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**Proposal for a**  
**COUNCIL DIRECTIVE**

**laying down basic safety standards for protection against the dangers arising from exposure  
to ionising radiation**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 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, and after having consulted the European Economic and Social Committee,

Having regard to the opinion of the European Economic and Social Committee,

Having regard to the opinion of the European Parliament,

Whereas:

- (1) Article 2(b) of the Treaty provides for the establishment of uniform safety standards to protect the health of workers and the general public and Article 30 of the Treaty defines 'basic standards' for the health protection of workers and the general public against the dangers arising from ionising radiations.



- (2) In order to perform its task, the Community laid down basic standards for the first time in 1959 pursuant to Article 218 of the Treaty by means of the Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation<sup>1</sup>. The Directives have been revised several times, most recently in 1996 by 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<sup>2</sup> which repealed the earlier Directives.
- (3) Directive 96/29/Euratom establishes the basic safety standards. The provisions of that Directive apply to normal and emergency situations and have been supplemented by more specific legislation.
- (4) Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure and repealing Directive 84/466/Euratom<sup>3</sup>, Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency<sup>4</sup>, Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas<sup>5</sup> and Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources<sup>6</sup> cover different specific aspects complementary to Directive 96/29/Euratom.
- (4a)[5] As recognised by the Court of Justice in its case-law, the tasks imposed on the Community by Article 2(b) of the Euratom Treaty to lay down uniform standards to protect the health of the population and of workers does not preclude, unless explicitly stated in the standards, a Member State from providing for more stringent measures of protection. As this Directive provides for minimum rules, Member States should be free to adopt or maintain more stringent measures in the subject-matter covered by this Directive, without prejudice to the free movement of goods and services in the internal market as defined by the case-law of the Court of Justice.

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<sup>1</sup> OJ 11, 20.2.1959, p. 221.

<sup>2</sup> OJ L 159, 29.6.1996, p. 1

<sup>3</sup> OJ L 180 9.7.1997, p. 22

<sup>4</sup> OJ L 357, 7.12.1989, p. 31

<sup>5</sup> OJ L 349, 13.12.1990, p. 21

<sup>6</sup> OJ L 346, 31.12.2003, p. 57

(6)[6]The Group of Experts appointed by the Scientific and Technical Committee has advised that the basic safety standards, established according to Articles 30 and 31 of Euratom Treaty<sub>2</sub> should take into account the new recommendations of the International Commission on Radiological Protection (ICRP), in particular those in Publication 103 (2007)<sup>7</sup>, and should be revised in the light of new scientific evidence and operational experience.

(7)[7]The provisions of this Directive should follow the situation based approach introduced by ICRP Publication 103 and distinguish between existing, planned and emergency exposure situations. Taking into account this new framework the Directive should cover all exposure situations and all categories of exposure, namely occupational, public and medical exposures.

(7a)[8] The definition of the term “undertaking” in this Directive, and its use in the context of the health protection of workers against ionising radiation, is without prejudice to the legal systems and the allocation of responsibilities to the employer introduced in national legislation transposing Directive 89/391/EEC.

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<sup>7</sup> The 2007 Recommendations of the International Commission on Radiological Protection

- (8a)[9] Calculation of doses from measurable quantities should rely on scientifically established values and relationships. Recommendations for such dose coefficients have been published and updated by ICRP, taking scientific progress into account. A collection of dose coefficients based on its earlier recommendations in ICRP 60, are available as publication ICRP 119. However, in ICRP 103, a new methodology was introduced by ICRP to calculate doses based on the latest knowledge on radiation risks, and this should, where possible, be taken into account in this Directive.
- (8b)[10] For external exposure, values and relationships have been published following the new methodology in ICRP 116. These data, as well as the well-established operational quantities, should be used for the purpose of this Directive.
- (8c)[11] For internal exposure, while ICRP has consolidated in Publication 119 all earlier publications (on the basis of ICRP Publication 60) on dose coefficients, updates of this publication will be provided and the coefficients that are tabulated in it will be superseded by values based on the radiation and tissue weighting factors and phantoms laid down in Publication 103. The Commission will invite the Group of Experts referred to in Article 31 of the Euratom Treaty to continue to monitor scientific developments and the Commission will make recommendations on any updated values, relationships and coefficients, including those for exposure to radon, taking relevant opinions of the Group of Experts into account.
- (8d)[12] Article 30 of the Euratom Treaty provides that the "basic standards" are meant to include "maximum permissible doses compatible with adequate safety", this Directive should lay down uniform dose limits for this purpose.

- (9)[13] The current annual effective dose limits for occupational and public exposure are maintained. However, there should be no further need for averaging over 5 years, except in special circumstances specified in national legislation.
- (10)[14] New scientific information on tissue effects calls for the optimisation principle to be applied to equivalent doses as well, where appropriate, in order to keep doses as low as reasonably achievable. The Directive should also follow new ICRP guidance on the limit for equivalent dose for the lens of the eye in occupational exposure.
- (11)[15] Industries processing naturally-occurring radioactive material extracted from the earth's crust subject workers and, if material is released into the environment, members of the public to increased <sup>8</sup>radiation exposure.
- (12)[16] Protection against natural radiation sources, rather than being addressed separately in a specific title, should be fully integrated within the overall requirements. In particular, industries processing materials containing naturally-occurring radionuclides should be managed within the same regulatory framework as other practices.
- (13)[17] It is appropriate for this Directive to establish reference levels for indoor radon concentrations and for indoor gamma radiation emitted from building materials, and to introduce requirements on the recycling of residues from industries processing naturally-occurring radioactive materials into building materials.
- (13a)[18] Regulation (EU) No. 305/2011<sup>9</sup> of the European Parliament and of the Council of 9 March 2011 (replacing Directive 89/106/EEC) lays down harmonised conditions for the marketing of construction products.
- (13b)[19] Building materials emitting gamma radiation should be within the scope of this Directive but should also be regarded as construction products as defined in Regulation (EU) No. 305/2011<sup>10</sup>, in the sense that it applies to construction works emitting dangerous substances or dangerous radiation.

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<sup>8</sup> Agreed at AQ 15 May

<sup>9</sup> OJ L 88, 4.4.2011, p. 5

<sup>10</sup> OJ L 88, 4.4.2011, p. 5

- (13c)[20] This Directive should be without prejudice to the provisions of Regulation (EU) 305/2011<sup>11</sup> on the declaration of performance, the establishment of harmonised standards or the means and conditions for making available the declaration of performance or with regard to CE marking.
- (13d)[21] Regulation (EU) No. 305/2011<sup>12</sup> requires information to be made available when products are placed on the market. This does not affect the right of Member States to specify in national legislation requirements for additional information they deem necessary to ensure radiation protection.
- (14)[22] Recent epidemiological findings from residential studies demonstrate a statistically significant increase of lung cancer risk from prolonged exposure to indoor radon at levels of the order of 100 Bq m<sup>-3</sup>. The new concept of exposure situations allows the provisions of Commission Recommendation 90/143/Euratom on the protection of members of the public against indoor exposure to radon<sup>13</sup> to be incorporated in the binding requirements of the Basic Safety Standards while leaving enough flexibility for implementation.
- (14aa)[23] National action plans are needed for<sup>14</sup> addressing long-term risks from radon exposure. It is recognized that the combination of smoking and high radon exposure presents a substantially higher individual lung cancer risk than either factor individually and that smoking amplifies the risk from radon exposure at the population level. It is important that Member States address both of these health hazards.
- 15(14ab) [24] Where, due to national prevailing circumstances, a Member State establishes a reference level for indoor radon concentrations in workplaces that is higher than 300 Bq m<sup>-3</sup>, the Member State should submit a justification to the European Commission.

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<sup>11</sup> OJ L 88, 4.4.2011, p. 5

<sup>12</sup> OJ L 88, 4.4.2011, p. 5

<sup>13</sup> OJ L 80, 27.03.1990, p. 26

<sup>14</sup> Change proposed at AQ 15 May

<sup>15</sup> The Presidency was reminded that this clarification appeared as footnote 141 in doc 8682/13 and given its importance and usefulness was proposed at AQ to be taken up as a recital. This is the first time it appears as a recital.

(14a)[25] Where radon enters from the ground into indoor workplaces, this should be considered to be an existing exposure situation since the presence of radon is largely independent of the human activities carried out within the workplace. Such exposures may be significant in certain areas or specific types of workplaces to be identified by Member States, and appropriate radon and exposure reduction measures should be taken if the national reference level is exceeded. Where levels continue to remain above the national reference level, these human activities carried out within the workplace should not be regarded as practices. However, Member States should ensure that these workplaces are notified and that, in cases where the exposure of workers is liable to exceed an effective dose of 6 mSv per year or a corresponding time-integrated radon exposure value, they are managed as a planned exposure situation and that dose limits apply, and determine which operational protection requirements need be applied.

(15)[26] The exposure of air crew to cosmic radiation should be managed as a planned exposure situation. The operation of spacecraft should come under the scope of this Directive and, if dose limits are exceeded, be managed as a specially authorised exposure.

(16)[27] The contamination of the environment may pose a threat to human health. The Community's secondary legislation so far has regarded such contamination only as a pathway of exposure to members of the public directly affected by radioactive effluent discharged to the environment. While the state of the environment can impact long-term human health, this calls for a policy protecting the environment against the harmful effects of ionising radiation. For the purpose of long-term human health protection, environmental criteria based on internationally recognised scientific data (such as published by EC, ICRP, UNSCEAR, IAEA) should be taken into account.

- (17)[28] In the medical area, important technological and scientific developments have led to a notable increase in the exposure of patients. In this respect, the Directive should emphasise the need for justification of medical exposure, including the exposure of asymptomatic individuals and should strengthen the requirements concerning information to be provided to patients, the recording and reporting of doses from medical procedures, the use of diagnostic reference levels and the availability of dose-indicating devices. It should be noted that according to the World Health Organisation the concept of health is understood to cover the physical, mental and social well-being of an individual and not merely the absence of disease or infirmity.
- (17a)[29] A high level of competence and a clear definition of responsibilities and tasks among all professionals involved in medical exposure is fundamental to ensure adequate protection of patients undergoing medical radiodiagnostic and radiotherapeutic procedures. This applies to medical doctors, dentists and other health professionals entitled to take clinical responsibility for individual medical exposures, to medical physicists and to other professionals carrying out practical aspects of medical radiological procedures, such as radiographers and technicians in radiodiagnostic medicine, nuclear medicine and radiotherapy.
- (18)[30] Accidental and unintended medical exposures are a source of continuing concern. Whereas for medical devices post-market surveillance is required under Directive 93/42/EEC of 14 June 1993 concerning medical devices<sup>16</sup>, it is the role of the competent authority in radiation protection to address their prevention and the follow-up in case of their occurrence. In this respect, the role of quality assurance programmes, including a study of risks in radiotherapy, to avoid such incidents should be emphasised, and recording, reporting, analysis and corrective action should be required in such cases.
- (18a)[31] In veterinary practice the use of ionising radiation for imaging is growing, often with second-hand equipment from the medical sector. Especially in the case of larger animals, or in the administration of radiopharmaceuticals to animals, there is a substantial risk of high occupational exposures and of exposure of accompanying persons. This calls for the provision of adequate information and the education of veterinarians and their <sup>17</sup>~~staff~~ **personnel**.

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<sup>16</sup> OJ L 169, 12.07.1993, p. 1

<sup>17</sup> Agreed at AQ 15 May

(19)[32] The so-called ‘medico-legal’ exposures introduced in Directive 97/43/Euratom have now been clearly identified as the deliberate exposure of individuals for other than medical purposes, or ‘non-medical imaging exposures’. Such practices need to be placed under appropriate regulatory control and should be justified in a similar way as for medical exposures. However, a different approach is needed on the one hand for procedures using medical radiological equipment and on the other hand for procedures not using such equipment. In general, the annual dose limits and corresponding constraints for public exposure should apply.

(20)[33] Member States should be required to submit certain practices involving a hazard from ionising radiation to a system of regulatory control or to prohibit certain practices.

(20a)[34] The application of radiation protection principles in relation to consumer products requires the regulatory control of practices to start at the stage of design and manufacture of products or at the time of import of such products. Therefore, the manufacture or import of consumer products should be regulated and specific procedures should be introduced, so as to allow the timely justification of the intended use of the consumer products, as well as to allow checking that this use can be exempted from regulatory control. While such assessment is carried out in the Member State in which these practices are conducted, this Member State should inform other Member States, so as to allow them to request relevant information from the undertaking and to make their own assessment.

(20b)[35] The deliberate addition of radioactive substances to certain categories of consumer products should remain prohibited, but it needs to be made clear that this applies also to the activation of such products by irradiation, without prejudice to existing legislation such as Directive 1999/2/EC<sup>18</sup> of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation.

(20c)[36] Member States should benefit from the application of a graded approach to regulatory control, which should be commensurate with the magnitude and likelihood of exposures resulting from the practices, and commensurate with the impact that regulatory control may have in reducing such exposures or improving the safety of installations.

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<sup>18</sup> OJ L 66, 13.3.1999, p. 16



- (21)[37] There is benefit in having the same activity concentration values both for the exemption of practices from regulatory control and for the clearance of materials from authorised practices. After a comprehensive review, it has been concluded that the values recommended in IAEA document RS-G-1.7<sup>19</sup> can be used both as default exemption values, replacing the activity concentration values laid down in Annex I to Directive 96/29/Euratom, and as general clearance levels, replacing the values recommended by the Commission in Radiation Protection No 122<sup>20</sup>.
- (22)[38] Member States could grant specific exemption from authorisation for certain practices involving activities above the exemption values.
- (23)[39] Specific clearance levels, as well as corresponding Community guidance,<sup>21</sup> remain important tools for the management of large volumes of materials arising from the dismantling of authorised facilities.
- (24)[40] Member States should ensure that outside workers receive the same protection as exposed workers employed by an undertakings performing practices with radiation sources. The specific arrangements for outside workers in Directive 90/641/Euratom should be extended to cover work in supervised areas as well.
- (25)[41] With regard to the management of emergency exposure situations, the current approach based on intervention levels should be replaced by a more comprehensive system comprising an assessment of potential emergency exposure situations, an overall emergency management system, emergency response plans, and pre-planned strategies for the management of each postulated event.
- (26)[42] The introduction of reference levels in emergency and existing exposure situations allows for the protection of the individual as well as consideration of other societal criteria in the same way as dose limits and dose constraints for planned exposure situations.
- (27)[43] The efficient management of an emergency with cross-border consequences calls for enhanced cooperation between Member States in emergency planning and response.

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<sup>19</sup> IAEA 2004 Safety Standards Series RS-G-1.7 "Application of the Concepts of Exclusion, Exemption and Clearance".

<sup>20</sup> Radiation Protection 122: Practical use of the Concepts of the Clearance and Exemption

<sup>21</sup> Radiation Protection 89: Recommended radiological protection criteria for the recycling of metals from dismantling of nuclear installations, Radiation Protection 113: Recommended Radiological Protection Criteria for the Clearance of Buildings and Building Rubble from the Dismantling of Nuclear Installations, Radiation Protection 122: Practical Use of the Concepts of the Clearance and Exemption.

- (27a) [44] While urgent information exchange between Member States and the Commission in the event of an emergency is established through Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency<sup>22</sup>, there is a need to put in place arrangements for information exchange beyond the scope of this Decision to allow cooperation with all other Member States and with third countries which may be involved or are likely to be affected.
- (28)[45]The International Atomic Energy Agency together with the World Health Organisation, the Food and Agricultural Organisation, the International Labour Organisation, the Nuclear Energy Agency of the Organisation for Economic Cooperation and Development, and the Pan-American Health Organisation have revised the International Basic Safety Standards in the light of the ICRP's new Publication 103, and the European Commission has informed the International Atomic Energy Agency of its decision of 6.8.2012 to co-sponsor this document on behalf of the European Atomic Energy Community.
- (29)[46] The roles and responsibilities of the national services and experts involved in ensuring that the technical and practical aspects of radiation protection are managed with a high level of competence need to be clarified. <sup>23</sup>This Directive should clearly distinguish between the different roles and responsibilities of the services and experts without precluding that national frameworks allow the grouping of responsibilities or allow the assignment of responsibilities for specific technical and practical tasks in radiation protection to specified experts.
- (30)[47] Commission Recommendation 2004/2/Euratom of 18 December 2003<sup>24</sup> introduced standardised information for the reporting of data on discharges from nuclear power plants and reprocessing facilities, for transmission of the data to the Commission under Article 36 of the Euratom Treaty.

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<sup>22</sup> OJ L 371, 30.12.1987, p. 76

<sup>23</sup> Agreed at AQ 15 May

<sup>24</sup> OJ L 2, 6.1.2004, p. 36

(30a)[48]<sup>25</sup> Member States should have in place precise requirements for the issuing of discharge authorisations and the monitoring of discharges. The reporting of data to the competent authority on discharges from nuclear power plants and reprocessing facilities should be based on standardised information.

(30b)[49] *Under Article 35 of the Euratom Treaty Member States shall ensure that an appropriate environmental monitoring programme is in place. Under Article 36 of the Euratom Treaty Member States shall report the results of such monitoring to the Commission. Reporting requirements under Article 36 of the Euratom Treaty have been specified in Commission Recommendation 2000/473/Euratom<sup>26</sup>.*

(30c)[50] Council Regulation (EU) No. 333/2011<sup>27</sup> of 31 March 2011 establishes criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC<sup>28</sup> of the European Parliament and of the Council; measures need to be taken to prevent the accidental melting of orphan sources as well as to ensure compliance of metals released from nuclear installations, for instance during their dismantling, with clearance criteria.

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<sup>25</sup> Agreed at AQ on 15 May

<sup>26</sup> OJ L 191/37, 27.7.2000

<sup>27</sup> OJ L 94, 8.4.2011, p. 2-11

<sup>28</sup> OJ L 312, 22.11.2008, p. 3-30

(31)[51] No major changes need to be made to the most recent Directive on the control of high-activity sealed radioactive sources and orphan sources (2003/122/Euratom), except to broaden some of the requirements to include any radioactive source. However, there are still unresolved problems with orphan sources and there have been significant cases of contaminated metal being imported from third countries. Accordingly, a requirement should be introduced for the notification of incidents with orphan sources or the contamination of metal. It is also important to harmonise the levels above which a source is regarded as a high-activity sealed source with those established by the IAEA.

