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NOTE

from:	General Secretariat of the Council
to:	Delegations
No. Cion prop.:	10926/12 ATO 90 SOC 501 SAN 149
Subject:	Proposal for a Council Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation

Based on the suggestions received and the preparatory work done at the WPAQ, the Presidency prepared and revised the attached text to be considered by the WPAQ.

The changes to doc. 8025/1/12 REV 1 are in **bold underline**; deletions are marked with ~~strikethrough~~. Numbers in brackets [...] next to article numbers refer to the new article numbers, after renumbering.

ANNEX

Proposal for a

COUNCIL DIRECTIVE

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

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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[1]. 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[2] 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[3], 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[4], 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[5] and Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources[6] cover different specific aspects complementary to Directive 96/29/Euratom.

(5) Over time, definitions used in that legislation have evolved and been adjusted to the specific scope, however many requirements laid down therein fit in the original context at the time of adoption of that legislation but cannot be extended for use in Directive 96/29/Euratom.

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1 OJ 11, 20.2.1959, p. 221.
2 OJ L 159, 29.6.1996, p. 1
3 OJ L 180 9.7.1997, p. 22
4 OJ L 357, 7.12.1989, p. 31
5 OJ L 349, 13.12.1990, p. 21
6 OJ L 346, 31.12.2003, p. 57

(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**,** should take into account the new recommendations of the International Commission on Radiological Protection (ICRP), in particular those in Publication 103 (2007)[7], and should be revised in the light of new scientific evidence and operational experience.

(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.

(8) A new methodology introduced by ICRP to calculate doses based on the latest knowledge on radiation risks should also be taken into account in this Directive.

(9) The current annual 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) New scientific information on tissue effects calls for the optimisation principle to be applied to organ doses as well, where appropriate, in order to keep doses as low as reasonably achievable. The ~~d~~**D**irective should also follow new ICRP guidance on the organ dose limit for the lens of the eye in occupational exposure.

(11) 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 radiation exposure.

(12) 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.

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[7] The 2007 Recommendations of the International Commission on Radiological Protection

(13) Regulation (EU) No. 305/2011[8] 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;

Building materials emitting gamma radiation or those exhaling radon or thoron gas should be within the scope of this Directive but should also be regarded as construction products as defined in this Regulation, in the sense that it applies to construction works emitting dangerous substances or dangerous radiation;

It is appropriate for this Directive to establish reference levels for indoor radon gas concentrations and for indoor gamma radiation exposure, and to introduce requirements on the recycling of residues from industries processing naturally occurring radioactive materials into building materials;

This Directive should be without prejudice to the provisions of Regulation 305/2011 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;

While this Regulation requires information to be made available to the user, there may be need to provide such information to the competent authority.

~~(13) The new requirements on radioactivity in building materials should allow for the free circulation of building materials.~~

(14) 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^{-3}. 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[9] to be incorporated in the binding requirements of the Basic Safety Standards while leaving enough flexibility for implementation.

(15) 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 should be managed as a specially authorised exposure.

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8 OJ L 88, 4.4.2011, p. 5

9 OJ L 80, 27.03.1990, p. 26

(16) The radioactive contamination of air, water and soil poses threats to human health. While 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, it should also be shown that the state of the environment ensures long-term health protection. As far as mankind is part of its environment, this calls for a policy protecting the environment, including environmental media and non-human species. For this purpose, available environmental criteria based on scientific knowledge should be taken into account.

~~(16) The health protection of the general public allows for the presence of radioactive substances in the environment. In addition to direct environmental exposure pathways, consideration should be given to the protection of the environment as a whole, including the exposure of biota, within a comprehensive and coherent overall framework. As far as a mankind is part of its environment, this policy benefits to long term health protection.~~

(17) 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**. In this context, 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. The**~~, 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 **should also be strengthened**.

(18) Accidental and unintended medical exposures are a source of continuing concern. ~~Their prevention and follow-up, should they occur, need to be fully addressed.~~ **Whereas for medical devices post-market surveillance is required under Directive 93/42/EEC of 14 June 1993 concerning medical devices[10], 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 risk analysis in radiotherapy, to avoid such incidents should be emphasised, and recording, reporting, analysis and corrective action should be required in such cases.

10 OJ L 169, 12.07.1993, p. 1

(19) 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 implemented by medical staff using medical equipment and on the other hand for procedures implemented by non-medical staff using non-medical equipment. In general, the annual dose limits and corresponding constraints for public exposure should apply.

(20) 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~~.~~**:**

(a) 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 must 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,

(b) 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[11] 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,

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11 OJ L 66, 13.3.1999, p. 16

(c) 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.

(21) 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** ~~regulated~~ practices. After a comprehensive review, it has been concluded that the values recommended in IAEA document RS-G-1.7[12] 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[13].

(22) Member States may grant specific exemption from authorisation for certain practices involving activities above the exemption values.

(23) Specific clearance levels, above the default values for exemption and clearance, as well as corresponding Community guidance[14] remain important tools for the management of large volumes of materials arising from the dismantling of authorised facilities.

(24) Member States should ensure that outside workers receive the same protection as exposed workers employed by **an** undertaking~~s~~ 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) 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 threat analysis, an overall emergency management system, emergency response plans for identified threats, and pre-planned strategies for the management of each postulated event.

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12 IAEA 2004 Safety Standards Series RS-G-1.7 "Application of the Concepts of Exclusion, Exemption and Clearance".

13 Radiation Protection 122: Practical use of the Concepts of the Clearance and Exemption — Part I, Guidance on General Clearance Levels for Practices.

14 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.

(26) 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) The efficient management of a nuclear emergency with cross-border consequences calls for enhanced cooperation between Member States in emergency planning and response.

(27a) Urgent information exchange between Member States and the Commission in the event of a radiological 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[15], there is a need to put in place arrangements for information exchange beyond the scope of this Decision to allow cooperation with neighbouring Member States and with countries far away from the accident site.

(28) 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 ~~are revising~~ **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) 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.

(30) More precise requirements should be introduced for the issuing discharge authorisations and for the monitoring of discharges. Commission Recommendation 2004/2/Euratom of 18 December 2003 on standardised information on radioactive airborne and liquid discharges into the environment from nuclear power reactors and reprocessing plants in normal operation[16] introduced standardised information for the reporting of data on discharges from nuclear power plants and reprocessing facilities.

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15 OJ L 371, 30.12.1987, p. 76

16 OJ L 2, 6.1.2004, p. 36

(30a) **Council Regulation (EU) No. 333/2011[17] of 31 March 2011 establishes criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC[18] of the European Parliament and of the Council; measures need to be taken to prevent the accidental melting of orphan sources as well as compliance of metals released from nuclear installations, for instance during their dismantling, to comply with clearance criteria.**

(31) 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 sealed 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. With regard to international security, 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) The basic safety standards established under the Euratom Treaty are meant to apply in a uniform way.

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

HAS ADOPTED THIS DIRECTIVE:

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17 OJ L 94, 8.4.2011, p. 2-11

18 OJ L 312, 22.11.2008, p. 3-30

CHAPTER I

SUBJECT MATTER AND SCOPE

Article 1

Subject matter

1. This Directive establishes **a Community framework for** the basic safety standards for the protection of the health of workers, **apprentices and students,** members of the public, patients and other individuals subject to medical exposure against the dangers arising from ionising radiation for the purpose of their uniform implementation by Member States.

2. ~~[This Directive applies to the protection of the environment as a pathway from radiation sources to the exposure of members of the public, complemented where appropriate with specific consideration of the exposure of biota in the environment as a whole.]~~

2~~3~~. This Directive sets out requirements for the safe management and control of radioactive sources and the provisions of appropriate information in an emergency exposure situation.

3~~4~~. This Directive sets out requirements for the purpose of prevention of exposure of workers and members of the public to ionising radiation arising ~~from orphan sources and~~ from inadequate control of high-activity sealed radioactive sources and for the harmonisation of controls in place in the Member States by defining specific requirements ensuring that each such source is kept under control.

4. This Directive sets out requirements for the purpose of prevention of exposure of workers and members of the public to ionising radiation arising from orphan sources.

5. This Directive defines at Community level common objectives with regard to measures and procedures for informing **members of** the public for the purpose of improving the operational health protection provided in the event of an emergency.

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 the radiation protection point of view with regard to the health protection of workers, **apprentices and students,** members of the public, or patients and other individuals subject to medical exposure or with regard to ~~the protection of~~ the environment **in view of long-term health protection**.

2. This Directive applies to **planned exposure situations** ~~all practices involving radiation sources~~, namely **resulting from**:

   (a) the manufacture, production, processing, ~~conversion,~~ handling, **disposing of,** use, storage, holding, transport, import to, and export from the Community ~~and the disposal~~ 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 **kilo volt (**kV**)** ~~and were charged particles may accelerate in the resulting electrical field~~;

   (c) ~~practices or~~ **planned exposure situations resulting from** activities which involve the presence of natural radiation sources that lead to a significant increase in the exposure of workers, in particular:

      i) the operation of aircraft and spacecraft, only in relation to the exposure of crews;

      ~~ii) activities leading to exposure to radon in workplaces;~~

   ~~(d)~~ **ii)** ~~the~~ activities in industries processing materials with naturally occurring radionuclides, or activities related to such processing**;** ~~that lead to a significant increase in the exposure of either workers or members of the public~~.

      iii) activities leading to exposure to radon in workplaces;

   (**d**~~e~~) any other **type of** practice **or activity** specified by the Member State.

3. This Directive applies to the management of existing exposure situations, **including the** ~~in particular the~~ exposure of members of the public to indoor radon, the external exposure from building materials and cases of lasting exposure resulting from the after-effects of an emergency or a past activity.

4. This Directive applies to the management of emergency exposure situations to the extent that these are deemed to warrant intervention to protect the health of members of the public or workers or to protect the environment; potential exposures as well as emergency preparedness and planning are part of planned exposure situations.

Article 3

Exclusion from the scope

This Directive shall not apply to radionuclides naturally contained in the human body, to cosmic radiation prevailing at ground level, and to aboveground exposure to radiation emitted by radionuclides present in the undisturbed earth's crust.

CHAPTER II

DEFINITIONS[19]

Article 4

For the purpose of this Directive, the following terms have the meaning hereby assigned to them:

(1) Absorbed dose (D) ~~means~~ **is** the energy absorbed per unit mass

$$D = \frac{\mathrm{d}\bar{\varepsilon}}{\mathrm{d}m}$$

where

– $\mathrm{d}\bar{\varepsilon}$ 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)** [92];

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19 *Comment: the number shown in [...] at the end of each definition is the number in the original Commission proposal, before rearrangement in alphabetic order.*

(2) Accelerator means an equipment or installation in which particles are accelerated, emitting ionising radiation with energy higher than 1 mega-electron volt (MeV) [58];

(3) Accidental exposure means an exposure of individuals, other than emergency workers, as a result of an accident [68];

(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 [52];

(5) Activity (A) ~~means~~ **is** the activity, ~~A,~~ 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 spontaneous nuclear transitions from that energy state in the time interval dt:

$$A = \frac{\mathrm{d}N}{\mathrm{d}t}$$

The unit of activity is becquerel (Bq) [94];

(6) Apprentice means a person receiving training or instruction within an undertaking with a view to exercising a specific skill [38];

(7) Authorisation means the granting of permission for an undertaking to perform specified activities subject to regulatory control in the form of registration or a licence [86];

(8) becquerel (Bq) is the special name of the unit of activity. One becquerel is equivalent to one nuclear transition per second: 1 Bq = 1 s^{-1} [95];

(9) Building material means any 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;

~~(9) Building material means a construction product (as defined in Regulation 305/2011/EC) from which gamma radiation may be emitted or from which radon or thoron gas may exhale into a building [12];~~

(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 [33];

(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 [65];

(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,** ~~indicated~~ and the application of new standards if necessary [79];

(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 exposure 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 [78];

(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 $E(\tau)$, τ 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, τ 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) [39];

(15) Committed equivalent dose (H(τ)) is the integral over time (τ) 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:

$$H_T(\tau) = \int_{t_0}^{t_0+\tau} \dot{H}(t)\,\mathrm{d}t$$

for an intake at time t0 where

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

τ is the time over which the integration is performed.

In specifying $H_T(\tau)$, τ is given in number of years over which the integration is made. For the purpose of complying with dose limits specified in this Directive, τ 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 sievert (Sv) [96];

(16) Competent authority means an authority or system of authorities designated **by Member States** ~~by the government~~ as having legal authority for **the purposes of this Directive** ~~regulatory control of practices or activities in planned exposure situations or for the management of existing or emergency exposure situations [New]~~;

(17) Consumer product means a device or manufactured item into which 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 [57];

(18) Contamination means **the unintended or undesirable presence of** radioactive substances on surfaces ~~(including the human body)~~ or within solids, liquids or gases **or on the human body,** ~~where their presence is unintended or undesirable~~ ~~[New]~~;

(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 [67];

(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 [51];

(21) Disposal means the emplacement of ~~radioactive matrial, radioactive~~ waste or spent fuel in a~~n authorised~~ facility without the intention of retrieval [13];

(22) 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 [59];

(23) 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 planned exposure situation [28];

(24) Dose limit: the value of the effective dose (where applicable, committed effective dose) or the equivalent dose in a specified period which **shall** ~~may~~ not be exceeded for an individual [27];

(25) Dosimetry service means a body or an individual having the competence for calibration, reading or interpretation of individual monitoring devices, **or for record keeping of doses,** 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 authorit**y**~~ies~~ [46];

(26) 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** ~~irradiation~~. 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 appropriate w_T and w_R values are specified in Publication 103 of the International Commission on Radiological Protection. The unit for effective dose is sievert (Sv) [26];

(27) Emergency exposure situation means a situation of exposure due to any **adverse** ~~sudden~~ event which requires urgent decisions to be taken in order to control this situation~~; the event may result from an accident (whether or not envisaged as a potential exposure) or from a malicious act~~ [4];

(28) Emergency management system means legal or administrative framework establishing responsibilities for emergency preparedness and response, and arrangements for decision making in the event of an emergency exposure situation [47];

(29) Emergency means a non-routine situation or event that necessitates prompt action primarily to mitigate ~~a hazard or~~ **serious** adverse consequences for human health and safety, quality of life, property or the environment**, or serious hazards that would arise such consequences**. This includes nuclear and radiological emergencies~~;~~ [3]**;**

(30) Emergency occupational exposure means occupational exposure received in an emergency exposure situation by individuals taking action to mitigate the consequences of the emergency [69];

(31) Emergency response plan means arrangements to plan for adequate response in the event of an emergency exposure situation ~~related to a specific facility or activity~~ on the basis of postulated events and related scenarios [44];

(32) Emergency worker means any person having a defined role as a worker in an emergency and who might be exposed while taking action in response to the emergency [45];

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

(34) 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 appropriate w_R values are specified in Publication 103 of the International Commission on Radiological Protection. The unit for equivalent dose is sievert (Sv) [29];

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

(36) 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 [14];

(37) Exposed worker means **a** person, either self-employed or working under an employer, **including a person working for a charity organisation,** ~~and~~ 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 [35];

(38) 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) [5];

~~(39) Exposure situation means a situation giving rise to exposure, including the radiation sources and the activities or actions which may affect the exposure from these radiation sources [6];~~

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

(41) gray (Gy) is the unit of absorbed dose. One gray is equal to one joule per kilogram: $1\ Gy = 1\ J\ kg^{-1}$ [93];

(42) Health detriment means an estimate of the risk of reduction in length and quality of life occurring in a population following exposure **due to radiation**. This includes loss arising from tissue reactions, cancer and severe genetic disorder [25];

(43) Health screening means a procedure using medical radiological installations for early diagnosis in population groups at risk [70];

(44) High-activity sealed source means a sealed source**, including devices containing a number of sealed sources with the same radionuclide,** in which the **total activity level** ~~amount~~ of **the** radioactive material is equal to or exceeds the values laid down in Annex II [43];

(45) 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 [74];

(46) Inspection means an investigation by **or on behalf of** any competent authority to verify compliance with national **legal requirements** ~~provisions~~ [60];

(47) Intake means the activities of radionuclides entering the body from the external environment [37];

(48) Interventional radiology means the use of X-ray imaging techniques **to facilitate the introduction and guidance of devices in the body**~~, to introduce and guide devices in the body~~ for diagnostic or treatment purposes [75];

(49) Ionising radiation means ~~the transfer of~~ energy **transferred** in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less (a frequency of $3x10^{15}$ Hertz or more) capable of producing ions directly or indirectly [2];

(50) Licence means permission granted **in writing** by the competent authority, on application, to carry out a practice in accordance with spe**c**ific conditions laid down in a licence document [64];

