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

CHAPTER I

SUBJECT MATTER AND SCOPE

Article 1

Subject matter

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

Article 2

Scope

1 This Directive applies to any planned, existing or emergency exposure situation which involves a risk from exposure to ionising radiation which cannot be disregarded from a radiation protection point of view or with regard to the environment in view of long-term human health protection.

2 This Directive applies in particular to:

a the manufacture, production, processing, handling, disposal, use, storage, holding, transport, import to, and export from the Community of radioactive material;

b the manufacture and the operation of electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5 kilovolt (kV);

c human activities which involve the presence of natural radiation sources that lead to a significant increase in the exposure of workers or members of the public, in particular:

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

(ii) the processing of materials with naturally-occurring radionuclides;

d the exposure of workers or members of the public to indoor radon, the external exposure from building materials and cases of lasting exposure resulting from the after-effects of an emergency or a past human activity.

e the preparedness for, the planning of response to and the management of emergency exposure situations that are deemed to warrant measures to protect the health of members of the public or workers.

Article 3

Exclusion from the scope

This Directive shall not apply to:

(a) exposure to the natural level of radiation, such as radionuclides contained in the human body and cosmic radiation prevailing at ground level;

(b) exposure of members of the public or workers other than air or spacecrew to cosmic radiation in flight or in space;

(c) aboveground exposure to radionuclides present in the undisturbed earth's crust.

CHAPTER II

DEFINITIONS

Article 4

Definitions

For the purpose of this Directive, the following definitions shall apply:

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

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

where

$d\bar{\varepsilon}$ 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) where one gray is equal to one joule per kilogram:

$$1\ \mathrm{Gy} = 1\ \mathrm{J\ kg^{-1}}$$

;

(2) "accelerator" means equipment or installation in which particles are accelerated, emitting ionising radiation with energy higher than 1 mega-electron volt (MeV);

(3) "accidental exposure" means an exposure of individuals, other than emergency workers, as a result of an accident;

(4) "activation" means a process through which a stable nuclide is transformed into a radionuclide by irradiating with particles or high-energy photons the material in which it is contained;

(5) "activity" (A) is the activity of an amount of a radionuclide in a particular energy state at a given time. It is the quotient of dN by dt, where dN is the expectation value of the number of nuclear transitions from that energy state in the time interval dt:

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

The unit of activity is the becquerel (Bq);

(6) "apprentice" means a person receiving training or instruction within an undertaking with a view to exercising a specific skill;

(7) "authorisation" means the registration or licensing of a practice;

(8) "becquerel" (Bq) is the special name of the unit of activity. One becquerel is equivalent to one nuclear transition per second:

$$1\ \mathrm{Bq} = 1\ \mathrm{s}^{-1}$$

;

(9) "building material" means any construction product for incorporation in a permanent manner in a building or parts thereof and the performance of which has an effect on the performance of the building with regard to exposure of its occupants to ionising radiation;

(10) "carers and comforters" means individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone medical exposure;

(11) "clearance levels" means values established by the competent authority or in national legislation, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of this Directive;

(12) "clinical audit" means a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary;

(13) "clinical responsibility" means responsibility of a practitioner for individual medical exposures, in particular, justification; optimisation; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical radiological procedures; obtaining information, if appropriate, on previous examinations; providing existing medical radiological information and/or records to other practitioners and/or the referrer, as required; and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate;

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

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

In specifying $E(\tau)$, 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, 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 the sievert (Sv);

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

It is given by:

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

for an intake at time t_0 where

$\dot{H}_T(t)$	is the relevant equivalent dose rate in organ or tissue T at time *t*,
τ	is the time over which the integration is performed.

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

(16) "competent authority" means an authority or system of authorities designated by Member States as having legal authority for the purposes of this Directive;

(17) "consumer product" means a device or manufactured item into which one or more radionuclides have deliberately been incorporated or produced by activation, or which generates ionising radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale;

(18) "contamination" means the unintended or undesirable presence of radioactive substances on surfaces or within solids, liquids or gases or on the human body;

(19) "controlled area" means an area subject to special rules for the purpose of protection against ionising radiation or preventing the spread of radioactive contamination and to which access is controlled;

(20) "diagnostic reference levels" means dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment;

(21) "disused source" means a sealed source which is no longer used or intended to be used for the practice for which authorisation was granted but continues to require safe management;

(22) "dose constraint" means a constraint set as a prospective upper bound of individual doses, used to define the range of options considered in the process of optimisation for a given radiation source in a planned exposure situation;

(23) "dose limit" means the value of the effective dose (where applicable, committed effective dose) or the equivalent dose in a specified period which shall not be exceeded for an individual;

(24) "dosimetry service" means a body or an individual competent to calibrate, read or interpret individual monitoring devices, or to measure radioactivity in the human body or in biological samples, or to assess doses, whose capacity to act in this respect is recognised by the competent authority;

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

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

where

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

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

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

(27) "emergency exposure situation" means a situation of exposure due to an emergency;

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

(29) "emergency occupational exposure" means exposure received in an emergency exposure situation by an emergency worker;

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

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

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

(33) "equivalent dose" (H_T) is the absorbed dose, in tissue or organ T weighted for the type and quality of radiation R. It is given by:

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

,

where

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

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

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

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

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

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

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

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

(38) "extremities" means the hands, forearms, feet and ankles;

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

(40) "health screening" means a procedure using medical radiological installations for early diagnosis in population groups at risk;

(41) "high-activity sealed source" means a sealed source for which the activity of the contained radionuclide is equal to or exceeds the relevant activity value laid down in Annex III;

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

(43) "inspection" means an investigation by or on behalf of any competent authority to verify compliance with national legal requirements;

(44) "intake" means the total activity of a radionuclide entering the body from the external environment;

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

(46) "ionising radiation" means energy transferred in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less (a frequency of 3×10^{15} hertz or more) capable of producing ions directly or indirectly;

(47) "licence" means permission granted in a document by the competent authority to carry out a practice in accordance with specific conditions laid down in that document;

(48) "medical exposure" means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research;

(49) "medical physics expert" means an individual or, if provided for in national legislation, a group of individuals, having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognised by the competent authority;

(50) "medical radiological" means pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes;

(51) "medical radiological installation" means a facility where medical radiological procedures are performed;

(52) "medical radiological procedure" means any procedure giving rise to medical exposure;

(53) "members of the public" means individuals who may be subject to public exposure;

(54) "natural radiation source" means a source of ionising radiation of natural, terrestrial or cosmic origin;

(55) "non-medical imaging exposure" means any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed;

(56) "normal exposure" means exposure expected to occur under the normal operating conditions of a facility or activity (including maintenance, inspection, decommissioning), including minor incidents that can be kept under control, i.e. during normal operation and anticipated operational occurrences;

(57) "notification" means submission of information to the competent authority to notify the intention to carry out a practice within the scope of this Directive;

(58) "occupational exposure" means exposure of workers, apprentices and students, incurred in the course of their work;

(59) "occupational health service" means a health professional or body competent to perform medical surveillance of exposed workers and whose capacity to act in that respect is recognised by the competent authority;

(60) "orphan source" means a radioactive source which is neither exempted nor under regulatory control, e.g. because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation;

(61) "outside worker" means any exposed worker who is not employed by the undertaking responsible for the supervised and controlled areas, but performs activities in those areas, including, apprentices and students;

(62) "planned exposure situation" means an exposure situation that arises from the planned operation of a radiation source or from a human activity which alters exposure pathways, so as to cause the exposure or potential exposure of people or the environment. Planned exposure situations may include both normal exposures and potential exposures.

