective measures to avoid such events.

## SECTION 5

### **Emergency exposure situations**

#### Article 97

#### **Emergency management system**

1 Member States shall ensure that account is taken of the fact that emergencies may occur on their territory and that they may be affected by emergencies occurring outside their territory. Member States shall establish an emergency management system and adequate administrative provisions to maintain such a system. The emergency management system shall include the elements listed in Section A of Annex XI.

2 The emergency management system shall be designed to be commensurate with the results of an assessment of potential emergency exposure situations and to be able to respond effectively to emergency exposure situations in connection with practices or unforeseen events.

3 The emergency management system shall provide for the establishment of emergency response plans with the objective of avoiding tissue reactions leading to severe deterministic effects in any individual from the affected population and reducing the risk of stochastic effects, taking account of the general principles of radiation protection and the reference levels referred to in Chapter III.

#### Article 98

#### **Emergency preparedness**

1 Member States shall ensure that emergency response plans are established in advance for the various types of emergencies identified by an assessment of potential emergency exposure situations.

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2 The emergency response plans shall include the elements defined in Section B of Annex XI.

3 The emergency response plans shall also include provision for the transition from an emergency exposure situation to an existing exposure situation.

4 Member States shall ensure that emergency response plans are tested, reviewed and, as appropriate, revised at regular intervals, taking into account lessons learned from past emergency exposure situations and taking into account the results of the participation in emergency exercises at national and international level.

5 The emergency response plans shall, where appropriate, incorporate relevant elements of the emergency management system referred to in Article 97.

#### *Article 99*

### **International cooperation**

1 Member States shall cooperate with other Member States and with third countries in addressing possible emergencies on its territory which may affect other Member States or third countries, in order to facilitate the organisation of radiological protection in those Member States or third countries.

2 Each Member State shall, in the event of an emergency occurring on its territory or likely to have radiological consequences on its territory, promptly establish contact with all other Member States and with third countries which may be involved or are likely to be affected with a view to sharing the assessment of the exposure situation and coordinating protective measures and public information by using, as appropriate, bilateral or international information exchange and coordination systems. These coordination activities shall not prevent or delay any necessary actions to be taken on a national level.

3 Each Member State shall promptly share information and cooperate with other relevant Member States, relevant third countries and relevant international organisations regarding the loss, theft or discovery of high-activity sealed sources, other radioactive sources and radioactive material of concern and regarding related follow-up or investigations, without prejudice to relevant confidentiality requirements and relevant national legislation.

4 Each Member State shall, where appropriate, cooperate with other Member States and with third countries in the transition from an emergency exposure situation to an existing exposure situation.

#### *SECTION 6*

### ***Existing exposure situations***

#### *Article 100*

### **Programmes on existing exposure situations**

1 Member States shall ensure that measures are taken, upon indication or evidence of exposures that cannot be disregarded from a radiation protection point of view, to identify and evaluate existing exposure situations taking into account the types of existing exposure

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situations listed in Annex XVII, and to determine the corresponding occupational and public exposures.

2 Member States may decide, having regard to the general principle of justification, that an existing exposure situation warrants no consideration of protective or remedial measures.

3 Existing exposure situations which are of concern from a radiation protection point of view and for which legal responsibility can be assigned shall be subject to the relevant requirements for planned exposure situations and accordingly such exposure situations shall be required to be notified as specified in Article 25(2).

#### *Article 101*

##### **Establishment of strategies**

1 Member States shall arrange for the establishment of strategies to ensure the appropriate management of existing exposure situations commensurate with the risks and with the effectiveness of protective measures.

2 Each strategy shall contain

- a the objectives pursued;
- b appropriate reference levels, taking into account the reference levels laid down in Annex I.

#### *Article 102*

##### **Implementation of strategies**

1 Member States shall assign responsibilities for the implementation of strategies for the management of existing exposure situations, and ensure appropriate coordination between relevant parties involved in the implementation of remedial and protective measures. Member States shall provide as appropriate for the involvement of stakeholders in decisions regarding the development and implementation of strategies for managing exposure situations.

2 The form, scale and duration of all protective measures considered for implementation of a strategy shall be optimised.

3 The distribution of doses that has resulted from the implementation of a strategy shall be assessed. Further efforts shall be considered with the aim of optimising protection and reducing any exposures that are still above the reference level.

4 Member States shall ensure that those responsible for the implementation of a strategy shall regularly:

- a evaluate the available remedial and protective measures for achieving the objectives and the efficiency of planned and implemented measures;
- b provide information to exposed populations on the potential health risks and on the available means for reducing their exposure;
- c provide guidance for the management of exposures at individual or local level;
- d with regard to activities that involve naturally occurring radioactive material and are not managed as planned exposure situations, provide information on appropriate means for monitoring concentrations and exposures and for taking protective measures.

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### *Article 103*

#### **Radon action plan**

- 1 In application of Article 100(1), Member States shall establish a national action plan addressing long-term risks from radon exposures in dwellings, buildings with public access and workplaces for any source of radon ingress, whether from soil, building materials or water. The action plan shall take into account the issues set out in Annex XVIII and be updated on a regular basis.
- 2 Member States shall ensure that appropriate measures are in place to prevent radon ingress into new buildings. These measures may include specific requirements in national building codes.
- 3 Member States shall identify areas where the radon concentration (as an annual average) in a significant number of buildings is expected to exceed the relevant national reference level.

### *SECTION 7*

#### ***System of enforcement***

### *Article 104*

#### **Inspections**

- 1 Member States shall establish a system or systems of inspection to enforce the provisions adopted pursuant to this Directive and to initiate surveillance and corrective action where necessary.
- 2 Member States shall ensure that the competent authority establishes an inspection programme taking into account the potential magnitude and nature of the hazard associated with practices, a general assessment of radiation protection issues in the practices, and the state of compliance with the provisions adopted pursuant to this Directive.
- 3 Member States shall ensure that the findings from each inspection are recorded and communicated to the undertaking concerned. If the findings are related to an outside worker or workers, where appropriate, the findings shall also be communicated to the employer.
- 4 Member States shall ensure that outlines of the inspection programmes and the main findings from their implementation are available to the public.
- 5 Member States shall ensure that mechanisms are in place for the timely dissemination to relevant parties, including manufacturers and suppliers of radiation sources and, where appropriate, international organisations, of protection and safety information concerning significant lessons learned from inspections and from reported incidents and accidents and related findings.

### *Article 105*

#### **Enforcement**

Member States shall ensure that the competent authority has the power to require any individual or legal person to take action to remedy deficiencies and prevent their recurrence or to withdraw, where appropriate, authorisation when the results of a regulatory inspection or another regulatory assessment indicate that the exposure situation is not in compliance with the provisions adopted pursuant to this Directive.