(32)[52] Pursuant to Article 106a (3) of the <sup>29</sup>Euratom Treaty, the legislation adopted on the basis of the provisions of the Treaty on European Union and of the Treaty on the Functioning of the European Union should not derogate from the provisions of this Directive, and consequently the justification and optimisation principles should apply notably for medical devices and construction products covered by CE marking.

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<sup>29</sup> Agreed at AQ 15 May

(32b)[53] In accordance with the Joint Political declaration of Member States and the Commission on explanatory documents of 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.

(33)[54] Directive 96/29/Euratom and the complementary Directives 89/618/Euratom, 90/641/Euratom, 97/43/Euratom and 2003/122/Euratom should be repealed,

HAS ADOPTED THIS DIRECTIVE:

# CHAPTER I

## SUBJECT MATTER AND SCOPE

### *Article 1*

#### *Subject matter*

This Directive establishes uniform basic safety standards for the protection of the health of individuals subject to occupational, medical and public exposures against the dangers arising from ionising radiation.

### *Article 2*

#### *Scope*

1. This Directive applies to any planned, existing or emergency exposure situation which involves a risk from exposure to ionising radiation which cannot be disregarded from a radiation protection point of view or with regard to the environment in view of long-term human health protection.
2. This Directive applies in particular to:
  - (a) the manufacture, production, processing, handling, disposal, use, storage, holding, transport, import to, and export from the Community of radioactive material;
  - (b) the manufacture and the operation of electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5 kilovolt (kV);

- (c) human activities which involve the presence of natural radiation sources that lead to a significant increase in the exposure of workers or members of the public, in particular:
  - i) the operation of aircraft and spacecraft, in relation to the exposure of crews;
  - ii) the processing of materials with naturally-occurring radionuclides;
- (d) the exposure of workers or members of the public to <sup>30</sup>indoor radon, the external exposure from building materials and cases of lasting exposure resulting from the after-effects of an emergency or a past human activity.
- (e) the preparedness for, the planning of response to and the management of emergency exposure situations that are deemed to warrant measures to protect the health of members of the public or workers.

*Article 3*

*Exclusion from the scope*

This Directive shall not apply to:

- (a) exposure to the natural level of radiation, such as radionuclides contained in the human body and cosmic radiation prevailing at ground level;
- (b) exposure of members of the public or workers other than air or spacecrew to cosmic radiation in flight or in space;
- (c) aboveground exposure to radionuclides present in the undisturbed earth's crust.

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<sup>30</sup> Change proposed at AQ 15 May

## CHAPTER II

### DEFINITIONS

#### *Article 4*

#### *Definitions*

- (1) Absorbed dose (D) is the energy absorbed per unit mass

$$D = \frac{d\bar{\epsilon}}{dm}$$

where

–  $d\bar{\epsilon}$  is the mean energy imparted by ionising radiation to the matter in a volume element,

–  $dm$  is the mass of the matter in this volume element.

In this Directive, absorbed dose denotes the dose averaged over a tissue or an organ. The unit for absorbed dose is the gray (Gy) where one gray is equal to one joule per kilogram: 1 Gy = 1 J kg<sup>-1</sup>;

- (2) Accelerator means an equipment or installation in which particles are accelerated, emitting ionising radiation with energy higher than 1 mega-electron volt (MeV);
- (3) Accidental exposure means an exposure of individuals, other than emergency workers, as a result of an accident;
- (4) Activation means process through which a stable nuclide is transformed into a radionuclide by irradiating with particles or high-energy photons the material in which it is contained;
- (5) Activity (A) is the activity of an amount of a radionuclide in a particular energy state at a given time. It is the quotient of  $dN$  by  $dt$ , where  $dN$  is the expectation value of the number of nuclear transitions from that energy state in the time interval  $dt$ :

$$A = \frac{dN}{dt}$$

The unit of activity is the becquerel (Bq);



- (6) Apprentice means a person receiving training or instruction within an undertaking with a view to exercising a specific skill;
- (7) Authorisation means the registration or licensing of a practice;
- (8) Becquerel (Bq) is the special name of the unit of activity. One becquerel is equivalent to one nuclear transition per second:  $1 \text{ Bq} = 1 \text{ s}^{-1}$ ;
- (9) Building material means any construction product for incorporation in a permanent manner in a building or parts thereof and the performance of which has an effect on the performance of the building with regard to exposure of its occupants to ionising radiation;
- (10) Carers and comforters means individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone medical exposure;
- (11) Clearance levels means values established by the competent authority or in national legislation, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of this Directive;
- (12) Clinical audit means a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary;
- (13) Clinical responsibility means responsibility of a practitioner for individual medical exposures, notably: justification; optimisation; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical radiological procedures; obtaining information, if appropriate, on previous examinations; providing existing medical radiological information and/or records to other practitioners and/or the referrer, as required; and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate;

- (14) Committed effective dose ( $E(\tau)$ ) is the sum of the committed organ or tissue equivalent doses  $H_T(\tau)$  resulting from an intake, each multiplied by the appropriate tissue weighting factor  $w_T$ . It is defined by:

$$E(\tau) = \sum_T w_T H_T(\tau)$$

In specifying  $E(\tau)$ ,  $\tau$  is given in the number of years over which the integration is made. For the purpose of complying with dose limits specified in this Directive,  $\tau$  is a period of 50 years following intake for adults and up to the age of 70 for infants and children. The unit for committed effective dose is sievert (Sv);

- (15) Committed equivalent dose ( $H_T(\tau)$ ) is the integral over time ( $t$ ) of the equivalent dose rate in tissue or organ T that will be received by an individual as a result of an intake.

It is given by:

$$H_T(\tau) = \int_{t_0}^{t_0 + \tau} \dot{H}_T(t) dt$$

for an intake at time  $t_0$  where

$\dot{H}_T(t)$  is the relevant equivalent dose rate in organ or tissue T at time  $t$ ,

$\tau$  is the time over which the integration is performed.

In specifying  $H_T(\tau)$ ,  $\tau$  is given in number of years over which the integration is made. For the purpose of complying with dose limits specified in this Directive,  $\tau$  is a period of 50 years for adults and up to the age of 70 for infants and children. The unit for committed equivalent dose is the sievert (Sv);

- (16) Competent authority means an authority or system of authorities designated by Member States as having legal authority for the purposes of this Directive;
- (17) Consumer product means a device or manufactured item into which one or more radionuclides have deliberately been incorporated or produced by activation, or which generates ionising radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale;

- (18) Contamination means the unintended or undesirable presence of radioactive substances on surfaces or within solids, liquids or gases or on the human body;
- (19) Controlled area means an area subject to special rules for the purpose of protection against ionising radiation or preventing the spread of radioactive contamination and to which access is controlled;
- (20) Diagnostic reference levels means dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment;
- (22)[21] Disused sealed source means a sealed source which is no longer used or intended to be used for the practice for which authorisation was granted but continues to require safe management;
- (23)[22] Dose constraint means a constraint set as a prospective upper bound of an individual dose, used to define the range of options considered in the process of optimisation for a given radiation source in a planned exposure situation;
- (24)[23] Dose limit means the value of the effective dose (where applicable, committed effective dose) or the equivalent dose in a specified period which shall not be exceeded for an individual;
- (25)[24] Dosimetry service means a body or an individual having the competence for calibration, reading or interpretation of individual monitoring devices, or for measurement of radioactivity in the human body or in biological samples, or for assessment of doses, whose capacity to act in this respect is recognised by the competent authority;

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<sup>31</sup> Change proposed at AQ 15 May

(26)[25] Effective dose (E) is the sum of the weighted equivalent doses in all the tissues and organs of the body from internal and external exposure. It is defined by the expression:

$$E = \sum_T w_T H_T = \sum_T w_T \sum_R w_R D_{T,R}$$

where

$D_{T,R}$  is the absorbed dose averaged over tissue or organ T, due to radiation R,

$w_R$  is the radiation weighting factor and

$w_T$  is the tissue weighting factor for tissue or organ T.

The values for  $w_T$  and  $w_R$  are specified in Annex Ia. The unit for effective dose is the sievert (Sv);

(27)[26] Emergency exposure situation means a situation of exposure due to an emergency;

(28)[27] Emergency management system means a legal or administrative framework establishing responsibilities for emergency preparedness and response, and arrangements for decision making in the event of an emergency exposure situation;

(29)[28] Emergency means a non-routine situation or event involving a radiation source that necessitates prompt action to mitigate serious adverse consequences for human health and safety, quality of life, property or the environment, or a hazard that could give rise to such serious adverse consequences;

(30)[29] Emergency occupational exposure means exposure received in an emergency exposure situation by an emergency worker;

(31)[30] Emergency response plan means arrangements to plan for adequate response in the event of an emergency exposure situation on the basis of postulated events and related scenarios;

(32)[31] Emergency worker means any person having a defined role in an emergency and who might be exposed to radiation while taking action in response to the emergency;

(33)[32] Environmental monitoring means the measurement of external dose rates due to radioactive substances in the environment or of concentrations of radionuclides in environmental media;

(34)[33] Equivalent dose ( $H_T$ ) is the absorbed dose, in tissue or organ T weighted for the type and quality of radiation R. It is given by:

$$H_{T,R} = w_R D_{T,R},$$

Where

$D_{T,R}$  is the absorbed dose averaged over tissue or organ T, due to radiation R,  
 $w_R$  is the radiation weighting factor.

When the radiation field is composed of types and energies with different values of  $w_R$ , the total equivalent dose,  $H_T$ , is given by:

$$H_T = \sum_R w_R D_{T,R}$$

The values for  $w_R$  are specified in Annex Ia, Part A. The unit for equivalent dose is the sievert (Sv);

(35)[34] Exemption level means a value established by a competent authority or in legislation and expressed in terms of activity concentration or total activity at or below which a radiation source is not subject to notification or authorisation;

(36)[35] Existing exposure situation means an exposure situation that already exists when a decision on its control has to be taken and which does not call or no longer calls for urgent measures to be taken;

(37)[36] Exposed worker means a person, either self-employed or working under an employer, who is subject to exposure at work carried out within a practice regulated by this Directive and who is liable to receive doses exceeding one or other of the dose limits for public exposure;

(38)[37] Exposure means the act of exposing or condition of being exposed to ionising radiation emitted outside the body (external exposure) or within the body (internal exposure);

(39)<sup>32</sup>

(40)[38] Extremities means hands, forearms, feet and ankles;

(41)<sup>33</sup>

(42)[39] Health detriment means reduction in length and quality of life occurring in a population following exposure, including those arising from tissue reactions, cancer and severe genetic disorder;

(43)[40] Health screening means a procedure using medical radiological installations for early diagnosis in population groups at risk;

(44)[41] High-activity sealed source means a sealed source for which the activity of the contained radionuclide is equal to or exceeds the relevant activity values laid down in Annex II;

(45)[42] Individual detriment means clinically observable deleterious effects in individuals or their descendants, the appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance;

(46)[43] Inspection means an investigation by or on behalf of any competent authority to verify compliance with national legal requirements;

(47)[44] Intake means the total activity of a radionuclides entering the body from the external environment;

(48)[45] Interventional radiology means the use of X-ray imaging techniques to facilitate the introduction and guidance of devices in the body for diagnostic or treatment purposes;

(49)[46] Ionising radiation means energy transferred in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less (a frequency of  $3 \times 10^{15}$  Hertz or more) capable of producing ions directly or indirectly;

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<sup>32</sup> Definition of exposure situation has been deleted in 17623/1/12 REV1

<sup>33</sup> Definition of gray (Gy) has been moved to definition 1 Activity

- (50)[47] Licence means permission granted in a document by the competent authority to carry out a practice in accordance with specific conditions laid down in a licence document;
- (51)[48] Medical exposure means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research;
- (52)[49] Medical physics expert means an individual or, if provided for in national legislation, a group of individuals, having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence ~~and~~<sup>34</sup> ~~capacity~~ in this respect is recognised by the competent authority;
- (53)[50] Medical radiological installation means a facility where medical radiological procedures are performed;
- (54)[51] Medical radiological means pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes;
- (55)[52] Medical radiological procedure means any procedure giving rise to medical exposure;
- (56)[53] Members of the public means individuals who may be subject to public exposure;
- (57)[54] Natural radiation source means a sources of ionising radiation of natural, terrestrial or cosmic origin;
- (58)[55] Non-medical imaging exposure means any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed;
- (59)[56] Normal exposure means exposure expected to occur under the normal operating conditions of a facility or activity (including maintenance, inspection, decommissioning), including minor incidents that can be kept under control, i.e. during normal operation and anticipated operational occurrences;
- (60)[57] Notification means submission of information to the competent authority to notify the intention to carry out a practice within the scope of this Directive;

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<sup>34</sup> Agreed at AQ 15 May

- (61)[58] Occupational exposure means exposure of workers, apprentices and students, incurred in the course of their work;
- (62)[59] Occupational health service means a health professional or body having competence for the medical surveillance of exposed workers and whose capacity to act in that respect is recognised by the competent authority;
- (63)<sup>35</sup>
- (64)<sup>36</sup>
- (65)[60] Orphan source means a radioactive source which is neither exempted nor under regulatory control, e.g. because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation;
- (66)[61] Outside worker means any exposed worker who is not employed by the undertaking responsible for the supervised and controlled areas, but performs activities in these areas, including, apprentices and students;
- (67)<sup>37</sup>
- (68)[62] Planned exposure situation means an exposure situation that arises from the planned operation of a radiation source or from a human activity which alters exposure pathways, so as to cause the exposure or potential exposure of people or the environment. Planned exposure situations may include both normal exposures and potential exposures.
- (69)[63] Potential exposure means exposure that is not expected with certainty but may result from an event or sequence of events of a probabilistic nature, including equipment failures and operating errors;

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<sup>35</sup> Definition of optimisation was deemed no longer necessary given the detail provided in Article 5b dealing with optimisation.

<sup>36</sup> Definition of organ dose deleted in 8682/13

<sup>37</sup> No definition 67 in 17623/1/12 REV 1



- (70)[64] Practical aspects of medical radiological procedures means the physical conduct of a medical exposure and any supporting aspects, including handling and use of medical radiological equipment, the assessment of technical and physical parameters (including radiation doses), calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals, and image processing.
- (71)[65] Practice means a human activity that can increase the exposure of individuals to radiation from a radiation source and is managed as a planned exposure situation;
- (72)[66] Practitioner means a medical doctor, dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements;
- (72a)[67] Processing means chemical or physical operations on radioactive material including the mining, conversion, enrichment of fissile or fertile nuclear material and the reprocessing of spent fuel;
- (73)<sup>38</sup>
- (74)[68] Protective measures means measures, other than remedial measures, for the purpose of avoiding or reducing doses that might otherwise be received in an emergency exposure situation or an existing exposure situation;
- (75)[69] Public exposure means exposure of individuals, excluding any occupational or medical exposure;

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<sup>38</sup> Definition of projected dose deleted in 8682/13.

- (76)[70] Quality assurance means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. Quality control is a part of quality assurance;
- (77)[71] Quality control means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled;
- (78)[72] Radiation generator means a device capable of generating ionising radiation, such as X-rays, neutrons, electrons or other charged particles;
- (79)[73] Radiation protection expert means an individual or, if provided for in the national legislation, a group of individuals having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose competence in this respect<sup>39</sup> is recognised by the competent authority;
- (80)<sup>40</sup>
- (81)[74] Radiation protection officer means an individual who is technically competent in radiation protection matters relevant for a given type of practice to supervise or perform the implementation of the radiation protection arrangements;
- (82)[75] Radiation source means an entity that may cause exposure, such as by emitting ionising radiation or by releasing radioactive material;
- (83)[76] Radioactive material means material incorporating radioactive substances;
- (84)[77] Radioactive source means a radiation source incorporating radioactive material for the purpose of utilising its radioactivity;

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<sup>39</sup> Agreed at AQ 15 May

<sup>40</sup> No definition 80 in 17623/1/12 REV 1

<sup>41</sup> Agreed at AQ 15 May

- (85)[78] Radioactive substance means any substance that contains one or more radionuclides the activity or activity concentration of which cannot be disregarded from a radiation protection point of view;
- (86)[79] Radioactive waste means radioactive material in gaseous, liquid or solid form for which no further use is foreseen or considered by the Member State or by a legal or natural person whose decision is accepted by the Member State, and which is regulated as radioactive waste by a competent regulatory authority under the legislative and regulatory framework of the Member State;
- (87)[80] Radiodiagnostic means pertaining to in-vivo diagnostic nuclear medicine, medical diagnostic radiology using ionising radiation, and dental radiology;
- (88)[81] Radiotherapeutic means pertaining to radiotherapy, including nuclear medicine for therapeutic purposes;
- <sup>42</sup>(89)[82] Radon means the radionuclide Rn-222 and its progeny, as appropriate;
- (90)<sup>43</sup>
- (89a)[83] Exposure to radon means exposure to radon progeny;
- (91)[84] Reference level means in an emergency exposure situation or in an existing exposure situation, the level of effective dose or equivalent dose or activity concentration above which it is judged inappropriate to allow exposures to occur as a result of that exposure situation, even though it is not a limit that may not be exceeded;
- (92)[85] Referrer means a medical doctor, dentist or other health professional who is entitled to refer individuals for medical radiological procedures to a practitioner, in accordance with national requirements;

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<sup>42</sup> It has been proposed that this definition should simply read “Radon means the radionuclide Rn-222”; while this proposal would appear to have some merit on a technical level, following consultation, the Presidency’s assessment is that due to variations in national provisions in this regard the flexibility offered by the current definition is generally preferred

<sup>43</sup> Definition 90 ‘Radon prone’ deleted in 17623/1/12 REV 1

- (93)[86] Registration means permission granted in a document by the competent authority, or granted by national legislation, through a simplified procedure, to carry out a practice in accordance with conditions laid down in national legislation or specified by a competent authority for this type or class of practice;
- (94)[87] Regulatory control means any form of control or regulation applied to human activities for the enforcement of radiation protection requirements;
- (95)[88] Remedial measures means the removal of a source or the reduction of its magnitude (in terms of activity or amount) or the interruption of exposure pathways or the reduction of their impact for the purposes of avoiding or reducing doses that might otherwise be received in an existing exposure situation;
- (96)[89] Representative person means an individual receiving a dose that is representative of the more highly exposed individuals in the population, excluding those individuals having extreme or rare habits;
- (97)<sup>44</sup>
- (98)<sup>45</sup>
- (99)<sup>46</sup>
- (100)[90] Sealed source means a radioactive source in which the radioactive material is permanently sealed in a capsule or incorporated in a solid form with the objective of preventing, under normal conditions of use, any dispersion of radioactive substances;
- (101) [91] Sievert (Sv) is the special name of the unit of equivalent or effective dose. One sievert is equivalent to one joule per kilogram:  $1 \text{ Sv} = 1 \text{ J kg}^{-1}$ ;
- (102) [92] Storage means the holding of radioactive material, including spent fuel, a radioactive source or radioactive waste, in a facility with the intention of retrieval;
- (103) [93] Supervised area means an area subject to supervision for the purpose of protection against ionising radiation;

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<sup>44</sup> Deletion of definition of residual dose agreed at AQ 29 April

<sup>45</sup> No definition 98 in 17623/1/12/ REV 1

<sup>46</sup> Definition 99 'Risk constraint' deleted in 17623/1/12 REV 1

(104)<sup>47</sup>

(105) [94] Source container means an assembly of components intended to guarantee the containment of a sealed source, where this is not an integral part of the source but is meant for shielding the source during its transport and handling;

(106) [95] Spacecraft means a manned vehicle designed to operate at an altitude of more than 100km above sea level;

(106a)[96] Standard values and relationships means values and relationships recommended in chapters 4 and 5 of Publication 116 of the International Commission for Radiological Protection for the estimation of doses from external exposure and chapter 1 of Publication 119 of the International Commission on Radiological Protection for the estimation of doses from internal exposure, including updates approved by Member States. Member State may approve the use of specific methods in specified cases relating to the physico-chemical properties of the radionuclide or other features of the exposure situation or of the exposed individual  
[New];

(107)[97]Thoron means the radionuclide Rn-220 and its progeny, as appropriate;

(108) [98] Undertaking means a natural or legal person who has legal responsibility under national law for carrying out a practice, or for a radiation source (including cases where the owner or holder of a radiation source does not conduct related human activities);

(109)[99] Unintended exposure means medical exposure that is significantly different from the medical exposure intended for a given purpose.