(51) 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 ~~or well-being~~, as well as exposure incurred by carers and comforters and by volunteers in biomedical **or medical** research [1];

(52) Medical physics expert means an individual **or 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 to act is recognised by the competent authorit**y**~~ies~~ [40];

(53) Medical radiological installation means a facility ~~containing~~ **where** medical radiological **procedures are performed** ~~equipment~~ [80];

(54) Medical radiological means pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other planning and guiding radiology using ionising radiation [48];

(55) Medical radiological procedure means any procedure giving rise to medical exposure [72];

(56) Members of the public mean**s** individuals~~,~~ subject to public exposure [7];

(57) Natural radiation source means a source~~s~~ of ionising radiation of natural terrestrial or cosmic origin [15];

(58) Non-medical imaging exposure means any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not ~~related~~ to **bring a health benefit to** ~~the health or well-being of~~ the individual being exposed [54];

(59) Normal exposure means exposure expected to occur under the normal operating conditions of a facility or activity (including maintenance, inspection, decommissioning), including **minor incidents** ~~possible minor mishaps~~ that can be kept under control, i.e. during normal operation and anticipated operational occurrences [97];

(60) Notification means submission of ~~specified~~ information to the competent authority to notify the intention to carry out a practice within the scope of this Directive [55];

(61) Occupational exposure means exposure of workers**, apprentices and students** incurred in the course of their work [24];

(62) 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 authorit**y**~~ies~~ [41];

(63) Optimisation means a forward-looking iterative process to establish adequate radiation protection measures taking into account the prevailing circumstances, the available options, and the nature of the exposure situation, with the aim of keeping the magnitude and likelihood of exposure and the number of people exposed as low as reasonably achievable [22];

(64) Organ dose means the equivalent dose in a specific tissue or organ ~~[New]~~;

(65) 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 [11];

(66) Outside worker means any exposed worker ~~[of category A]~~ who is not employed by the undertaking responsible for the supervised and controlled areas, but performs activities in these areas, including trainees, apprentices and students [30];

(68) Planned exposure situation means an exposure situation that arises from the planned operation or introduction of a radiation source or from activities which alter 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 [16];

(69) 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 [17];

(70) Practical aspects of medical exposure procedures means the physical conduct of a medical exposure and any supporting aspects including handling and use of medical radiological equipment, and the assessment of technical and physical parameters, including radiation doses, calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals, and image processing as carried out by, among others, radiographers and technicians in nuclear medicine and radiotherapy [49];

(71) Practice means any **human** activity that involves the operation ~~or introduction~~ of radiation sources or which alters exposure pathways and is managed as a planned exposure situation [19];

(72) 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 [50];

(72a) 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) Projected dose means the dose that would be expected to be incurred if no protective measures were to be taken [98];

(74) 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 [85];

(75) Public exposure means exposure of **members of the public, including exposures relevant to long-term health protection and** excluding any occupational or medical exposure [23];

(76) 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 [63];

(77) 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 [99];

(78) Radiation generator means a device capable of generating ionising radiation, such as X rays, neutrons, electrons or other charged particles~~, which may be used for scientific, industrial or medical purposes~~ [61];

(79) Radiation protection expert means an individual **or 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 capacity to act is recognised by the competent authorit**y**~~ies~~ [42];

(81) Radiation protection officer means an individual who is technically competent in radiation protection matters relevant for a given type of practice and is designated by the undertaking to oversee the implementation of the radiation protection arrangements of the undertaking [83];

(82) Radiation source means an entity that may cause radiation exposure**,** such as by emitting ionising radiation or by releasing radioactive material [8];

(83) Radioactive material means material incorporating radioactive substances [10];

(84) Radioactive source means a radiation source incorporating radioactive material for the purpose of utilising its radioactivity [9];

(85) Radioactive substance means any substance that contains one or more radionuclides the activity or activity concentration of which cannot be disregarded as far as radiation protection is concerned [53];

(86) Radioactive waste means radioactive material in gaseous, liquid or solid form for which no further use is foreseen [62];

(87) Radiodiagnostic means pertaining to in-vivo diagnostic nuclear medicine, medical diagnostic radiology using ionising radiation, and dental radiology [76];

(88) Radiotherapeutic means pertaining to radiotherapy, including nuclear medicine for therapeutic purposes [77];

(89) Radon means the radionuclide Rn-222 and its progeny, as appropriate (exposure to radon means exposure to radon progeny) [20];

~~(90) Radon-prone area means a geographic area or administrative region defined on the basis of surveys of concentrations of radon, in indoor air or soil gas, indicating that the percentage of buildings expected to exceed the national reference level is significantly higher than in other parts of the country [71];~~

(91) Reference level means in an emergency exposure situation or in an existing exposure situation, the level of dose or ~~risk~~ **activity concentration** above which it is judged inappropriate to allow exposures to occur, **even though it is not a limit that may not be exceeded,** and below which optimisation of protection should continue to be implemented [34];

(92) 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 [73];

(93) Registration means permission granted in a document by the competent authority, or granted by national legislation, through a simplified procedure, to carry out a ~~practise~~ **practice** in accordance with conditions laid down in national legislation [56];

(94) Regulatory control means any form of control or regulation applied to practices or activities for the enforcement of radiation protection requirements ~~[New]~~;

(95) Remedial measures means the removal of a source or the reduction of its magnitude (in terms of activity or amount) or the inter**r**uption 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 [84];

(96) Representative person means an individual receiving a dose that is representative of the more highly exposed individuals in the population**, exluding those individuals having extreme or rare habits** [82];

(97) Residual dose means the dose expected to be incurred from all exposure pathways after protective measures have been fully implemented, or where a decision has been taken not to implement any protective measures [91];

~~(99) Risk constraint means a constraint set as a restriction on the individual risk from a radiation source (risk in the sense of probability of health detriment due to a potential exposure, which is a function of the probability of an unintended event causing a dose and the probability of detriment due to that dose) [32];~~

(100) 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 substance into the environment** ~~closely bonded in a solid form~~ [87];

(101) sievert (Sv) ~~means~~ **is** the special name of the unit of equivalent or effective dose. One sievert is equivalent to one joule per kilogram: 1 Sv = 1 J kg^{-1} [36];

(102) Storage means the holding of radioactive material**, a radioactive source** or radioactive waste in a facility, with the intention of retrieval [21];

(103) Supervised area means an area subject to supervision for the purpose of protection against ionising radiation [66];

(104) Supplier means an undertaking supplying or making available ~~a~~ **radioactive materials, including** radioactive source**s** [88];

(105) Source container means an assembly of components **intended to** guarantee~~ring~~ 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 use, transport, handling, etc. [89];

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

(107) Thoron means the radionuclide Rn-220 and its progeny [90];

(108) Undertaking means a natural or legal person who has legal responsibility for carrying out a practice~~, including the responsibility as employer~~, or who has legal responsibility for a radiation source or the management of an exposure situation (including cases where the owner or holder of a radiation source does not conduct related activities) [31];

(109) Unintended exposure means medical exposure that is significantly different from the medical exposure intended for a given purpose [81].

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 new type of]~~ a radiation source, **or** introducing or altering an exposure pathway or decisions on **the management of** actual exposures 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 them outweighs the detriment that they may cause.

(b) Optimisation: Radiation protection of members of the public, workers, apprentices and students shall be optimised with the aim of keeping the magnitude **of individual doses, the** ~~and~~ likelihood of exposure and the number of individuals exposed as low as reasonably achievable, taking into account economic and soci**al**~~etal~~ factors; the optimisation of the protection of individuals undergoing medical exposure shall **apply** ~~be applied~~ to the magnitude of individual doses **and be commensurate with the medical purpose of the exposure,** as described in Article 55. This principle shall be applied not only in terms of effective dose **or committed effective dose** but also, where a**p**propriate, in terms of organ 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 from all ~~authorised practises~~ **practices** ~~may~~ **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 and public exposure

1. For the purpose of prospective optimisation of protection, the competent authority shall ensure, where appropriate, that dose constraints be established for occupational and public exposure:
   (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 authorit**y**~~ies~~. 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 authorit**y**~~ies~~ shall ~~ensure that~~ **set** the constraint**s** **so as to ensure compliance** ~~are compatible~~ with the dose limit for the sum of doses to the same individual from all authorised practices.
2. With regard to potential exposures, optimisation shall include adequate management of the safety ~~and control~~ of sources and facilities. ~~Where appropriate, dose constraint may be replaced by or complemented with risk constraints defined for this purpose.~~
3. Dose constraints shall be ~~defined~~ **established** in terms of individual effective or equivalent doses over a year or any other appropriate shorter time period.
4. ~~Where d~~**D**ose constraints **that** are introduced to restrict any ~~prolonged~~ protracted ~~accumulated~~ exposure~~,~~ shall be ~~defined~~ **established** in terms of annual effective doses or organ doses.

Article 7

Dose constraints for medical exposure

Dose constraints shall ~~not~~ apply **to** ~~for the~~ medical exposure**s only with regard to the protection** of ~~patients or asymptomatic individuals. For~~ carers**,** ~~and~~ comforters and ~~for~~ volunteers participating in medical and biomedical research (for whom no direct medical benefit is expected from the exposure)**:** ~~,~~ **such** dose constraints shall, where a**p**propriate, be established **by the competent authority** in terms of **a level of** the individual dose **that is as low as reasonably achievable and** ~~that~~ complies with good medical practice~~s~~ for the examination, treatment or research project in question.

Article 8

Reference levels

1. **For emergency and existing exposure situations, the competent authority or the undertaking or organisation responsible for emergency preparedness and response, as appropriate, shall establish** ~~R~~reference levels**,** ~~shall be established for emergency and existing exposure situations~~ as ~~a~~ level**s** of effective dose or organ dose above which it is judged inappropriate to allow exposures to occur **as a result of that exposure situation**. Optimisation of protection shall give priority to exposures above the reference level. Optimised protective strategies shall be planned and implemented with the objective of reducing individual doses below the reference levels.
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 choice of reference levels for the effective dose shall take into account the three bands 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 gas concentration in air as specified in Article ~~73~~**74** for members of the public and Article 53 for workers.

SECTION 2

DOSE LIMITATION

Article 9

Age limit for exposed workers

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

Dose limits for occupational exposure

1 ~~1a~~. Dose limits for occupational exposure shall apply to the sum of annual occupational exposures of a worker ~~from all authorised practices~~ and to occupational exposure to radon in workplaces **in accordance with** ~~referred to in~~ Article 53(4).

2~~1~~. 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 ~~per year~~ may be authorised in a single year, provided that the average **annual** dose over any five consecutive years does not exceed 20 mSv ~~per year~~. For emergency workers Article 52 shall apply.

3~~2~~. In addition to limits of effective dose laid down in paragraph **2**~~1~~, 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 year or, where applicable, the same value as specified for the limit on effective dose;

(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 cm², regardless of the area exposed;

(c) the limit on the equivalent dose for the extremities shall be 500 mSv in a year.

Article 11

*Protection of pregnant and breastfeeding **female** workers*

1. The protection of the unborn child shall be comparable with that provided for members of the public. As soon as a ~~pregnant~~ **female** worker informs the undertaking or, in the case of an outside worker, the employer, **that she is pregnant** ~~of her condition~~, in accordance with national legislation or national practice**,** ~~. T~~ **t**he undertaking, respectively 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. A **female** worker who is breastfeeding shall not be employed in work involving a significant risk of intake of radionuclides or of contamination **that cannot be disregarded from the radiation protection point of view**. As soon as a worker informs the undertaking or, in case of an outside worker the employer, that she is breastfeeding an infant, the undertaking**, or the employer, shall ensure that the employment conditions for the worker are such that prevent risk of intake or bodily contamination** ~~shall take appropriate measures~~.

Article 12

Dose limits for apprentices and students

1. 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. 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 per year.

3 ~~2a.~~ In addition to limits of 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**~~20~~ 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 cm², regardless of the area exposed;

(c) the limit on the equivalent dose for the extremities shall be 150 mSv in a year.

4~~3~~. The dose limits for apprentices and students who are not subject to the provisions of paragraphs 1 and 2 shall be the same as the dose limits for members of the public as specified in Article 13.

Article 13

Dose limits for public exposure

1. 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. The limit on the effective dose for public exposure shall be 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 cm² area of skin, regardless of the area exposed.

Article 14

Estimation of the effective and equivalent dose

For the estimation of effective and equivalent doses, the following values and relationships **or equivalent methods approved by the competent authority** shall be used:

(a) For external radiation, the values and relationships laid down in Publication 103 of the International Commission on Radiological Protection shall be used to estimate the effective and equivalent doses.

(b) For internal exposure from a radionuclide or from a mixture of radionuclides, the values and relationships laid down in Publication 103 of the International Commission on Radiological Protection and the ingestion and inhalation dose coefficients laid down in Publication **119**[20] ~~72~~ of the International Commission on Radiological Protection shall be used to estimate the committed effective doses.

CHAPTER IV

REQUIREMENTS FOR RADIATION PROTECTION EDUCATION, TRAINING AND INFORMATION

Article 15

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 training, retraining and information of relevant individuals shall be repeated at appropriate intervals **not exceeding 5 years** and documented.

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[20] **ICRP, 2012. Compendium of Dose Coefficients based on ICRP Publication 60. ICRP Publication 119. Ann. ICRP 41(Suppl.).**

2. **In addition,** Member States shall make arrange**ment**s for **the establishment of** education, training and retraining to allow the recognition **by the competent authority** of radiation protection experts~~,~~ **and** medical physics experts**, as well as** occupational health services and dosimetry services**,** in relation to **the type of** conducted practices ~~and other national circumstances~~.

Article 16

Training of exposed workers, apprentices and students and information provided to them

1. Member States shall require the undertaking to inform exposed workers, apprentices and students who are subject to occupational exposure on:
   (a) the health risks involved in their work;
   (b) the general radiation protection procedures and precautions to be taken, in particular those 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 provide the information required in (a), (b) and (d).

   ~~(e) In the case of outside workers, their employer shall provide the information required in (a9, (b) and (d).~~
2. Member States shall require the undertaking or, in case of outside workers, the employer, to inform ~~women~~ **female workers** on the importance of making an early declaration of pregnancy in view of the risks of exposure for the unborn child.

3 ~~3a~~. Member States shall require the undertaking or, in case of outside workers, the employer, to inform ~~women~~ **female workers** on the importance of announ**n**cing the intention to breast-feed an infant in view of the risks of exposure for a breast-fed infant after intake of radionuclides or skin contamination.

4~~3~~. 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, **and for** apprentices and students who **in the course of their studies are obliged to work with radiation sources** ~~are subject to occupational exposure~~.

5~~4~~. In addition to the information and training in the field of radiation protection as specified in paragraphs 1, 2**, 3** and **4**~~3~~, **Member States shall require that the** ~~an~~ 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

Information and training of workers potentially exposed to orphan sources

1. Member States shall ~~provide encourgaement to~~ **make arrangements to** ensure that the management of ~~in~~ installations where orphan sources are most likely to be found or processed, ~~in particular~~ **including** large metal scrap yards and major metal scrap recycling plants, and in significant nodal transit points**, including customs posts, are**:

(a) ~~are~~ informed of the possibility that they may be confronted with a source;

(b) ~~are~~ advised and trained in the visual detection of sources and their containers;

(c) ~~are~~ informed of basic facts about ionising radiation and its effects;

(d) ~~are~~ informed about detection systems;

2. **Member States shall require that the management of installations referred to in paragraph 1** ~~(c)~~ ensure**s** that workers in their installation~~s~~ receive similar information as above and **are informed of and** ~~are~~ trained in the action to be taken on site in the event of the detection or suspected detection of a source.

Article 18

Information and training for emergency workers

1. Member States shall ensure that emergency workers 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. **Following a graded approach,** Member States shall ensure that **the undertaking or the organisation responsible for the protection of emergency workers provides to** emergency workers ~~receive~~ regular training as provided for in the emergency management system set out in Article 97. Where appropriate, this training shall include practical exercises.
4. Members States shall ensure that, in addition to the emergency response training referred to in paragraph 3 ~~of this Article~~, the **undertaking or the** organisation responsible for the protection of emergency workers ~~as referred to in Article 30(1)(b)~~ provides these workers with appropriate radiation protection training and information.

Article 19

Education, information and training in the field of medical exposure

1. Practitioners and the individuals involved in the practical aspects of medical exposure procedures shall 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** ~~curriculum~~ 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 exposure procedures as set out in Article 56(4).

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~~5~~. Member States shall ensure that **a** radiation protection **course** is included in the basic curriculum of medical**, paramedical,** ~~and~~ dental**, and veterinary** schools.