(63) "potential exposure" means exposure that is not expected with certainty but may result from an event or sequence of events of a probabilistic nature, including equipment failures and operating errors;

(64) "practical aspects of medical radiological procedures" means the physical conduct of a medical exposure and any supporting aspects, including handling and use of medical radiological equipment, the assessment of technical and physical parameters

(including radiation doses), calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals, and image processing;

(65) "practice" means a human activity that can increase the exposure of individuals to radiation from a radiation source and is managed as a planned exposure situation;

(66) "practitioner" means a medical doctor, dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements;

(67) "processing" means chemical or physical operations on radioactive material including the mining, conversion, enrichment of fissile or fertile nuclear material and the reprocessing of spent fuel;

(68) "protective measures" means measures, other than remedial measures, for the purpose of avoiding or reducing doses that might otherwise be received in an emergency exposure situation or an existing exposure situation;

(69) "public exposure" means exposure of individuals, excluding any occupational or medical exposure;

(70) "quality assurance" means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. Quality control is a part of quality assurance;

(71) "quality control" means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled;

(72) "radiation generator" means a device capable of generating ionising radiation, such as X-rays, neutrons, electrons or other charged particles;

(73) "radiation protection expert" means an individual or, if provided for in the national legislation, a group of individuals having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose competence in this respect is recognised by the competent authority;

(74) "radiation protection officer" means an individual who is technically competent in radiation protection matters relevant for a given type of practice to supervise or perform the implementation of the radiation protection arrangements;

(75) "radiation source" means an entity that may cause exposure, such as by emitting ionising radiation or by releasing radioactive material;

(76) "radioactive material" means material incorporating radioactive substances;

(77) "radioactive source" means a radiation source incorporating radioactive material for the purpose of utilising its radioactivity;

(78) "radioactive substance" means any substance that contains one or more radionuclides the activity or activity concentration of which cannot be disregarded from a radiation protection point of view;

(79) "radioactive waste" means radioactive material in gaseous, liquid or solid form for which no further use is foreseen or considered by the Member State or by a legal or

natural person whose decision is accepted by the Member State, and which is regulated as radioactive waste by a competent regulatory authority under the legislative and regulatory framework of the Member State;

(80) "radiodiagnostic" means pertaining to in-vivo diagnostic nuclear medicine, medical diagnostic radiology using ionising radiation, and dental radiology;

(81) "radiotherapeutic" means pertaining to radiotherapy, including nuclear medicine for therapeutic purposes;

(82) "radon" means the radionuclide Rn-222 and its progeny, as appropriate;

(83) "exposure to radon" means exposure to radon progeny;

(84) "reference level" means in an emergency exposure situation or in an existing exposure situation, the level of effective dose or equivalent dose or activity concentration above which it is judged inappropriate to allow exposures to occur as a result of that exposure situation, even though it is not a limit that may not be exceeded;

(85) "referrer" means a medical doctor, dentist or other health professional who is entitled to refer individuals for medical radiological procedures to a practitioner, in accordance with national requirements;

(86) "registration" means permission granted in a document by the competent authority, or granted by national legislation, through a simplified procedure, to carry out a practice in accordance with conditions laid down in national legislation or specified by a competent authority for this type or class of practice;

(87) "regulatory control" means any form of control or regulation applied to human activities for the enforcement of radiation protection requirements;

(88) "remedial measures" means the removal of a radiation source or the reduction of its magnitude (in terms of activity or amount) or the interruption of exposure pathways or the reduction of their impact for the purposes of avoiding or reducing doses that might otherwise be received in an existing exposure situation;

(89) "representative person" means an individual receiving a dose that is representative of the more highly exposed individuals in the population, excluding those individuals having extreme or rare habits;

(90) "sealed source" means a radioactive source in which the radioactive material is permanently sealed in a capsule or incorporated in a solid form with the objective of preventing, under normal conditions of use, any dispersion of radioactive substances;

(91) "sievert" (Sv) is the special name of the unit of equivalent or effective dose. One sievert is equivalent to one joule per kilogram:

$$1\,\mathrm{Sv} = 1\,\mathrm{J\,kg^{-1}}$$

;

(92) "storage" means the holding of radioactive material, including spent fuel, a radioactive source or radioactive waste, in a facility with the intention of retrieval;

(93) "supervised area" means an area subject to supervision for the purpose of protection against ionising radiation;

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

(95) "spacecraft" means a manned vehicle designed to operate at an altitude of more than 100 km above sea level;

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

(97) "thoron" means the radionuclide Rn-220 and its progeny, as appropriate;

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

(99) "unintended exposure" means medical exposure that is significantly different from the medical exposure intended for a given purpose.

CHAPTER III

SYSTEM OF RADIATION PROTECTION

Article 5

General principles of radiation protection

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

(a) Justification: Decisions introducing a practice shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause. Decisions introducing or altering an exposure pathway for existing and emergency exposure situations shall be justified in the sense that they should do more good than harm.

(b) Optimisation: Radiation protection of individuals subject to public or occupational exposure shall be optimised with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable taking into account the current state of technical knowledge and economic and societal factors. The optimisation of the protection of individuals subject to medical exposure shall apply to the magnitude of individual doses and be consistent with the medical purpose of the exposure, as described in Article 56. This principle shall be applied not only in terms of effective dose but also, where appropriate, in terms of equivalent doses, as a precautionary measure to allow for uncertainties as to health detriment below the threshold for tissue reactions.

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

SECTION 1

Tools for optimisation

Article 6

Dose constraints for occupational, public, and medical exposure

1 Member States shall ensure that, where appropriate, dose constraints are established for the purpose of prospective optimisation of protection:

a for occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking under the general supervision of the competent authority. In the case of outside workers the dose constraint shall be established in cooperation between the employer and the undertaking.

b for public exposure, the dose constraint shall be set for the individual dose that members of the public receive from the planned operation of a specified radiation source. The competent authority shall ensure that the constraints are consistent with the dose limit for the sum of doses to the same individual from all authorised practices.

c for medical exposure, dose constraints shall apply only with regard to the protection of carers and comforters and volunteers participating in medical or biomedical research.

2 Dose constraints shall be established in terms of individual effective or equivalent doses over a defined appropriate time period.

Article 7

Reference levels

1 Member States shall ensure that reference levels are established for emergency and existing exposure situations. Optimisation of protection shall give priority to exposures above the reference level and shall continue to be implemented below the reference level.

2 The values chosen for reference levels shall depend upon the type of exposure situation. The choices of reference levels shall take into account both radiological protection requirements and societal criteria. For public exposure the establishment of reference levels shall take into account the range of reference levels set out in Annex I.

3 For existing exposure situations involving exposure to radon, the reference levels shall be set in terms of radon activity concentration in air as specified in Article 74 for members of the public and Article 54 for workers.

SECTION 2

Dose limitation

Article 8

Age limit for exposed workers

Member States shall ensure that subject to Article 11(2), persons under 18 years of age may not be assigned to any work which would result in their being exposed workers.

Article 9

Dose limits for occupational exposure

1 Member States shall ensure that dose limits for occupational exposure apply to the sum of annual occupational exposures of a worker from all authorised practices, occupational exposure to radon in workplaces requiring notification in accordance with Article 54(3), and other occupational exposure from existing exposure situations in accordance with Article 100(3). For emergency occupational exposure Article 53 shall apply.

2 The limit on the effective dose for occupational exposure shall be 20 mSv in any single year. However, in special circumstances or for certain exposure situations specified in national legislation, a higher effective dose of up to 50 mSv may be authorised by the competent authority in a single year, provided that the average annual dose over any five consecutive years, including the years for which the limit has been exceeded, does not exceed 20 mSv.