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<sup>47</sup> Definition of supplier deleted in 8682/13

## CHAPTER III

### SYSTEM OF RADIATION PROTECTION

#### *Article 5*

#### *General principles*

Member States shall establish legal requirements and an appropriate regime of regulatory control which, for all exposure situations, reflect a system of radiation protection based on the principles of justification, optimisation and dose limitation:

- (a) **Justification:** Decisions introducing a practice shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment, that it may cause. Decisions introducing or altering an exposure pathway for existing and emergency exposure situations shall be justified in the sense that they should do more good than harm.
  
- (b) **Optimisation:** Radiation protection of individuals subject to public or occupational exposure shall be optimised with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable taking into account the current state of technical knowledge and economic and societal factors. The optimisation of the protection of individuals subject to medical exposure shall apply to the magnitude of individual doses and be consistent with the medical purpose of the exposure, as described in Article 55. This principle shall be applied not only in terms of effective dose but also, where appropriate, in terms of equivalent doses, as a precautionary measure to allow for uncertainties as to health detriment below the threshold for tissue reactions.

- (c) Dose limitation: In planned exposure situations, the sum of doses to an individual shall not exceed the dose limits laid down for occupational exposure or public exposure. Dose limits shall not apply to medical exposures.

## **SECTION 1**

### **TOOLS FOR OPTIMISATION**

#### *Article 6*

##### *Dose constraints for occupational, public, and medical exposure*

1. Member States shall ensure that, where appropriate, dose constraints are established for the purpose of prospective optimisation of protection:
  - (a) for occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking under the general supervision of the competent authority. In the case of outside workers the dose constraint shall be established in cooperation between the employer and the undertaking.
  - (b) for public exposure, the dose constraint shall be set for the individual dose that members of the public receive from the planned operation of a specified radiation source. The competent authority shall ensure that the constraints are consistent with the dose limit for the sum of doses to the same individual from all authorised practices.
  - (c) for medical exposures, dose constraints shall apply only with regard to the protection of carers and comforters and volunteers participating in medical or biomedical research.
2. Dose constraints shall be established in terms of individual effective or equivalent doses over a defined appropriate time period.

*Article 8 [7]*  
*Reference levels*

1. Member States shall ensure that reference levels are established for emergency and existing exposure situations. Optimisation of protection shall give priority to exposures above the reference level and shall continue to be implemented below the reference level.
2. The values chosen for reference levels shall depend upon the type of exposure situation. The choices of reference levels shall take into account both radiological protection requirements and societal criteria. For public exposure the establishment of reference levels shall take into account the range of reference levels set out in Annex I.
3. For existing exposure situations involving exposure to radon, the reference levels shall be set in terms of radon activity concentration in air as specified in Article 74 for members of the public and Article 53 for workers.

**SECTION 2**  
**DOSE LIMITATION**

*Article 9 [8]*  
*Age limit for exposed workers*

Member States shall ensure that subject to Article 12(2), persons under 18 years of age may not be assigned to any work which would result in their being exposed workers.



*Article 10 [9]*

*Dose limits for occupational exposure*

1. Member States shall ensure that dose limits for occupational exposure shall apply to the sum of annual occupational exposures of a worker from all authorised practices, occupational exposure to radon in workplaces requiring notification in accordance with Article 53(3), and other occupational exposure from existing exposure situations in accordance with Article 100(3). For emergency occupational exposure Article 52 shall apply.
2. The limit on the effective dose for occupational exposure shall be 20 mSv in any single year. However, in special circumstances or for certain exposure situations specified in national legislation, a higher effective dose of up to 50 mSv may be authorised by the competent authority in a single year, provided that the average annual dose over any five consecutive years, including the years for which the limit has been exceeded, does not exceed 20 mSv.
3. In addition to the limits on effective dose laid down in paragraph 2, the following limits on equivalent dose shall apply:
  - (a) the limit on the equivalent dose for the lens of the eye shall be 20 mSv in a single year or 100 mSv in any five consecutive years subject to a maximum dose of 50 mSv in a single year, as specified in national legislation.
  - (b) the limit on the equivalent dose for the skin shall be 500 mSv in a year, this limit shall apply to the dose averaged over any area of 1 cm<sup>2</sup>, regardless of the area exposed;
  - (c) the limit on the equivalent dose for the extremities shall be 500 mSv in a year.

*Article 11 [10]*

*Protection of pregnant and breastfeeding workers*

1. Member States shall ensure that the protection of the unborn child is comparable with that provided for members of the public. As soon as a pregnant worker informs the undertaking or, in the case of an outside worker, the employer, of the pregnancy, in accordance with national legislation the undertaking, and the employer, shall ensure that the employment conditions for the pregnant worker are such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy.
2. As soon as a worker informs the undertaking, or in case of an outside worker, the employer, that they are breastfeeding an infant, they shall not be employed in work involving a significant risk of intake of radionuclides or of bodily contamination.

*Article 12 [11]*

*Dose limits for apprentices and students*

1. Member States shall ensure that the dose limits for apprentices aged 18 years or over and students aged 18 years or over who, in the course of their studies, are obliged to work with radiation sources, shall be the same as the dose limits for occupational exposure laid down in Article 10.
2. Member States shall ensure that the limit on the effective dose for apprentices aged between 16 and 18 years and for students aged between 16 and 18 years who, in the course of their studies, are obliged to work with radiation sources, shall be 6 mSv in a year.
3. In addition to the limits on effective dose laid down in paragraph 2, the following limits on equivalent dose shall apply:
  - (a) the limit on the equivalent dose for the lens of the eye shall be 15 mSv in a year;
  - (b) the limit on the equivalent dose for the skin shall be 150 mSv in a year, averaged over any area of 1 cm<sup>2</sup>, regardless of the area exposed;

- (c) the limit on the equivalent dose for the extremities shall be 150 mSv in a year.
4. Member States shall ensure that the dose limits for apprentices and students who are not subject to the provisions of paragraphs 1, 2 and 3 shall be the same as the dose limits for members of the public as specified in Article 13.

*Article 13 [12]*

*Dose limits for public exposure*

1. Member States shall ensure that the dose limits for public exposure shall apply to the sum of annual exposures of a member of the public resulting from all authorised practices.
2. Member States shall set the limit on the effective dose for public exposure at 1 mSv in a year.
3. In addition to the dose limit referred to in paragraph 2, the following limits on the equivalent dose shall apply:
  - (a) the limit on the equivalent dose for the lens of the eye shall be 15 mSv in a year;
  - (b) the limit on the equivalent dose for the skin shall be 50 mSv in a year, averaged over any 1 cm<sup>2</sup> area of skin, regardless of the area exposed.

*Article 14 [13]*

*Estimation of the effective and equivalent dose*

For the estimation of effective and equivalent doses, the appropriate standard shall be used. For external radiation, the operational quantities defined in section 2.3 of Publication 116 of the International Commission on Radiological Protection shall be used.

## **CHAPTER IV**

### **REQUIREMENTS FOR RADIATION PROTECTION EDUCATION, TRAINING AND INFORMATION**

#### *Article 15 [14]*

##### *General responsibilities for the education, training and provision of information*

1. Member States shall establish an adequate legislative and administrative framework ensuring the provision of appropriate radiation protection education, training and information to all individuals whose tasks require specific competences in radiation protection. The provision of training and information shall be repeated at appropriate intervals and documented.
2. Member States shall ensure that arrangements are made for the establishment of education, training and retraining to allow the recognition of radiation protection experts and medical physics experts, as well as occupational health services and dosimetry services, in relation to the type of practices.
3. Member States may make arrangements for the establishment of education, training and retraining to allow the recognition of radiation protection officers, if such recognition is provided for in national legislation.

#### *Article 16 [15]*

##### *Training of exposed workers and information provided to them*

1. Member States shall require the undertaking to inform exposed workers on:
  - (a) the radiation health risks involved in their work;
  - (b) the general radiation protection procedures and precautions to be taken;

- (ba) the radiation protection procedures and precautions connected with the operational and working conditions of both the practice in general and each type of workstation or work to which they may be assigned;
- (c) the relevant parts of the emergency response plans and procedures;
- (d) the importance of complying with the technical, medical and administrative requirements.

In the case of outside workers, their employer shall ensure that the information required in (a), (b) and (d) is provided.

2. Member States shall require the undertaking or, in case of outside workers, the employer, to inform exposed workers on the importance of making an early declaration of pregnancy in view of the risks of exposure for the unborn child.
3. Member States shall require the undertaking or, in case of outside workers, the employer, to inform exposed workers on the importance of announcing the intention to breast-feed an infant in view of the risks of exposure for a breast-fed infant after intake of radionuclides or bodily contamination.
4. Member States shall require that the undertaking or, in case of outside workers, the employer, provides appropriate radiation protection training and information programmes for exposed workers.
5. In addition to the information and training in the field of radiation protection as specified in paragraphs 1, 2, 3 and 4, Member States shall require that the undertaking responsible for high-activity sealed sources shall ensure that such training includes specific requirements for the safe management and control of high-activity sealed sources with a view to preparing the relevant workers adequately for any events affecting the radiation protection. The information and training shall place particular emphasis on the necessary safety requirements and shall contain specific information on the possible consequences of the loss of adequate control of high-activity sealed sources.

*Article 17 [16]*

*Information and training of workers potentially exposed to orphan sources*

1. Member States shall ensure that the management of installations where orphan sources are most likely to be found or processed, including large metal scrap yards and major metal scrap recycling installations, and in significant nodal transit points, are informed of the possibility that they may be confronted with a source.
2. Member States shall encourage the management of installations referred to in paragraph 1 to ensure that where workers in their installation may be confronted with a source, they are:
  - (a) advised and trained in the visual detection of sources and their containers;
  - (b) informed of basic facts about ionising radiation and its effects;
  - (c) informed of and trained in the actions to be taken on site in the event of the detection or suspected detection of a source.

*Article 18 [17]*

*Prior information and training for emergency workers*

1. Member States shall ensure that emergency workers who are identified in an emergency response plan or management system are given adequate and regularly updated information on the health risks their intervention might involve and on the precautionary measures to be taken in such an event. This information shall take into account the range of potential emergencies and the type of intervention.
2. As soon as an emergency occurs, the information referred to in paragraph 1 shall be supplemented appropriately, having regard to the specific circumstances.

3. Member States shall ensure that the undertaking or the organisation responsible for the protection of emergency workers provides to emergency workers referred to in paragraph 1 appropriate training as provided for in the emergency management system set out in Article 97. Where appropriate, this training shall include practical exercises.
4. Member States shall ensure that, in addition to the emergency response training referred to in paragraph 3, the undertaking or the organisation responsible for the protection of emergency workers provides these workers with appropriate radiation protection training and information.

*Article 19 [18]*

*Education, information and training in the field of medical exposure*

1. Member States shall ensure that practitioners and the individuals involved in the practical aspects of medical radiological procedures have adequate education, information and theoretical and practical training for the purpose of medical radiological practices, as well as relevant competence in radiation protection.  
For this purpose Member States shall ensure that appropriate curricula are established and shall recognise the corresponding diplomas, certificates or formal qualifications.
2. Individuals undergoing relevant training programmes may participate in practical aspects of medical radiological procedures as set out in Article 56(2).
3. Member States shall ensure that continuing education and training after qualification is provided and, in the special case of the clinical use of new techniques, training is provided on these techniques and the relevant radiation protection requirements.
4. Member States shall encourage the introduction of a course on radiation protection in the basic curriculum of medical and dental schools.

## CHAPTER V

### JUSTIFICATION AND REGULATORY CONTROL OF PRACTICES

#### *Article 20 [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 54.



*Article 21 [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 III, Section A, so as to allow the implementation of the justification requirement in Article 20(1).
2. On the basis of an assessment of this information, Member States shall ensure that the competent authority, as outlined in Annex III, 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 25c.

*Article 22 [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<sup>48</sup> of the European Parliament and of the Council, 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.

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<sup>48</sup> OJ L 66, 13.3.1999, p. 16.

*Article 23 [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 IV.
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 <sup>49</sup> 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 Article 6(1)(b) and from the dose limits set out in Article 13.
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;

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<sup>49</sup> Agreed at AQ 15 May

- (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;

*Article 24 [23]*

*Identification of practices involving naturally-occurring radioactive material*

Member States shall ensure the identification of classes or types of practices 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 V.

*Article 25a [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 27a and 27b, where appropriate, and in accordance with the general exemption criteria set out in Annex VI, 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 VI; in the case of moderate amounts of material, as specified by Member States, the activity concentration values laid down in Annex VI, 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 25b [25]*

*Notification*

1. Member States shall ensure that notification is required for all justified practices, including those identified according to Article 24. 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 25c.
2. Member States shall ensure that notification is required for workplaces specified in Article 53(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 25c, in situations identified by Member States where there is concern that a practice identified in accordance with Article 24 may lead to the presence of naturally-occurring radionuclides in water liable to affect the quality of drinking water supplies<sup>50</sup> 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 29 shall not be managed as a planned exposure situation and, hence, are not required to be notified.

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<sup>50</sup> Official Journal reference to Euratom Drinking Water Directive to be inserted when available

*Article 25c [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 VI, 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 VI; or
  - (b) without prejudice to Article 25b(4), radioactive materials where the activity concentrations do not exceed the exemption values set out in Table A of Annex VI, 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 VI; 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  $1 \mu\text{Sv}\cdot\text{h}^{-1}$  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.

- (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  $1 \mu\text{Sv}\cdot\text{h}^{-1}$  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 VI, on the basis of an assessment showing that exemption is the best option.

*Article 27a [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 (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 27b [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 <sup>51</sup>radioactive waste for this purpose;
- (f) practices discharging significant amounts of radioactive material with airborne or liquid effluent into the environment.

*Article 28 [29]*

*Authorisation procedure*

1. For authorisation purposes, Member States shall require the provision of ~~all~~ 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 VIIa.

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<sup>51</sup> Agreed at AQ 15 May

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 29 [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. <sup>52</sup>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 VI; 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 VI, and taking into account technical guidance provided by the Community.

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<sup>52</sup> Agreed at AQ 15 May

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. <sup>53</sup>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.

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<sup>53</sup> Change proposed at AQ 15 May

## CHAPTER VI OCCUPATIONAL EXPOSURES

### *Article 30 [31] Responsibilities*

1. Member States shall ensure that the undertaking is responsible for assessing and implementing arrangements for the radiation protection of exposed workers.
2. In the case of outside workers, the responsibilities of the undertaking and the employer of outside workers are stipulated in Article 50.
3. Notwithstanding paragraphs 1 and 2, Member States shall arrange for a clear allocation of responsibilities for the protection of workers in any exposure situation, to an undertaking, an employer or any other organisation, in particular for the protection of:
  - (a) emergency workers;
  - (b) workers involved in the remediation of contaminated land, buildings and other constructions;
  - (c) workers who are exposed to radon at work, in the situation specified in Article 53(3).

This shall also apply to the protection of self-employed individuals and individuals who work on a voluntary basis.

4. Member States shall ensure that employers have access to information on the possible exposure of their employees under the responsibility of another employer or undertaking.

*Article 31 [32]*

*Operational protection of exposed workers*

Member States shall ensure that the operational protection of exposed workers is based, in accordance with the relevant provisions of this Directive, on:

- (a) prior evaluation to identify the nature and magnitude of the radiological risk to exposed workers;
- (b) optimisation of radiation protection in all working conditions, including occupational exposures as a consequence of practices involving medical exposures;
- (c) classification of exposed workers into different categories;
- (d) control measures and monitoring relating to the different areas and working conditions, including, where necessary, individual monitoring;
- (e) medical surveillance;
- (f) education and training.