CHAPTER V

JUSTIFICATION AND REGULATORY CONTROL OF PRACTICES

Article 20

Justification of practices

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

~~2. [Member States shall list the approved types of practices in legislation or administrative acts.]~~

3. ~~Existing classes and types of practices may be reviewed as to their~~ **A review of the** justification **shall be considered** whenever **there is** new and important evidence about their efficacy~~,~~ **or** potential consequences **or information about other techniques and** ~~or alternative~~ technologies ~~not using ionising radiation is acquired~~.

4. ~~Types of p~~ **P**ractices involving medical exposure shall be justified both as a class **or type** of practice~~s~~ and at the level of each **individual medical** exposure as specified in Article 54.

Article 21

*Justification of **new classes or types of** practices **involving consumer products** ~~with apparatus or products emitting ionising radiation~~*

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,** ~~or export a new type of apparatus or product emitting ionising radiation~~ to provide the competent **authority** ~~authorities~~ with **all** relevant information**,** ~~such~~ as ~~that~~ listed in Annex III, Section A, **so as to allow the implementation of the justification requirement in Article 20(1)** ~~in order to enable the authorities, on the basis of assessment of information set out in Annex III, Section B, to decide whether the intended use of the apparatus or product can be justified~~.

2. On the basis of an assessment of this information, the competent authority shall, as outlined in Annex III, Section B, decide whether the intended use of the consumer product is justified.

3. Without prejudice to paragraph 1, the competent authority which has received information according to that paragraph, shall inform the competent authorities of other Member States of this receipt.

4. Member States shall allow consumer products to be sold or made available to the public only if their intended use is found to be justified and their use would fulfil the criteria for exemption from notification under Article 25c.

~~2. The competent authority shall share the information received according to paragraph 1 with the competent authorities of the other Member States to allow them to take their own decision on the justification of the intended use of the apparatus or product.~~

~~3. The undertaking shall be informed on the decisions of the Member States' competent authorities within a period of 6 months.~~]

Article 22

Prohibition of practices

1. Member States shall prohibit the deliberate addition of radioactive substances in the production ~~or manufacture~~ of foodstuffs, animal feeding stuffs, ~~toys, personal ornaments~~ and cosmetics, and shall prohibit the import or export of such products.
2. [Without prejudice to the Directive 1999/2/EC[21] of the European Parliament and of the Council], practices involving the activation of material resulting in an increase in activity **in a consumer product or a construction product, which** at the time of placing on the market ~~which~~ cannot be disregarded as far as radiation protection is concerned**,** shall be deemed not to be justified. Nevertheless, 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, as well as practices involving the activation of materials used in these products, 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 as far as radiation protection is concerned, and shall prohibit the import or export of such products or materials.**

[21] OJ L 66, 13.3.1999, p. 16.

Article 23

*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, **taking into account the practices included** ~~as set out~~ 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, ~~as listed in Annex IV,~~ shall be justified ~~in advance~~ 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 ~~as listed in section A of Annex IV implemented by medical staff~~ 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 ~~by the competent authority~~.

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~~3~~. 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** ~~agencies~~ and ~~professional bodies~~ **medical scientific societies,** as appropriate;

(c) for procedures using medical radiological equipment

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

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

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

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

~~(c) dose constraints are established for procedures implemented by non-medical staff using non-medical equipment (section B in Annex IV). These dose constraints shall be below the dose limit for members of the public and satisfy the requirements of Article 6(2);~~

~~(d) for procedures implemented by medical staff using medical radiological equipment, relevant requirements of Chapter VII are met, including those for equipment, optimisation, responsibilities and special protection during pregnancy~~;

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

(f) ~~[~~where the exposure is routinely carried out for security purposes**,** the screened individuals are provided with **information on, and** a choice of an alternative technique which does not involve exposure to ionising radiation.~~]~~

Article 24

Identification of practices involving naturally occurring radioactive material

Member States shall ensure the identification 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 means of surveys or by any other appropriate means taking into account industrial sectors listed in Annex V.

Article 25a [25]

Graded approach

~~*Article 26*~~

~~Regulatory control~~

1. Member States shall require ~~any notified practice~~ **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 the radiological safety ~~of installations~~.

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** ~~The competent authority may~~ exempt notified practices from the requirement of authorisation on the basis of the general criteria specified in Annex VI~~.~~**; in** ~~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** ~~the~~ purpose ~~of exemption~~.

3~~4~~. Notified practices which are not exempted from authorisation shall be subject to regulatory control through registration or licensing.

Article 25b [26]

Notification

1. Notification shall be 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. Practices may be exempted from notification, as specified in Article 25c.

2. Notification shall be required for workplaces where radon exposure is managed as a planned exposure situation, as specified in Article 53(4), 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, practices that recycle or process residues originating from practices involving naturally-occurring radioactive material, for incorporation in such building materials as are listed in Annex XI, Part 2, are subject to notification, if the activity concentration index, as defined in Annex VII, in the resulting building materials is liable to exceed 1 or any other value that according to national regulations would cause the reference level of 1mSv per year for indoor gamma exposure to be exceeded. Such practices are also subject to notification if any specific requirements related to radon exhalation established by the competent authority in accordance with Article 103(2) are not met.

4. 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[22] 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.

5. For practices subject to notification, Member States shall specify the information to be provided in conjunction with the notification, so as to allow the competent authority to establish appropriate means of regulatory control. Where an application for an authorisation is submitted, no separate notification is needed.

6. Activities involving radioactively contaminated materials resulting from authorised releases or cleared materials shall not be managed as a planned exposure situation and, hence, do not need to be notified.

[22] *[reference to Euratom Drinking Water Directive]*

Article 25c [27]

Exemption from notification

1. 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 authorised by the competent authority and satisfy the general exemption and clearance criteria set out in Annex VI; or

(b) without prejudice to Article 25b(3) and (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 authorised 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 an approved type;

(ii) the apparatus does not cause, in normal operating conditions, a dose rate exceeding 1 $\mu Sv \cdot h^{-1}$ at a distance of 0.1 m from any accessible surface; and

(iii) conditions for 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 an approved type; and

(ii) it does not cause, in normal operating conditions, a dose rate exceeding 1 $\mu Sv \cdot h^{-1}$ 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 [28]

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 other non-medical purposes;

(c) the manufacture of electrical equipment emitting ionising radiation and operating at a potential difference of more than 30 kilo volt (kV).

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

3. The regulatory decision to submit types of practices to 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 [29]

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 facility of the nuclear fuel cycle 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) the manufacture, import, export, use or taking possession of a high-activity sealed source;

(e) the operation, decommissioning and closure of any facility for the processing, long-term storage or disposal of radioactive waste;

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

~~*Article 25*~~

~~*Notification*~~

~~1. Member States shall require all practices, including those practices identified in accordance with Article 24, to be notified, except for justified practices involving the following:~~

~~(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 authorised by the competent authorities and satisfy the general exemption and clearance criteria set out in Annex VI; or~~

~~(b) radioactive materials where the concentrations of activity per unit mass do not exceed the exemption values set out in Table A of Annex VI, or higher values that, for specific applications, are authorised by the competent authorities and satisfy the general exemption and clearance criteria set out in Annex VI; or~~

~~(ba) apparatus containing radioactive substances provided that:~~

~~(i) it is of a type approved by the competent authorities of the member State; and~~

~~(ii) the radioactive substances are embedded in a capsule or fixed to a solid holder; and~~

~~(iii) it does not cause, in normal operating conditions, a dose rate exceeding 1 $\mu Sv \cdot h^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus; and~~

~~(iv) conditions for disposal have been specified by the competent authorities.~~

~~(c) any cathode ray tube intended for the display of visual images, or other electrical apparatus operating at a potential difference not exceeding 30 kV, or any other electrical apparatus which is of a type approved by the competent authorities of the Member State, provided that it does not cause, in normal operating conditions, a dose rate exceeding 1 $\mu Sv \cdot h^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus.~~

~~2. Member States may exempt further types of practices from the notification requirement subject to compliance with the general exemption criteria established in point 3 of Annex VI, or in such cases where an assessment of the optimisation of protection shows that exemption is the best option.~~

3. Practices that involve naturally occurring radioactive material, identified in accordance with Article 24, and produce or process residues which are known to be recycled into identified building materials are subject to notification if the activity concentration index as defined in Annex VII in the resulting building materials is liable to exceed 1. The undertaking shall also in this case inform the user of the residue about the activity concentration of the residue.

4. 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 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 irrespective of the provisions of paragraph 1(b).

5. For types of practices subject to notification, Member States shall specify the information to be provided by the undertaking so as to allow the competent authority to establish appropriate means of regulatory control.

6. [For the purpose of exemption under paragraph 1(c), Member States shall exchange information on the type approvals that have been granted and on the underlying documentation and assessment. Competent authorities shall take into account such information received, as well as applicable European and international standards, in making their own decisions with regard to the exemption of corresponding practices.]

Article 27

Authorisation

2. Member States shall require licensing for the following practices:

(a) the operation and decommissioning of any facility of the nuclear fuel cycle and the exploitation and closure of uranium mining;

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

(c) the manufacture, import, export, use or taking possession of a high-activity sealed source;

(d) the operation, decommissioning and closure of any facility for the processing, storage or disposal of radioactive waste;

(e) [practices in which workers are liable to receive an annual effective dose of more than 6 mSv in normal operation and under normal working conditions;]

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

3. Member States shall require either registration or licensing of 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 use of radiation generators or radioactive sources for industrial radiography, the processing of products or research, and the use of accelerators, except electron microscopes;

(c) the use of radiation generators or radioactive sources for medical exposures;

(d) the manufacture and operation of electrical equipment emitting ionising radiation as well as the import or export of such equipment;

(e) practices in which workers are liable to receive an annual effective dose of more than 1 mSv in normal operation and under normal working conditions;

(f) industries involving naturally occurring radioactive material identified by Member States as required in Article 24, and liable to lead to an effective dose to a member of the public equal to or exceeding 0.3 mSv per year.

4. Member States may require registration or licensing for types of practices other than those listed in paragraphs 2 and 3.

5. In cases where a limited risk of exposure does not necessitate the examination of individual cases and the practice is undertaken in accordance with conditions laid down in national legislation, competent authorities may limit regulatory control to registration of the practice and an appropriate frequency of inspections.

Article 28 ***[30]***

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. **For the purpose of granting a licence, the information referred to in paragraph 1 shall take into account the indicative list of information in Annex VIIa**.

~~2. The information referred to in paragraph 1 shall, for the purpose of granting a licence or, where apropriate, for the purpose of registration, cover at least, if applicable, the following:~~

~~(a) responsibilities and organisational arrangements for protection and safety;~~

~~(b) staff competences, including information and training;~~

~~(c) design features of the installation and radiation sources;~~

~~(d) anticipated occupational and public exposures in normal operation;~~

~~(e) safety assessment of the activities and the installation 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 installation 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.~~

3. A licence shall include, as ap**p**ropriate, specific conditions and reference to requirements in national legislation so as to ensure that the elements of the licence are legally enforceable**, and** ~~or to~~ impose appropriate restrictions on the operational limits ~~or~~ **and** conditions of operation. The conditions shall also require**,** when ap**p**ropriate**,** the formal **and**~~,~~ documented implementation of the principle of optimisation.
4. Where applicable, a licence shall include **conditions on the** ~~a~~ discharge **of radioactive effluent,** ~~authorisation issued~~ in accordance with the requirements laid down in Chapter VIII for **the** authorisation of the release of liquid or airborne radioactive effluent into the environment.
5. Member States shall require the undertaking to 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 licensing requirements**,** with regard to occupational or public exposure or as defined by the authorities for medical exposure.

Article 29 ***[31]***

Release from regulatory control

1. The disposal **of radioactive waste, and the** recycling or reuse of radioactive materials arising from any authorised practice is subject to authorisation.
2. The materials for disposal, recycling or reuse may be released from regulatory control provided that the **activity** concentrations ~~of activity per unit mass~~:
   (a) do not exceed the values set out in ~~Annex VI, part 1 of~~ 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, in addition to the general clearance levels referred to in (a), shall be established 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.

3. For the clearance of materials containing naturally-occurring radionuclides, ~~the values for the concentrations of activity per unit mass shall be those laid down in Annex VI, part 2 of Table A. Nevertheless the following requirements shall apply:~~ **where these result from authorised practices in which natural radionuclides are processed for their radioactive fissile or fertile properties, in particular those forming part of the nuclear fuel cycle, the clearance levels shall comply with the dose criteria for clearance of materials containing artificial radionuclides.**~~;~~

~~(a) for practices subject to authorisation as specified in Article 27(3)(f), the dose criteria for clearance of naturally occurring radionuclides shall be complied with;~~

~~(b) for other authorised practices, in particular those forming part of the nuclear fuel cycle, the clearance levels shall comply with the dose criteria for clearance of materials containing artificial radionuclides;~~

4. The deliberate dilution of radioactive **materials** ~~residues~~, other than the mixing of materials that takes place in normal operation when radioactivity is not a consideration, shall not be permitted. The competent authority may authorise in specific situations the mixing of radioactive **material with non-radioactive materials, if the reuse or recycling of this type of radioactive material is a justified practice**. ~~residues, for instance those containing radioactive material with other materials if:~~

~~(a) the radioactive residues results from practices involving naturally occuring radioactive material or:~~

~~(b) the radioactive residues are intended for reuse or recycling that are justified from a radiation protection point of view.~~

CHAPTER VI

~~PROTECTION OF WORKERS, APPRENTICES AND STUDENTS~~

OCCUPATIONAL EXPOSURES

Article 30 ***[32]***

Responsibilities

1. The relevant requirements for occupational exposure in this Directive~~,~~ shall apply to the protection of workers, apprentices and students in any exposure situation where their exposure is the legal responsibility of an undertaking**,** ~~or~~ an employer **or any other organisation** responsible for the **protection of**:
   (a) ~~protection of~~ outside workers;
   (b) ~~protection of~~ emergency workers;
   (c) ~~protection of~~ workers ~~for~~ **involved in** the remediation of contaminated land, buildings and other constructions;
   (d) ~~protection of~~ workers **who are exposed** to radon at work, in the situation specified in Article 53(4).

~~2. The responsibility of an undertaking for occupational exposure shall extend to individuals who are self-employed or work on a voluntary basis or for a charity organisation.~~

2~~3~~. The undertaking shall be responsible for assessing and implementing arrangements for the radiation protection of exposed workers. ~~If an exposed worker is not employed by the undertaking responsible for the radiation source to which the worker may be exposed or for the exposure situation in which the worker is performing activities, the responsibilities for occupational exposure of workers shall be shared between the undertaking and the employer of the exposed worker. The shall be responsible for the categorisation of these workers, their individual monitoring, the recording and reporting of results of the individual monitoring, ensuring compliance with the dose limits, medical surveillance and protection of pregnant and breastfeeding workers.~~

3. In the case of outside workers, the responsibilities of the undertaking and the employer of outside workers are stipulated in Article 50.

4. All workers, apprentices and students shall be obliged to make their contribution, as far as possible, towards the protection offered to them through the requirements laid down in this ~~c~~**C**hapter.

Article 31 ***[33]***

Operational protection ~~of workers~~

The operational protection of exposed workers**, apprentices and students** shall be based on:

(a) prior evaluation to identify the nature and magnitude of the radiological risk to exposed workers**, apprentices and students**;

(b) optimisation of radiation protection in all working conditions;

(c) ~~identification and~~ classification of 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 ~~of workers~~, in accordance with Article 16.

Article 32 ***[34]***

Consultations with a radiation protection expert

Member States shall require ~~the~~ undertaking**s** to consult, where ap**p**ropriate, ~~a~~ radiation protection expert**s, within their areas of competence as outlined in Article 84,** ~~on the examination and testing of protective devices and measuring instruments,~~ in particular for:

(a) the examination and testing of protective devices and measuring instruments;

(**b**~~a~~) prior critical review of plans for installations from the point of view of radiation protection;

(**c**~~b~~) the acceptance into service of new or modified radiation sources from the point of view of radiation protection;

(**d**~~c~~) regular checking of the effectiveness of protective devices and techniques;

(**e**~~d~~) regular calibration of measuring instruments and regular checking that they are serviceable and correctly used.

*Article 33 **[35]***

Arrangements in workplaces

1. For the purposes of radiation protection, arrangements shall be made as regards all workplaces where workers are liable to receive an exposure to ionising radiation in excess of 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.
2. For ~~practices or~~ workplaces **where** ~~involving~~ exposure **to radon is managed as a planned exposure situation as specified in Article 53(4), and** where the effective dose to workers is liable to exceed 6 mSv per year, **the Member States shall determine which** ~~the relevant~~ requirements set out in this Chapter **are appropriate** ~~shall apply~~. **In these circumstances and where** ~~Where~~ the effective dose to workers is less than or equal to 6 mSv per year ~~and liable to be above 1 mSv per year~~, the competent authorit**y**~~ies~~ shall ~~at least~~ require the undertaking to keep exposures under review~~, taking into account the potential for protection to be improved or the potential for doses to increase over time or as a result of changes in the process or the work arrangements~~.
3. For an undertaking~~s~~ 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**.
   Where the effective dose to the crew is less than or equal to 6 mSv per year and liable to be above 1 mSv per year, the competent authorit**y**~~ies~~ shall ~~at least~~ require the undertaking to keep exposures under review~~, taking into account the potential for doses to change over time or as a result of changes in the work arrangements~~. The undertaking~~s~~ shall 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.