3 In addition to the limits on effective dose laid down in paragraph 2, the following limits on equivalent dose shall apply:

a the limit on the equivalent dose for the lens of the eye shall be 20 mSv in a single year or 100 mSv in any five consecutive years subject to a maximum dose of 50 mSv in a single year, as specified in national legislation.

b the limit on the equivalent dose for the skin shall be 500 mSv in a year, this limit shall apply to the dose averaged over any area of 1 cm^2, regardless of the area exposed;

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

Article 10

Protection of pregnant and breastfeeding workers

1 Member States shall ensure that the protection of the unborn child is comparable with that provided for members of the public. As soon as a pregnant worker informs the undertaking or, in the case of an outside worker, the employer, of the pregnancy, in accordance with national legislation the undertaking, and the employer, shall ensure that the employment conditions for the pregnant worker are such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy.

2 As soon as workers inform the undertaking, or in case of outside workers, the employer, that they are breastfeeding an infant, they shall not be employed in work involving a significant risk of intake of radionuclides or of bodily contamination.

Article 11

Dose limits for apprentices and students

1 Member States shall ensure that the dose limits for apprentices aged 18 years or over and students aged 18 years or over who, in the course of their studies, are obliged to work with radiation sources, shall be the same as the dose limits for occupational exposure laid down in Article 9.

2 Member States shall ensure that the limit on the effective dose for apprentices aged between 16 and 18 years and for students aged between 16 and 18 years who, in the course of their studies, are obliged to work with radiation sources, shall be 6 mSv in a year.

3 In addition to the limits on effective dose laid down in paragraph 2, the following limits on equivalent dose shall apply:

a the limit on the equivalent dose for the lens of the eye shall be 15 mSv in a year;

b the limit on the equivalent dose for the skin shall be 150 mSv in a year, averaged over any area of 1 cm^2, regardless of the area exposed;

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

4 Member States shall ensure that the dose limits for apprentices and students who are not subject to the provisions of paragraphs 1, 2 and 3 shall be the same as the dose limits for members of the public as specified in Article 12.

Article 12

Dose limits for public exposure

1 Member States shall ensure that the dose limits for public exposure shall apply to the sum of annual exposures of a member of the public resulting from all authorised practices.

2 Member States shall set the limit on the effective dose for public exposure at 1 mSv in a year.

3 In addition to the dose limit referred to in paragraph 2, the following limits on the equivalent dose shall apply:

a the limit on the equivalent dose for the lens of the eye shall be 15 mSv in a year;

b the limit on the equivalent dose for the skin shall be 50 mSv in a year, averaged over any 1 cm^2 area of skin, regardless of the area exposed.

Article 13

Estimation of the effective and equivalent dose

For the estimation of effective and equivalent doses, the appropriate standard values and relationships shall be used. For external radiation, the operational quantities defined in section 2.3 of ICRP Publication 116 shall be used.

CHAPTER IV

REQUIREMENTS FOR RADIATION PROTECTION EDUCATION, TRAINING AND INFORMATION

Article 14

General responsibilities for the education, training and provision of information

1 Member States shall establish an adequate legislative and administrative framework ensuring the provision of appropriate radiation protection education, training and information to

all individuals whose tasks require specific competences in radiation protection. The provision of training and information shall be repeated at appropriate intervals and documented.

2 Member States shall ensure that arrangements are made for the establishment of education, training and retraining to allow the recognition of radiation protection experts and medical physics experts, as well as occupational health services and dosimetry services, in relation to the type of practice.

3 Member States may make arrangements for the establishment of education, training and retraining to allow the recognition of radiation protection officers, if such recognition is provided for in national legislation.

Article 15

Training of exposed workers and information provided to them

1 Member States shall require the undertaking to inform exposed workers on:

a the radiation health risks involved in their work;

b the general radiation protection procedures and precautions to be taken;

c the radiation protection procedures and precautions connected with the operational and working conditions of both the practice in general and each type of workstation or work to which they may be assigned;

d the relevant parts of the emergency response plans and procedures;

e the importance of complying with the technical, medical and administrative requirements.

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

2 Member States shall require the undertaking or, in case of outside workers, the employer, to inform exposed workers on the importance of making an early declaration of pregnancy in view of the risks of exposure for the unborn child.

3 Member States shall require the undertaking or, in case of outside workers, the employer, to inform exposed workers on the importance of announcing the intention to breast-feed an infant in view of the risks of exposure for a breast-fed infant after intake of radionuclides or bodily contamination.

4 Member States shall require that the undertaking or, in case of outside workers, the employer, provides appropriate radiation protection training and information programmes for exposed workers.

5 In addition to the information and training in the field of radiation protection as specified in paragraphs 1, 2, 3 and 4, Member States shall require that the undertaking responsible for high-activity sealed sources shall ensure that such training includes specific requirements for the safe management and control of high-activity sealed sources with a view to preparing the relevant workers adequately for any events affecting the radiation protection. The information and training shall place particular emphasis on the necessary safety requirements and shall contain specific information on the possible consequences of the loss of adequate control of high-activity sealed sources.

Article 16

Information and training of workers potentially exposed to orphan sources

1 Member States shall ensure that the management of installations where orphan sources are most likely to be found or processed, including large metal scrap yards and major metal scrap recycling installations, and in significant nodal transit points, are informed of the possibility that they may be confronted with a source.

2 Member States shall encourage the management of installations referred to in paragraph 1 to ensure that where workers in their installation may be confronted with a source, they are:

a advised and trained in the visual detection of sources and their containers;

b informed of basic facts about ionising radiation and its effects;

c informed of and trained in the actions to be taken on site in the event of the detection or suspected detection of a source.

Article 17

Prior information and training for emergency workers

1 Member States shall ensure that emergency workers who are identified in an emergency response plan or management system are given adequate and regularly updated information on the health risks their intervention might involve and on the precautionary measures to be taken in such an event. This information shall take into account the range of potential emergencies and the type of intervention.

2 As soon as an emergency occurs, the information referred to in paragraph 1 shall be supplemented appropriately, having regard to the specific circumstances.

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

4 Members States shall ensure that, in addition to the emergency response training referred to in paragraph 3, the undertaking or the organisation responsible for the protection of emergency workers provides these workers with appropriate radiation protection training and information.

Article 18

Education, information and training in the field of medical exposure

1 Member States shall ensure that practitioners and the individuals involved in the practical aspects of medical radiological procedures have adequate education, information and theoretical and practical training for the purpose of medical radiological practices, as well as relevant competence in radiation protection.

For this purpose Member States shall ensure that appropriate curricula are established and shall recognise the corresponding diplomas, certificates or formal qualifications.

2 Individuals undergoing relevant training programmes may participate in practical aspects of medical radiological procedures as set out in Article 57(2).

3 Member States shall ensure that continuing education and training after qualification is provided and, in the special case of the clinical use of new techniques, training is provided on these techniques and the relevant radiation protection requirements.

4 Member States shall encourage the introduction of a course on radiation protection in the basic curriculum of medical and dental schools.

CHAPTER V

JUSTIFICATION AND REGULATORY CONTROL OF PRACTICES

SECTION 1

Justification and prohibition of practices

Article 19

Justification of practices

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

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

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

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

Article 20

Practices involving consumer products

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

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

3 Without prejudice to paragraph 1, Member States shall ensure that the competent authority which has received information according to that paragraph, informs the point of

contact for the competent authorities of other Member States of this receipt and, upon request, of its decision and the basis for that decision.