*Article 31bis[33]*

*Operational protection of apprentices and students*

1. Member States shall ensure that the exposure conditions and operational protection of apprentices and students aged 18 years or over referred to in Article 12(1) is equivalent to that of exposed workers of category A or B as appropriate.
2. Member States shall ensure that the exposure conditions and operational protection of apprentices and students aged between 16 and 18 years referred to in Article 12(2) is equivalent to that of exposed workers of category B.

*Article 32 [34]*

*Consultations with a radiation protection expert*

Member States shall require undertakings to seek advice from a radiation protection expert within their areas of competence as outlined in Article 84, on the issues below that are relevant to the practice:

- (a) the examination and testing of protective devices and measuring instruments;
- (b) prior critical review of plans for installations from the point of view of radiation protection;
- (c) the acceptance into service of new or modified radiation sources from the point of view of radiation protection;
- (d) regular checking of the effectiveness of protective devices and techniques;
- (e) regular calibration of measuring instruments and regular checking that they are serviceable and correctly used.

*Article 33 [35]*

*Arrangements in workplaces*

1. Member States shall ensure that for the purposes of radiation protection, arrangements are made as regards all workplaces where workers are liable to receive an exposure greater than an effective dose of 1 mSv per year or an equivalent dose of 15 mSv per year for the lens of the eye or 50 mSv per year for the skin and extremities.

Such arrangements shall be appropriate to the nature of the installations and sources and to the magnitude and nature of the risks.

- <sup>54</sup>2. For workplaces specified in Article 53(3), and where the exposure of workers is liable to exceed an effective dose of 6 mSv per year or a corresponding time-integrated radon exposure value determined by the Member State, these shall be treated as a planned exposure situation and the Member States shall determine which requirements set out in this Chapter are appropriate. For workplaces specified in Article 53(3), and where the effective dose to workers is less than or equal to 6 mSv per year or the exposure less than the a corresponding time-integrated radon exposure value, the competent authority shall requires that exposures are kept under review.
3. For an undertakings operating aircraft where the effective dose to the crew from cosmic radiation is liable to exceed 6 mSv per year, the relevant requirements set out in this Chapter shall apply, allowing for the specific features of this exposure situation. Member States shall ensure that where the effective dose to the crew is liable to be above 1 mSv per year, the competent authority requires the undertaking to take appropriate measures, in particular:
- (a) to assess the exposure of the crew concerned;
  - (b) to take into account the assessed exposure when organising working schedules with a view to reducing the doses of highly exposed crew;
  - (c) to inform the workers concerned of the health risks their work involves and their individual dose.
  - (d) to apply Article 11(1) to pregnant air crew.

*Article 34 [36]*

*Classification of workplaces*

1. Member States shall ensure that arrangements in workplaces include a classification into different areas, where appropriate, on the basis of an assessment of the expected annual doses and the probability and magnitude of potential exposures.

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<sup>54</sup> Change proposed at AQ 15 May

2. A distinction shall be made between controlled areas and supervised areas. Member States shall ensure that the competent authority establishes guidance on the classification of controlled and supervised areas with regard to particular circumstances.
3. Member States shall ensure that the undertaking keeps under review the working conditions in controlled and supervised areas.

*Article 35 [37]*

*Controlled areas*

1. Member States shall ensure that the minimum requirements for a controlled area are the following:
  - (a) the controlled area shall be delineated and access to it shall be restricted to individuals who have received appropriate instructions and shall be controlled in accordance with written procedures provided by the undertaking. Wherever there is a significant risk of the spread of radioactive contamination, specific arrangements shall be made, including for the access and exit of individuals and goods and for monitoring contamination within the controlled area and, where appropriate, in the adjacent area.
  - (b) taking into account the nature and extent of radiological risks in the controlled area, radiological surveillance of the workplace shall be organised in accordance with the provisions of Article 37.
  - (c) Signs indicating the type of area, the nature of the sources and their inherent risks shall be displayed.



- (d) Working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.
  - (e) The worker shall receive specific training in connection with the characteristics of the workplace and the activities.
  - (f) The worker shall be provided with the appropriate personal protective equipment.
2. Member States shall ensure that the undertaking is responsible for implementation of these duties taking into account the advice provided by the radiation protection expert.

*Article 36 [38]*

*Supervised areas*

1. Member States shall ensure that the requirements for a supervised area are the following:
- (a) taking into account the nature and extent of radiological risks in the supervised area, radiological surveillance of the workplace shall be organised in accordance with the provisions of Article 37;
  - (b) if appropriate, signs indicating the type of area, the nature of the sources and their inherent risks shall be displayed;
  - (c) if appropriate, working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.
2. Member States shall ensure that the undertaking is responsible for implementation of these duties taking into account the advice provided by the radiation protection expert.

*Article 37 [39]*

*Radiological surveillance of the workplace*

1. Member States shall ensure that the radiological surveillance of the workplace referred to in Articles 35(1)(b) and 36(1)(a) comprises, where appropriate:
  - (a) the measurement of external dose rates, indicating the nature and quality of the radiation in question;
  - (b) the measurement of the activity concentration in air and the surface density of contaminating radionuclides, indicating their nature and their physical and chemical states.
2. The results of these measurements shall be recorded and shall be used, if necessary, for estimating individual doses, as provided for in Article 39.

*Article 38 [40]*

*Categorisation of exposed workers*

1. Member States shall ensure that for the purposes of monitoring and surveillance, a distinction is made between two categories of exposed workers:
  - (a) category A: those exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than 150 mSv per year for skin and extremities;
  - (b) category B: those exposed workers who are not classified as category A workers.
2. Member States shall require the undertaking or, in the case of outside workers, the employer, to decide on the categorisation of individual workers prior to their taking up work that may give rise to exposure, and to regularly review this categorisation on the basis of working conditions and medical surveillance. The distinction shall also take into account potential exposures.

*Article 39 [41]*

*Individual monitoring*

1. Member States shall ensure that category A workers are systematically monitored based on individual measurements performed by a dosimetry service. In cases where category A workers are liable to receive significant internal exposure or significant exposure of the lens of the eye or extremities, an adequate system for monitoring shall be set up.
2. Member States shall ensure that monitoring for category B workers is at least sufficient to demonstrate that such workers are correctly classified in category B. Member States may require individual monitoring and if necessary individual measurements, performed by a dosimetry service, for category B workers.
3. In cases where individual measurements are not possible or inadequate, the individual monitoring shall be based on an estimate arrived at from individual measurements made on other exposed workers, from the results of the surveillance of the workplace provided for in Article 37 or on the basis of calculation methods approved by the competent authority.

*Article 40 [42]*

*Dose assessment in the case of accidental exposure*

Member States shall ensure that in the case of accidental exposure, the undertaking is required to assess the relevant doses and their distribution in the body.

*Article 41 [43]*

*Recording and reporting of results*

1. Member States shall ensure that a record containing the results of individual monitoring is made for each category A worker and for each category B worker where such monitoring is required by the Member State.
2. For the purposes of paragraph 1, the following information on exposed workers shall be retained:
  - (a) a record of the exposures measured or estimated, as the case may be, of individual doses pursuant to Articles 39, 40, 50, 51, 52 and, <sup>55</sup>if decided by the Member State pursuant to Article 33(2), 53(3);
  - (b) in the case of exposures as referred to in Articles 40, 51 and 52, the reports relating to the circumstances and the action taken;
  - (c) the results of workplace monitoring used to assess individual doses where necessary.
3. The information referred to in paragraph 1 shall be retained during the period of their working life involving exposure to ionising radiation and afterwards until they have or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure.
4. Exposures as referred to in Articles 40, 51 52 and, <sup>56</sup>if decided by the Member State pursuant to Article 33(2), 53(3) shall be recorded separately in the dose record referred to in paragraph 1.
5. The dose record referred to in paragraph 1 shall be submitted to the data system for individual radiological monitoring established by the Member State in accordance with the provisions of Annex VIII.

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<sup>55</sup> Change proposed at AQ 15 May

<sup>56</sup> Change proposed at AQ 15 May

Article 42 [44]

*Access to the results of individual monitoring*

1. The Member States shall require that the results of the individual monitoring set out in Articles 39, 40, 51, 52 and, <sup>57</sup>if decided by the Member State pursuant to Article 33(2), 53(3) be:
  - (a) made available to the competent authority, to the undertaking, and to the employer of outside workers;
  - (b) made available to the worker concerned in accordance with paragraph 2;
  - (c) submitted to the occupational health services in order for them to interpret the implications of the results for human health, as provided for in Article 44(2);
  - (d) submitted to the data system for individual radiological monitoring established by the Member State in accordance with provisions set out in Annex VIII.
2. Member States shall require the undertaking, or in case of outside workers, the employer, to grant workers, at their request, access to the results of their individual monitoring, including the results of measurements which may have been used in estimating these results, or to the results of the assessment of their doses made as a result of surveillance of the workplace.
3. Member States shall determine the arrangements under which the results of individual monitoring are conveyed.
4. The data system for individual radiological monitoring shall cover at least the data listed in Annex VIII, Section A.
5. In the case of an accidental exposure, Member States shall require the undertaking to communicate the results of individual monitoring and dose assessments to the individual and the competent authority without delay.
6. Member States shall ensure that arrangements are in place for the appropriate exchange, among the undertaking, in the case of an outside worker, the employer, the competent authority, occupational health services, radiation protection experts, or dosimetry services of all relevant information on the doses previously received by a worker in order to perform the medical examination prior to employment or classification as a category A worker pursuant to Article 44 and to control the further exposure of workers.

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<sup>57</sup> Change proposed at AQ 15 May

*Article 44 [45]*

*Medical surveillance of exposed workers*

1. Member States shall ensure that the medical surveillance of exposed workers is based on the principles that govern occupational medicine generally.
2. The medical surveillance of category A workers shall be undertaken by the occupational health services. This medical surveillance shall allow for the state of health of workers under surveillance to be ascertained as regards their fitness for the tasks assigned to them. To this end, the occupational health services shall have access to any relevant information they require, including the environmental conditions in the working premises.
3. Medical surveillance shall include:
  - (a) a medical examination prior to employment or classification as a category A worker to determine the worker's fitness for a post as a category A worker for which the worker is being considered;
  - (b) periodic reviews of health.

The state of health of all category A workers shall be reviewed at least once a year, in order to determine whether they remain fit to perform their duties. The nature of these reviews, which can be performed as many times as the occupational health services considers necessary, shall depend on the type of work and on the individual worker's state of health.
4. The occupational health services may indicate the need for medical surveillance to continue after cessation of work for as long as they consider it necessary to safeguard the health of the person concerned.

*Article 45 [46]*  
*Medical classification*

Member States shall ensure that the following medical classification is established with respect to fitness for work as a category A worker:

- (a) fit;
- (b) fit, subject to certain conditions;
- (c) unfit.

*Article 46 [47]*  
*Prohibition to employ or classify unfit workers*

Member States shall ensure that no worker may be employed or classified for any period in a specific post as a category A worker if medical surveillance establishes that the worker is unfit for that specific post.

*Article 47 [48]*  
*Medical records*

1. Member States shall ensure that a medical record is opened for each category A worker and kept up to date so long as the worker remains a worker in that category. Thereafter, it shall be retained until the individual has or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure to ionising radiation.
2. The medical record shall include information regarding the nature of the employment, the results of the medical examinations prior to employment or classification as a category A worker, the periodic reviews of health and the record of doses required by Article 41.

*Article 48 [49]*

*Special medical surveillance*

1. Member States shall ensure that in addition to the medical surveillance of exposed workers provided for in Article 44, provision is made for any further action considered necessary by the occupational health services for the health protection of exposed individuals, such as further examinations, decontamination measures, urgent remedial treatment or other actions identified by the occupational health service.
2. Special medical surveillance shall be performed in each case where any of the dose limits laid down in Article 10 has been exceeded.
3. Subsequent exposure conditions shall be subject to the agreement of the occupational health services.

*Article 49 [50]*

*Appeals*

Member States shall lay down the procedure for appeal against the findings and decisions made pursuant to Articles 45, 46 and 48.

*Article 50 [51]*

*Protection of outside workers*

1. Member States shall ensure that the system for individual radiological monitoring affords outside workers equivalent protection to that for exposed workers employed on a permanent basis by the undertaking.
2. Member States shall ensure that the undertaking is responsible, either directly or through contractual agreements with the employer of outside workers, for the operational aspects of the radiation protection of outside workers that are directly related to the nature of their activities in the undertaking.



3. In particular, Member States shall ensure that, as a minimum requirement, the undertaking shall:
- (a) for category A workers entering controlled areas, check that the outside worker concerned has been passed as medically fit for the activities to be assigned to the worker;
  - (aa) check whether the categorisation of the outside worker is appropriate in relation to the doses liable to be received within the undertaking;
  - (b) for entry into controlled areas, ensure that, in addition to the basic training in radiation protection the outside worker has received specific instructions and training in connection with the characteristics of the workplace and the conducted activities, in accordance with Article 16(1) (ba) and (c);
  - (bb) for entry into supervised areas, ensure that the outside worker has received working instructions appropriate to the radiological risk associated with the sources and the operations involved, as required in Article 36(1)(c);
  - (c) ensure that the outside worker has been issued with the necessary personal protective equipment;
  - (d) ensure that the outside worker receives individual exposure monitoring appropriate to the nature of the activities, and any operational dosimetric monitoring that may be necessary;
  - (e) ensure compliance with the system of protection as defined in Chapter III;
  - (f) for entry into controlled areas, ensure or take all appropriate steps to ensure that after every activity the radiological data from individual exposure monitoring of each category A outside worker within the meaning of Annex VIII, Section B, point 2, are recorded.
4. Member States shall ensure that employers of outside workers shall, either directly or through contractual agreements with the undertaking, ensure that the radiation protection of their workers is in accordance with the relevant provisions of this Directive, in particular by:
- (a) ensuring compliance with the system of protection as defined in Chapter III;

- (b) ensuring that the information and training in the field of radiation protection referred to in Article 16.1 (a), (b), (d), 16(2), 16(3) and 16(4) is provided.
  - (c) guaranteeing that their workers are subject to appropriate assessment of exposure and, for category A workers, medical surveillance, under the conditions laid down in Articles 37 and 39 to 48;
  - (d) ensuring that the radiological data from the individual exposure monitoring of each of their category A workers within the meaning of Annex VIII, Section B, point 1, are kept up to date in the data system for individual radiological monitoring referred to in Article 42(1)(d).
5. Member States shall ensure that all outside workers make their own contributions, as far as practicable, towards the protection to be afforded to them by the radiological monitoring system referred to in paragraph 1, notwithstanding the responsibilities of the undertaking or employer.

*Article 51 [52]*

*Specially authorised exposures*

1. Member States may decide that in exceptional circumstances evaluated case by case, excluding emergencies, the competent authority may, where a specific operation so requires, authorise individual occupational exposures of identified workers exceeding the dose limits set out in Article 10, provided that such exposures are limited in time, confined to certain working areas and within the maximum exposure levels defined for the particular case by the competent authority. The following conditions shall be taken into account:
- (a) only category A workers as defined in Article 38 or spacecraft crew may be subject to such exposures;

- (b) apprentices, students, pregnant workers, and, if there is a risk of intake of radionuclides or bodily contamination, breastfeeding workers, shall be excluded from such exposures;
  - (c) the undertaking shall justify such exposures in advance and thoroughly discuss them with the workers, their representatives, the occupational health services and the radiation protection expert;
  - (d) information about the risks involved and the precautions to be taken during the operation shall be provided to the relevant workers in advance;
  - (dd) the workers have consented;
  - (e) all doses relating to such exposures shall be separately recorded in the medical record referred to in Article 47 and the individual record referred to in Article 41.
2. The exceeding of dose limits as a result of specially authorised exposures shall not necessarily constitute a reason for excluding workers from their usual occupation or relocating them, without their agreement.
  3. Member States shall ensure that the exposure of spacecraft crew above the dose limits is managed as a specially authorised exposure.

*Article 52 [53]*

*Emergency occupational exposure*

1. Member States shall ensure that emergency occupational exposures shall remain, whenever possible, below the values of the dose limits laid down in Article 10.

2. For situations where the above condition is not feasible, the following conditions shall apply:
  - a) reference levels for emergency occupational exposure shall be set, in general below an effective dose of 100 mSv;
  - b) in exceptional situations, in order to save life, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions, a reference level for an effective dose from external radiation of emergency workers may be set above 100 mSv, but not exceeding 500 mSv.
3. Member States shall ensure that emergency workers who are liable to undertake actions whereby an effective dose of 100 mSv may be exceeded are clearly and comprehensively informed in advance of the associated health risks and the available protection measures and undertake these actions voluntarily.
4. In the event of an emergency occupational exposure, Member States shall require radiological monitoring of emergency workers. Individual monitoring or assessment of the individual doses shall be carried out as appropriate to the circumstances.
5. In the event of an emergency occupational exposure, Member States shall require special medical surveillance of emergency workers, as defined in Article 48, to be carried out as appropriate to the circumstances.

*Article 53 [54]*  
*Radon in workplaces*

1. Member States shall establish national reference levels for indoor radon concentrations in workplaces. The reference level for the annual average activity concentration in air shall not be higher than  $300 \text{ Bq m}^{-3}$ , unless it is warranted by national prevailing circumstances.
2. Member States shall require that radon measurements are carried out:
  - (a) in workplaces within the areas identified in accordance with Article 103(3), that are located on the ground floor or basement level, taking into account parameters contained in the national action plan as under point 2 of Annex XVI, as well as
  - (b) in specific types of workplaces identified in the national action plan taking into account point 3 of Annex XVI.
3. In areas within workplaces, where the radon concentration (as an annual average), continues to exceed the national reference level, despite the action taken in accordance with the principle of optimisation as set out in Chapter III, Member States shall require this situation to be notified in accordance with Article 25b(2) and Article 33(2) shall apply.

