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 V

JUSTIFICATION AND REGULATORY CONTROL OF PRACTICES

SECTION 1

Justification and prohibition of practices

Article 19

Justification of practices

1 Member States shall ensure that new classes or types of practices resulting in exposure to ionising radiation are justified before being adopted.

2 Member States shall consider a review of existing classes or types of practices with regard to their justification whenever there is new and important evidence about their efficacy or potential consequences or new and important information about other techniques and technologies.

3 Practices involving occupational and public exposures shall be justified as a class or type of practice, taking into account both categories of exposures.

4 Practices involving medical exposure shall be justified both as a class or type of practice, taking into account medical and, where relevant, associated occupational and public exposures, and at the level of each individual medical exposure as specified in Article 55.

Article 20

Practices involving consumer products

1 Member States shall require any undertaking intending to manufacture or import a consumer product for which the intended use is likely to be a new class or type of practice, to provide the competent authority with all relevant information, including that listed in Annex IV, Section A, so as to allow the implementation of the justification requirement in Article 19(1).

2 On the basis of an assessment of this information, Member States shall ensure that the competent authority, as outlined in Annex IV, Section B, decides whether the intended use of the consumer product is justified.

3 Without prejudice to paragraph 1, Member States shall ensure that the competent authority which has received information according to that paragraph, informs the point of contact for the competent authorities of other Member States of this receipt and, upon request, of its decision and the basis for that decision.

4 Member States shall prohibit the sale or the making available to the public of consumer products if their intended use is not justified or their use would not fulfil the criteria for exemption from notification under Article 26.

Article 21

Prohibition of practices

1 Member States shall prohibit the deliberate addition of radioactive substances in the production of foodstuffs, animal feeding stuffs, and cosmetics, and shall prohibit the import or export of such products.

2 Without prejudice to the Directive 1999/2/EC, practices involving the activation of material resulting in an increase in activity in a consumer product, which at the time of placing on the market cannot be disregarded from a radiation protection point of view, shall be deemed not to be justified. However, the competent authority may evaluate specific types of practices within this class with regard to their justification.

3 Member States shall prohibit the deliberate addition of radioactive substances in the manufacture of toys and personal ornaments and shall prohibit the import or export of such products.

4 Member States shall prohibit practices involving the activation of materials used in toys and personal ornaments, resulting, at the time of the placing on the market of the products or of their manufacture, in an increase in activity, which cannot be disregarded from a radiation protection point of view, and shall prohibit the import or export of such products or materials.

Article 22

Practices involving the deliberate exposure of humans for non-medical imaging purposes

1 Member States shall ensure the identification of practices involving non-medical imaging exposure, in particular taking into account the practices included in Annex V.

2 Member States shall ensure that special attention is given to the justification of practices involving non-medical imaging exposure, in particular:

a all types of practices involving non-medical imaging exposure shall be justified before being generally accepted;

b each particular application of a generally accepted type of practice shall be justified;

c all individual non-medical imaging exposure procedures using medical radiological equipment shall be justified in advance, taking into account the specific objectives of the procedure and the characteristics of the individual involved;

d the general and particular justification of practices involving non-medical imaging exposure, as specified in (a) and (b), may be subject to review;

e circumstances warranting non-medical imaging exposures, without individual justification of each exposure, shall be subject to regular review.

3 Member States may exempt justified practices involving non-medical imaging exposure using medical radiological equipment from the requirement for dose constraints according to point (b) of Article 6(1) and from the dose limits set out in Article 12.

4 Where a Member State has determined that a particular practice involving non-medical imaging exposure is justified, it shall ensure that:

a the practice is subject to authorisation;

b requirements for the practice, including criteria for individual implementation, are established by the competent authority, in cooperation with other relevant bodies and medical scientific societies, as appropriate;

c for procedures using medical radiological equipment

(i) relevant requirements identified for medical exposure as set out in Chapter VII are applied, including those for equipment, optimisation, responsibilities, training and special protection during pregnancy and the appropriate involvement of the medical physics expert;

(ii) where appropriate, specific protocols, consistent with the objective of the exposure and required image quality, are put in place;

(iii) where practicable, specific diagnostic reference levels are put in place;

d for procedures not using medical radiological equipment, dose constraints are significantly below the dose limit for members of the public;

e information is provided to and consent sought from the individual to be exposed, allowing for cases where the law enforcement authorities may proceed without consent of the individual according to national legislation;

SECTION 2

Regulatory control

Article 23

Identification of practices involving naturally-occurring radioactive material

Member States shall ensure the identification of classes or types of practice involving naturally–occurring radioactive material and leading to exposure of workers or members of the public which cannot be disregarded from a radiation protection point of view. Such identification shall be carried out by appropriate means taking into account industrial sectors listed in Annex VI.

Article 24

Graded approach to regulatory control

1 Member States shall require practices to be subject to regulatory control for the purpose of radiation protection, by way of notification, authorisation and appropriate inspections, commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the impact that regulatory control may have in reducing such exposures or improving radiological safety.

2 Without prejudice to Articles 27 and 28, where appropriate, and in accordance with the general exemption criteria set out in Annex VII, regulatory control may be limited to notification and an appropriate frequency of inspections. For this purpose, Member States may establish general exemptions or allow the competent authority to decide to exempt notified practices from

the requirement of authorisation on the basis of the general criteria specified in Annex VII; in the case of moderate amounts of material, as specified by Member States, the activity concentration values laid down in Annex VII, Table B, column 2 may be used for this purpose.

3 Notified practices which are not exempted from authorisation shall be subject to regulatory control through registration or licensing.