Article 34 ***[36]***

Classification of workplaces

1. Arrangements in workplaces shall include a classification ~~of workplaces~~ into different areas, where appropriate, on the basis of an assessment of the expected annual doses and the probability and magnitude of potential exposures.
2. A distinction shall be made between controlled areas and supervised areas. The competent authorit**y**~~ies~~ shall establish guidance on the classification of controlled and supervised areas with regard to particular circumstances.
3. The undertaking shall keep under review the working conditions in controlled and supervised areas.

Article 35 ***[37]***

Requirements for controlled areas

1. The minimum requirements for a controlled area shall be 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 **and local rules** 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) <u>The worker shall be provided with the necessary personal protective equipment.</u>

2. The undertaking shall be responsible for implementation of these duties following consultations with the radiation protection expert.

Article 36 ***[38]***

Requirements for supervised areas

1. The requirements for a supervised area shall be 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. The undertaking shall be responsible for implementation of these duties following consultations with the radiation protection expert.

Article 37 ***[39]***

Radiological surveillance of the workplace

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

Article 38 ***[40]***

Categorisation of exposed workers

1. For the purposes of monitoring and surveillance, a distinction shall be 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. The undertaking or, in the case of outside workers, the employer, shall decide on the categorisation of individual workers prior to their taking up work that may give rise to exposure, and shall regularly review this categorisation on the basis of working conditions and medical surveillance. The distinction shall also take into account potential **exposures** ~~exposure and the risk for accidents~~.

3. Female workers who have declared pregnancy or breastfeeding shall in general not be assigned to work requiring categorisation as a category A worker, for the duration of their condition.

4~~3~~. For emergency workers, the distinction referred to in paragraph 1 ~~of this Article~~, **shall** have no effect on the requirements for monitoring set out in Articles 37~~,~~ **and** 39 **to** 43 as long as the workers are not involved in an actual emergency exposure situation.

Article 39 ***[41]***

Individual monitoring

1. Category A workers shall be 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. Monitoring for category B workers shall be 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 **systematic** individual measurements are impossible 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** ~~working environment~~ provided for in Article 37 or on the basis of ~~approved~~ calculation methods **approved by the competent authority**.

Article 40 ***[42]***

Monitoring in the case of accidental exposure

In the case of accidental exposure, the undertaking, in consultation with the radiation protection expert and **in collaboration with** the dosimetry service, shall assess the relevant doses and their distribution in the body.

Article 41 ***[43]***

Recording and reporting of results

1. A record containing the results of individual monitoring shall be made for each exposed worker for whom such monitoring is performed.
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~~,~~and 52;
   (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 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. Exposure as referred to in Articles 40, 51~~,~~ and 52 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.

~~5. Where the results of monitoring are used for the management of planned exposure situations, appropriate arrangements shall be made for not including in the records exposures attributed to background external radiation or radon ingress from soil in the case of industries processing naturally occurring radioactive material.~~

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 and 52 be:
   (a) made available to the competent authorit**y**~~ies~~, 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 service~~s~~ in order for them to interpret the implications of the results for human health, as provided for in Article 44;
   (d) submitted to the data system for individual radiological monitoring established by the Member State in accordance with provisions set out ~~n~~ **in** Annex VIII.

2~~1~~**a**. Member States shall require the undertaking ~~and~~**, or in case of outside workers,** the employer**,** to grant workers ~~to have access~~**,** 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~~2~~. Member States shall determine the arrangements under which the results of individual monitoring are conveyed.

4~~3~~. The data system for individual radiological monitoring shall cover at least the data listed in Annex VIII, Section A.

5~~4~~. In the case of an accidental or emergency exposure, the undertaking shall communicate the results of individual monitoring **to the competent authority** without delay.

6 ~~5~~. Member States shall facilitate the exchange among **the** competent authorit**y**~~ies~~, occupational health services, radiation protection experts, or dosimetry services ~~within the Union~~ 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.

Article 44 ***[45]***

Medical surveillance of exposed workers

1. The medical surveillance of exposed workers shall be based on the principles that govern occupational medicine generally.
2. The medical surveillance of category A workers shall be **undertaken by** the ~~responsibility of~~ occupational health service~~s~~.
   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 service~~s~~ 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 service~~s~~ consider necessary, shall depend on the type of work and on the individual worker's state of health.
4. The occupational health service~~s~~ 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

The following medical classification shall be 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

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. A medical record shall be 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. In addition to the medical surveillance of exposed workers provided for in Article 44, provision shall be made for any further action considered necessary by the occupational health service~~s~~ 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~~s~~.
2. Special medical surveillance shall be performed in each case where ~~an annual effective dose of [50 mSv] in a year or~~ any of the ~~other~~ dose limits laid down in Article 10~~(2)~~ has been exceeded.
3. Subsequent exposure conditions shall be subject to the agreement of the occupational health service~~s~~.

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 workers employed on a permanent basis by the undertaking.
2. The undertaking shall be 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, **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;

   (b) **for entry into controlled areas**, ensure that, in addition to the basic training in radiation protection referred to in Article 16, the outside worker has received specific training in connection with the characteristics of the workplace and the activities;

   (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. 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) providing the information and training in the field of radiation protection referred to in Article 16;

   (c) guaranteeing that their workers are subject to ~~the~~ **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).

Article 51 ***[52]***

Specially authorised exposures

1. In exceptional circumstances evaluated case by case, excluding emergencies, the competent authorit**y**~~ies~~ may, where a specific operation so requires, authorise individual occupational exposures of identified **volunteer** 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 authorit**y**~~ies~~. 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 **female workers**~~women~~, and, if there is a risk of intake of radionuclides **or bodily contamination**, breastfeeding **female workers**~~women~~**,** shall be excluded from such exposures;
   (c) the undertaking shall carefully justify such exposures in advance and thoroughly discuss them with the **volunteer** ~~voluntary~~ workers, their representatives, the occupational health service~~s or~~ **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;
   (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. The exposure of spacecraft crew above the dose limits shall be managed as a specially authorised exposure.

Article 52 ***[53]***

Emergency occupational exposure

1. Emergency occupational exposures shall remain, whenever possible, below the dose limits laid down in Article 10.

2. In situations, identified in the emergency plan, where the above condition is anticipated not to be feasible, the following conditions shall apply:

a) Reference levels for emergency occupational exposure shall be set, in general below 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 external exposure of emergency workers may be set above 100 mSv, but not exceeding 500 mSv;

c) Doses shall not exceed thresholds for deterministic effects.

~~Emergency response organisations shall ensure that no emergency worker undertakes actions resulting in doses as a result of these actions in excess of~~ 100 ~~mSv, except in specific cases identified in the national emergency plan.~~

~~**2.** In such cases, appropriate reference levels shall be defined. In exceptional situations, in order to save life, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions, a reference level above 100 mSv may be set, up to a maximum of 500 mSv.~~

3~~2~~. **Member States shall ensure** ~~Emergency response organisations shall ensure~~ that ~~emergency~~ workers who are liable to undertake actions whereby 100 mSv may be exceeded have been clearly and comprehensively informed in advance of the associated health risks and the available protection measures and undertake these actions voluntarily.

4~~3~~. In the event of an emergency exposure, Member States shall require ~~that~~ radiological monitoring ~~[and medical surveillance~~ 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 exposure, Member States shall require medical surveillance of emergency workers, as defined in Articles 44 and 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**, which shall not exceed (as an annual average) 300 Bq m^{-3}, unless it is warranted by national prevailing circumstances**. ~~Such reference levels shall be equal to or above the reference level set for any type of existing buildings but shall not exceed an annual average of 1 000 Bq m^{-3} for workplaces.~~
2. Under the national action plan referred to in Article 103, Member States shall **require** ~~ensure~~ that radon measurements are carried out in ~~underground workplaces and in~~ specific types of workplaces ~~in radon prone areas,~~ as identified **under point 3 of Annex XVI** ~~in the action plan~~.
3. Member States shall require undertakings in which the national reference level for ~~existing~~ workplaces is exceeded to take appropriate action in order to reduce radon concentrations or exposures, in accordance with the principle of optimisation set out in Chapter III.
4. Where **areas within** workplaces ~~or specific rooms within a building~~ continue to exceed the reference level**,** despite the action taken in accordance with paragraph 3, ~~the~~ Member States shall **require** ~~manage~~ this situation **to be managed** as a planned exposure situation and **Article 33(2) shall** apply ~~the relevant requirements for occupational exposure as specified in Article 30~~(d).

CHAPTER VII

~~PROTECTION OF PATIENTS AND OTHER INDIVIDUALS SUBJECTED TO MEDICAL EXPOSURE~~

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 ~~or well-being~~ 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. In particular:

   (a) New types of practices involving medical exposure shall be justified in advance before being generally adopted~~. Justification of new types of practices shall also take into account the individual detriment from the exposure of the medical radiological staff and other individuals~~;

   (**b** ~~c~~) All individual medical exposures shall be justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.

   (**c** ~~d~~) If a type of practice involving a medical exposure is not justified in general, a specific individual exposure of this type may be justified in special circumstances, to be evaluated on a case-by-case basis and documented.

   (**d** ~~e~~) The referrer and the practitioner**, as specified by Member States,** shall 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** ~~f~~) Medical exposure for biomedical and medical research shall be examined by an ethics committee, set up in accordance with national procedures and/or by the competent authority~~ies~~;

(**f** ~~g~~) Specific justification for medical radiological procedures to be performed as part of a health screening programme shall be carried out by the competent authority in conjunction with appropriate medical scientific societies **or professional bodies**.

(**g** ~~h~~) The exposure of carers and comforters shall show a sufficient net benefit, taking into account the direct health benefits to a patient, the benefits to the carer / comforter and the detriment that the exposure might cause.

(**h** ~~i~~) Any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, shall be part of a health screening programme, or shall require specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant **medical scientific societies** ~~professional bodies~~ and **the** competent authorit**y**~~ies~~. Special attention shall be given to the provision of information to the **exposed individual** ~~patients~~, as required by Article 56(3).

Article 55 ***[56]***

Optimisation

1. All doses due to medical exposure for radiodiagnostic, ~~and~~ interventional **radiology, planning and guiding** ~~radiology~~ purposes shall be kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and social factors**.**

   For all medical exposure of **patients** for radiotherapeutic purposes, exposures of target volumes shall be individually planned **and their delivery verified as appropriate**, taking into account that doses of 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 biomedical and medical research project:
   (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. The optimisation shall include the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical exposure procedures, quality assurance, and the assessment and evaluation of patient **doses or the verification of** ~~and staff doses or~~ administered activities **and any associated staff doses**, taking into account economic and social 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,** ~~appropriate,~~ provides the patient or legal guardian with **information on the risks of ionising radiation and appropriate** ~~written~~ instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable**. For therapeutic procedures these should be written instuctions.** ~~and providing information on the risks of ionising radiation.~~

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

*Article 56 **[57]***

Responsibilities

1. The referrer and the practitioner shall be involved in the justification process as specified by Member States.
2. Member States shall ensure that any medical exposure takes place under the clinical responsibility of a practitioner.
3. **Wherever practicable and prior to the exposure taking place, the** ~~The~~ practitioner **or the referrer, as specified by Member States,** shall ensure that the patient or legal guardian is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure. ~~This information should be part of the informed consent process as specified by Member States.~~ Similar information as well as relevant guidance ~~in accordance with Article 55(5)(b)~~ shall be given to carers and comforters**, in accordance with Article 55(5)(b)**.
4. Practical aspects of medical exposure 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

1. Written protocols for every type of standard medical radiological procedure shall be established for each equipment for relevant categories of patients.

2. The parameters for assessing the patient dose, as specified in Article 59, paragraphs 5 and 6, shall form part of the report of the examination.

3~~2~~. Member States shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to the referrers.

4~~3~~. In medical radiological practices, a medical physics expert shall be appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice. In particular:

(a) in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved;

(b) in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, a medical physics expert shall be involved;

(c) for other simple radiodiagnostic **practices** ~~procedures~~, a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.

5~~4~~. Clinical audits shall be carried out in accordance with national procedures.

6~~5~~. Member States shall ensure that appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that corrective action is taken **promptly** where appropriate.

*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(4).

*Article 59 **[60]***

Equipment

~~1. Member States shall take such steps as they may consider necessary with a view to avoiding unnecessary proliferation of medical radiological equipment.~~

1~~2~~. 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 authorit**y**~~ies~~;

(c) appropriate quality assurance programmes ~~and dose or administered activity assessments~~ are implemented by the undertaking; and

(d) acceptance testing~~, involving the medical physics expert,~~ 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 major maintenance procedure.

2~~3~~. ~~C~~ **The c**ompetent authorit**y**~~ies~~ shall take steps to ensure that the necessary measures are taken by the undertaking to improve inadequate or defective **performance** ~~features~~ 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, if appropriate, taking the equipment out of service.

3~~4~~. The use of fluoroscopy equipment without a device to **automatically** control the dose rate, or without an image intensifier or equivalent device, shall be prohibited.

4. Equipment used for external beam radiotherapy operating at a potential difference exceeding 1 mega volt (MV) and brought into use after this directive has entered into force shall have a device to verify key treatment parameters.

5. Any equipment used for interventional radiology and computed tomography shall have a device or a feature informing the practitioner of **relevant parameters for assessing the patient dose. Equipment used for interventional radiology and computed tomography shall have the capacity to transfer this information to the report of the examination.** ~~the quantity of radiation produced by the equipment during the medical radiological procedure. Any other medical radiodiagnostic equipment brought into use after this Directive has entered into force shall have such a device or a feature informing the practitioner of relevant equipment parameters during the medical radiological procedure for assessing the patient dose or a dose indicator_ or a feature or equivalent means of determining the quantity of radiation produced. The radiation dose or the dose indicator shall form part of the report on the examination.~~

6. ~~Any equipment used for interventional radiology and computed tomography~~ **Without prejudice to paragraph 5, new medical radiodiagnostic equipment** shall have a device or ~~a feature~~ **equivalent means** informing the practitioner of relevant ~~equipment~~ parameters ~~during the medical radiological procedure~~ for assessing the patient dose ~~or a dose indicator~~. ~~The radiation dose or the dose indicator shall form part of~~ **Where appropriate, the equipment shall have the capacity to transfer this information to** the report **of** ~~on~~ the examination.

Article 60 ***[61]***

Special practices

1. Member States shall ensure that appropriate [or specially adapted] medical radiological equipment, practical techniques and ancillary equipment **is** ~~are~~ used **in** ~~for~~ medical exposure:
   (a) of children;
   (b) as part of a health screening programme;
   (c) involving high doses to the patient, such as interventional radiology, **nuclear medicine,** computed tomography or radiotherapy.

   ~~Member Staes shall adopt be given to specific provisions for~~ **Special attention shall be given to** quality assurance programmes and the assessment of dose or administered activity~~, as mentioned in Article 59(2)(c),~~ for these practices.

2. Member States shall ensure that practitioners and those individuals referred to in Article 56(4) who perform the exposures referred to in paragraph 1 obtain appropriate training **on** ~~in~~ these medical radiological practices as required by Article 19.

Article 61 ***[62]***

Special protection during pregnancy and breastfeeding

1. In the case of a ~~woman~~ **female patient** of childbearing age, the referrer and the practitioner shall inquire**,** as specified by Member States**,** whether she is pregnant or breastfeeding, if relevant.