## CHAPTER VII

### MEDICAL EXPOSURES

*Article 54 [55]*

*Justification*

1. Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.
2. Member States shall ensure that the principle defined in paragraph 1 is applied and in particular that:
  - (a) new types of practices involving medical exposure are justified in advance before being generally adopted;
  - (b) all individual medical exposures are justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.
  - (c) if a type of practice involving medical exposure is not justified in general, a specific individual exposure of this type can be justified, where appropriate, in special circumstances, to be evaluated on a case-by-case basis and documented.

- (d) the referrer and the practitioner, as specified by Member States, seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure.
- (e) medical exposure for medical or biomedical research are examined by an ethics committee, set up in accordance with national procedures and/or by the competent authority;
- (f) specific justification for medical radiological procedures to be performed as part of a health screening programme are carried out by the competent authority in conjunction with appropriate medical scientific societies or relevant bodies.
- (g) the exposure of carers and comforters show a sufficient net benefit, taking into account the direct health benefits to a patient, the possible benefits to the carer / comforter and the detriment that the exposure might cause.
- (h) any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, is part of a health screening programme, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant medical scientific societies and the competent authority. Special attention shall be given to the provision of information to the individual subject to medical exposure, as required by Article 56(1)(d).

*Article 55 [56]*

*Optimisation*

1. Member States shall ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.

For all medical exposure of patients for radiotherapeutic purposes, exposures of target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

2. Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radiodiagnostic examinations, having regard to the recommended European diagnostic reference levels where available, and when appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.

3. Member States shall ensure that for each medical or biomedical research project involving medical exposure:

- (a) the individuals concerned participate voluntarily;
- (b) these individuals are informed about the risks of exposure;
- (c) a dose constraint is established for individuals for whom no direct medical benefit is expected from exposure;
- (d) in the case of patients who voluntarily accept to undergo an experimental medical practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the dose levels concerned shall be considered on an individual basis by the practitioner and/or referrer prior to the exposure taking place.



4. Member States shall ensure that the optimisation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities, taking into account economic and societal factors.
5. Member States shall ensure that:
  - (a) dose constraints are established for the exposure of carers and comforters, where appropriate;
  - (b) appropriate guidance is established for the exposure of carers and comforters.
6. Member States shall ensure that in the case of a patient undergoing treatment or diagnosis with radionuclides, the practitioner or the undertaking, as specified by Member States, provides the patient or their representative with information on the risks of ionising radiation and appropriate instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable. For therapeutic procedures these shall be written instructions.

These instructions shall be handed out before leaving the hospital or clinic or a similar institution.

*Article 56 [57]*  
*Responsibilities*

1. Member States shall ensure that:
  - (a) any medical exposure takes place under the clinical responsibility of a practitioner;
  - (b) the practitioner, the medical physics expert and those entitled to carry out practical aspects of medical radiological procedures are involved, as specified by Member States, in the optimisation process;
  - (c) the referrer and the practitioner are involved, as specified by Member States, in the justification process of individual medical exposures;
  - (d) wherever practicable and prior to the exposure taking place, the practitioner or the referrer, as specified by Member States, ensures that the patient or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure. Similar information as well as relevant guidance shall be given to carers and comforters, in accordance with Article 55(5)(b).
2. Practical aspects of medical radiological procedures may be delegated by the undertaking or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognised field of specialisation.

*Article 57 [58]*

*Procedures*

Member States shall ensure that:

- (a) written protocols for every type of standard medical radiological procedure are established for each equipment for relevant categories of patients;
- (b) information relating to patient exposure forms part of the report of the medical radiological procedure;
- (c) referral guidelines for medical imaging, taking into account the radiation doses, are available to the referrers;
- (d) in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice. In particular:
  - (i) in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved;
  - (ii) in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, involving high doses as referred to in Article 60(1)(c), a medical physics expert shall be involved;
  - (iii) for other medical radiological practices not covered by (a) and (b), a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.
- (e) clinical audits are carried out in accordance with national procedures;
- (f) appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that appropriate corrective action is taken without undue delay.

*Article 58 [59]*

*Training*

Member States shall ensure that training and recognition requirements, as laid down in Articles 81, 15 and 19, are met for the practitioner, the medical physics expert and the individuals referred to in Article 56(2).

*Article 59 [60]*

*Equipment*

1. Member States shall ensure that:
  - (a) all medical radiological equipment in use is kept under strict surveillance regarding radiation protection;
  - (b) an up-to-date inventory of medical radiological equipment for each medical radiological installation is available to the competent authority;
  - (c) appropriate quality assurance programmes and assessment of dose or verification of administered activity are implemented by the undertaking; and
  - (d) acceptance testing is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any maintenance procedure liable to affect the performance.
2. Member States shall ensure that the competent authority takes steps to ensure that the necessary measures are taken by the undertaking to improve inadequate or defective performance of medical radiological equipment in use. They shall also adopt specific criteria for the acceptability of equipment in order to indicate when appropriate corrective action is necessary, including taking the equipment out of service.
3. Member States shall ensure that:
  - (a) the use of fluoroscopy equipment without a device to automatically control the dose rate, or without an image intensifier or equivalent device, is prohibited.

- (b) equipment used for external beam radiotherapy with a nominal beam energy exceeding 1 MeV has a device to verify key treatment parameters. Equipment installed prior to <sup>58</sup>[...] may be exempted from this requirement.
- (c) any equipment used for interventional radiology has a device or a feature informing the practitioner and those carrying out practical aspects of the medical procedures of quantity of radiation produced by the equipment during the procedure. Equipment installed prior to <sup>59</sup>[...] may be exempted from this requirement.
- (d) any equipment used for interventional radiology and computed tomography and any new equipment used for planning, guiding and verification purposes has a device or a feature informing the practitioner, at the end of the procedure, of relevant parameters for assessing the patient dose.
- (e) equipment used for interventional radiology and computed tomography has the capacity to transfer the information required under 3(d) to the record of the examination. Equipment installed prior to <sup>60</sup>[...] may be exempted from this requirement.

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<sup>58</sup> CLS advise that the transposition deadline (4 years after the publication date in the OJ) will be inserted here upon finalisation of the directive. The following footnote will remain in the draft until publication: "To Official Journal: Please insert the date 4 years after the date of entry into force of this Directive."

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- (f) without prejudice to paragraph 3(c), (d), and (e), new medical radiodiagnostic equipment producing ionising radiation has a device or equivalent means informing the practitioner of relevant parameters for assessing the patient dose. Where appropriate, the equipment shall have the capacity to transfer this information to the record of the examination.

*Article 60 [61]*

*Special practices*

1. Member States shall ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment is used in medical exposure:
  - (a) of children;
  - (b) as part of a health screening programme;
  - (c) involving high doses to the patient, which may be the case in interventional radiology, nuclear medicine, computed tomography or radiotherapy.Special attention shall be given to quality assurance programmes and the assessment of dose or verification of administered activity for these practices.
  
2. Member States shall ensure that practitioners and those individuals referred to in Article 56(2) who perform the exposures referred to in paragraph 1 obtain appropriate training on these medical radiological practices as required by Article 19.

*Article 61 [62]*

*Special protection during pregnancy and breastfeeding*

1. Member States shall ensure that the referrer or the practitioner, as appropriate, inquire, as specified by Member States, whether the individual subject to medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure.
2. If pregnancy cannot be ruled out and depending on the medical radiological procedure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the expectant individual and the unborn child.
3. In the case of a breastfeeding individual, in nuclear medicine, depending on the medical radiological procedure, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the individual and the child.
4. Without prejudice to paragraphs 1, 2 and 3, Member States shall take measures to increase the awareness of individuals to whom this Article applies, through measures such as public notices in appropriate places.

*Article 62 [63]*

*Accidental and unintended exposures*

Member States shall ensure that:

- (a) all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure;
- (b) for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures;
- (c) for all medical exposures the undertaking implements an appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice;
- (d) arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis;
- (e) (i) the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority;  
(ii) the results of the investigation and the corrective measures to avoid such events are reported to the competent authority within the time period specified by the Member State;
- (f) mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events.



*Article 63 [64]*  
*Estimates of population doses*

Member States shall ensure that the distribution of individual dose estimates from medical exposure for radiodiagnostic and interventional radiology purposes is determined, taking into consideration, as where<sup>61</sup> appropriate, the distribution by age and gender of the exposed population.

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<sup>61</sup> Change proposed at AQ 15 May

## **CHAPTER VIII**

### **PUBLIC EXPOSURES**

#### **SECTION 1**

#### **PROTECTION OF MEMBERS OF THE PUBLIC AND LONG-TERM HEALTH**

#### **PROTECTION IN NORMAL CIRCUMSTANCES**

*Article 65 [65]*

*Operational protection of members of the public*

1. Member States shall ensure that the operational protection of members of the public in normal circumstances from practices subject to licensing shall include, for relevant facilities, the following:
  - (a) examination and approval of the proposed siting of the facility from a radiation protection point of view, taking into account relevant demographic, meteorological, geological, hydrological and ecological conditions;
  - (b) acceptance into service of the facility subject to adequate protection being provided against any exposure or radioactive contamination liable to extend beyond the perimeter of the facility or radioactive contamination liable to extend to the ground beneath the facility;
  - (c) examination and approval of plans for the discharge of radioactive effluents;
  - (d) measures to control the access of members of the public to the facility.

2. The competent authority shall where appropriate establish authorised limits as part of the discharge authorisation and conditions for discharging radioactive effluents which shall:
  - (a) take into account the results of the optimisation of radiation protection;
  - (b) reflect good practice in the operation of similar facilities.

In addition, these discharge authorisations shall take into account, where appropriate, the results of a generic screening assessment based on internationally recognised scientific guidance, where such an assessment has been required by the Member State, to demonstrate that environmental criteria for long-term human health protection are met.

3. For practices subject to registration, Member States shall ensure the protection of members of the public in normal circumstances through appropriate national regulations and guidance.

*Article 66 [66]*

*Estimation of doses to the members of the public*

1. Member States shall ensure that arrangements are made for the estimation of doses to members of the public from authorised practices. The extent of such arrangements shall be proportionate to the exposure risk involved.

2. Member States shall ensure the identification of practices for which an assessment of doses to members of the public shall be carried out. Member States shall specify those practices for which this assessment needs to be carried out in a realistic way and those for which a screening assessment is sufficient.
3. For the realistic assessment of doses to the members of the public, the competent authority shall:
  - (a) decide on a reasonable extent of surveys to be conducted and information to be taken into account in order to identify the representative person, taking into account the effective pathways for transmission of the radioactive substances;
  - (b) decide on a reasonable frequency of monitoring of the relevant parameters as determined in (a);
  - (c) ensure that the estimates of doses to the representative person include:
    - i) assessment of the doses due to external radiation, indicating, where appropriate, the type of the radiation in question;
    - ii) assessment of the intake of radionuclides, indicating the nature of the radionuclides and, where necessary, their physical and chemical states, and determination of the activity concentrations of these radionuclides in food and drinking water or other relevant environmental media;
    - iii) assessment of the doses that the representative person, as identified in (a), is liable to receive;
  - (d) require records to be kept and be made available on request to all stakeholders relating to measurements of external exposure and contamination, estimates of intakes of radionuclides, and the results of the assessment of the doses received by the representative person.

*Article 67 [67]*

*Monitoring of radioactive discharges*

1. Member States shall require the undertaking responsible for practices where a discharge authorisation is granted to monitor appropriately or where appropriate evaluate the radioactive airborne or liquid discharges into the environment in normal operation and to report the results to the competent authority.
2. Member States shall require any undertaking responsible for a nuclear power reactor or reprocessing plant to monitor radioactive discharges and report them in accordance with standardised information.

*Article 68 [68]*

*Tasks for the undertakings*

Member States shall require the undertaking to carry out the following tasks:

- (a) achieve and maintain an optimal level of protection of members of the public;
- (b) accept into service adequate equipment and procedures for measuring and assessing exposure of members of the public and radioactive contamination of the environment;
- (c) check the effectiveness and maintenance of equipment as referred to in (b) and ensure the regular calibration of measuring instruments;
- (d) seek advice from a radiation protection experts in the performance of the tasks referred to in (a), (b) and (c).

## SECTION 2

### EMERGENCY EXPOSURE SITUATIONS

#### *Article 70 [69]*

#### *Emergency response*

1. Member States shall require the undertaking to notify the competent authority immediately of any emergency in relation to the practices for which it is responsible and to take all appropriate action to reduce the consequences.
2. Member States shall ensure that, in the event of an emergency on their territory, the undertaking concerned makes an initial provisional assessment of the circumstances and consequences of the emergency and assists with protective measures.
3. Member States shall ensure that provision is made for protective measures with regard to:
  - (a) the radiation source, to reduce or stop the radiation, including the release of radionuclides;
  - (b) the environment, to reduce the exposure to individuals resulting from radioactive substances through relevant pathways;
  - (c) individuals, to reduce their exposure.
4. In the event of an emergency on or outside its territory, the Member State shall require:
  - (a) the organisation of appropriate protective measures, taking account of the real characteristics of the emergency and in accordance with the optimised protection strategy as part of the emergency response plan, whereby the elements to be included in an emergency response plan are indicated in Section B of Annex IX;
  - (b) the assessment and recording of the consequences of the emergency and of the effectiveness of the protective measures.

5. The Member State shall, if the situation so requires, ensure that provision is made to organise the medical treatment of those affected.

*Article 71 [70]*

*Information to the members of the public likely to be affected in the event of an emergency*

1. Member States shall ensure that the members of the public likely to be affected in the event of an emergency are given information about the health protection measures applicable to them and about the action they should take in the event of such an emergency.
2. The information supplied shall include at least the elements set out in Section A of Annex X.
3. The information shall be communicated to the members of the public referred to in paragraph 1 without any request being made.
4. Member States shall ensure that the information is updated and distributed at regular intervals and whenever significant changes take place. This information shall be permanently available to the public.

*Article 72 [71]*

*Information to the members of the public actually affected in the event of an emergency*

1. Member States shall ensure that, when an emergency occurs, the members of the public actually affected are informed without delay about the facts of the emergency, the steps to be taken and, as appropriate, the health protection measures applicable to these members of the public.
2. The information provided shall cover those points listed in Section B of Annex X which are relevant to the type of emergency.

### **SECTION 3**

#### **EXISTING EXPOSURE SITUATION**

*Article 72A [72] Environmental  
monitoring programme*

Member States shall ensure that an appropriate environmental monitoring programme is in place.

*Article 73 [73]  
Contaminated areas*

1. Member States shall ensure that optimised protection strategies for managing contaminated areas shall include, where applicable, the following:
  - (a) objectives, including long-term goals pursued by the strategy and corresponding reference levels, in accordance with Article 8.
  - (b) delineation of the affected areas and identification of the affected members of the public;
  - (c) consideration of the need for and extent of protective measures to be applied to the affected areas and members of the public;
  - (d) consideration of the need to prevent or control access to the affected areas, or to impose restrictions on living conditions in these areas;
  - (e) assessment of the exposure of different groups in the population and assessment of the means available to individuals for controlling their own exposure.



2. For areas with long-lasting residual contamination in which the Member State has decided to allow habitation and the resumption of social and economic activities, Member States shall ensure, in consultation with stakeholders, that arrangements are in place, as necessary, for the ongoing control of exposure with the aim of establishing living conditions that can be considered as normal, including:
  - (a) establishment of appropriate reference levels;
  - (b) establishment of an infrastructure to support continuing self-help protective measures in the affected areas, such as information provision, advice and monitoring;
  - (c) if appropriate, remediation measures;
  - (d) if appropriate, delineated areas.

*Article 74 [74] Indoor  
exposure to radon*

1. Member States shall establish national reference levels for indoor radon concentrations. The reference levels for the annual average activity concentration in air shall not be higher than 300 Bq m<sup>-3</sup>.
2. Under the national action plan referred to in Article 103, Member States shall promote action to identify dwellings, with radon concentrations (as an annual average) exceeding the reference level and encourage, where appropriate, by technical or <sup>62</sup>other means, radon concentration-reducing measures in these dwellings.
3. Member States shall ensure that local and national information is made available on indoor radon exposure and the associated health risks, on the importance of performing radon measurements and on the technical means available for reducing existing radon concentrations.

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<sup>62</sup> Following consultation with CLS it has been concluded that limiting the means to “technical or financial” could unintentionally exclude other possibilities such as local regulations, guidance and other forms of incentives

*Article 75 [75]*

*Gamma radiation from building materials*

1. The reference level applying to indoor external exposure to gamma radiation emitted by building materials, in addition to outdoor external exposure, shall be 1 mSv per year.
2. For building materials which are identified <sup>63</sup> by the Member State as being of concern from a radiation protection point of view, taking into account the indicative list of materials set out in Annex XI with regard to their emitted gamma radiation, Member States shall ensure that, before such materials are placed on the market:
  - a) the activity concentrations of the radionuclides specified in Annex VII are determined, and that,
  - b) information to the competent authority on the results of measurements and the corresponding activity concentration index, as well as other relevant factors, as defined in Annex VII, are provided if requested.
3. For types of building materials identified in accordance with paragraph 2 which are liable to give doses exceeding the reference level, Member States shall decide on appropriate measures, which may include specific requirements in relevant building codes or restrictions on the envisaged use of such materials.

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<sup>63</sup> Agreed at AQ 15 May

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

**SECTION 1**  
**INSTITUTIONAL INFRASTRUCTURE**

*Article 80 [76]*

*Competent authority*

1. Member States shall designate a competent authority to carry out tasks in accordance with this Directive.
  - (a) Member States shall ensure that the competent authority 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) Member States shall ensure that the competent authority 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 80a [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 made available to undertakings, workers, members of the public, as well as patients and other individuals subject to medical exposures. This obligation includes ensuring that the competent authority informs 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 80b[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 81 [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 82 [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 83 [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 84 [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.
- <sup>64</sup>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 85 [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 Article 23(4)(c) of this Directive.

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<sup>64</sup> Change proposed at AQ 15 May

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 subjected 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 86 [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.

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 86a [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 87 [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.