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

Article 21

Prohibition of practices

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

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

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

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

Article 22

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

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

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

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

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

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

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

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

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

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

a the practice is subject to authorisation;

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

c for procedures using medical radiological equipment

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

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

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

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

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

SECTION 2

Regulatory control

Article 23

Identification of practices involving naturally-occurring radioactive material

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

Article 24

Graded approach to regulatory control

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

2 Without prejudice to Articles 27 and 28, where appropriate, and in accordance with the general exemption criteria set out in Annex VII, regulatory control may be limited to notification and an appropriate frequency of inspections. For this purpose, Member States may establish general exemptions or allow the competent authority to decide to exempt notified practices from the requirement of authorisation on the basis of the general criteria specified in Annex VII; in the case of moderate amounts of material, as specified by Member States, the activity concentration values laid down in Annex VII, Table B, column 2 may be used for this purpose.

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

Article 25

Notification

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

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

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

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

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

Article 26

Exemption from notification

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

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

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

c apparatus containing a sealed source, provided that:

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

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

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

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

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

d any electrical apparatus provided that:

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

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

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

at a distance of 0.1 m from any accessible surface.

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

Article 27

Registration or licensing

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

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

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

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

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

Article 28

Licensing

Member States shall require licensing for the following practices:

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

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

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

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

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

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

Article 29

Authorisation procedure

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

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

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

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

Article 30

Release from regulatory control

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

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

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

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

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

4 Member States shall not permit the deliberate dilution of radioactive materials for the purpose of them being released from regulatory control. The mixing of materials that takes place in normal operations where radioactivity is not a consideration is not subject to this prohibition. The Competent Authority may authorise, in specific circumstances, the mixing of radioactive and non-radioactive materials for the purposes of re-use or recycling.

CHAPTER VI

OCCUPATIONAL EXPOSURES

Article 31

Responsibilities

1 Member States shall ensure that the undertaking is responsible for assessing and implementing arrangements for the radiation protection of exposed workers.

2 In the case of outside workers, the responsibilities of the undertaking and the employer of outside workers are stipulated in Article 51.

3 Without prejudice to paragraphs 1 and 2, Member States shall arrange for a clear allocation of responsibilities for the protection of workers in any exposure situation, to an undertaking, an employer or any other organisation, in particular for the protection of:

a emergency workers;

b workers involved in the remediation of contaminated land, buildings and other constructions;

c workers who are exposed to radon at work, in the situation specified in Article 54(3).

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

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

Article 32

Operational protection of exposed workers

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

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

(b) optimisation of radiation protection in all working conditions, including occupational exposures as a consequence of practices involving medical exposures;

(c) classification of exposed workers into different categories;

(d) control measures and monitoring relating to the different areas and working conditions, including, where necessary, individual monitoring;

(e) medical surveillance;

(f) education and training.

Article 33

Operational protection of apprentices and students

1 Member States shall ensure that the exposure conditions and operational protection of apprentices and students aged 18 years or over referred to in Article 11(1) is equivalent to that of exposed workers of category A or B as appropriate.

2 Member States shall ensure that the exposure conditions and operational protection of apprentices and students aged between 16 and 18 years referred to in Article 11(2) is equivalent to that of exposed workers of category B.

Article 34

Consultations with a radiation protection expert

Member States shall require undertakings to seek advice from a radiation protection expert within their areas of competence as outlined in Article 82, on the issues below that are relevant to the practice:

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

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

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

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

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

Article 35

Arrangements in workplaces

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

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

2 For workplaces specified in Article 54(3), and where the exposure of workers is liable to exceed an effective dose of 6 mSv per year or a corresponding time-integrated radon exposure value determined by the Member State, these shall be managed as a planned exposure situation and the Member States shall determine which requirements set out in this Chapter are appropriate. For workplaces specified in Article 54(3), and where the effective dose to workers is less than or equal to 6 mSv per year or the exposure less than the corresponding

time-integrated radon exposure value, the competent authority shall require that exposures are kept under review.

3 For an undertaking operating aircraft where the effective dose to the crew from cosmic radiation is liable to exceed 6 mSv per year, the relevant requirements set out in this Chapter shall apply, allowing for the specific features of this exposure situation. Member States shall ensure that where the effective dose to the crew is liable to be above 1 mSv per year, the competent authority requires the undertaking to take appropriate measures, in particular:

a to assess the exposure of the crew concerned;

b to take into account the assessed exposure when organising working schedules with a view to reducing the doses of highly exposed crew;

c to inform the workers concerned of the health risks their work involves and their individual dose.

d to apply Article 10(1) to pregnant air crew.

Article 36

Classification of workplaces

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

2 A distinction shall be made between controlled areas and supervised areas. Member States shall ensure that the competent authority establishes guidance on the classification of controlled and supervised areas with regard to particular circumstances.

3 Member States shall ensure that the undertaking keeps under review the working conditions in controlled and supervised areas.

Article 37

Controlled areas

1 Member States shall ensure that the minimum requirements for a controlled area are the following:

a The controlled area shall be delineated and access to it shall be restricted to individuals who have received appropriate instructions and shall be controlled in accordance with written procedures provided by the undertaking. Wherever there is a significant risk of the spread of radioactive contamination, specific arrangements shall be made, including for the access and exit of individuals and goods and for monitoring contamination within the controlled area and, where appropriate, in the adjacent area.

b Taking into account the nature and extent of radiological risks in the controlled area, radiological surveillance of the workplace shall be organised in accordance with the provisions of Article 39.

c Signs indicating the type of area, the nature of the sources and their inherent risks shall be displayed.

d Working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.

e The worker shall receive specific training in connection with the characteristics of the workplace and the activities.

f The worker shall be provided with the appropriate personal protective equipment.

2 Member States shall ensure that the undertaking is responsible for implementation of these duties taking into account the advice provided by the radiation protection expert.

Article 38

Supervised areas

1 Member States shall ensure that the requirements for a supervised area are the following:

a taking into account the nature and extent of radiological risks in the supervised area, radiological surveillance of the workplace shall be organised in accordance with the provisions of Article 39;

b if appropriate, signs indicating the type of area, the nature of the sources and their inherent risks shall be displayed;

c if appropriate, working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.

2 Member States shall ensure that the undertaking is responsible for implementation of these duties taking into account the advice provided by the radiation protection expert.

Article 39

Radiological surveillance of the workplace

1 Member States shall ensure that the radiological surveillance of the workplace referred to in point (b) of Articles 37(1) and point (a) of Article 38(1) comprises, where appropriate:

a the measurement of external dose rates, indicating the nature and quality of the radiation in question;

b the measurement of the activity concentration in air and the surface density of contaminating radionuclides, indicating their nature and their physical and chemical states.

2 The results of these measurements shall be recorded and shall be used, if necessary, for estimating individual doses, as provided for in Article 41.

Article 40

Categorisation of exposed workers

1 Member States shall ensure that for the purposes of monitoring and surveillance, a distinction is made between two categories of exposed workers:

a category A: those exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than 150 mSv per year for skin and extremities;

b category B: those exposed workers who are not classified as category A workers.

2 Member States shall require the undertaking or, in the case of outside workers, the employer, to decide on the categorisation of individual workers prior to their taking up work that may give rise to exposure, and to regularly review this categorisation on the basis of working

conditions and medical surveillance. The distinction shall also take into account potential exposures.

Article 41

Individual monitoring

1 Member States shall ensure that category A workers are systematically monitored based on individual measurements performed by a dosimetry service. In cases where category A workers are liable to receive significant internal exposure or significant exposure of the lens of the eye or extremities, an adequate system for monitoring shall be set up.