2. If pregnancy cannot be excluded, depending on the ~~type of~~ medical **radiological procedure** ~~exposure~~, 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** ~~the urgency of the procedure, and the exposure~~ both ~~of~~ the expectant mother and the unborn child**.** ~~shall be given particular consideration in the justification and optimisation.~~

3~~2~~. In the case of **a** breastfeeding **female patient** ~~women,~~ in nuclear medicine, depending on the ~~type of~~ medical **radiological procedure** ~~examination or treatment~~, **special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the breastfeeding female patient** ~~the urgency of the procedure, and the exposure both of the mother~~ and the child**.** ~~shall be given particular consideration in the justification and optimisation.~~

4~~3~~. Without prejudice to paragraphs 1, **2 and 3**~~2~~, Member States shall take measures to increase the awareness of ~~women~~ **female patients** to whom this Article applies~~, 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 ~~medical~~ exposures **of individuals subject to medical exposure** ~~from all medical radiological procedures~~, taking into account economic and social factors;

(b) for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures~~, commensurate with the hazard and probability of the event~~;

(c) for all medical exposures the undertaking implements **an appropriate** ~~a~~ 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** ~~hazard and probability of the event~~;

(**d** ~~ca~~)arrangements are made to inform the referrer~~, the patient and, where relevant,~~ **and** the practitioner**, and where practicable the patient, or their representative,** about **clinically significant** ~~an~~ unintended or accidental exposure**s** and the results of the analysis;

(**e**~~d~~) **(i)** the undertaking declares as soon as possible to the competent authorit**y**~~ies~~ the occurrence of significant events**;** ~~as defined by the authorities, including~~
(ii) the results of the investigation and the corrective measures to avoid such events **shall be reported to the competent authority within the time period specified by the Member State**;

(**f**~~e~~) mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events~~, includiong the results of investigations referred to under (e)~~.

*Article 63 **[64]***

Estimates of population doses

Member States shall ensure that the distribution of individual dose estimates from medical exposure **for radiodiagnostic, interventional radiology, planning and guiding purposes** is determined and shall take into account**, as appropriate,** the age distribution and the gender of the exposed population.

CHAPTER VIII

~~PROTECTION OF MEMBERS OF THE PUBLIC~~
PUBLIC EXPOSURES

SECTION 1

PROTECTION OF THE MEMBERS OF THE PUBLIC AND LONG-TERM HEALTH PROTECTION IN NORMAL CIRCUMSTANCES

~~Article 64~~[23]

~~Principles of protection of members of the public~~

~~Member States shall create the conditions necessary to ensure the best possible protection of members of the public under the prevailing circumstances, based on the principles set out in Chapter III on the system of radiation protection and applying the requirements laid down in the present Chapter.~~

Article 65 ***[65]***

Operational protection of members of the public

1. **Member States shall ensure that the** ~~The~~ operational protection of members of the public in normal circumstances from practices subject to licensing shall include ~~all arrangements and surveys for detecting and minimising factors which, in the course of any operation involving exposure to ionising radiation, are liable to create a risk of exposure for the members of the public which cannot be disregarded from the radiation protection point of view. Such protection shall include~~ the following ~~tasks~~:
   (a) examination ~~and approval of plans for installations involving an exposure risk, and~~ of the ~~proposed siting of such~~ **information provided on the facility** ~~installations~~ within **licensed practices as referred to in Article 28** ~~the territory concerned, from the point of view of radiation protection~~;
   (b) examination and approval of the proposed siting of the facility, taking into account, relevant demographic, meteorological, geological, hydrological and ecological conditions;

[23] **Not needed, in consistency with chapters on occupational and medical exposures.**

(**c**~~b~~) acceptance into service of ~~new~~ **the facility** ~~installations involving an exposure risk,~~ 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**~~, taking into account, if relevant, demographic, meteorological, geological, hydrological and ecological conditions~~;

(**d**~~e~~) examination and approval of plans for the discharge of radioactive effluents**:**~~;~~

(e) measures to control the access of members of the public to the facility.

~~These tasks shall be carried out in accordance with rules laid down by the competent authorities on the basis of the exposure risk involved.~~

2. The competent authority shall establish authorised limits for discharging radioactive effluents. These discharge authorisations shall**:**

(a) take into account the results of the optimisation of **radiation protection** ~~public exposure~~;

(b) reflect good practice in the operation of similar facilities;

(c) allow a **reasonable** margin for operational flexibility ~~of a facility~~ **if so requested by the undertaking;**

(d) take into account, where appropriate, the results of a generic screening assessment conducted by the Member State to provide assurance that environmental criteria for long-term health protection based on available scientific knowledge are met.

3. For practices subject to registration, Member States shall insure 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 **make arrangements**~~, on the basis of the exposure risk involved, establish a system~~ for the estimation of doses to members of the public from authorized practices. **The extent of such arrangements shall be proportionate to the exposure risk involved.**

2. The competent authorit**y**~~ies~~ shall identify practices **for which** ~~where an~~ **a regular** assessment of doses to members of the public shall be carried out **and specify whether this assessment needs to be carried out in a realistic way or, for specific types of practices, a screening assessment with generic data is sufficient**. ~~The assessment shall be carried out in a realistic way, if appropriate.~~

3. For the realistic assessment of doses to the members of the public, the competent authority shall:

   (a) ~~ensure that dose estimates for representative persons as referred to in Article 65 are made as realistic as reasonably feasible;~~

   ~~(b)~~ decide on **a reasonable extent of surveys to be conducted and information to be taken into account in order to identify** ~~the frequency of assessments and take all necessary steps to ensure the identification of~~ 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~~, taking into account the radiological risks,~~ that the estimates of doses to **the representative person** ~~members of the public~~ 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 ~~and specification of the characteristics of the representative person~~;

   (d) require records to be kept and be made available to all stakeholders relating to measurements of external exposure **and radioactive contamination**, estimates of intakes of radionuclides ~~and radioactive contamination~~, 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 the radioactive airborne or liquid discharges into the environment **in normal operation** and to report the results of this monitoring to the competent authority.
2. Member States shall require any undertaking responsible for a nuclear power reactor or reprocessing plant to **ensure that the** monitor**ing of** discharges **is** ~~in normal operation~~ in accordance with the standardised information selected for monitoring and reporting to the European Commission ~~as laid down in~~**, taking into account the** Commission Recommendation 2004/2/Euratom[24].

Article 68 ***[68]***

Tasks for the undertakings

~~1.~~ 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~~ance~~ into service~~, for the purpose of surveillance of radiation protection, of~~ **adequate** equipment and procedures for measuring and assessing~~, as appropriate,~~ exposure of members of the public and radioactive contamination of the environment;

(c) check the effectiveness and maintenance of **equipment** ~~technical devices~~ as referred to in (b) and ensure the regular calibration of measuring instruments.

~~2.~~ **(d) appoint** ~~R~~**r**adiation protection experts ~~and, as appropriate, radiation protection officers~~ ~~shall~~ **to supervise** ~~be involved in~~ the performance of the tasks referred to in **(a), (b) and (c).** ~~paragraph 1.~~

[24] OJ L 2/36, 6.1.2000.

~~*Article 69*~~[25]

~~*Environmental monitoring programme*~~

~~Member States shall ensure that an appropriate environmental monitoring programme is in place, allowing for the reporting requirements under Article 36 of the Euratom Treaty and in particular as specified in Commission Recommendation 2000/473/Euratom for estimating the exposure of members of the public.~~

SECTION 2

EMERGENCY EXPOSURE SITUATIONS

Article 70 ***[69]***

Emergency response

1. Member States shall require the undertaking responsible for a practice to notify the competent authorit**y**~~ies~~ immediately of any emergency occurring in its facility or **is** related to its activities and to take all appropriate action to reduce the consequences.
2. Member States shall ensure that, in the event of an emergency on its own territory, the undertaking 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 ~~emitted radiation and~~ emission of **radiation and the release of** radionuclides~~, or to prevent exposure or contamination resulting from orphan sources~~;
   (b) the environment, to reduce ~~or stop pathways leading to~~ the exposure ~~of radioactive substances~~ to individuals **resulting from radioactive substances through relevant pathways**;
   (c) individuals, to reduce **their** exposure.

[25] *Moved to Section 3.*

4. In the event of an emergency on or outside its territory, the **Member State or the competent** ~~emergency response~~ authority 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**.**~~;~~
   ~~(c) the assessment of residual dose and comparison of it with the reference levels set in accordance with Article 8.~~
5. The **Member State or the competent** ~~emergency response~~ authority shall, if the situation so requires, ensure that provision is made to organise the medical treatment of victims.

Article 71 ***[70]***

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

1. Member States shall ensure that the members of the public **most** likely to be affected in the event of an emergency ~~giving rise to a significant release~~ 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 ~~of~~ **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 ~~contained~~ **listed** in Section B of Annex X which are relevant to the type of emergency.

SECTION 3

EXISTING EXPOSURE SITUATIONS

Article 72A[26] ***[72]***

Environmental monitoring programme

Member States shall ensure that an appropriate environmental monitoring programme is in place, allowing for the reporting requirements under Article 36 of the Euratom Treaty and in particular as specified in Commission Recommendation 2000/473/Euratom[27]**.**

Article 73 ***[73]***

Contaminated areas

1. Optimised protection strategies for managing contaminated areas shall include, where applicable, the following:
   (a) objectives **including** ~~and~~ long-term goals pursued by the strategy and corresponding reference levels, in accordance with Article 8.

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[26] *Moved from Article 69.*

[27] OJ L 191/37, 27.7.2000.

(b) delineation of the affected regions 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 regions and members of the public;

(d) consideration of the need to prevent or control access to the affected regions, or to impose restrictions on living conditions in these regions;

(e) assessment of the ~~long-term~~ 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 reference levels consistent with day-to-day life;

(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.

Article 74 [74]

Indoor exposure to radon

1. Member States shall establish national reference levels for indoor radon concentrations, which shall not exceed (as an annual average) 300 Bq m^{-3}.

2. Under the national action plan referred to in Article 103, Member States shall promote action to identify dwellings exceeding the reference level and encourage, where appropriate, by technical or financial 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.

~~*Article 74*~~

~~*Radon in dwellings and buildings with public access*~~

~~1. Member States shall establish national reference levels for indoor radon concentrations, which shall not exceed (as an annual average):~~

~~(a) [200 Bq m^{-3} for new dwellings and new buildings with public access;~~

~~(b) 300 Bq m^{-3} for existing dwellings;~~

~~(c) 300 Bq m^{-3} for existing buildings with public access. In specific cases where the occupancy time is low, a reference level of up to 1 000 Bq m^{-3} can be set.]~~

~~2. Under the national action plan referred to in Article 103, Member States shall~~

~~(a) promote action to identify existing dwellings exceeding the reference level and to encourage, where appropriate by technical or financial means, radon-reducing measures in existing dwellings where the reference levels are exceeded;~~

~~(b) ensure that radon measurements are carried out in identified types of buildings with public access.~~

~~3. Member States shall ensure that local and national information on prevailing radon concentrations, on the associated health risks and on the technical means available for reducing existing radon concentrations is provided.~~

Article 75 ***[75]***

Gamma radiation from ~~*B*~~***b****uilding materials*

1. The requirements in **this** Article ~~75(2) to (6)~~ shall apply to ~~the following~~:

~~(a)~~ building materials which are identified and listed by the ~~relevant~~ competent authority as being of concern from the 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.~~; or~~

~~(b) building materials which the authority has assessed to be of concern in the national action plan for radon, as specified in Article 103.~~

2. For identified types of building materials, the industries placing such materials on the market:

   (a) shall determine the **activity** concentrations of the radionuclides specified in Annex VII;

   (b) shall provide, **on request,** 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.

3. **The reference level applying to indoor external exposure to gamma rays emitted by building materials, in addition to outdoor external exposure, shall be 1 mSv per year.**

   ~~The competent authority shall ensure that identified types of building materials are classified, as laid down in Annex VII, on the basis of their intended use and activity concentration index.~~

~~4. Identified types of building materials which are not liable to give doses exceeding the reference level of 1 mSv per year for indoor external exposure from building materials, in excess of prevailing outdoor external exposure, shall be exempt from requirements at national level, without prejudice to Article 103. Such building materials shall nevertheless be further monitored to ensure that the activity concentration continues to comply with this reference level. Building materials of category A as specified in Annex VII shall be exempt from any restrictions with regard to their placing on the market in the Union.~~

4~~5~~. For identified types of building materials which are liable to give doses exceeding the reference level ~~of 1 mSv per year for indoor external exposure from building materials, in excess of the prevailing outdoor external exposure~~, the competent authority shall decide on appropriate measures, **which may include specific requirements in relevant building codes or** ~~ranging from registration and general application of relevant building codes to specific~~ restrictions on the envisaged use of such materials.

~~6. Information on identified types of building materials, relevant to the implementation of building codes, including their radionuclide concentrations, activity concentration index and corresponding classification, shall be made available prior to their placing on the market.~~

~~[CHAPTER IX~~

~~PROTECTION OF THE ENVIRONMENT~~

~~*Article 76*~~

~~*Environmental criteria*~~

~~Member States shall include, in their legal framework for radiation protection and in particular within the overall system of human health protection, provision for the radiation protection of non-human species in the environment. This legal framework shall introduce environmental criteria aiming to protect populations of vulnerable or representative non-human species in the light of their significance as part of the ecosystem. Where appropriate, types of practices shall be identified for which regulatory control is warranted in order to implement the requirements of this legal framework.~~

~~*Article 77*~~

~~*Authorised limits on discharges*~~

~~Member States' competent authorities, when establishing authorised limits on discharges of radioactive effluents, in accordance with Article 65(2), shall also ensure adequate protection of non-human species. For this purpose, a generic screening assessment may be conducted to provide assurance that the environmental criteria are met.~~

~~*Article 78*~~

~~*Accidental releases*~~

~~Member States shall require undertakings to take appropriate technical measures to avoid significant environmental damage in the event of an accidental release or to mitigate the extent of such damage.~~

~~*Article 79*~~

~~*Environmental monitoring*~~

~~When establishing environmental monitoring programmes, or requiring such programmes to be carried out, Member States' competent authorities shall include representative non-human species, if necessary, and also environmental media which constitute a pathway of exposure for members of the public.~~]

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

SECTION I

INSTITUTIONAL INFRASTRUCTURE

Article 80 ***[76]***

Competent authority

1. Member States shall designate a competent authority ~~or authorities~~ to carry out tasks in accordance with this Directive.

   (a) Member States shall ensure that the competent authority**ies** ~~ies~~ **is** ~~are~~ 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 possible to list all such points of contact for different areas of competence, Member States may designate a single point of contact.

3~~2~~. Member States shall forward to the Commission the name and address of the **points of contact** ~~competent authority or authorities~~ and their respective areas of competence to **enable** ~~ensure~~ rapid communication**, where appropriate,** with ~~such~~ **their** authorities.

~~3. Where a Member State has more than one competent authority for a given field of competence, it shall designate one point of contact for communication with the competent authorities of other Member States.~~

4. Member States shall forward to the Commission any changes to the information referred to in paragraphs 2 and 3.

5. The Commission shall communicate the information referred to in paragraphs 2, 3 and 4 to all competent authorities **in 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 necessary information in relation to 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 ~~regulatory~~ 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 81 ***[78]***

Recognition of services and experts

1. Member States shall make the necessary arrangements for the recognition **by the competent authority** 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 **and its maintenance at an appropriate level**.

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

2. Member States shall specify the recognition requirements and communicate them to the Commission ~~together with the name and address of the competent authority in charge of recognition. Where Member States have more than one competent authority for this purpose, they may instead communicate to the Commission the name and address of a designated point of contact. Member States shall communicate any changes to this information~~.

3. Member States shall specify other services or experts requiring particular radiation protection qualifications and, where appropriate, the process for the recognition of such qualifications.

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

Article 82 ***[79]***

Occupational health services

Occupational health services shall 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 ***[80]***

Dosimetry services

Dosimetry services shall determine internal or external doses to exposed workers subject to individual monitoring in order to record the dose in cooperation with the undertaking and the occupational health service. ~~Dosimetry services shall include the calibration, reading and interpretation of individual monitoring devices, and the measurement of radioactivity in the human body and in biological samples.~~[28]

Article 84 ***[81]***

Radiation protection expert

1. The radiation protection expert shall~~, on the basis of professional judgment, measurements and assessments,~~ give competent advice to the undertaking on matters relating to **compliance with applicable legal requirements, in respect of** occupational ~~exposure~~ 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**~~b~~) ~~the~~ categorisation of controlled and supervised areas;

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[28] *Already included in the definition of "dosimetry services".*

(**d**~~c~~) ~~the~~ classification of workers;

(**e**~~d~~) ~~the content of~~ workplace and individual monitoring programmes **and related personal dosimetry**;

(**f**~~e~~) ~~the~~ appropriate radiation monitoring instrumentation ~~to be used~~;

~~(f) the appropriate personal dosimetry strategy;~~

~~(g) the optimisation and establishment of appropriate dose constraints;~~

(**g**~~h~~) quality assurance;

(**h**~~i~~) ~~the~~ environmental monitoring programme;

(**i**~~j~~) **arrangements for** radioactive waste **management** ~~disposal requirements~~;

(**j**~~k~~) ~~the~~ arrangements for prevention of accidents and incidents;

(**k**~~l~~) preparedness and response in emergency exposure situations;

(**l**~~m~~) training and retraining programmes for exposed workers;

(**m**~~n~~) investigation **and analysis** of **accidents**~~al~~ **and incidents and appropriate remedial actions** ~~exposures~~;

(n) employment conditions for pregnant and breastfeeding female workers;

(o) preparation of appropriate documentation such as prior risk assessments and written procedures;

~~(o) where appropriate, liaising with the medical physics expert~~**;**

3. ~~Where appropriate, the task of the~~ **The** radiation protection expert **shall, where appropriate, liaise with the medical physics expert** ~~may be carried out by a group of specialists who together have the necessary expertise~~.