*Article 88 [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 89 [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 90 [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 XII 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 91 [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 92 [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 XIV.
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 XV.

## SECTION 3 ORPHAN SOURCES

### *Article 93 [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 <sup>65</sup> 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 where orphan sources may generally be encountered, or at significant nodal transit points, wherever appropriate.

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<sup>65</sup> Agreed at AQ 15 May

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.

<sup>66</sup>*Article 94 [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 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.

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<sup>66</sup> Reordering and text amendments agreed at AQ 15 May



*Article 95 [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 96 [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 95.

**SECTION 3a**

**SIGNIFICANT EVENTS**

*Article 92a [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 4 EMERGENCY EXPOSURE SITUATIONS

### *Article 97 [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 IX.
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 [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.
2. The emergency response plans shall include the elements defined in Section B of Annex IX.
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 [99]*

*International cooperation*

1. Member States shall cooperate with other Member States and third countries in addressing possible emergencies on their own territory which may affect other Member States or third countries, in order to facilitate the organisation of radiological protection in these Member States or third countries.
2. Member States shall, in the event of an emergency occurring on their territory or likely to have radiological consequences on their 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. Member States shall promptly exchange information and cooperate with other relevant Member States, 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. Member States shall, where appropriate, cooperate with other Member States and third countries in the transition from an emergency exposure situation to an existing exposure situation.

## **SECTION 5**

### **EXISTING EXPOSURE SITUATIONS**

#### *Article 100 [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 situations listed in Annex XVa, 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 25b(2).

*Article 101 [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 [102]*  
*Implementation of strategies*

1. Member States shall assign responsibilities for the implementation of strategies for the management of existing exposures 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.

*Article 103 [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 XVI 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 6**

### **SYSTEM OF ENFORCEMENT**

#### *Article 104 [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.
- <sup>67</sup>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.

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<sup>67</sup> Agreed at AQ 15 May

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 [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.



## **CHAPTER X FINAL PROVISIONS**

### *Article 107 [106]*

#### *Transposition*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 00.00.0000 at the latest 4 years after adoption of the Directive depending on the final text.
2. When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.
3. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

*Article 108 [107]*

*Repeal*

Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom, and 2003/122/Euratom shall be repealed with effect from 00.00.0000.

References to the repealed Directives shall be construed as references to this Directive.

*Article 109 [108]*

*Entry into force*

The Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

*Article 110 [109]*

*Addressees*

This Directive is addressed to the Member States.

## ANNEX I

### *Reference levels for public exposure as referred to in Articles 8 and 101*

1. Without prejudice to reference levels set for equivalent doses, reference levels expressed in effective doses shall be set in the range of 1 to 20 mSv per year for existing exposure situations and 20 to 100 mSv (acute or annual) for emergency exposure situations.
2. In specific situations, a reference level below ranges referred to in point 1 may be considered, in particular:
  - (a) a reference level below 20 mSv may be set in an emergency exposure situation where appropriate protection can be provided without causing a disproportionate detriment from the corresponding countermeasures or an excessive cost;
  - (b) a reference level below 1 mSv per year may be set, where appropriate, in an existing exposure situation for specific source-related exposures or pathways of exposure.
3. For the transition from an emergency exposure situation to an existing exposure situation, appropriate reference levels shall be set, in particular upon the termination of long-term countermeasures such as relocation.
4. The reference levels set shall take account of the features of prevailing situations as well as societal criteria, which may include the following:
  - (a) for exposures below or equal to 1 mSv per year, general information on the level of exposure, without specific consideration of individual exposures;
  - (b) in the range up to or equal to 20 mSv per year, specific information to enable individuals to manage their own exposure, if possible;
  - (c) in the range up to or equal to 100 mSv per year, assessment of individual doses and specific information on radiation risks and on available actions to reduce exposures.

## ANNEX Ia [II]

*Radiation and tissue weighting factors as referred to in Article 4(26), 4(34)*

### A. Radiation weighting factors

Radiation type	$w_R$
Photons	1
Electrons and muons	1
Protons and charged pions	2
Alpha particles, fission fragments, heavy ions	20
Neutrons, $E_n < 1$ MeV	$2.5 + 18.2 e^{-[\ln(E_n)]^2/6}$
Neutrons, $1 \text{ MeV} \leq E_n \leq 50 \text{ MeV}$	$5.0 + 17.0 e^{-[\ln(2 E_n)]^2/6}$
Neutrons, $E_n > 50 \text{ MeV}$	$2.5 + 3.25 e^{-[\ln(0.04 E_n)]^2/6}$

Note: All values relate to the radiation incident on the body or, for internal radiation sources, emitted from the incorporated radionuclide(s).

### B. Tissue weighting factors

Tissue	$w_T$
Bone-marrow (red)	0.12
Colon	0.12
Lung	0.12
Stomach	0.12

Breast	0.12
Remainder tissues*	0.12
Gonads	0.08
Bladder	0.04
Oesophagus	0.04
Liver	0.04
Thyroid	0.04
Bone surface	0.01
Brain	0.01
Salivary glands	0.01
Skin	0.01

\* The  $w_T$  for the remainder tissues (0.12) applies to the arithmetic mean dose of the 13 organs and tissues for each sex listed below. Remainder tissues: adrenals, extrathoracic (ET) region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate (male), small intestine, spleen, thymus, uterus/cervix (female).

## ANNEX II [III]

*Activity values defining high-activity sealed sources as referred to in Article 4(44)*

For radionuclides not listed in the table below, the relevant activity is identical to the D-value defined in the IAEA publication 'Dangerous quantities of radioactive material (D-values)', <sup>68</sup>(EPR-D-VALUES 2006).

Radionuclide	Activity (TBq)
Am-241	$6 \times 10^{-2}$
Am-241/Be-9 <sup>69</sup>	$6 \times 10^{-2}$
Cf-252	$2 \times 10^{-2}$
Cm-244	$5 \times 10^{-2}$
Co-60	$3 \times 10^{-2}$
Cs-137	$1 \times 10^{-1}$
Gd-153	$1 \times 10^0$
Ir-192	$8 \times 10^{-2}$
Pm-147	$4 \times 10^1$
Pu-238	$6 \times 10^{-2}$
Pu-239/Be-9 <sup>70</sup>	$6 \times 10^{-2}$
Ra-226	$4 \times 10^{-2}$
Se-75	$2 \times 10^{-1}$
Sr-90 (Y-90)	$1 \times 10^0$
Tm-170	$2 \times 10^1$
Yb-169	$3 \times 10^{-1}$

<sup>68</sup> Consideration to be given to changing the reference to IBSS

<sup>69</sup> The activity given is that of the alpha-emitting radionuclide

<sup>70</sup> The activity given is that of the alpha-emitting radionuclide

## ANNEX III [IV]

### *Justification of new classes or types of practices involving consumer products as referred to in Article 21*

- A. Any undertaking intending to manufacture or import into a Member State consumer products for which the intended use is likely to lead to a new class or type of practice, shall provide the competent authority of this Member State with all relevant information, as to the:
- (1) intended use of the product;
  - (2) technical characteristics of the product;
  - (3) in the case of products containing radioactive substances, information as to their means of fixation;
  - (4) dose rates at relevant distances for the use of the product, including dose rates at a distance of 0.1 m from any accessible surface;
  - (5) expected doses to regular users of the product.
- B. The competent authority shall examine this information and in particular assess whether:
- (1) the performance of the product justifies its intended use;
  - (2) the design is adequate in order to minimise exposures in normal use and the likelihood and consequences of misuse or accidental exposures, or whether there should be conditions imposed on the technical and physical characteristics of the product;
  - (3) the product is adequately designed to meet the exemption criteria, and, where applicable, is of an approved type and does not necessitate specific precautions for disposal when no longer in use;
  - (4) the product is appropriately labelled and suitable documentation is provided to the consumer with instructions for proper use and disposal.

## ANNEX IV [V]

### *Indicative list of practices involving non-medical imaging exposure as referred to in Article 23*

#### Practices using medical radiological equipment:

1. Radiological health assessment for employment purposes;
2. Radiological health assessment for immigration purposes;
3. Radiological health assessment for insurance purposes;
4. Radiological evaluation of the physical development of children and adolescents with a view to a career in sports, dancing, etc;
5. Radiological age assessment;
6. Use of ionising radiation for the identification of concealed objects within the human body.

#### Practices not using medical radiological equipment:

1. Use of ionising radiation for detection of concealed objects on or attached to the human body;
2. Use of ionising radiation for detection of concealed humans as part of cargo screening;
3. Practices involving the use of ionising radiation for legal or security purposes.



## ANNEX V [VI]

*List of industrial sectors involving naturally-occurring radioactive material as referred to in Article*

24

When applying Article 24 the following list of industrial sectors involving naturally-occurring radioactive material, including research and relevant secondary processes, shall be taken into account:

- Extraction of rare earths from monazite
- Production of thorium compounds and manufacture of thorium-containing products
- Processing of niobium/tantalum ore
- Oil and gas production
- Geothermal energy production
- TiO<sub>2</sub> pigment production
- Thermal phosphorus production
- Zircon and zirconium industry
- Production of phosphate fertilisers
- Cement production, maintenance of clinker ovens
- Coal-fired power plants, maintenance of boilers
- Phosphoric acid production,
- Primary iron production,
- Tin/lead/copper smelting,
- Ground water filtration facilities,
- Mining of ores other than uranium ore.

## ANNEX VI [VII]

### *Exemption and clearance criteria as referred to in Articles 25a, 25c and 29*

#### 1. Exemption

Practices may be exempted from notification either directly, on the basis of compliance with exemption levels (activity values (in Bq) or activity concentration values (in kBq kg<sup>-1</sup>)) laid down in section 2, or on the basis of higher values that, for specific applications, are established by the competent authority, satisfying the general exemption and clearance criteria set out in section 3. Practices subject to notification may be exempted from authorisation by law or general administrative act, or through an ad-hoc regulatory decision, on the basis of the information provided in conjunction with the notification of the practice and in line with general exemption criteria set out in section 3.

#### 2. Exemption and clearance levels

The total activity values (in Bq) for exemption apply to the total activity involved in a practice and are laid down in column 3 of Table B for artificial radionuclides and for some naturally-occurring radionuclides used in consumer products. For other practices involving naturally-occurring radionuclides, such values are, in general, not applicable.

The exempt activity concentration values (in kBq kg<sup>-1</sup>) for the materials involved in the practice are laid down in Table A, Part 1, for artificial radionuclides, and in Table A, Part 2, for naturally-occurring radionuclides. The values in Table A, Part 1, are given for individual radionuclides, where applicable, including short-lived radionuclides in equilibrium with the parent nuclide, as indicated. The values in Table A, Part 2, apply to all radionuclides in the decay chain of U-238 or Th-232, but for segments of the decay chain, which are not in equilibrium with the parent radionuclide, higher values may be applied.

The concentration values in Table A, Part 1, or in Table A, Part 2, also apply to the clearance of solid materials for reuse, recycling, conventional disposal or incineration. Higher values may be defined for specific materials or specific pathways, taking Community guidance into account, including, where appropriate, additional requirements, in terms of surface activity or monitoring requirements.

For mixtures of artificial radionuclides, the weighted sum of nuclide-specific activities or concentrations (for various radionuclides contained in the same matrix) divided by the corresponding exemption value shall be less than unity. Where appropriate, this condition can be verified on the basis of best estimates of the composition of the radionuclide mix. The values in Table A, Part 2, apply individually to each parent nuclide. Some elements in the decay chain, e.g. Po-210 or Pb-210, may warrant the use of higher values taking Community guidance into account.

The values in Table A, Part 2, may not be used to exempt the incorporation into building materials of residues from industries processing naturally-occurring radioactive material. For this purpose, compliance with the provisions of Article 75 shall be verified. The values laid down in Table B, column 3, apply to the total inventory of radioactive substances held by a person or undertaking as part of a specific practice at any point in time. However, the competent authority may apply these values to smaller entities or packages, for instance to exempt the transport or storage of exempted consumer products, if the general exemption criteria in section 3 are satisfied.

### 3. General exemption and clearance criteria

The general criteria for the exemption of practices from notification or authorisation or for the clearance of materials from authorised practices are as follows:

- (a) the radiological risks to individuals caused by the practice are sufficiently low, as to be of no regulatory concern; and
- (b) the type of practice has been determined to be justified; and
- (c) the practice is inherently safe.

Practices involving small amounts of radioactive substances or low activity concentrations, comparable to the exemption values laid down in Table A or Table B are deemed to fulfil criterion (c).

Practices involving amounts of radioactive substances or activity concentrations below the exemption values laid down in Table A, Part 1, or Table B, are deemed to comply with criterion (a) without further consideration. This is also the case for the values in Table A, Part 2, with the exception of the recycling of residues in building materials or the case of specific exposure pathways, for instance, drinking water.

In the case of moderate amounts of material, as specified by Member States for specific types of practice, the activity concentration values laid down in Table B, column 2, may be used instead of the values laid down in Table A, Part 1, for the purpose of exemption from authorisation.

For the purpose of exemption from notification or for the purpose of clearance, where amounts of radioactive substances or activity concentrations do not comply with the values laid down in Table A or Table B, an assessment shall be made in the light of the general criteria (a) to (c) above. For compliance with the general criterion (a), it shall be demonstrated that workers should not be classified as exposed workers, and the following criteria for the exposure of members of the public are met in all feasible circumstances:

- For artificial radionuclides:

The effective dose expected to be incurred by a member of the public due to the exempted practice is of the order of 10  $\mu$ Sv or less in a year.

- For naturally-occurring radionuclides:

The dose increment, allowing for the prevailing background radiation from natural radiation sources, liable to be incurred by an individual due to the exempted practice is of the order of 1 mSv or less in a year. The assessment of doses to members of the public shall take into account not only pathways of exposure through airborne or liquid effluent, but also pathways resulting from the disposal or recycling of solid residues. Member States may specify dose criteria lower than 1 mSv per year for specific types of practices or specific pathways of exposure.

For the purpose of exemption from authorisation, less restrictive dose criteria may be applied.

TABLE A:

Activity concentration values for exemption or clearance of materials which can be applied by default to any amount and to any type of solid material.

TABLE A Part 1: Artificial radionuclides

Activity Radionuclide concentration (kBq kg <sup>-1</sup> )		Activity Radionuclide concentration (kBq kg <sup>-1</sup> )		Activity Radionuclide concentration (kBq kg <sup>-1</sup> )	
H-3	100	Sc-48	1	Co-60m	1000
Be-7	10	V-48	1	Co-61	100
C-14	1	Cr-51	100	Co-62m	10
F-18	10	Mn-51	10	Ni-59	100
Na-22	0.1	Mn-52	1	Ni-63	100
Na-24	1	Mn-52m	10	Ni-65	10
Si-31	1000	Mn-53	100	Cu-64	100
P-32	1000	Mn-54	0.1	Zn-65	0.1
P-33	1000	Mn-56	10	Zn-69	1000
S-35	100	Fe-52 <sup>a</sup>	10	Zn-69m <sup>a</sup>	10
Cl-36	1	Fe-55	1000	Ga-72	10
Cl-38	10	Fe-59	1	Ge-71	10000
K-42	100	Co-55	10	As-73	1000
K-43	10	Co-56	0.1	As-74	10
Ca-45	100	Co-57	1	As-76	10
Ca-47	10	Co-58	1	As-77	1000
Sc-46	0.1	Co-58m	10000	Se-75	1
Sc-47	100	Co-60	0.1	Br-82	1

Activity Radionuclide concentration (kBq kg <sup>-1</sup> )		Activity Radionuclide concentration (kBq kg <sup>-1</sup> )		Activity Radionuclide concentration (kBq kg <sup>-1</sup> )	
Rb-86	100	Nb-95	1	Rh-105	100
Sr-85	1	Nb-97 <sup>a</sup>	10	Pd-103 <sup>a</sup>	1000
Sr-85m	100	Nb-98	10	Pd-109 <sup>a</sup>	100
Sr-87m	100	Mo-90	10	Ag-105	1
Sr-89	1000	Mo-93	10	Ag-110m <sup>a</sup>	0.1
Sr-90a	1	Mo-99a	10	Ag-111	100
Sr-91a	10	Mo-101 <sup>a</sup>	10	Cd-109 <sup>a</sup>	1
Sr-92	10	Tc-96	1	Cd-115 <sup>a</sup>	10
Y-90	1000	Tc-96m	1000	Cd-115m <sup>a</sup>	100
Y-91	100	Tc-97	10	In-111	10
Y-91m	100	Tc-97m	100	In-113m	100
Y-92	100	Tc-99	1	In-114m <sup>a</sup>	10
Y-93	100	Tc-99m	100	In-115m	100
Zr-93	10	Ru-97	10	Sn-113 <sup>a</sup>	1
Zr-95 <sup>a</sup>	1	Ru-103 <sup>a</sup>	1	Sn-125	10
Zr-97 <sup>a</sup>	10	Ru-105 <sup>a</sup>	10	Sb-122	10
Nb-93m	10	Ru-106 <sup>a</sup>	0.1	Sb-124	1
Nb-94	0.1	Rh-103m	10000	Sb-125 <sup>a</sup>	0.1

Activity Radionuclide concentration (kBq kg <sup>-1</sup> )		Activity Radionuclide concentration (kBq kg <sup>-1</sup> )		Activity Radionuclide concentration (kBq kg <sup>-1</sup> )	
Te-123m	1	I-132	10	Ce-143	10
Te-125m	1000	I-133	10	Ce-144	10
Te-127	1000	I-134	10	Pr-142	100
Te-127m <sup>a</sup>	10	I-135	10	Pr-143	1000
Te-129	100	Cs-129	10	Nd-147	100
Te-129m <sup>a</sup>	10	Cs-131	1000	Nd-149	100
Te-131	100	Cs-132	10	Pm-147	1000
Te-131m <sup>a</sup>	10	Cs-134	0.1	Pm-149	1000
Te-132 <sup>a</sup>	1	Cs-134m	1000	Sm-151	1000
Te-133	10	Cs-135	100	Sm-153	100
Te-133m	10	Cs-136	1	Eu-152	0.1
Te-134	10	Cs-137 <sup>a</sup>	0.1	Eu-152m	100
I-123	100	Cs-138	10	Eu-154	0.1
I-125	100	Ba-131	10	Eu-155	1
I-126	10	Ba-140	1	Gd-153	10
I-129	0.01	La-140	1	Gd-159	100
I-130	10	Ce-139	1	Tb-160	1
I-131	10	Ce-141	100	Dy-165	1000