2 Member States shall ensure that monitoring for category B workers is at least sufficient to demonstrate that such workers are correctly classified in category B. Member States may require individual monitoring and if necessary individual measurements, performed by a dosimetry service, for category B workers.

3 In cases where individual measurements are not possible or inadequate, the individual monitoring shall be based on an estimate arrived at from individual measurements made on other exposed workers, from the results of the surveillance of the workplace provided for in Article 39 or on the basis of calculation methods approved by the competent authority.

Article 42

Dose assessment in the case of accidental exposure

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

Article 43

Recording and reporting of results

1 Member States shall ensure that a record containing the results of individual monitoring is made for each category A worker and for each category B worker where such monitoring is required by the Member State.

2 For the purposes of paragraph 1, the following information on exposed workers shall be retained:

a a record of the exposures measured or estimated, as the case may be, of individual doses pursuant to Articles 41, 42, 51, 52, 53 and, if decided by the Member State pursuant to Article 35(2), 54(3);

b in the case of exposures as referred to in Articles 42, 52 and 53, the reports relating to the circumstances and the action taken;

c the results of workplace monitoring used to assess individual doses where necessary.

3 The information referred to in paragraph 1 shall be retained during the period of their working life involving exposure to ionising radiation and afterwards until they have or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure.

4 Exposures as referred to in Articles 42, 52 53 and, if decided by the Member State pursuant to Article 35(2), 54(3) shall be recorded separately in the dose record referred to in paragraph 1.

5 The dose record referred to in paragraph 1 shall be submitted to the data system for individual radiological monitoring established by the Member State in accordance with the provisions of Annex X.

Article 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 41, 42, 52, 53 and, if decided by the Member State pursuant to Article 35(2), 54(3) be:

a made available to the competent authority, to the undertaking, and to the employer of outside workers;

b made available to the worker concerned in accordance with paragraph 2;

c submitted to the occupational health service in order for it to interpret the implications of the results for human health, as provided for in Article 45(2);

d submitted to the data system for individual radiological monitoring established by the Member State in accordance with provisions set out in Annex X.

2 Member States shall require the undertaking, or in case of outside workers, the employer, to grant workers, at their request, access to the results of their individual monitoring, including the results of measurements which may have been used in estimating these results, or to the results of the assessment of their doses made as a result of surveillance of the workplace.

3 Member States shall determine the arrangements under which the results of individual monitoring are conveyed.

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

5 In the case of an accidental exposure, Member States shall require the undertaking to communicate the results of individual monitoring and dose assessments to the individual and the competent authority without delay.

6 Member States shall ensure that arrangements are in place for the appropriate exchange, among the undertaking, in the case of an outside worker, the employer, the competent authority, occupational health services, radiation protection experts, or dosimetry services of all relevant information on the doses previously received by a worker in order to perform the medical examination prior to employment or classification as a category A worker pursuant to Article 45 and to control the further exposure of workers.

Article 45

Medical surveillance of exposed workers

1 Member States shall ensure that the medical surveillance of exposed workers is based on the principles that govern occupational medicine generally.

2 The medical surveillance of category A workers shall be undertaken by the occupational health service. 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 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 at least once a year, in order to determine whether the category A workers remain fit to perform their duties. The nature of these reviews, which can be performed as many times as the occupational health service considers necessary, shall depend on the type of work and on the individual worker's state of health.

4 The occupational health service 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 46

Medical classification

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

(a) fit;

(b) fit, subject to certain conditions;

(c) unfit.

Article 47

Prohibition to employ or classify unfit workers

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

Article 48

Medical records

1 Member States shall ensure that a medical record is opened for each category A worker and kept up to date so long as the worker remains a worker in that category. Thereafter, it shall be retained until the individual has or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure to ionising radiation.

2 The medical record shall include information regarding the nature of the employment, the results of the medical examinations prior to employment or classification as a category A worker, the periodic reviews of health and the record of doses required by Article 43.

Article 49

Special medical surveillance

1 Member States shall ensure that in addition to the medical surveillance of exposed workers provided for in Article 45, provision is made for any further action considered necessary by the occupational health service for the health protection of exposed individuals, such as further examinations, decontamination measures, urgent remedial treatment or other actions identified by the occupational health service.

2 Special medical surveillance shall be performed in each case where any of the dose limits laid down in Article 9 has been exceeded.

3 Subsequent exposure conditions shall be subject to the agreement of the occupational health service.

Article 50

Appeals

Member States shall lay down the procedure for appeal against the findings and decisions made pursuant to Articles 46, 47 and 49.

Article 51

Protection of outside workers

1 Member States shall ensure that the system for individual radiological monitoring affords outside workers equivalent protection to that for exposed workers employed on a permanent basis by the undertaking.

2 Member States shall ensure that the undertaking is responsible, either directly or through contractual agreements with the employer of outside workers, for the operational aspects of the radiation protection of outside workers that are directly related to the nature of their activities in the undertaking.

3 In particular, Member States shall ensure that, as a minimum requirement, the undertaking shall:

a for category A workers entering controlled areas, check that the outside worker concerned has been passed as medically fit for the activities to be assigned to the worker;

b check whether the categorisation of the outside worker is appropriate in relation to the doses liable to be received within the undertaking;

c for entry into controlled areas, ensure that, in addition to the basic training in radiation protection the outside worker has received specific instructions and training in connection with the characteristics of the workplace and the conducted activities, in accordance with points (c) and (d) of Article 15(1);

d for entry into supervised areas, ensure that the outside worker has received working instructions appropriate to the radiological risk associated with the sources and the operations involved, as required in point (c) of Article 38(1);

e ensure that the outside worker has been issued with the necessary personal protective equipment;

f 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;

g ensure compliance with the system of protection as defined in Chapter III;

h 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 X, Section B, point 2, are recorded.

4 Member States shall ensure that employers of outside workers ensure, either directly or through contractual agreements with the undertaking, that the radiation protection of their workers is in accordance with the relevant provisions of this Directive, in particular by:

a ensuring compliance with the system of protection as defined in Chapter III;

b ensuring that the information and training in the field of radiation protection referred to in points (a), (b) and (e) of Article 15(1), Article 15(2), (3) and (4) is provided.

c guaranteeing that their workers are subject to appropriate assessment of exposure and, for category A workers, medical surveillance, under the conditions laid down in Articles 39 and 41 to 49;

d ensuring that the radiological data from the individual exposure monitoring of each of their category A workers within the meaning of Annex X, Section B, point 1, are kept up to date in the data system for individual radiological monitoring referred to in point (d) of Article 44(1).

5 Member States shall ensure that all outside workers make their own contributions, as far as practicable, towards the protection to be afforded to them by the radiological monitoring system referred to in paragraph 1, without prejudice to the responsibilities of the undertaking or employer.

Article 52

Specially authorised exposures

1 Member States may decide that in exceptional circumstances evaluated case by case, excluding emergencies, the competent authority may, where a specific operation so requires, authorise individual occupational exposures of identified workers exceeding the dose limits set out in Article 9, provided that such exposures are limited in time, confined to certain working areas and within the maximum exposure levels defined for the particular case by the competent authority. The following conditions shall be taken into account:

a only category A workers as defined in Article 40 or spacecraft crew may be subject to such exposures;

b apprentices, students, pregnant workers, and, if there is a risk of intake or bodily contamination, breastfeeding workers, are excluded from such exposures;

c the undertaking justifies such exposures in advance and thoroughly discuss them with the workers, their representatives, the occupational health service and the radiation protection expert;

d information about the risks involved and the precautions to be taken during the operation are provided to the relevant workers in advance;

e the workers have consented;

f all doses relating to such exposures are separately recorded in the medical record referred to in Article 48 and the individual record referred to in Article 43.