Article 85 ***[82]***

Medical physics expert

1. ~~Within the health care environment, t~~**T**he medical physics expert shall, as appropriate, act or give specialist advice on matters relating to radiation physics **for implementing the requirements in Chapter VII of this Directive** ~~as applied to medical exposure~~.
2. Depending on the medical radiological practice, the medical physics expert shall take responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient **and other individuals subject to medical exposure**, give advice on medical radiological equipment, and contribute in particular to the following:

(a) optimisation of the radiation protection of patients and other individuals subject~~ed~~ 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**~~e~~) the preparation of technical specifications for medical radiological equipment and installation design;

(**e**~~d~~) the surveillance of the medical radiological installations with regard to **medical exposures** ~~radiation protection~~;

(f) implementation of the undertaking's system for record keeping and analysis of events involving, or potentially involving, accidental or unintended medical exposures;

(**g**~~e~~) the selection of equipment required to perform radiation protection measurements **with regard to medical exposures**;

(**h**~~f~~) the training of practitioners and other staff in relevant aspects of radiation protection **with regard to medical exposures**;

(**i**~~g~~) liaising with the radiation protection expert.

~~Where appropriate, the task of the medical physics expert may be carried out by a group of specialists who together have the necessary expertise.~~

Article 86 ***[83]***

Radiation protection officer

1. Member States shall decide in which practices the designation of a radiation protection officer is necessary to supervise 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.
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** ~~radioactive~~ 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 employees with an introduction to local rules and procedures;
(h) giving advice and comments on work plans;
(i) **establishing** ~~authorising~~ 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.

SECTION 2

CONTROL OF RADIOACTIVE SOURCES

*Article 86a **[84]***

General requirements for unsealed source

1. Member States shall make arrangements for keeping adequate control of unsealed sources with regard to their location, use and**, when no longer required, their recycling or disposal** ~~disuse~~.
2. Member States shall require the undertaking, as appropriate and to the extent possible, to keep record of unsealed sources under its responsibility, their location, their transfer and their disposal as radioactive waste.

Article 87 ***[85]***

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

1. Member States shall make arrangements for keeping adequate control of sealed sources with regard to their location, use and**, when no longer required, their recycling or disposal** ~~disuse~~.
2. Member States shall require the undertaking to keep records of all such sources under its responsibility, their location and their transfer.
3. Member States shall set up a system to enable them to be adequately informed of individual transfers of sealed sources, where necessary, and in any event of transfers of high-activity sealed sources.
4. Member States shall require each undertaking holding a sealed source to notify the competent authority promptly of any loss, theft or unauthorised use of a sealed source**, unless the radiological impact of such a loss is trivial**.

Article 88 ***[86]***

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) **the radioactive material in high-activity sealed sources is permanently sealed in a capsule or closely bonded in a solid form and adequately shielded;**

(**b**~~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;

(**c**~~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 ***[87]***

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** the manufacture, supply, use or taking possession of a high-activity sealed source includes:

(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**~~b~~) work procedures to be followed;

(f) maintenance of equipment, sources and containers;

(**g**~~e~~) 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 ***[88]***

Record keeping by the undertaking~~s~~

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 authorit**y**~~ies~~ with a copy of all or part of these records upon request and at least as set out in Annex XIII. The undertaking's records shall be available for inspection by the competent authority.

Article 91 ***[89]***

*Record keeping by the competent authorit**y**~~ies~~*

The competent authorit**y**~~ies~~ shall keep records of **any** undertaking~~s~~ authorised to perform practices with high-activity sealed sources and of the high-activity sealed sources ~~they~~ hold**ed**. 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 authorit**y**~~ies~~ shall keep the records up to date, taking transfers of the sources and other factors into account.

Article 92 ***[90]***

Control of high-activity sealed sources

1. The undertaking carrying out activities involving high activity sealed sources shall comply with requirements set out in Annex XIV.
2. The manufacturer, the supplier, and each undertaking shall ensure that high-activity sealed sources and containers comply with the requirements for identification and marking as set out in Annex XV.

SECTION 2A

SIGNIFICANT EVENTS

*Article 92a **[91]***

Notification and recording of significant events

Member States shall require the undertaking to:

(a) implement, as appropriate, a ~~registration~~ **recording** and analysis system of significant events involving or potentially involving accidental or unintended exposures;

(b) promptly notify the competent authorit**y**~~ies~~ 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 authorizing requirements with regard to occupational or public exposure or as defined by the **competent** authorit**y**~~ies~~ for medical exposure, including the results of the investigation and the corrective measures to avoid such events.

SECTION 3

ORPHAN SOURCES

*Article 93 **[92]***

Detection of orphan sources

1. Member States shall require undertakings and make other persons aware of the need to promptly notify ~~the emergency organisation or~~ the competent authority when encountering an orphan source and, unless having the appropriate expertise, to refrain from any further action on the source until these bodies have given appropriate instructions.

2. Member States shall ~~encourage~~ **make arrangements for** the establishment of systems to detect orphan sources in places where orphan sources may generally be encountered, or at significant nodal transit points, wherever appropriate ~~taking note of the Council Regulation (EU) No. 333/2011 of 31 March 2011 establishing criteria determining when certain types of scrap metal cease to be waste~~.

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** ~~who work in the places referred to in paragraph 2~~ and who are not normally involved in operations subject to radiation protection requirements. The primary aim of advice and assistance shall be the protection of workers and members of the public from radiation and the safety of the source.

Article 94 ***[93]***

Metal contamination

1. Member States shall require that a metal scrap recycling installation promptly notifies the competent authority **if it suspects or has knowledge** of any melting of an orphan source and shall require that the contaminated metal not be further processed without authorisation by the competent authority.

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

Article 95 ***[94]***

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

1. Member States shall ensure that the competent authorit**y**~~ies~~ **is** ~~are~~ prepared, or ha**s**~~ve~~ 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 and disposing of the sources and may also include surveys of historical records of authorities, such as customs, 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, on the basis of arrangements to be decided by Member States, 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 4

EMERGENCY EXPOSURE SITUATIONS

Article 97 ***[96]***

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 ~~and financial~~ 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 a threat assessment and to be able to respond effectively to emergency exposure situations in connection with practices or unforeseen events~~, including malevolent acts and the discovery of orphan sources~~.

3. The emergency management system shall provide for the establishment of emergency response plans with the objective of avoiding tissue reactions **leading to deterministic effects** in any individual from the affected **population** ~~members of the public~~ 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. ~~The emergency management system shall include the elements listed in Section A of Annex IX.~~

Article 98 ***[97]***

Emergency preparedness

1. Member States shall ensure that emergency response plans are established in advance for the various ~~scenarios and~~ types of emergencies identified by the threat assessment~~, including the preparedness for the transition to the post-accidental situation following the emergency phase~~.

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 to the existing exposure situation following the emergency phase.

4~~2~~. Member States shall ensure that emergency response plans are tested, reviewed and revised**, as appropriate,** at regular intervals**, taking into account the results of the participation in emergency exercises at national and international level**.

5~~3~~. The emergency response plans shall, where appropriate, incorporate relevant elements of the emergency management system referred to in Article 97.

~~4. The emergency response plans shall include the elements defined in Section B of Annex IX.~~

Article 99 ***[98]***

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** ~~its~~ territory, establish contact **[with other Member States and third countries which may be involved and at EU level with a view to coordinating protective measures, sharing the assessment of the exposure situation and coordinating public information by using as appropriate bilateral, Union or international information exchange systems].**~~to obtain the cooperation of any other Member State or third country which may be involved.~~
3. Member States shall promptly exchange information and cooperate with other relevant Member States or third countries and with relevant international organisations regarding the loss, removal, 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.

SECTION 5

EXISTING EXPOSURE SITUATIONS

Article 100 ***[99]***

Programmes on existing exposure situations

1. Member States shall ensure that programmes are established, where ap**p**ropriate, to identify and evaluate existing exposure situations **that cannot be disregarded from a radiation protection point of view, taking into account the types of existing exposure situations listed in Annex XVa,** and to determine ~~which~~ **the corresponding** occupational and public exposures ~~that cannot be disregarded from a radiation protection point of view~~.

~~2. The requirements for existing exposure situations shall apply to:~~

~~(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;~~

~~(ii) indoor external exposure from building materials;~~

~~(c) exposure to commodities incorporating~~

~~(i) radionuclides from contaminated areas specified in point (a), or~~

~~(ii) naturally occurring radionuclides, in particular in foodstuffs, drinking water and building materials;~~

~~(d) other existing exposure situations which cannot be disregarded from a radiation protection point of view.~~

2~~3~~. 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~~4~~. Existing exposure situations which are the legal responsibility of an undertaking and which are of concern from a radiation protection point of view 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 ***[100]***

Establishment of strategies

1. Member States shall arrange for the establishment of strategies to ensure **the appropriate management of** ~~that~~ existing exposure situations ~~are managed appropriately and that the resources made available for their management are~~ commensurate with the risks and with the effectiveness of protective measures.
2. The ~~relevant~~ competent authority charged with establishing a strategy for managing an existing exposure situation shall ensure that the strategy contains:
   (a) the objectives pursued by the strategy;
   (b) appropriate reference levels, taking into account the bands of reference levels laid down in Annex I.

Article 102 ***[101]***

Implementation of strategies

1. Member States shall assign responsibilities to a competent authority for the implementation of strategies for the management of existing exposures, and, as appropriate, to undertakings and ensure coordination and liaison with other relevant authorities and parties involved in the implementation of remedial and protective measures, and shall provide as appropriate for the involvement of stakeholders in decisions regarding the development and implementation of strategies for managing exposures.
2. The form, scale and duration of all protective measures considered for implementation of a strategy shall be optimised.

3. The distribution of residual doses that has resulted from the implementation of a strategy shall be assessed. Further efforts shall be considered with the aim of reducing any exposures that are still above the reference level.
4. Throughout the implementation of a strategy, the competent authority 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 ~~individuals~~ **populations** on the potential health risks and on the available means for reducing their ~~own~~ 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 to undertakings on appropriate means for monitoring concentrations and exposures and for taking protective measures in the context of overall health and safety requirements.

Article 103 ***[102]***

Radon action plan

1. **In application of Article 100(1),** Member States shall establish a national action plan to manage 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. This may include specific requirements in national building codes.

~~2. Member States shall establish specific requirements in building codes to prevent radon ingress from soil and, as specified in the national action plan, from building materials, and require compliance with such building codes, in particular in radon-prone areas, so as to avoid radon concentrations exceeding the reference level for new buildings.~~

SECTION 6

SYSTEM OF ENFORCEMENT

Article 104 ***[103]***

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 wherever necessary.
2. The competent authority shall establish a systematic inspection programme taking into account the potential magnitude and nature of the hazard associated with practices, a general assessment of radiation protection issues in the practices, and the state of compliance with the provisions adopted pursuant to this Directive.
3. Member States shall ensure that the findings from each inspection are recorded and the reports communicated to the undertaking concerned.
4. Member States shall make **an outline of** the inspection programme and the main findings from its implementation available to the public.
5. ~~The competent authority~~ **Member States** shall ensure that mechanisms are in place for the timely dissemination to relevant parties, including manufacturers and suppliers of sources and, where appropriate, international organisations, of protection and safety information concerning lessons learned from inspections and from reported incidents and accidents and related findings.

Article 105 ***[104]***

Enforcement

Member States shall ensure that the competent authority has the power to require the undertaking 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 undertaking is not in compliance with the provisions adopted pursuant to this Directive.

Article 106 ***[105]***

Penalties

[The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by the date specified in Article 107 at the latest and shall notify it without delay of any subsequent amendment affecting them.**]**

CHAPTER XI~~I~~

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 [3 years after adoption of the Directive depending on the final text]. ~~The provisions laid down in Chapter IX with regard to the protection of the environment shall be transposed by 00.00.0000.~~
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 ~~[~~and a correlation table between those provisions and 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.

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.

Done at Brussels,

For the Council
The President

ANNEX I

(Articles 8 and 101)

Bands of reference levels for public exposure

1. The optimisation of public exposures in emergency and existing exposure situations shall be based on a reference level to be established within the following bands, expressed in ~~mSv~~ effective dose (acute or annual) **(in mSv)**:

   (a**)** greater than 20 and less or equal to 100

   (b**)** greater than 1 and less or equal to 20

   (c**)** 1 or less.

   The choice of the reference level shall fulfil the conditions set out in points 2-5.

2. Without prejudice to reference levels set for organ 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 for emergency exposure situations.

3. 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.

4. 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.

5. 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 or~~ 1 mSv per year, general information on the level of exposure, without specific consideration of individual exposures;

   (b) in the range up to ~~20 mSv~~ 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 or~~ 100 mSv per year, assessment of individual doses and specific information on radiation risks and on available actions to reduce exposures.

ANNEX II

(Article 4(44))

Activity values defining high-activity sealed sources

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

Radionuclide	Activity level (TBq)
Am-241	6×10^{-2}
Am-241/Be	6×10^{-2}
Cf-252	2×10^{-2}
Cm-244	5×10^{-2}
Co-60	3×10^{-2}
Cs-137	1×10^{-1}
Gd-153	1×10^{0}
Ir-192	8×10^{-2}
Pm-147	4×10^{1}
Pu-238	6×10^{-2}
Pu-239/Be[1]	6×10^{-2}
Ra-226	4×10^{-2}
Se-75	2×10^{-1}
Sr-90 (Y-90)	1×10^{0}
Tm-170	2×10^{1}
Yb-169	3×10^{-1}

[1] The activity given is that of the alpha-emitting radionuclide

ANNEX III

(Article 21)

Justification of new classes or types of practices involving consumer products

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 reduce 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 III~~

~~Placing on the market of apparatus or products~~

~~A. Any undertaking intending to place on the market apparatus or products shall provide the competent authorities with all relevant information, including the following:~~

~~1. technical characteristics of the apparatus or product;~~

~~2. in the case of apparatus containing radioactive substances, information on the means of fixation of the source in a holder and on shielding;~~

~~3. dose rates at relevant distances for the use of the apparatus or product, including dose rates at a distance of 0.1 m from any accessible surface;~~

~~4. intended use of the apparatus or product and information on the relative performance of the new apparatus or product compared to existing ones;~~

~~5. expected doses to regular users of the apparatus or product.~~

~~B. The competent authorities shall assess the information, listed in Section A and in particular shall assess:~~

~~1. whether the performance of the apparatus or product justifies its intended use;~~

~~2. whether the design is adequate in order to reduce exposures in normal use and the likelihood and consequences of misuse or accidental exposures;~~

~~3. in the case of a consumer product, whether the product is adequately designed to meet the exemption criteria and does not necessitate specific precautions for disposal when no longer in use;~~

~~4. in the case of apparatus or products for use in practices exempted from authorisation, whether conditions for disposal are adequate;~~

~~5. whether the apparatus or product is appropriately labelled and suitable documentation is provided to the customer with instructions for proper use and disposal.~~

ANNEX IV

(Article 23)

Indicative list of practices involving non-medical imaging exposure

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 IV~~

~~Practices involving non-medical imaging exposure~~

~~For the purposes of Article 23, the following list of practices involving non-medical imaging exposure shall be taken into account:~~

~~A. Procedures implemented by medical staff 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 health assessment for other purposes not intended to benefit the health and well-being of the exposed individual;~~

~~5. Radiological evaluation of the physical development of children and adolescents with a view to a career in sports, dancing, etc.;~~

~~6. Radiological age assessment;~~

~~7. Use of ionising radiation for the identification of concealed objects within the human body.~~

~~B. Procedures implemented by non-medical staff using non-medical 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. Other practices involving the use of ionising radiation for legal or security purposes.~~

ANNEX V

(Article 24)

List of industrial sectors involving naturally occurring radioactive material

When applying Article **24** ~~49~~ 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_2 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.

– **Practices producing or processing residues for recycling in building materials, such as listed in Annex XI part 2.**

ANNEX VI

(Articles 25a, 25c and 29)

Exemption and clearance criteria

1. Exemption

Practices may be exempted from notification either directly, on the basis of compliance with numerical exemption criteria (activity values (in Bq) or activity concentration values (in kBq kg^{-1})) 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 values[1]

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.