Article 25

Notification

1 Member States shall ensure that notification is required for all justified practices, including those identified according to Article 23. The notification shall be made prior to the practice commencing or, for existing practices, as soon as possible once this requirement is applicable. For practices subject to notification, Member States shall specify the information to be provided in conjunction with the notification. Where an application for an authorisation is submitted, no separate notification is needed.

Practices may be exempted from notification, as specified in Article 26.

2 Member States shall ensure that notification is required for workplaces specified in Article 54(3), and for existing exposure situations that are managed as a planned exposure situation, as specified in Article 100(3).

3 Notwithstanding the exemption criteria laid down in Article 26, in situations identified by Member States where there is concern that a practice identified in accordance with Article 23 may lead to the presence of naturally-occurring radionuclides in water liable to affect the quality of drinking water supplies or affect any other exposure pathways, so as to be of concern from a radiation protection point of view, the competent authority may require that the practice be subject to notification.

4 Human activities involving radioactively contaminated materials resulting from authorised releases or materials cleared in accordance with Article 30 shall not be managed as a planned exposure situation and, hence, are not required to be notified.

Article 26

Exemption from notification

1 Member States may decide that justified practices involving the following do not need to be notified:

a radioactive materials where the quantities of the activity involved do not exceed in total the exemption values set out in Table B, column 3, of Annex VII, or higher values that, for specific applications, are approved by the competent authority and satisfy the general exemption and clearance criteria set out in Annex VII; or

b without prejudice to Article 25(4), radioactive materials where the activity concentrations do not exceed the exemption values set out in Table A of Annex VII, or higher values that, for specific applications, are approved by the competent authority and satisfy the general exemption and clearance criteria set out in Annex VII; or

c apparatus containing a sealed source, provided that:

(i) the apparatus is of a type approved by the competent authority;

(ii) the apparatus does not cause, in normal operating conditions, a dose rate exceeding

$$1\ \mu Sv \times h^{-1}$$

at a distance of 0.1 m from any accessible surface; and

(iii) conditions for recycling or disposal have been specified by the competent authority; or

d any electrical apparatus provided that:

(i) it is a cathode ray tube intended for the display of visual images, or other electrical apparatus operating at a potential difference not exceeding 30 kilo volt (kV), or it is of a type approved by the competent authority; and

(ii) it does not cause, in normal operating conditions, a dose rate exceeding

$$1\ \mu Sv \times h^{-1}$$

at a distance of 0.1 m from any accessible surface.

2 Member States may exempt specific types of practices from the notification requirement subject to compliance with the general exemption criteria established in point 3 of Annex VII, on the basis of an assessment showing that exemption is the best option.

Article 27

Registration or licensing

1 Member States shall require either registration or licensing of the following practices:

a the operation of radiation generators or accelerators or radioactive sources for medical exposures or for non-medical imaging purposes;

b the operation of radiation generators or accelerators, except electron microscopes, or radioactive sources for purposes not covered by point (a).

2 Member States may require registration or licensing for other types of practices.

3 The regulatory decision to submit types of practices to either registration or licensing may be based on regulatory experience, taking into account the magnitude of expected or potential doses, as well as the complexity of the practice.

Article 28

Licensing

Member States shall require licensing for the following practices:

(a) the deliberate administration of radioactive substances to persons and, in so far as the radiation protection of human beings is concerned, animals for the purpose of medical or veterinary diagnosis, treatment or research;

(b) the operation and decommissioning of any nuclear facility and the exploitation and closure of uranium mines;

(c) the deliberate addition of radioactive substances in the production or manufacture of consumer products or other products, including medicinal products, and the import of such products;

(d) any practice involving a high-activity sealed source;

(e) the operation, decommissioning and closure of any facility for the long term storage or disposal of radioactive waste, including facilities managing radioactive waste for this purpose;

(f) practices discharging significant amounts of radioactive material with airborne or liquid effluent into the environment.

Article 29

Authorisation procedure

1 For authorisation purposes, Member States shall require the provision of information relevant to radiation protection that is commensurate with the nature of the practice and the radiological risks involved.

2 In the case of licensing and when determining what information must be provided under paragraph 1, Member States shall take into account the indicative list in Annex IX.

3 A licence shall include, as appropriate, specific conditions and reference to requirements in national legislation so as to ensure that the elements of the licence are legally enforceable, and impose appropriate restrictions on the operational limits and conditions of operation. National legislation or the specific conditions shall also require, when appropriate, the formal and documented implementation of the principle of optimisation.

4 Where applicable, national legislation or a licence shall include conditions on the discharge of radioactive effluent, in accordance with the requirements laid down in Chapter VIII for the authorisation of the release of radioactive effluent into the environment.

Article 30

Release from regulatory control

1 Member States shall ensure that the disposal, recycling or reuse of radioactive materials arising from any authorised practice is subject to authorisation.

2 Materials for disposal, recycling or reuse may be released from regulatory control provided that the activity concentrations:

a for solid material do not exceed the clearance levels set out in Table A of Annex VII; or

b comply with specific clearance levels and associated requirements for specific materials or for materials originating from specific types of practices; these specific clearance levels shall be established in national legislation or by the national competent authority, following the general exemption and clearance criteria set out in Annex VII, and taking into account technical guidance provided by the Community.

3 Member States shall ensure that for the clearance of materials containing naturally-occurring radionuclides, where these result from authorised practices in which natural radionuclides are processed for their radioactive, fissile or fertile properties, the clearance levels comply with the dose criteria for clearance of materials containing artificial radionuclides.

4 Member States shall not permit the deliberate dilution of radioactive materials for the purpose of them being released from regulatory control. The mixing of materials that takes place in normal operations where radioactivity is not a consideration is not subject to this prohibition.

The Competent Authority may authorise, in specific circumstances, the mixing of radioactive and non-radioactive materials for the purposes of re-use or recycling.