2 The exceeding of dose limits as a result of specially authorised exposures shall not necessarily constitute a reason for excluding workers from their usual occupation or relocating them, without their agreement.

3 Member States shall ensure that the exposure of spacecraft crew above the dose limits is managed as a specially authorised exposure.

Article 53

Emergency occupational exposure

1 Member States shall ensure that emergency occupational exposures shall remain, whenever possible, below the values of the dose limits laid down in Article 9.

2 For situations where the above condition is not feasible, the following conditions shall apply:

a) reference levels for emergency occupational exposure shall be set, in general below an effective dose of 100 mSv;

b) in exceptional situations, in order to save life, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions, a reference level for an effective dose from external radiation of emergency workers may be set above 100 mSv, but not exceeding 500 mSv.

3 Member States shall ensure that emergency workers who are liable to undertake actions whereby an effective dose of 100 mSv may be exceeded are clearly and comprehensively informed in advance of the associated health risks and the available protection measures and undertake these actions voluntarily.

4 In the event of an emergency occupational exposure, Member States shall require radiological monitoring of emergency workers. Individual monitoring or assessment of the individual doses shall be carried out as appropriate to the circumstances.

5 In the event of an emergency occupational exposure, Member States shall require special medical surveillance of emergency workers, as defined in Article 49, to be carried out as appropriate to the circumstances.

Article 54

Radon in workplaces

1 Member States shall establish national reference levels for indoor radon concentrations in workplaces. The reference level for the annual average activity concentration in air shall not be higher than 300 Bq m^{-3}, unless it is warranted by national prevailing circumstances.

2 Member States shall require that radon measurements are carried out:

a in workplaces within the areas identified in accordance with Article 103(3), that are located on the ground floor or basement level, taking into account parameters contained in the national action plan as under point 2 of Annex XVIII, as well as

b in specific types of workplaces identified in the national action plan taking into account point 3 of Annex XVIII.

3 In areas within workplaces, where the radon concentration (as an annual average), continues to exceed the national reference level, despite the action taken in accordance with the principle of optimisation as set out in Chapter III, Member States shall require this situation to be notified in accordance with Article 25(2) and Article 35(2) shall apply.

CHAPTER VII

MEDICAL EXPOSURES

Article 55

Justification

1 Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

2 Member States shall ensure that the principle defined in paragraph 1 is applied and in particular that:

a new types of practices involving medical exposure are justified in advance before being generally adopted;

b all individual medical exposures are justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.

c if a type of practice involving medical exposure is not justified in general, a specific individual exposure of this type can be justified, where appropriate, in special circumstances, to be evaluated on a case-by-case basis and documented.

d the referrer and the practitioner, as specified by Member States, seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure.

e medical exposure for medical or biomedical research are examined by an ethics committee, set up in accordance with national procedures and/or by the competent authority;

f specific justification for medical radiological procedures to be performed as part of a health screening programme are carried out by the competent authority in conjunction with appropriate medical scientific societies or relevant bodies.

g the exposure of carers and comforters show a sufficient net benefit, taking into account the direct health benefits to a patient, the possible benefits to the carer / comforter and the detriment that the exposure might cause.

h any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, is part of a health screening programme, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant medical scientific societies and the competent authority. Special attention shall be given to the provision of information to the individual subject to medical exposure, as required by point (d) of Article 57(1).

Article 56

Optimisation

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

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

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

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

a the individuals concerned participate voluntarily;

b these individuals are informed about the risks of exposure;

c a dose constraint is established for individuals for whom no direct medical benefit is expected from exposure;

d in the case of patients who voluntarily accept to undergo an experimental medical practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the dose levels concerned shall be considered on an individual basis by the practitioner and/or referrer prior to the exposure taking place.

4 Member States shall ensure that the optimisation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities, taking into account economic and societal factors.

5 Member States shall ensure that:

a dose constraints are established for the exposure of carers and comforters, where appropriate;

b appropriate guidance is established for the exposure of carers and comforters.

6 Member States shall ensure that in the case of a patient undergoing treatment or diagnosis with radionuclides, the practitioner or the undertaking, as specified by Member States, provides the patient or their representative with information on the risks of ionising radiation and appropriate instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable. For therapeutic procedures these shall be written instructions.

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

Article 57

Responsibilities

1 Member States shall ensure that:

a any medical exposure takes place under the clinical responsibility of a practitioner;

b the practitioner, the medical physics expert and those entitled to carry out practical aspects of medical radiological procedures are involved, as specified by Member States, in the optimisation process;

c the referrer and the practitioner are involved, as specified by Member States, in the justification process of individual medical exposures;

d wherever practicable and prior to the exposure taking place, the practitioner or the referrer, as specified by Member States, ensures that the patient or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure. Similar information as well as relevant guidance shall be given to carers and comforters, in accordance with point (b) of Article 56(5).

2 Practical aspects of medical radiological procedures may be delegated by the undertaking or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognised field of specialisation.

Article 58

Procedures

Member States shall ensure that:

(a) written protocols for every type of standard medical radiological procedure are established for each equipment for relevant categories of patients;

(b) information relating to patient exposure forms part of the report of the medical radiological procedure;

(c) referral guidelines for medical imaging, taking into account the radiation doses, are available to the referrers;

(d) in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice. In particular:

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

(ii) in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, involving high doses as referred to in point (c) of Article 61(1), a medical physics expert shall be involved;

(iii) **[**[X1]for other medical radiological practices not covered by points (i) and (ii), a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.**]**

(e) clinical audits are carried out in accordance with national procedures;

(f) appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that appropriate corrective action is taken without undue delay.

Editorial Information

X1 Substituted by Corrigendum to Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (Official Journal of the European Union L 13 of 17 January 2014).

Article 59

Training and recognition

Member States shall ensure that training and recognition requirements, as laid down in Articles 79, 14 and 18, are met for the practitioner, the medical physics expert and the individuals referred to in Article 57(2).

Article 60

Equipment

1 Member States shall ensure that:

a all medical radiological equipment in use is kept under strict surveillance regarding radiation protection;

b an up-to-date inventory of medical radiological equipment for each medical radiological installation is available to the competent authority;

c appropriate quality assurance programmes and assessment of dose or verification of administered activity are implemented by the undertaking; and

d acceptance testing is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any maintenance procedure liable to affect the performance.

2 Member States shall ensure that the competent authority takes steps to ensure that the necessary measures are taken by the undertaking to improve inadequate or defective performance of medical radiological equipment in use. They shall also adopt specific criteria for the acceptability of equipment in order to indicate when appropriate corrective action is necessary, including taking the equipment out of service.

3 Member States shall ensure that:

a the use of fluoroscopy equipment without a device to automatically control the dose rate, or without an image intensifier or equivalent device, is prohibited.

b equipment used for external beam radiotherapy with a nominal beam energy exceeding 1 MeV has a device to verify key treatment parameters. Equipment installed prior to 6 February 2018 may be exempted from this requirement.

c any equipment used for interventional radiology has a device or a feature informing the practitioner and those carrying out practical aspects of the medical procedures

of quantity of radiation produced by the equipment during the procedure. Equipment installed prior to 6 February 2018 may be exempted from this requirement.

d any equipment used for interventional radiology and computed tomography and any new equipment used for planning, guiding and verification purposes has a device or a feature informing the practitioner, at the end of the procedure, of relevant parameters for assessing the patient dose.

e equipment used for interventional radiology and computed tomography has the capacity to transfer the information required under 3(d) to the record of the examination. Equipment installed prior to 6 February 2018 may be exempted from this requirement.