[1] *These values are defined for planned exposure situations for the purpose of exempting practices from the requirement of notification or for clearance of materials from authorised practices. Therefore, these values are not intended to be used as such, for any purposes, in case of emergency or existing exposure situation.*

The exempt activity concentration values (in kBq kg^{-1}) 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 re-use, 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 values significantly higher, by up to two orders of magnitude, 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. Such recycling of residues from identified industries shall be managed as an authorised practice or be exempted, on the basis of the general exemption criteria laid down in section 3. For this purpose, compliance of the sum of radionuclide concentrations with the appropriate value of the radionuclide index I for building materials, as defined in Annex VII, 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, Part 1, or Table B, and, in general, all practices involving naturally-occurring radionuclides 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, automatically 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 Annex VI, 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 pupose 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 µSv 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, higher dose criteria may be applied.

~~ANNEX VI~~

~~Exemption and clearance criteria~~

~~1. Exemption~~

~~Practices may be exempted from requirements of this Directive either directly, on the basis of compliance with numerical exemption criteria (activity values (Bq) or concentration values (Bq g^{-1})) laid down in Section 2, or through a 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, to exempt the practice from further requirements.~~

~~2. Exemption and clearance values~~

~~The total activity values (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 (Bq g^{-1}) 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_1, 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 re-use, 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 values significantly higher, by up to two orders of magnitude, 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. Such recycling of residues from identified industries shall be managed as an authorised practice or be exempted on the basis of the general exemption criteria laid down in Section 3. For this purpose, compliance of the sum of radionuclide concentrations with the appropriate value of the radionuclide index I for building materials as defined in Annex VII 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 regulatory 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 notified practices or 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 Tables A, Part 1 or B, and in general all practices involving naturally occurring radionuclides 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 automatically 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.~~

~~For notified practices not complying with these values, an assessment shall be made of the resulting exposure of individuals. For compliance with the general criterion (a), it shall be demonstrated that the following dose criteria are met in all feasible circumstances:~~

~~**For artificial radionuclides:**~~

~~The effective dose expected to be incurred by an individual due to the exempted practice is of the order of 10 μSv 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 300 μSv or less in a year for members of the public and less than 1 mSv for workers.~~

~~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.~~

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

Radionuclide	Activity concentration (**k**Bq **k**g^{-1})	Radionuclide	Activity concentration (**k**Bq **k**g^{-1})	Radionuclide	Activity concentration (**k**Bq **k**g^{-1})
H-3	100	Mn-52m	10	Ga-72	10
Be-7	10	Mn-53	100	Ge-71	10000
C-14	1	Mn-54	0.1	As-73	1000
F-18	10	Mn-56	10	As-74	10
Na-22	0.1	Fe-52[a]	10	As-76	10
Na-24	1	Fe-55	1000	As-77	1000
Si-31	1000	Fe-59	1	Se-75	1
P-32	1000	Co-55	10	Br-82	1
P-33	1000	Co-56	0.1	Rb-86	100
S-35	100	Co-57	1	Sr-85	1
Cl-36	1	Co-58	1	Sr-85m	100
Cl-38	10	Co-58m	10 000	Sr-87m	100
K-42	100	Co-60	0.1	Sr-89	1000
K-43	10	Co-60m	1000	Sr-90a	1
Ca-45	100	Co-61	100	Sr-91a	10
Ca-47	10	Co-62m	10	Sr-92	10
Sc-46	0.1	Ni-59	100	Y-90	1000
Sc-47	100	Ni-63	100	Y-91	100
Sc-48	1	Ni-65	10	Y-91m	100
V-48	1	Cu-64	100	Y-92	100
Cr-51	100	Zn-65	0.1	Y-93	100
Mn-51	10	Zn-69	1000	Zr-93	10
Mn-52	1	Zn-69m[a]	10	Zr-95[a]	1

Radionuclide	Activity concentration (**k**Bq **k**g^{-1})	Radionuclide	Activity concentration (**k**Bq **k**g^{-1})	Radionuclide	Activity concentration (**k**Bq **k**g^{-1})
Zr-97[a]	10	Pd-109[a]	100	Te-131m[a]	10
Nb-93m	10	Ag-105	1	Te-132[a]	1
Nb-94	0.1	Ag-110m[a]	0.1	Te-133	10
Nb-95	1	Ag-111	100	Te-133m	10
Nb-97[a]	10	Cd-109[a]	1	Te-134	10
Nb-98	10	Cd-115[a]	10	I-123	100
Mo-90	10	Cd-115m[a]	100	I-125	100
Mo-93	10	In-111	10	I-126	10
Mo-99a	10	In-113m	100	I-129	0.01
Mo-101[a]	10	In-114m[a]	10	I-130	10
Tc-96	1	In-115m	100	I-131	10
Tc-96m	1000	Sn-113[a]	1	I-132	10
Tc-97	10	Sn-125	10	I-133	10
Tc-97m	100	Sb-122	10	I-134	10
Tc-99	1	Sb-124	1	I-135	10
Tc-99m	100	Sb-125[a]	0.1	Cs-129	10
Ru-97	10	Te-123m	1	Cs-131	1000
Ru-103[a]	1	Te-125m	1000	Cs-132	10
Ru-105[a]	10	Te-127	1000	Cs-134	0.1
Ru-106[a]	0.1	Te-127m[a]	10	Cs-134m	1000
Rh-103m	10000	Te-129	100	Cs-135	100
Rh-105	100	Te-129m[a]	10	Cs-136	1
Pd-103[a]	1000	Te-131	100	Cs-137[a]	0.1

Radionuclide	Activity concentration (**k**Bq **k**g^{-1})	Radionuclide	Activity concentration (**k**Bq **k**g^{-1})	Radionuclide	Activity concentration (**k**Bq **k**g^{-1})
Cs-138	10	Dy-165	1000	Pt-191	10
Ba-131	10	Dy-166	100	Pt-193m	1000
Ba-140	1	Ho-166	100	Pt-197	1000
La-140	1	Er-169	1000	Pt-197m	100
Ce-139	1	Er-171	100	Au-198	10
Ce-141	100	Tm-170	100	Au-199	100
Ce-143	10	Tm-171	1000	Hg-197	100
Ce-144	10	Yb-175	100	Hg-197m	100
Pr-142	100	Lu-177	100	Hg-203	10
Pr-143	1000	Hf-181	1	Tl-200	10
Nd-147	100	Ta-182	0.1	Tl-201	100
Nd-149	100	W-181	10	Tl-202	10
Pm-147	1000	W-185	1000	Tl-204	1
Pm-149	1000	W-187	10	Pb-203	10
Sm-151	1000	Re-186	1000	Bi-206	1
Sm-153	100	Re-188	100	Bi-207	0.1
Eu-152	0.1	Os-185	1	Po-203	10
Eu-152m	100	Os-191	100	Po-205	10
Eu-154	0.1	Os-191m	1000	Po-207	10
Eu-155	1	Os-193	100	At-211	1000
Gd-153	10	Ir-190	1	Ra-225	10
Gd-159	100	Ir-192	1	Ra-227	100
Tb-160	1	Ir-194	100	Th-226	1000

Radionuclide	Activity concentration (**k**Bq **k**g^{-1})
Th-229	0.1
Pa-230	10
Pa-233	10
U-230	10
U-231[a]	100
U-232[a]	0.1
U-233	1
U-236	10
U-237	100
U-239	100
U-240[a]	100
Np-237[a]	1
Np-239	100
Np-240	10
Pu-234	100
Pu-235	100
Pu-236	1
Pu-237	100
Pu-238	0.1
Pu-239	0.1
Pu-240	0.1
Pu-241	10
Pu-242	0.1
Pu-243	1000
Pu-244[a]	0.1
Am-241	0.1
Am-242	1000
Am-242m[a]	0.1
Am-243[a]	0.1
Cm-242	10
Cm-243	1
Cm-244	1
Cm-245	0.1
Cm-246	0.1
Cm-247[a]	0.1
Cm-248	0.1
Bk-249	100
Cf-246	1000
Cf-248	1
Cf-249	0.1
Cf-250	1
Cf-251	0.1
Cf-252	1
Cf-253	100
Cf-254	1
Es-253	100
Es-254[a]	0.1
Es-254m[a]	10
Fm-254	10000
Fm-255	100

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
Te132	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
Np237	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 **k**Bq **k**g^{-1}
Natural radionuclides from the Th-232 series	1 **k**Bq **k**g^{-1}
K-40	10 **k**Bq **k**g^{-1}

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 (**k**Bq **k**g^{-1})	Activity (Bq)
H-3	1×10^{6}	1×10^{9}
Be-7	1×10^{3}	1×10^{7}
C-14	1×10^{4}	1×10^{7}
O-15	1×10^{2}	1×10^{9}
F-18	1×10^{1}	1×10^{6}
Na-22	1×10^{1}	1×10^{6}
Na-24	1×10^{1}	1×10^{5}
Si-31	1×10^{3}	1×10^{6}
P-32	1×10^{3}	1×10^{5}
P-33	1×10^{5}	1×10^{8}
S-35	1×10^{5}	1×10^{8}
Cl-36	1×10^{4}	1×10^{6}
Cl-38	1×10^{1}	1×10^{5}
Ar-37	1×10^{6}	1×10^{8}
Ar-41	1×10^{2}	1×10^{9}
K-40[1]	1×10^{2}	1×10^{6}
K-42	1×10^{2}	1×10^{6}
K-43	1×10^{1}	1×10^{6}
Ca-45	1×10^{4}	1×10^{7}
Ca-47	1×10^{1}	1×10^{6}
Sc-46	1×10^{1}	1×10^{6}
Sc-47	1×10^{2}	1×10^{6}
Sc-48	1×10^{1}	1×10^{5}
V-48	1×10^{1}	1×10^{5}

Radionuclide	Activity concentration (**k**Bq **k**g^{-1})	Activity (Bq)
Cr-51	1×10^{3}	1×10^{7}
Mn-51	1×10^{1}	1×10^{5}
Mn-52	1×10^{1}	1×10^{5}
Mn-52m	1×10^{1}	1×10^{5}
Mn-53	1×10^{4}	1×10^{9}
Mn-54	1×10^{1}	1×10^{6}
Mn-56	1×10^{1}	1×10^{5}
Fe-52	1×10^{1}	1×10^{6}
Fe-55	1×10^{4}	1×10^{6}
Fe-59	1×10^{1}	1×10^{6}
Co-55	1×10^{1}	1×10^{6}
Co-56	1×10^{1}	1×10^{5}
Co-57	1×10^{2}	1×10^{6}
Co-58	1×10^{1}	1×10^{6}
Co-58m	1×10^{4}	1×10^{7}
Co-60	1×10^{1}	1×10^{5}
Co-60m	1×10^{3}	1×10^{6}
Co-61	1×10^{2}	1×10^{6}
Co-62m	1×10^{1}	1×10^{5}
Ni-59	1×10^{4}	1×10^{8}
Ni-63	1×10^{5}	1×10^{8}
Ni-65	1×10^{1}	1×10^{6}
Cu-64	1×10^{2}	1×10^{6}
Zn-65	1×10^{1}	1×10^{6}
Zn-69	1×10^{4}	1×10^{6}
Zn-69m	1×10^{2}	1×10^{6}

[1] Potassium salts in quantities less than 1000 kg are exempted.

Radionuclide	Activity concentration (**k**Bq **k**g^{-1})	Activity (Bq)
Ga-72	1×10^{1}	1×10^{5}
Ge-71	1×10^{4}	1×10^{8}
As-73	1×10^{3}	1×10^{7}
As-74	1×10^{1}	1×10^{6}
As-76	1×10^{2}	1×10^{5}
As-77	1×10^{3}	1×10^{6}
Se-75	1×10^{2}	1×10^{6}
Br-82	1×10^{1}	1×10^{6}
Kr-74	1×10^{2}	1×10^{9}
Kr-76	1×10^{2}	1×10^{9}
Kr-77	1×10^{2}	1×10^{9}
Kr-79	1×10^{3}	1×10^{5}
Kr-81	1×10^{4}	1×10^{7}
Kr-83m	1×10^{5}	1×10^{12}
Kr-85	1×10^{5}	1×10^{4}
Kr-85m	1×10^{3}	1×10^{10}
Kr-87	1×10^{2}	1×10^{9}
Kr-88	1×10^{2}	1×10^{9}
Rb-86	1×10^{2}	1×10^{5}
Sr-85	1×10^{2}	1×10^{6}
Sr-85m	1×10^{2}	1×10^{7}
Sr-87m	1×10^{2}	1×10^{6}
Sr-89	1×10^{3}	1×10^{6}
Sr-90[b]	1×10^{2}	1×10^{4}
Sr-91	1×10^{1}	1×10^{5}
Sr-92	1×10^{1}	1×10^{6}
Y-90	1×10^{3}	1×10^{5}
Y-91	1×10^{3}	1×10^{6}
Y-91m	1×10^{2}	1×10^{6}
Y-92	1×10^{2}	1×10^{5}
Y-93	1×10^{2}	1×10^{5}
Zr-93[b]	1×10^{3}	1×10^{7}
Zr-95	1×10^{1}	1×10^{6}
Zr-97[b]	1×10^{1}	1×10^{5}
Nb-93m	1×10^{4}	1×10^{7}
Nb-94	1×10^{1}	1×10^{6}
Nb-95	1×10^{1}	1×10^{6}
Nb-97	1×10^{1}	1×10^{6}
Nb-98	1×10^{1}	1×10^{5}
Mo-90	1×10^{1}	1×10^{6}
Mo-93	1×10^{3}	1×10^{8}
Mo-99	1×10^{2}	1×10^{6}
Mo-101	1×10^{1}	1×10^{6}
Tc-96	1×10^{1}	1×10^{6}
Tc-96m	1×10^{3}	1×10^{7}
Tc-97	1×10^{3}	1×10^{8}
Tc-97m	1×10^{3}	1×10^{7}
Tc-99	1×10^{4}	1×10^{7}
Tc-99m	1×10^{2}	1×10^{7}
Ru-97	1×10^{2}	1×10^{7}
Ru-103	1×10^{2}	1×10^{6}
Ru-105	1×10^{1}	1×10^{6}

Radionuclide	Activity concentration (**k**Bq **k**g^{-1})	Activity (Bq)
Ru-106[b]	1×10^{2}	1×10^{5}
Rh-103m	1×10^{4}	1×10^{8}
Rh-105	1×10^{2}	1×10^{7}
Pd-103	1×10^{3}	1×10^{8}
Pd-109	1×10^{3}	1×10^{6}
Ag-105	1×10^{2}	1×10^{6}
Ag-108m	1×10^{1}	1×10^{6}
Ag-110m	1×10^{1}	1×10^{6}
Ag-111	1×10^{3}	1×10^{6}
Cd-109	1×10^{4}	1×10^{6}
Cd-115	1×10^{2}	1×10^{6}
Cd-115m	1×10^{3}	1×10^{6}
In-111	1×10^{2}	1×10^{6}
In-113m	1×10^{2}	1×10^{6}
In-114m	1×10^{2}	1×10^{6}
In-115m	1×10^{2}	1×10^{6}
Sn-113	1×10^{3}	1×10^{7}
Sn-125	1×10^{2}	1×10^{5}
Sb-122	1×10^{2}	1×10^{4}
Sb-124	1×10^{1}	1×10^{6}
Sb-125	1×10^{2}	1×10^{6}
Te-123m	1×10^{2}	1×10^{7}
Te-125m	1×10^{3}	1×10^{7}
Te-127	1×10^{3}	1×10^{6}
Te-127m	1×10^{3}	1×10^{7}
Te-129	1×10^{2}	1×10^{6}
Te-129m	1×10^{3}	1×10^{6}
Te-131	1×10^{2}	1×10^{5}
Te-131m	1×10^{1}	1×10^{6}
Te-132	1×10^{2}	1×10^{7}
Te-133	1×10^{1}	1×10^{5}
Te-133m	1×10^{1}	1×10^{5}
Te-134	1×10^{1}	1×10^{6}
I-123	1×10^{2}	1×10^{7}
I-125	1×10^{3}	1×10^{6}
I-126	1×10^{2}	1×10^{6}
I-129	1×10^{2}	1×10^{5}
I-130	1×10^{1}	1×10^{6}
I-131	1×10^{2}	1×10^{6}
I-132	1×10^{1}	1×10^{5}
I-133	1×10^{1}	1×10^{6}
I-134	1×10^{1}	1×10^{5}
I-135	1×10^{1}	1×10^{6}
Xe-131m	1×10^{4}	1×10^{4}
Xe-133	1×10^{3}	1×10^{4}
Xe-135	1×10^{3}	1×10^{10}
Cs-129	1×10^{2}	1×10^{5}
Cs-131	1×10^{3}	1×10^{6}
Cs-132	1×10^{1}	1×10^{5}
Cs-134m	1×10^{3}	1×10^{5}
Cs-134	1×10^{1}	1×10^{4}
Cs-135	1×10^{4}	1×10^{7}