Activity Radionuclide concentration (kBq kg <sup>-1</sup> )		Activity Radionuclide concentration (kBq kg <sup>-1</sup> )		Activity Radionuclide concentration (kBq kg <sup>-1</sup> )	
Dy-166	100	Os-193	100	Bi-206	1
Ho-166	100	Ir-190	1	Bi-207	0.1
Er-169	1000	Ir-192	1	Po-203	10
Er-171	100	Ir-194	100	Po-205	10
Tm-170	100	Pt-191	10	Po-207	10
Tm-171	1000	Pt-193m	1000	At-211	1000
Yb-175	100	Pt-197	1000	Ra-225	10
Lu-177	100	Pt-197m	100	Ra-227	100
Hf-181	1	Au-198	10	Th-226	1000
Ta-182	0.1	Au-199	100	Th-229	0.1
W-181	10	Hg-197	100	Pa-230	10
W-185	1000	Hg-197m	100	Pa-233	10
W-187	10	Hg-203	10	U-230	10
Re-186	1000	Tl-200	10	U-231 <sup>a</sup>	100
Re-188	100	Tl-201	100	U-232 <sup>a</sup>	0.1
Os-185	1	Tl-202	10	U-233	1
Os-191	100	Tl-204	1	U-236	10
Os-191m	1000	Pb-203	10	U-237	100

Activity Radionuclide concentration (kBq kg <sup>-1</sup> )		Activity Radionuclide concentration (kBq kg <sup>-1</sup> )		Activity Radionuclide concentration (kBq kg <sup>-1</sup> )	
U-239	100	Am-242m <sup>a</sup>	0.1	Es-253	100
U-240 <sup>a</sup>	100	Am-243 <sup>a</sup>	0.1	Es-254 <sup>a</sup>	0.1
Np-237 <sup>a</sup>	1	Cm-242	10	Es-254m <sup>a</sup>	10
Np-239	100	Cm-243	1	Fm-254	10000
Np-240	10	Cm-244	1	Fm-255	100
Pu-234	100	Cm-245	0.1		
Pu-235	100	Cm-246	0.1		
Pu-236	1	Cm-247 <sup>a</sup>	0.1		
Pu-237	100	Cm-248	0.1		
Pu-238	0.1	Bk-249	100		
Pu-239	0.1	Cf-246	1000		
Pu-240	0.1	Cf-248	1		
Pu-241	10	Cf-249	0.1		
Pu-242	0.1	Cf-250	1		
Pu-243	1000	Cf-251	0.1		
Pu-244 <sup>a</sup>	0.1	Cf-252	1		
Am-241	0.1	Cf-253	100		
Am-242	1000	Cf-254	1		

a Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculation (thus requiring only the exemption level of the parent radionuclide to be considered), are listed in the following table:

Parent radionuclide	Progeny
Fe-52	Mn-52m
Zn-69m	Zn-69
Sr-90	Y-90
Sr-91	Y-91m
Zr-95	Nb-95
Zr-97	Nb-97m, Nb-97
Nb-97	Nb-97m
Mo-99	Tc-99m
Mo-101	Tc-101
Ru-103	Rh-103m
Ru-105	Rh-105m
Ru-106	Rh-106
Pd-103	Rh-103m
Pd-109	Ag-109m
Ag-110m	Ag-110
Cd-109	Ag-109m
Cd-115	In-115m
Cd-115m	In-115m
In-114m	In-114
Sn-113	In-113m

Parent radionuclide	Progeny
Sb-125	Te-125m
Te-127m	Te-127
Te-129m	Te-129
Te-131m	Te-131
Te-132	I-132
Cs-137	Ba-137m
Ce-144	Pr-144, Pr-144m
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208
U-240	Np-240m, Np-240
Np-237	Pa-233
Pu-244	U-240, Np-240m, Np-240
Am-242m	Np-238
Am-243	Np-239
Cm-247	Pu-243
Es-254	Bk-250
Es-254m	Fm-254

For radionuclides not listed in Table A, Part 1 the competent authority shall assign appropriate values for the quantities and concentrations of activity per unit mass where the need arises. Values thus assigned shall be complementary to those in Table A, Part 1.

**TABLE A Part 2: naturally occurring radionuclides**

Values for exemption or clearance for naturally occurring radionuclides in solid materials in secular equilibrium with their progeny:

Natural radionuclides from the U-238 series	1 kBq kg <sup>-1</sup>
Natural radionuclides from the Th-232 series	1 kBq kg <sup>-1</sup>
K-40	10 kBq kg <sup>-1</sup>

**TABLE B:**

**Total activity values for exemption (column 3) and exemption values for the activity concentration in moderate amounts of any type of material (column 2).**

Radionuclide	Activity concentration (kBq kg <sup>-1</sup> )	Activity (Bq)	Radionuclide	Activity concentration (kBq kg <sup>-1</sup> )	Activity (Bq)
H-3	1 × 10 <sup>6</sup>	1 × 10 <sup>9</sup>	Mn-51	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
Be-7	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>	Mn-52	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
C-14	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>	Mn-52m	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
O-15	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>	Mn-53	1 × 10 <sup>4</sup>	1 × 10 <sup>9</sup>
F-18	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Mn-54	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Na-22	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Mn-56	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
Na-24	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Fe-52	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Si-31	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Fe-55	1 × 10 <sup>4</sup>	1 × 10 <sup>6</sup>
P-32	1 × 10 <sup>3</sup>	1 × 10 <sup>5</sup>	Fe-59	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
P-33	1 × 10 <sup>5</sup>	1 × 10 <sup>8</sup>	Co-55	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
S-35	1 × 10 <sup>5</sup>	1 × 10 <sup>8</sup>	Co-56	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
Cl-36	1 × 10 <sup>4</sup>	1 × 10 <sup>6</sup>	Co-57	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Cl-38	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Co-58	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Ar-37	1 × 10 <sup>6</sup>	1 × 10 <sup>8</sup>	Co-58m	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>
Ar-41	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>	Co-60	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
K-40 <sup>71</sup>	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Co-60m	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
K-42	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Co-61	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
K-43	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Co-62m	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
Ca-45	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>	Ni-59	1 × 10 <sup>4</sup>	1 × 10 <sup>8</sup>
Ca-47	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Ni-63	1 × 10 <sup>5</sup>	1 × 10 <sup>8</sup>
Sc-46	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Ni-65	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Sc-47	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Cu-64	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Sc-48	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Zn-65	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
V-48	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Zn-69	1 × 10 <sup>4</sup>	1 × 10 <sup>6</sup>
Cr-51	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>	Zn-69m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
			Ga-72	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
			Ge-71	1 × 10 <sup>4</sup>	1 × 10 <sup>8</sup>

<sup>71</sup> Potassium salts in quantities less than 1000 kg are exempted.

Radionuclide	Activity concentration (kBq kg <sup>-1</sup> )	Activity (Bq)	Radionuclide	Activity concentration (kBq kg <sup>-1</sup> )	Activity (Bq)
As-73	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>	Y-92	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
As-74	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Y-93	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
As-76	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	Zr-93 <sup>b</sup>	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
As-77	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Zr-95	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Se-75	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Zr-97 <sup>b</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
Br-82	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Nb-93m	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>
Kr-74	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>	Nb-94	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Kr-76	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>	Nb-95	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Kr-77	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>	Nb-97	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Kr-79	1 × 10 <sup>3</sup>	1 × 10 <sup>5</sup>	Nb-98	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
Kr-81	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>	Mo-90	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Kr-83m	1 × 10 <sup>5</sup>	1 × 10 <sup>12</sup>	Mo-93	1 × 10 <sup>3</sup>	1 × 10 <sup>8</sup>
Kr-85	1 × 10 <sup>5</sup>	1 × 10 <sup>4</sup>	Mo-99	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Kr-85m	1 × 10 <sup>3</sup>	1 × 10 <sup>10</sup>	Mo-101	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Kr-87	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>	Tc-96	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Kr-88	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>	Tc-96m	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Rb-86	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	Tc-97	1 × 10 <sup>3</sup>	1 × 10 <sup>8</sup>
Sr-85	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Tc-97m	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Sr-85m	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>	Tc-99	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>
Sr-87m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Tc-99m	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Sr-89	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Ru-97	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Sr-90 <sup>b</sup>	1 × 10 <sup>2</sup>	1 × 10 <sup>4</sup>	Ru-103	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Sr-91	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Ru-105	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Sr-92	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Ru-106 <sup>b</sup>	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Y-90	1 × 10 <sup>3</sup>	1 × 10 <sup>5</sup>	Rh-103m	1 × 10 <sup>4</sup>	1 × 10 <sup>8</sup>
Y-91	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Rh-105	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Y-91m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Pd-103	1 × 10 <sup>3</sup>	1 × 10 <sup>8</sup>

Radionuclide	Activity concentration (kBq kg <sup>-1</sup> )	Activity (Bq)	Radionuclide	Activity concentration (kBq kg <sup>-1</sup> )	Activity (Bq)
Pd-109	$1 \times 10^3$	$1 \times 10^6$	Te-133m	$1 \times 10^1$	$1 \times 10^5$
Ag-105	$1 \times 10^2$	$1 \times 10^6$	Te-134	$1 \times 10^1$	$1 \times 10^6$
Ag-108m	$1 \times 10^1$	$1 \times 10^6$	I-123	$1 \times 10^2$	$1 \times 10^7$
Ag-110m	$1 \times 10^1$	$1 \times 10^6$	I-125	$1 \times 10^3$	$1 \times 10^6$
Ag-111	$1 \times 10^3$	$1 \times 10^6$	I-126	$1 \times 10^2$	$1 \times 10^6$
Cd-109	$1 \times 10^4$	$1 \times 10^6$	I-129	$1 \times 10^2$	$1 \times 10^5$
Cd-115	$1 \times 10^2$	$1 \times 10^6$	I-130	$1 \times 10^1$	$1 \times 10^6$
Cd-115m	$1 \times 10^3$	$1 \times 10^6$	I-131	$1 \times 10^2$	$1 \times 10^6$
In-111	$1 \times 10^2$	$1 \times 10^6$	I-132	$1 \times 10^1$	$1 \times 10^5$
In-113m	$1 \times 10^2$	$1 \times 10^6$	I-133	$1 \times 10^1$	$1 \times 10^6$
In-114m	$1 \times 10^2$	$1 \times 10^6$	I-134	$1 \times 10^1$	$1 \times 10^5$
In-115m	$1 \times 10^2$	$1 \times 10^6$	I-135	$1 \times 10^1$	$1 \times 10^6$
Sn-113	$1 \times 10^3$	$1 \times 10^7$	Xe-131m	$1 \times 10^4$	$1 \times 10^4$
Sn-125	$1 \times 10^2$	$1 \times 10^5$	Xe-133	$1 \times 10^3$	$1 \times 10^4$
Sb-122	$1 \times 10^2$	$1 \times 10^4$	Xe-135	$1 \times 10^3$	$1 \times 10^{10}$
Sb-124	$1 \times 10^1$	$1 \times 10^6$	Cs-129	$1 \times 10^2$	$1 \times 10^5$
Sb-125	$1 \times 10^2$	$1 \times 10^6$	Cs-131	$1 \times 10^3$	$1 \times 10^6$
Te-123m	$1 \times 10^2$	$1 \times 10^7$	Cs-132	$1 \times 10^1$	$1 \times 10^5$
Te-125m	$1 \times 10^3$	$1 \times 10^7$	Cs-134m	$1 \times 10^3$	$1 \times 10^5$
Te-127	$1 \times 10^3$	$1 \times 10^6$	Cs-134	$1 \times 10^1$	$1 \times 10^4$
Te-127m	$1 \times 10^3$	$1 \times 10^7$	Cs-135	$1 \times 10^4$	$1 \times 10^7$
Te-129	$1 \times 10^2$	$1 \times 10^6$	Cs-136	$1 \times 10^1$	$1 \times 10^5$
Te-129m	$1 \times 10^3$	$1 \times 10^6$	Cs-137 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^4$
Te-131	$1 \times 10^2$	$1 \times 10^5$	Cs-138	$1 \times 10^1$	$1 \times 10^4$
Te-131m	$1 \times 10^1$	$1 \times 10^6$	Ba-131	$1 \times 10^2$	$1 \times 10^6$
Te-132	$1 \times 10^2$	$1 \times 10^7$	Ba-140 <sup>b</sup>	$1 \times 10^1$	$1 \times 10^5$
Te-133	$1 \times 10^1$	$1 \times 10^5$	La-140	$1 \times 10^1$	$1 \times 10^5$

Radionuclide	Activity concentration (kBq kg <sup>-1</sup> )	Activity (Bq)	Radionuclide	Activity concentration (kBq kg <sup>-1</sup> )	Activity (Bq)
Ce-139	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Lu-177	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Ce-141	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>	Hf-181	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Ce-143	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Ta-182	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Ce-144 <sup>b</sup>	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	W-181	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Pr-142	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	W-185	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>
Pr-143	1 × 10 <sup>4</sup>	1 × 10 <sup>6</sup>	W-187	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Nd-147	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Re-186	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Nd-149	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Re-188	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Pm-147	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>	Os-185	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Pm-149	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Os-191	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Sm-151	1 × 10 <sup>4</sup>	1 × 10 <sup>8</sup>	Os-191m	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Sm-153	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Os-193	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Eu-152	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Ir-190	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Eu-152m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Ir-192	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Eu-154	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Ir-194	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Eu-155	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>	Pt-191	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Gd-153	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>	Pt-193m	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Gd-159	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Pt-197	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Tb-160	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Pt-197m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Dy-165	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Au-198	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Dy-166	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Au-199	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Ho-166	1 × 10 <sup>3</sup>	1 × 10 <sup>5</sup>	Hg-197	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Er-169	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>	Hg-197m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Er-171	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Hg-203	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Tm-170	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Tl-200	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Tm-171	1 × 10 <sup>4</sup>	1 × 10 <sup>8</sup>	Tl-201	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Yb-175	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>	Tl-202	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>



Radionuclide	Activity concentration (kBq kg <sup>-1</sup> )	Activity (Bq)	Radionuclide	Activity concentration (kBq kg <sup>-1</sup> )	Activity (Bq)
Tl-204	1 × 10 <sup>4</sup>	1 × 10 <sup>4</sup>	Th-231	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Pb-203	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Th-234 <sup>b</sup>	1 × 10 <sup>3</sup>	1 × 10 <sup>5</sup>
Pb-210 <sup>b</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>	Pa-230	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Pb-212 <sup>b</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Pa-231	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Bi-206	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Pa-233	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Bi-207	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	U-230	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
Bi-210	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	U-231	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Bi-212 <sup>b</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	U-232 <sup>b</sup>	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Po-203	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	U-233	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Po-205	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	U-234	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Po-207	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	U-235 <sup>b</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Po-210	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>	U-236	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
At-211	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>	U-237	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Rn-220 <sup>b</sup>	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>	U-238 <sup>b</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Rn-222 <sup>b</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>8</sup>	U-239	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Ra-223 <sup>b</sup>	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	U-240	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Ra-224 <sup>b</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	U-240 <sup>b</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Ra-225	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	Np-237 <sup>b</sup>	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Ra-226 <sup>b</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>	Np-239	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Ra-227	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Np-240	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Ra-228 <sup>b</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Pu-234	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Ac-228	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Pu-235	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Th-226 <sup>b</sup>	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>	Pu-236	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Th-227	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>	Pu-237	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Th-228 <sup>b</sup>	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>	Pu-238	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>
Th-229 <sup>b</sup>	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>	Pu-239	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>
Th-230	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>	Pu-240	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>

Radionuclide	Activity concentration (kBq kg <sup>-1</sup> )	Activity (Bq)
Pu-241	$1 \times 10^2$	$1 \times 10^5$
Pu-242	$1 \times 10^0$	$1 \times 10^4$
Pu-243	$1 \times 10^3$	$1 \times 10^7$
Pu-244	$1 \times 10^0$	$1 \times 10^4$
Am-241	$1 \times 10^0$	$1 \times 10^4$
Am-242	$1 \times 10^3$	$1 \times 10^6$
Am-242m <sup>b</sup>	$1 \times 10^0$	$1 \times 10^4$
Am-243 <sup>b</sup>	$1 \times 10^0$	$1 \times 10^3$
Cm-242	$1 \times 10^2$	$1 \times 10^5$
Cm-243	$1 \times 10^0$	$1 \times 10^4$
Cm-244	$1 \times 10^1$	$1 \times 10^4$
Cm-245	$1 \times 10^0$	$1 \times 10^3$
Cm-246	$1 \times 10^0$	$1 \times 10^3$
Cm-247	$1 \times 10^0$	$1 \times 10^4$
Cm-248	$1 \times 10^0$	$1 \times 10^3$
Bk-249	$1 \times 10^3$	$1 \times 10^6$
Cf-246	$1 \times 10^3$	$1 \times 10^6$
Cf-248	$1 \times 10^1$	$1 \times 10^4$
Cf-249	$1 \times 10^0$	$1 \times 10^3$
Cf-250	$1 \times 10^1$	$1 \times 10^4$
Cf-251	$1 \times 10^0$	$1 \times 10^3$
Cf-252	$1 \times 10^1$	$1 \times 10^4$
Cf-253	$1 \times 10^2$	$1 \times 10^5$
Cf-254	$1 \times 10^0$	$1 \times 10^3$
Es-253	$1 \times 10^2$	$1 \times 10^5$
Es-254	$1 \times 10^1$	$1 \times 10^4$
Es-254m	$1 \times 10^2$	$1 \times 10^6$

Radionuclide	Activity concentration (kBq kg <sup>-1</sup> )	Activity (Bq)
Fm-254	$1 \times 10^4$	$1 \times 10^7$
Fm-255	$1 \times 10^3$	$1 \times 10^6$

b Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculation (thus requiring only the exemption level of the parent radionuclide to be considered), are listed in the following:

Parent radionuclide	Progeny
Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Ag-108m	Ag-108
Cs-137	Ba-137m
Ba-140	La-140
Ce-144	Pr-144
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210

Parent radionuclide	Progeny
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

## ANNEX VII [VIII]

### *Definition and use of the activity concentration index for the gamma radiation emitted by building materials as referred to in Article 75*

For the purposes of Article 75(2), for identified types of building materials, the activity concentrations of primordial radionuclides Ra-226, Th-232 (or its decay product Ra-228) and K-40 shall be determined.