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

Article 61

Special practices

1 Member States shall ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment is used in medical exposure:

a of children;

b as part of a health screening programme;

c involving high doses to the patient, which may be the case in interventional radiology, nuclear medicine, computed tomography or radiotherapy.

Special attention shall be given to quality assurance programmes and the assessment of dose or verification of administered activity for these practices.

2 Member States shall ensure that practitioners and those individuals referred to in Article 57(2) who perform the exposures referred to in paragraph 1 obtain appropriate training on these medical radiological practices as required by Article 18.

Article 62

Special protection during pregnancy and breastfeeding

1 Member States shall ensure that the referrer or the practitioner, as appropriate, inquire, as specified by Member States, whether the individual subject to medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure.

2 If pregnancy cannot be ruled out and depending on the medical radiological procedure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the expectant individual and the unborn child.

3 In the case of a breastfeeding individual, in nuclear medicine, depending on the medical radiological procedure, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the individual and the child.

4 Without prejudice to paragraphs 1, 2 and 3, Member States shall take measures to increase the awareness of individuals to whom this Article applies, through measures such as public notices in appropriate places.

Article 63

Accidental and unintended exposures

Member States shall ensure that:

(a) all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure;

(b) for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures;

(c) for all medical exposures the undertaking implements an appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice;

(d) arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis;

(e) (i) the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority;

(ii) the results of the investigation and the corrective measures to avoid such events are reported to the competent authority within the time period specified by the Member State;

(f) mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events.

Article 64

Estimates of population doses

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

CHAPTER VIII

PUBLIC EXPOSURES

SECTION 1

Protection of members of the public and long-term health protection in normal circumstances

Article 65

Operational protection of members of the public

1 Member States shall ensure that the operational protection of members of the public in normal circumstances from practices subject to licensing shall include, for relevant facilities, the following:

a examination and approval of the proposed siting of the facility from a radiation protection point of view, taking into account relevant demographic, meteorological, geological, hydrological and ecological conditions;

b acceptance into service of the facility subject to adequate protection being provided against any exposure or radioactive contamination liable to extend beyond the perimeter of the facility or radioactive contamination liable to extend to the ground beneath the facility;

c examination and approval of plans for the discharge of radioactive effluents;

d measures to control the access of members of the public to the facility.

2 The competent authority shall where appropriate establish authorised limits as part of the discharge authorisation and conditions for discharging radioactive effluents which shall:

a take into account the results of the optimisation of radiation protection;

b reflect good practice in the operation of similar facilities.

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

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

Article 66

Estimation of doses to the members of the public

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

2 Member States shall ensure the identification of practices for which an assessment of doses to members of the public shall be carried out. Member States shall specify those practices

for which this assessment needs to be carried out in a realistic way and those for which a screening assessment is sufficient.

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

a decide on a reasonable extent of surveys to be conducted and information to be taken into account in order to identify the representative person, taking into account the effective pathways for transmission of the radioactive substances;

b decide on a reasonable frequency of monitoring of the relevant parameters as determined in point (a);

c ensure that the estimates of doses to the representative person include:

i) assessment of the doses due to external radiation, indicating, where appropriate, the type of the radiation in question;

ii) assessment of the intake of radionuclides, indicating the nature of the radionuclides and, where necessary, their physical and chemical states, and determination of the activity concentrations of these radionuclides in food and drinking water or other relevant environmental media;

iii) assessment of the doses that the representative person, as identified in point (a), is liable to receive;

d require records to be kept and be made available on request to all stakeholders relating to measurements of external exposure and contamination, estimates of intakes of radionuclides, and the results of the assessment of the doses received by the representative person.

Article 67

Monitoring of radioactive discharges

1 Member States shall require the undertaking responsible for practices where a discharge authorisation is granted to monitor appropriately or where appropriate evaluate the radioactive airborne or liquid discharges into the environment in normal operation and to report the results to the competent authority.

2 Member States shall require any undertaking responsible for a nuclear power reactor or reprocessing plant to monitor radioactive discharges and report them in accordance with standardised information.

Article 68

Tasks for the undertaking

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

(a) achieve and maintain an optimal level of protection of members of the public;

(b) accept into service adequate equipment and procedures for measuring and assessing exposure of members of the public and radioactive contamination of the environment;

(c) check the effectiveness and maintenance of equipment as referred to in point (b) and ensure the regular calibration of measuring instruments;

(d) seek advice from a radiation protection expert in the performance of the tasks referred to in points (a), (b) and (c).

SECTION 2

Emergency exposure situations

Article 69

Emergency response

1 Member States shall require the undertaking to notify the competent authority immediately of any emergency in relation to the practices for which it is responsible and to take all appropriate action to reduce the consequences.

2 Member States shall ensure that, in the event of an emergency on their territory, the undertaking concerned makes an initial provisional assessment of the circumstances and consequences of the emergency and assists with protective measures.

3 Member States shall ensure that provision is made for protective measures with regard to:

a the radiation source, to reduce or stop the radiation, including the release of radionuclides;

b the environment, to reduce the exposure to individuals resulting from radioactive substances through relevant pathways;

c individuals, to reduce their exposure.

4 In the event of an emergency on or outside its territory, the Member State shall require:

a the organisation of appropriate protective measures, taking account of the real characteristics of the emergency and in accordance with the optimised protection strategy as part of the emergency response plan, whereby the elements to be included in an emergency response plan are indicated in Section B of Annex XI;

b the assessment and recording of the consequences of the emergency and of the effectiveness of the protective measures.

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

Article 70

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

1 Member States shall ensure that the members of the public likely to be affected in the event of an emergency are given information about the health protection measures applicable to them and about the action they should take in the event of such an emergency.

2 The information supplied shall include at least the elements set out in Section A of Annex XII.

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 71

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

1 Member States shall ensure that, when an emergency occurs, the members of the public actually affected are informed without delay about the facts of the emergency, the steps to be taken and, as appropriate, the health protection measures applicable to these members of the public.

2 The information provided shall cover those points listed in Section B of Annex XII which are relevant to the type of emergency.

SECTION 3

Existing exposure situation

Article 72

Environmental monitoring programme

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

Article 73

Contaminated areas

1 Member States shall ensure that optimised protection strategies for managing contaminated areas shall include, where applicable, the following:

a objectives, including long-term goals pursued by the strategy and corresponding reference levels, in accordance with Article 7;

b delineation of the affected areas and identification of the affected members of the public;

c consideration of the need for and extent of protective measures to be applied to the affected areas and members of the public;

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

e assessment of the exposure of different groups in the population and assessment of the means available to individuals for controlling their own exposure.

2 For areas with long-lasting residual contamination in which the Member State has decided to allow habitation and the resumption of social and economic activities, Member States shall ensure, in consultation with stakeholders, that arrangements are in place, as necessary, for the ongoing control of exposure with the aim of establishing living conditions that can be considered as normal, including:

a establishment of appropriate reference levels;

b establishment of an infrastructure to support continuing self-help protective measures in the affected areas, such as information provision, advice and monitoring;

c if appropriate, remediation measures;

d if appropriate, delineated areas.

Article 74

Indoor exposure to radon

1 Member States shall establish national reference levels for indoor radon concentrations. The reference levels for the annual average activity concentration in air shall not be higher than 300 Bq m^{-3}.

2 Under the national action plan referred to in Article 103, Member States shall promote action to identify dwellings, with radon concentrations (as an annual average) exceeding the reference level and encourage, where appropriate by technical or other means, radon concentration-reducing measures in these dwellings.