Radionuclide	Activity concentration (**k**Bq **k**g^{-1})	Activity (Bq)
Cs-136	1×10^{1}	1×10^{5}
Cs-137[b]	1×10^{1}	1×10^{4}
Cs-138	1×10^{1}	1×10^{4}
Ba-131	1×10^{2}	1×10^{6}
Ba-140[b]	1×10^{1}	1×10^{5}
La-140	1×10^{1}	1×10^{5}
Ce-139	1×10^{2}	1×10^{6}
Ce-141	1×10^{2}	1×10^{7}
Ce-143	1×10^{2}	1×10^{6}
Ce-144[b]	1×10^{2}	1×10^{5}
Pr-142	1×10^{2}	1×10^{5}
Pr-143	1×10^{4}	1×10^{6}
Nd-147	1×10^{2}	1×10^{6}
Nd-149	1×10^{2}	1×10^{6}
Pm-147	1×10^{4}	1×10^{7}
Pm-149	1×10^{3}	1×10^{6}
Sm-151	1×10^{4}	1×10^{8}
Sm-153	1×10^{2}	1×10^{6}
Eu-152	1×10^{1}	1×10^{6}
Eu-152m	1×10^{2}	1×10^{6}
Eu-154	1×10^{1}	1×10^{6}
Eu-155	1×10^{2}	1×10^{7}
Gd-153	1×10^{2}	1×10^{7}
Gd-159	1×10^{3}	1×10^{6}
Tb-160	1×10^{1}	1×10^{6}
Dy-165	1×10^{3}	1×10^{6}
Dy-166	1×10^{3}	1×10^{6}
Ho-166	1×10^{3}	1×10^{5}
Er-169	1×10^{4}	1×10^{7}
Er-171	1×10^{2}	1×10^{6}
Tm-170	1×10^{3}	1×10^{6}
Tm-171	1×10^{4}	1×10^{8}
Yb-175	1×10^{3}	1×10^{7}
Lu-177	1×10^{3}	1×10^{7}
Hf-181	1×10^{1}	1×10^{6}
Ta-182	1×10^{1}	1×10^{4}
W-181	1×10^{3}	1×10^{7}
W-185	1×10^{4}	1×10^{7}
W-187	1×10^{2}	1×10^{6}
Re-186	1×10^{3}	1×10^{6}
Re-188	1×10^{2}	1×10^{5}
Os-185	1×10^{1}	1×10^{6}
Os-191	1×10^{2}	1×10^{7}
Os-191m	1×10^{3}	1×10^{7}
Os-193	1×10^{2}	1×10^{6}
Ir-190	1×10^{1}	1×10^{6}
Ir-192	1×10^{1}	1×10^{4}
Ir-194	1×10^{2}	1×10^{5}
Pt-191	1×10^{2}	1×10^{6}
Pt-193m	1×10^{3}	1×10^{7}
Pt-197	1×10^{3}	1×10^{6}
Pt-197m	1×10^{2}	1×10^{6}

Radionuclide	Activity concentration (**k**Bq **k**g^{-1})	Activity (Bq)
Au-198	1×10^{2}	1×10^{6}
Au-199	1×10^{2}	1×10^{6}
Hg-197	1×10^{2}	1×10^{7}
Hg-197m	1×10^{2}	1×10^{6}
Hg-203	1×10^{2}	1×10^{5}
Tl-200	1×10^{1}	1×10^{6}
Tl-201	1×10^{2}	1×10^{6}
Tl-202	1×10^{2}	1×10^{6}
Tl-204	1×10^{4}	1×10^{4}
Pb-203	1×10^{2}	1×10^{6}
Pb-210[b]	1×10^{1}	1×10^{4}
Pb-212[b]	1×10^{1}	1×10^{5}
Bi-206	1×10^{1}	1×10^{5}
Bi-207	1×10^{1}	1×10^{6}
Bi-210	1×10^{3}	1×10^{6}
Bi-212[b]	1×10^{1}	1×10^{5}
Po-203	1×10^{1}	1×10^{6}
Po-205	1×10^{1}	1×10^{6}
Po-207	1×10^{1}	1×10^{6}
Po-210	1×10^{1}	1×10^{4}
At-211	1×10^{3}	1×10^{7}
Rn-220[b]	1×10^{4}	1×10^{7}
Rn-222[b]	1×10^{1}	1×10^{8}
Ra-223[b]	1×10^{2}	1×10^{5}
Ra-224[b]	1×10^{1}	1×10^{5}
Ra-225	1×10^{2}	1×10^{5}
Ra-226[b]	1×10^{1}	1×10^{4}
Ra-227	1×10^{2}	1×10^{6}
Ra-228[b]	1×10^{1}	1×10^{5}
Ac-228	1×10^{1}	1×10^{6}
Th-226[b]	1×10^{3}	1×10^{7}
Th-227	1×10^{1}	1×10^{4}
Th-228[b]	1×10^{0}	1×10^{4}
Th-229[b]	1 x 10^{0}	1×10^{3}
Th-230	1×10^{0}	1×10^{4}
Th-231	1×10^{3}	1×10^{7}
Th-234[b]	1×10^{3}	1×10^{5}
Pa-230	1×10^{1}	1×10^{6}
Pa-231	1×10^{0}	1×10^{3}
Pa-233	1×10^{2}	1×10^{7}
U-230	1×10^{1}	1×10^{5}
U-231	1×10^{2}	1×10^{7}
U-232[b]	1×10^{0}	1×10^{3}
U-233	1×10^{1}	1×10^{4}
U-234	1×10^{1}	1×10^{4}
U-235[b]	1×10^{1}	1×10^{4}
U-236	1×10^{1}	1×10^{4}
U-237	1×10^{2}	1×10^{6}
U-238[b]	1×10^{1}	1×10^{4}
U-239	1×10^{2}	1×10^{6}
U-240	1×10^{3}	1×10^{7}
U-240[b]	1×10^{1}	1×10^{6}

Radionuclide	Activity concentration (kBq kg^{-1})	Activity (Bq)
Np-237[b]	1×10^{0}	1×10^{3}
Np-239	1×10^{2}	1×10^{7}
Np-240	1×10^{1}	1×10^{6}
Pu-234	1×10^{2}	1×10^{7}
Pu-235	1×10^{2}	1×10^{7}
Pu-236	1×10^{1}	1×10^{4}
Pu-237	1×10^{3}	1×10^{7}
Pu-238	1×10^{0}	1×10^{4}
Pu-239	1×10^{0}	1×10^{4}
Pu-240	1×10^{0}	1×10^{3}
Pu-241	1×10^{2}	1×10^{5}
Pu-242	1×10^{0}	1×10^{4}
Pu-243	1×10^{3}	1×10^{7}
Pu-244	1×10^{0}	1×10^{4}
Am-241	1×10^{0}	1×10^{4}
Am-242	1×10^{3}	1×10^{6}
Am-242m[b]	1×10^{0}	1×10^{4}
Am-243[b]	1×10^{0}	1×10^{3}
Cm-242	1×10^{2}	1×10^{5}
Cm-243	1×10^{0}	1×10^{4}
Cm-244	1×10^{1}	1×10^{4}
Cm-245	1×10^{0}	1×10^{3}
Cm-246	1×10^{0}	1×10^{3}
Cm-247	1×10^{0}	1×10^{4}
Cm-248	1×10^{0}	1×10^{3}
Bk-249	1×10^{3}	1×10^{6}
Cf-246	1×10^{3}	1×10^{6}
Cf-248	1×10^{1}	1×10^{4}
Cf-249	1×10^{0}	1×10^{3}
Cf-250	1×10^{1}	1×10^{4}
Cf-251	1×10^{0}	1×10^{3}
Cf-252	1×10^{1}	1×10^{4}
Cf-253	1×10^{2}	1×10^{5}
Cf-254	1×10^{0}	1×10^{3}
Es-253	1×10^{2}	1×10^{5}
Es-254	1×10^{1}	1×10^{4}
Es-254m	1×10^{2}	1×10^{6}
Fm-254	1×10^{4}	1×10^{7}
Fm-255	1×10^{3}	1×10^{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:

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
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
Np237	Pa-233
Am-242m	Am-242
Am-243	Np-239

ANNEX VII

(Articles 25b and 75)

Definition and use of the activity concentration index for the gamma radiation emitted by building materials

For the purposes of Article**s 25b and** 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:

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

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

The index relates ~~directly~~ to the gamma radiation dose, in excess of typical outdoor exposure, in a building constructed from a specified building material. ~~It~~ **The index** applies to the building material, not to its constituents. 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 ~~shall be used as~~ **is** a screening tool for identifying materials that may **cause the reference level to be exceeded; by default, for bulk, dense materials the value of the index corresponding to a dose of 1 mSv per year is equal to 1. 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).**~~be exempted or subject to restrictions. For this purpose the activity concentration index I may be used for the classification of the materials into four classes, leading to two categories of building materials (A and B):~~

	Category (corresponding default dose)	
Use	A (≤ 1 mSv)	B (> 1 mSv)
(1) materials used in bulk amounts	A1 I≤1	B1 I>1
(2) superficial and other materials with restricted use.	A2 I≤6	B2 I>6

The division of materials into (1) or (2) according to their use shall be based on national building codes.

Where appropriate, actual doses for comparison with the reference level shall be assessed using more elaborate models which may also take into account the background outdoor external exposure from local prevailing activity concentrations in the undisturbed earth's crust.

ANNEX VIIa

(Article 28)

Indicative list of information for licence applications

(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

(Articles 41, 42 and 50)

Data system for individual radiological monitoring

General Provisions

The data system for individual radiological monitoring established by a Member State may be realised either as a centralised national network or as a national dose register. These networks or registers may be supplemented by the issuance of individual radiological monitoring documents for every outside worker.

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 illegal 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 medical surveillance of the worker shall include:~~

~~(a) the medical classification of the worker in accordance with Article 45 (fit; fit, subject to certain conditions; unfit);~~

~~(b) information on any restrictions on working with radiation;~~

~~(c) the date of the last periodic health review;~~

~~(d) the responsible occupational health service; and~~

~~(e) the period of validity of the result.~~

5. Data on the undertaking shall include the name, address and unique identification number of the undertaking.

6. 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** ~~employment~~; and

(c) the categorisation of the worker in accordance with Article 38.

7. The results of the individual monitoring of the exposed worker shall include:

(a) the official dose record for the last 5 calendar years (year; effective dose in mSv; in the event of non-uniform exposure, dose-equivalent in the different parts of the body in mSv; and in the event of internal contamination, the committed dose in mSv); and

(b) the official dose record for the current year (period; effective dose in mSv; in the event of non-uniform exposure, dose-equivalent in the different parts of the body in mSv; and in the event of internal contamination, the committed 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 employ**ment**~~er~~ of the outside worker in accordance with Section A, point 6;

   (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;

      (iv) the responsible occupational health service; and

      (v) the period of validity of the result.

   ~~(b) data on the medical surveillance of the outside worker in accordance with Section A, point 4;~~

   (c) the results of the outside worker's individual exposure monitoring in accordance with Section A, point 7.

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 (operational dose for the period covered by the activity);

   (c) in the event of non-uniform exposure, an estimate of the dose-equivalent in the different parts of the body;

   (d) in the event of internal contamination, an estimate of the intake or the committed 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

(Articles 70, 97 and 98)

Emergency management systems and emergency response plans

A. Elements to be included in an emergency management system

1. ~~Threat assessment~~ **Assessment of potential emergency exposure situations including exposures as a result of accidents related to a specific facility or activity and malevolent and malicious acts**;

2. Clear allocation of the responsibilities of persons and organisations having a role in preparedness and response arrangements, including establishment and coordination of emergency response organisations with overall responsibilities in managing emergency exposure situations ~~and, where appropriate, creation of special teams for protective measures~~;

3. Establishment of emergency response plans at **appropriate levels and related to a specific facility or activity** ~~national level, at local level and within installations~~;

4. Reliable communications and efficient and effective arrangements for cooperation and coordination at the installation and local, national and international levels;

5. Health protection of emergency workers;

6. Education and training of emergency workers and all other persons with duties or responsibilities in emergency response, including regular exercises;

7. Arrangements for individual monitoring of emergency workers and the recording of doses;

8. Public information arrangements;

9. Involvement of stakeholders;

10. Transition from emergency response to recovery and remediation.

B. Elements to be included in an emergency response plan

For emergency preparedness:

1. Reference levels, taking into account the criteria laid down in Annex I;

2. Optimised protection strategies for members of the public who may be exposed, for different postulated events and related scenarios;

3. Predefined generic criteria for particular protective measures, expressed in terms of projected and received doses;

4. Default triggers or operational criteria such as observables and indicators of on-scene conditions;

5. Arrangements for prompt coordination with the emergency response organisation **which has overall responsibilities in managing emergency exposure situations** in a neighbouring Member State or non-Member State, for facilities in the vicinity of a national border;

6. 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 ~~expected residual~~ 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

(Articles 71 and 72)

Information to members of the public about health protection measures to be applied and steps to be taken in the event of an emergency

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~~ies~~.
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

(Articles 25b and 75)

Indicative list of types of building materials considered for control measures with regard to their emitted gamma radiation

1. Natural materials

(b) Alum-shale.

(e) Building materials or additives of natural igneous origin, such as:

- granite,
- gneiss;
- porphyries;
- syenite;
- basalt;
- 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 (Article 90)

Information to be provided in the records for high-activity sealed sources (HASS)

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

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

ANNEX XIII
(Article 90)

Provision of data on high-activity sealed sources

The undertaking shall provide the competent authority with an electronic or written copy of the records for high-activity sealed sources, referred to in Article 90 and covering the information set out in Annex XII, as follows:

1. without undue delay, at the time of the establishment of such records, which shall be as soon as possible after the source is acquired;
2. at intervals, to be determined by Member States, of not more than 12 months after the acquisition of the source;
3. if the situation indicated on the information sheet has changed;
4. 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 and storage facility to which the source is transferred shall be included;
5. without undue delay upon the closure of such records when the undertaking no longer holds any sources.

ANNEX XIV

(Article 92)

Requirements for undertakings responsible for a high-activity sealed source

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 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 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

(Article 92)

Identification and marking of high-activity sealed sources

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

3. The undertaking shall ensure 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

(Article 100)

Indicative list of types of existing exposure situations

(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 incorporating

(i) radionuclides from contaminated areas specified in point (a), or

(ii) naturally occurring radionuclides.

ANNEX XVI

(Articles 53 and 103)

Indicative list of items to be covered in the national action plan to manage long-term risks from radon exposures

1. **Strategy for conducting surveys of indoor radon concentrations or soil gas concentrations, for the management of measurement data (national radon database) and for the establishment of other relevant parameters (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 where the percentage of buildings expected to exceed the national reference levels is significantly higher than the national average.**

3. **Identification of types of buildings with public access, for instance schools, and of workplaces, for instance underground workplaces, spas or other workplaces located on the ground floor or at basement level in certain areas, where measurements are required, on the basis of the indicators specified in point 2 as well as of a risk assessment, considering for instance occupancy hours.**

4. **The basis for the establishment of reference levels for dwellings and workplaces.**

5. **Assignment of responsibilities (governmental and non-governmental), coordination mechanisms and available resources for implementation of the action plan.**

6. **Strategy for reducing radon exposure in dwellings and for giving priority to addressing the situations identified under point 2.**

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 audits and reviews of the action plan.**

9. **Strategy for communication to increase public awareness and inform local decision makers of the risks of radon in relation to smoking.**

10. **Where appropriate, 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).**

~~ANNEX XVI~~

~~Indicative list of items to be covered in the national action plan to manage long term risks from radon exposures~~

~~1. Strategy for conducting surveys of indoor radon concentrations, for the management of measurement data (national radon database) and for the establishment of other parameters (soil and rock types, soil gas concentration, permeability and radium-226 content of rock or soil).~~

~~2. Available data and criteria used for the delineation of radon-prone areas or for the identification of radon-prone buildings.~~

~~3. Identification of types of buildings with public access and workplaces, e.g. schools, underground workplaces or spas, where measurements are needed, based on a risk assessment including occupancy hours.~~

~~4. The basis for the establishment of reference levels for existing dwellings, workplaces, buildings with public access and for new buildings.~~

~~5. Assignment of responsibilities (governmental and non-governmental), coordination mechanisms and available resources for implementation of the action plan.~~

~~6. Strategy for reducing radon exposure in dwellings, particularly in radon-prone areas.~~

~~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 audits and reviews of the action plan.~~

~~9. Strategy for communication to increase public awareness and inform local decision makers of the risks of radon in relation to smoking.~~

~~10. Where appropriate, 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).~~