The activity concentration index I is given by the following formula:

$$I = C_{\text{Ra226}}/300 \text{ Bq/kg} + C_{\text{Th232}}/200 \text{ Bq/kg} + C_{\text{K40}}/3000 \text{ Bq/kg}$$

where  $C_{\text{Ra226}}$ ,  $C_{\text{Th232}}$  and  $C_{\text{K40}}$  are the activity concentrations in Bq/kg of the corresponding radionuclides in the building material.

The index relates to the gamma radiation dose, in excess of typical outdoor exposure, in a building constructed from a specified building material. The index applies to the building material, not to its constituents except when those constituents are building materials themselves and are separately assessed as such. For application of the index to such constituents, in particular residues from industries processing naturally-occurring radioactive material recycled into building materials, an appropriate partitioning factor needs to be applied. The activity concentration index value of 1 can be used as a conservative screening tool for identifying materials that may cause the reference level laid down in Article 75.1 to be exceeded. The calculation of dose needs to take into account other factors such as density, thickness of the material as well as factors relating to the type of building and the intended use of the material (bulk or superficial).

## ANNEX VIIa [IX]

### *Indicative list of information for licence applications as referred to in Article 28*

- (a) Responsibilities and organisational arrangements for protection and safety.
- (b) Staff competences, including information and training.
- (c) Design features of the facility and of radiation sources.
- (d) Anticipated occupational and public exposures in normal operation.
- (e) Safety assessment of the activities and the facility in order to:
  - (i) identify ways in which potential exposures or accidental and unintended medical exposures could occur;
  - (ii) estimate, to the extent practicable, the probabilities and magnitude of potential exposures;
  - (iii) assess the quality and extent of protection and safety provisions, including engineering features, as well as administrative procedures;
  - (iv) define the operational limits and conditions of operation.
- (f) Emergency procedures.
- (g) Maintenance, testing, inspection and servicing so as to ensure that the radiation source and the facility continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime.
- (h) Management of radioactive waste and arrangements for the disposal of such waste, in accordance with applicable regulatory requirements.
- (i) Management of disused sealed sources.
- (j) Quality assurance.

## ANNEX VIII [X]

*Data system for individual radiological monitoring as referred to in Articles 41, 42 and 50*

### General Provisions

The data system for individual radiological monitoring established by a Member State may be realised either as a network or as a national dose register. This data system may include the issuance of individual radiological monitoring documents for outside workers.

1. Any data system of the Member States for individual radiological monitoring of exposed workers shall comprise the following sections:
  - (a) particulars concerning the worker's identity;
  - (b) particulars concerning the medical surveillance of the worker;
  - (c) particulars concerning the undertaking of the worker and, in the case of an outside worker, the employer of the worker;
  - (d) the results of the individual monitoring of the exposed worker.
2. The competent authorities of the Member States shall take the measures necessary to prevent any forgery or misuse of, or tampering with, the data system for individual radiological monitoring.

#### **A: Data to be included in the data system for individual radiological monitoring**

3. Data on the worker's identity shall include the worker's:
  - (a) surname;
  - (b) first name;

- (c) sex;
  - (d) date of birth;
  - (e) nationality; and
  - (f) unique identification number.
4. Data on the undertaking shall include the name, address and unique identification number of the undertaking.
5. Data on the employment of the worker shall include:
- (a) the name, address and unique identification number of the employer;
  - (b) the starting date of individual monitoring; and where available, the end date;
  - (c) the categorisation of the worker in accordance with Article 38.
6. The results of the individual monitoring of the exposed worker shall include the official dose record (year; effective dose in mSv; in the event of non-uniform exposure, equivalent doses in the different parts of the body in mSv; and in the event of an intake of radionuclides, the committed effective dose in mSv);

**B: Data on outside workers to be supplied via the data system for individual radiological monitoring**

1. Before the start of any activity, the employer of the outside worker shall supply the following data to the undertaking via the data system for individual radiological monitoring:
  - (a) data on the employment of the outside worker in accordance with Section A, point 5;
  - (b) data on the medical surveillance of the worker shall include:
    - (i) the medical classification of the worker in accordance with Article 45 (fit; fit, subject to certain conditions; unfit);
    - (ii) information on any restrictions on working with radiation;
    - (iii) the date of the last periodic health review; and
    - (iv) the period of validity of the result.
  - (c) the results of the outside worker's individual exposure monitoring in accordance with Section A, point 6, and at least for the last five calendar years including the current year.
2. The following data shall be recorded or have been recorded by the undertaking in the data system for individual radiological monitoring after the end of any activity:
  - (a) the period covered by the activity;
  - (b) an estimate of any effective dose received by the outside worker (for the period covered by the activity);



- (c) in the event of non-uniform exposure, an estimate of the equivalent doses in the different parts of the body;
- (d) in the event of an intake of radionuclides, an estimate of the intake or the committed effective dose.

### **C. Provisions concerning the individual radiological monitoring document**

1. Member States may decide to issue an individual radiological monitoring document for every outside worker.
2. The document shall be non-transferable.
3. Member States shall take the measures necessary to prevent a worker from being issued with more than one valid individual monitoring document at the same time.
4. In addition to the information required in Part A and Part B, the document shall include the name and address of the issuing body and the issuing date.

## ANNEX IX [XI]

*Emergency management systems and emergency response plans as referred to in Articles 70, 97 and 98*

### A. Elements to be included in an emergency management system

1. Assessment of potential emergency exposure situations and associated public and emergency occupational exposures;
2. Clear allocation of the responsibilities of persons and organisations having a role in preparedness and response arrangements;
3. Establishment of emergency response plans at appropriate levels and related to a specific facility or human activity;
4. Reliable communications and efficient and effective arrangements for cooperation and coordination at the installation and at appropriate national and international levels;
5. Health protection of emergency workers;
6. Arrangements for the provision of prior information and training for emergency workers and all other persons with duties or responsibilities in emergency response, including regular exercises;

7. Arrangements for individual monitoring or assessment of individual doses of emergency workers and the recording of doses;
8. Public information arrangements;
9. Involvement of stakeholders;
10. Transition from an emergency exposure situation to an existing exposure situation including recovery and remediation.

B. Elements to be included in an emergency response plan

**For emergency preparedness:**

1. Reference levels for public exposure, taking into account the criteria laid down in Annex I;
2. Reference levels for emergency occupational exposure taking into account Article 52.
3. Optimised protection strategies for members of the public who may be exposed, for different postulated events and related scenarios;
4. Predefined generic criteria for particular protective measures;
5. Default triggers or operational criteria such as observables and indicators of on-scene conditions;

6. Arrangements for prompt coordination between organisations having a role in emergency preparedness and response and with all other Member States and with third countries which may be involved or are likely to be affected;
7. Arrangements for the emergency response plan to be reviewed and revised to take account of changes or lessons learned from exercises and events.

Arrangements shall be established in advance to revise these elements, as appropriate during an emergency exposure situation, to accommodate the prevailing conditions as these evolve throughout the response.

**For emergency response:**

The response to an emergency exposure situation shall be undertaken through the timely implementation of preparedness arrangements, including but not limited to:

1. Promptly implementing protective measures, if possible, before any exposure occurs;
2. Assessing the effectiveness of strategies and implemented actions and adjusting them as appropriate to the prevailing situation;
3. Comparing the doses against the applicable reference level, focusing on those groups whose doses exceed the reference level;
4. Implementing further protection strategies, as necessary, based on prevailing conditions and available information.

## ANNEX X [XII]

*Information to members of the public about health protection measures to be applied and steps to be taken in the event of an emergency as referred to in Articles 71 and 72*

### A. Prior information to the members of the public likely to be affected by an emergency:

1. Basic facts about radioactivity and its effects on human beings and on the environment;
2. The various types of emergency covered and their consequences for the public and the environment;
3. Emergency measures envisaged to alert, protect and assist the public in the event of an emergency;
4. Appropriate information on action to be taken by the public in the event of an emergency.

### B. Information to be provided to the affected members of the public in the event of an emergency

1. On the basis of the emergency response plan previously drawn up in the Member States, the members of the public actually affected in the event of an emergency shall rapidly and regularly receive:
  - (a) information on the type of emergency which has occurred and, where possible, its characteristics (e.g. its origin, extent and probable development);
  - (a) advice on protection, which, depending on the type of emergency, may:
    - i) cover the following: restrictions on the consumption of certain foodstuffs and water likely to be contaminated, simple rules on hygiene and decontamination, recommendations to stay indoors, distribution and use of protective substances, evacuation arrangements;

- ii) be accompanied, where necessary, by special warnings for certain groups of the members of the public;
  - (b) announcements recommending cooperation with instructions or requests by the competent authority.
- 2. If the emergency is preceded by a pre-alarm phase, the members of the public likely to be affected shall already receive information and advice during that phase, such as:
  - (a) an invitation to the members of the public concerned to tune in to relevant communication channels;
  - (c) preparatory advice to establishments with particular collective responsibilities;
  - (d) recommendations to occupational groups particularly affected.
- 3. This information and advice shall be supplemented, if time permits, by a reminder of the basic facts about radioactivity and its effects on human beings and on the environment.

## ANNEX XI [XIII]

*Indicative list of types of building materials considered with regard to their emitted gamma radiation as referred to in Article 75*

1. Natural materials
  - (a) Alum-shale.
  - (b) Building materials or additives of natural igneous origin, such as:
    - granitoides (such as granites, syenite and orthogneiss),
    - porphyries;
    - tuff;
    - pozzolana;
    - lava.

2. Materials incorporating residues from industries processing naturally-occurring radioactive material, such as:

- fly ash;
- phosphogypsum;
- phosphorus slag;
- tin slag;
- copper slag;
- red mud (residue from aluminium production);
- residues from steel production



**ANNEX XII [XIV]**

*Information to be provided in the records for high-activity sealed sources (HASS) as referred to in Article 90*

STANDARD RECORD SHEET FOR HIGH-ACTIVITY SEALED SOURCES (HASS) (*optional in italics*)

<p>1. HASS identification number</p> <p>_____</p> <p><i>Manufacturer device number</i></p> <p>_____</p> <p><i>Field of use:</i></p> <p>_____</p>	<p>2. Identification of the licenced undertaking</p> <p>Name: _____</p> <p>Address: _____</p> <p>Country: _____</p> <p>Manufacturer <input type="checkbox"/>    Supplier <input type="checkbox"/>    User <input type="checkbox"/></p>	<p>3. <b>Location of HASS</b> (Use or storage) if not the same as in 2.</p> <p>Name: _____</p> <p>Address: _____</p> <p>Country: _____</p> <p>Fixed use <input type="checkbox"/>    Storage <input type="checkbox"/>    Mobile use <input type="checkbox"/></p>
<p>4. Recording</p> <p>Date of start of recording: _____</p> <p>Date of transfer of records to historic file: _____</p>	<p>5. Licence</p> <p>Number: _____</p> <p>Date of issue: _____</p> <p>Date of expiry: _____</p>	<p>6. Operational controls of HASS</p> <p>Date: _____</p> <p>Date: _____</p> <p>Date: _____</p>
<p>7. HASS characteristics</p> <p><i>Year of manufacture:</i> _____</p> <p>Radionuclide: _____</p> <p>Activity at the date of manufacturing: _____</p> <p>_____</p> <p>Activity reference date: _____</p> <p>Manufacturer/Supplier*:</p> <p>Name: _____</p> <p>Address: _____</p> <p>Country: _____</p> <p>Physical and chemical characteristics</p> <p>_____</p>	<p>8. Receipt of HASS</p> <p>Date of receipt: _____</p> <p>Receipt from:</p> <p>Name: _____</p> <p>Address: _____</p> <p>Country: _____</p> <p>Manufacturer <input type="checkbox"/>    Supplier <input type="checkbox"/>    Another user <input type="checkbox"/></p>	<p>Date: _____</p> <p>Date: _____</p> <p>Date: _____</p> <p>Date: _____</p> <p>Date: _____</p> <p>Date: _____</p> <p>Date: _____</p> <p>Date: _____</p>
<p><i>Source type identification:</i> _____</p> <p><i>Capsule identification:</i> _____</p> <p><i>ISO classification:</i> _____</p> <p><i>ANSI classification:</i> _____</p> <p><i>IAEA source category:</i> _____</p> <p>_____</p> <p><i>Neutron source:</i> Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p><i>Neutron source target:</i> _____</p> <p><i>Neutron flux:</i> _____</p>	<p>9. Transfer of HASS</p> <p>Date of transfer: _____</p> <p>Transfer to:</p> <p>Name: _____</p> <p>Address: _____</p> <p>Country: _____</p> <p>Licence number: _____</p> <p>Date of issue: _____</p> <p>Date of expiry: _____</p> <p>Manufacturer <input type="checkbox"/>    Supplier <input type="checkbox"/>    Other undertaking <input type="checkbox"/></p> <p>Facility for long term storage and disposal <input type="checkbox"/></p>	<p>10. Further information</p> <p>Loss <input type="checkbox"/>    Date of loss: _____</p> <p>Theft <input type="checkbox"/>    Date of theft: _____</p> <p><i>Finding:</i> Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>_____</p> <p><i>Date:</i> _____</p> <p><i>Place:</i> _____</p> <p><i>Other information:</i></p> <p>_____</p>

\* Where the manufacturer of the source is established outside the Community, the name and address of the importer-supplier may be provided instead.

## ANNEX XIV [XV]

### *Requirements for undertakings responsible for a high-activity sealed source as referred to in Article 92*

Each undertaking responsible for a high-activity sealed source 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 are still present and in apparently good condition at their place of use or 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, leakage 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 facility for long term storage ~~or~~ and disposal or transfer it to another authorised undertaking 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 accident or incident resulting in unintentional exposure of a worker or a member of the public.

## ANNEX XV [XVI]

### *Identification and marking of high-activity sealed sources as referred to in Article 92*

1. The manufacturer or supplier ensures that:
  - (a) Each high-activity sealed source is identified by a unique number. This number shall be engraved or stamped on the source, where practicable.

The 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, bear information on the nature of the source.
  - (b) The source container and, where practicable, the source are marked and labelled with an appropriate sign to warn people of the radiation hazard.
2. The manufacturer provides a photograph of each manufactured source design type and a photograph of the typical source container.
3. The undertaking ensures that each high-activity sealed source is accompanied by written information indicating that the source is identified and marked in compliance with point 1 and that the markings and labels referred to in point 1 remain legible. The information shall include photographs of the source, source container, transport packaging, device and equipment as appropriate.

## ANNEX XVa [XVIII]

*Indicative list of types of existing exposure situations as referred to in Article 100*

- (a) Exposure due to contamination of areas by residual radioactive material from:
  - (i) past activities that were never subject to regulatory control or were not regulated in accordance with the requirements laid down by this Directive;
  - (ii) an emergency, after the emergency exposure situation has been declared ended, as provided for in the emergency management system;
  - (iii) residues from past activities for which the undertaking is no longer legally accountable;
- (b) Exposure to natural radiation sources, including:
  - (i) indoor exposure to radon and thoron, in workplaces, dwellings and other buildings;
  - (ii) indoor external exposure from building materials;
- (c) Exposure to commodities excluding food, animal feeding stuffs and drinking water incorporating
  - (i) radionuclides from contaminated areas specified in point (a), or
  - (ii) naturally-occurring radionuclides.

## ANNEX XVI [XVIII]

*List of items to be considered in preparing the national action plan to <sup>72</sup>address ~~manage~~ long-term risks from radon exposures as referred to in Articles 53, 74 and 103*

- (1) Strategy for conducting surveys of indoor radon concentrations or soil gas concentrations for the purpose of estimating the distribution of indoor radon concentrations, for the management of measurement data and for the establishment of other relevant parameters (such as soil and rock types, permeability and radium-226 content of rock or soil).
- (2) Approach, data and criteria used for the delineation of areas or for the definition of other parameters that can be used as specific indicators of situations with potentially high exposure to radon.
- (3) Identification of types of workplaces and buildings with public access, such as schools, underground workplaces, and those in certain areas, where measurements are required, on the basis of a risk assessment, considering for instance occupancy hours.
- (4) The basis for the establishment of reference levels for dwellings and workplaces. If applicable, the basis for the establishment of different reference levels for different uses of buildings (dwellings, buildings with public access, workplaces) as well as for existing and for new buildings.
- (5) Assignment of responsibilities (governmental and non-governmental), coordination mechanisms and available resources for implementation of the action plan.

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<sup>72</sup> Change proposed at AQ 15 May

- (6) Strategy for reducing radon exposure in dwellings and for giving priority to addressing the situations identified under point 2.
- (6a) Strategies for facilitating post construction remedial action.
- (7) Strategy, including methods and tools, for preventing radon ingress in new buildings, including identification of building materials with significant radon exhalation.
- (8) Schedules for reviews of the action plan.
- (9) Strategy for communication to increase public awareness and inform local decision makers, employers and employees of the risks of radon, including in relation to smoking.
- (10) Guidance on methods and tools for measurements and remedial measures. Criteria for the accreditation of measurement and remediation services shall also be considered.
- (11) Where appropriate, provision of financial support for radon surveys and for remedial measures, in particular for private dwellings with very high radon concentrations.
- (12) Long-term goals in terms of reducing lung cancer risk attributable to radon exposure (for smokers and non-smokers).
- (13) Where appropriate, consideration of other related issues and corresponding programmes such as programmes on energy saving and indoor air quality.