3 Member States shall ensure that local and national information is made available on indoor radon exposure and the associated health risks, on the importance of performing radon measurements and on the technical means available for reducing existing radon concentrations.

Article 75

Gamma radiation from building materials

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

2 For building materials which are identified by the Member State as being of concern from a radiation protection point of view, taking into account the indicative list of materials set out in Annex XIII with regard to their emitted gamma radiation, Member States shall ensure that, before such materials are placed on the market:

a the activity concentrations of the radionuclides specified in Annex VIII are determined, and that,

b information to the competent authority on the results of measurements and the corresponding activity concentration index, as well as other relevant factors, as defined in Annex VIII, are provided if requested.

3 For types of building materials identified in accordance with paragraph 2 which are liable to give doses exceeding the reference level, Member States shall decide on appropriate measures, which may include specific requirements in relevant building codes or restrictions on the envisaged use of such materials.

CHAPTER IX

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

SECTION 1

Institutional infrastructure

Article 76

Competent authority

1 Member States shall designate a competent authority to carry out tasks in accordance with this Directive. They shall ensure that the competent authority:

a is functionally separate from any other body or organisation concerned with the promotion or utilisation of practices under this Directive, in order to ensure effective independence from undue influence on its regulatory function;

b is given the legal powers and human and financial resources necessary to fulfil its obligations.

2 Where a Member State has more than one competent authority for a given area of competence, it shall designate one point of contact for communication with the competent authorities of other Member States. Where it is not reasonably practicable to list all such points of contact for different areas of competence, Member States may designate a single point of contact.

3 Member States shall forward to the Commission the name and address of the points of contact and their respective areas of competence to enable rapid communication, where appropriate, with their authorities.

4 Member States shall forward to the Commission any changes to the information referred to in paragraph 3.

5 The Commission shall communicate the information referred to in paragraphs 3 and 4 to all points of contact in a Member State and shall publish it periodically in the *Official Journal of the European Union*, at intervals of no more than two years.

Article 77

Transparency

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

Article 78

Information on equipment

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

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

Article 79

Recognition of services and experts

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

a occupational health services;

b dosimetry services;

c radiation protection experts;

d medical physics experts.

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

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

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

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

Article 80

Occupational health services

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

Article 81

Dosimetry services

Member State shall ensure that dosimetry services determine internal or external doses to exposed workers subject to individual monitoring, in order to record the dose in

cooperation with the undertaking and in the case of outside workers, the employer, and where relevant the occupational health service.

Article 82

Radiation protection expert

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

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

a optimisation and establishment of appropriate dose constraints;

b plans for new installations and the acceptance into service of new or modified radiation sources in relation to any engineering controls, design features, safety features and warning devices relevant to radiation protection;

c categorisation of controlled and supervised areas;

d classification of workers;

e workplace and individual monitoring programmes and related personal dosimetry;

f appropriate radiation monitoring instrumentation;

g quality assurance;

h environmental monitoring programme;

i arrangements for radioactive waste management;

j arrangements for prevention of accidents and incidents;

k preparedness and response in emergency exposure situations;

l training and retraining programmes for exposed workers;

m investigation and analysis of accidents and incidents and appropriate remedial actions;

n employment conditions for pregnant and breastfeeding workers;

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

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

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

Article 83

Medical physics expert

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

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

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

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

Article 84

Radiation protection officer

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

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

a ensuring that work with radiation is carried out in accordance with the requirements of any specified procedures or local rules;
b supervise implementation of the programme for workplace monitoring;
c maintaining adequate records of all radiation sources;
d carrying out periodic assessments of the condition of the relevant safety and warning systems;
e supervise implementation of the personal monitoring programme;
f supervise implementation of the health surveillance programme;
g providing new workers with an appropriate introduction to local rules and procedures;
h giving advice and comments on work plans;
i establishing work plans;
j providing reports to the local management;
k participating in the arrangements for prevention, preparedness and response for emergency exposure situations;
l information and training of exposed workers;
m liaising with the radiation protection expert.

3 The task of the radiation protection officer may be carried out by a radiation protection unit established within an undertaking or by a radiation protection expert.

SECTION 2

Control of radioactive sources

Article 85

General requirements for unsealed sources

1 Member States shall ensure that arrangements are made for keeping control of unsealed sources with regard to their location, use and, when no longer required, their recycling or disposal.

2 Member States shall require the undertaking, as appropriate and to the extent possible, to keep records of unsealed sources under its responsibility, including location, transfer and disposal or discharge.

3 Member States shall require each undertaking holding an unsealed radioactive source to notify the competent authority promptly of any loss, theft, significant spill, or unauthorised use or release.

Article 86

General requirements for sealed sources

1 Member States shall ensure that arrangements are made for keeping control of sealed sources with regard to their location, use and, when no longer required, their recycling or disposal.

2 Member States shall require the undertaking to keep records of all sealed sources under its responsibility, including location, transfer and disposal.

3 Member States shall establish a system to enable them to be adequately informed of any transfer of high activity sealed sources and where necessary individual transfers of sealed sources.

4 Member States shall require each undertaking holding a sealed source to notify the competent authority promptly of any loss, significant leakage, theft or unauthorised use of a sealed source.

Article 87

Requirements for control of high-activity sealed sources

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

(a) adequate arrangements have been made for the safe management and control of sources, including when they become disused sources. Such arrangements may provide for the transfer of disused sources to the supplier or their placement in a disposal or storage facility or an obligation for the manufacturer or the supplier to receive them;

(b) adequate provision, by way of a financial security or any other equivalent means appropriate for the source in question, has been made for the safe management of

sources when they become disused sources, including the case where the undertaking becomes insolvent or ceases its activities.

Article 88

Specific requirements for licensing of high-activity sealed sources

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

(a) responsibilities;

(b) minimum staff competencies, including information and training;

(c) minimum performance criteria for the source, source container and additional equipment;

(d) requirements for emergency procedures and communication links;

(e) work procedures to be followed;

(f) maintenance of equipment, sources and containers;

(g) adequate management of disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a manufacturer, a supplier, another authorised undertaking or a waste disposal or storage facility.

Article 89

Record keeping by the undertaking

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

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

(b) at intervals to be determined by Member States;

(c) if the situation indicated on the information sheet has changed;

(d) without undue delay upon the closure of the records for a specific source when the undertaking no longer holds this source, whereby the name of the undertaking or waste disposal or storage facility to which the source is transferred shall be included;

(e) without undue delay upon the closure of such records when the undertaking no longer holds any sources.

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

Article 90

Record keeping by the competent authority

Member States shall ensure that the competent authority keeps records of any undertaking authorised to perform practices with high-activity sealed sources and of the high-activity sealed sources held. These records shall include the radionuclide involved, the activity at the time of manufacture or, if this activity is not known, the activity at the time of the first placing on the market or at the time the undertaking acquired the source, and the type of source. The competent authority shall keep the records up to date, taking transfers of the sources and other factors into account.

Article 91

Control of high-activity sealed sources

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

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

SECTION 3

Orphan sources

Article 92

Detection of orphan sources

1 Member States shall ensure that arrangements are made for:

a raising general awareness of the possible occurrence of orphan sources and associated hazards; and

b issuing guidance for persons who suspect or have knowledge of the presence of an orphan source on informing the competent authority and on the actions to be taken.

2 Member States shall encourage the establishment of systems aimed at detecting orphan sources in places such as large metal scrap yards and major metal scrap recycling installations where orphan sources may generally be encountered, or at significant nodal transit points, wherever appropriate.

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

Article 93

Metal contamination

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

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

Article 94

Recovery, management, control and disposal of orphan sources

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

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

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

Article 95

Financial security for orphan sources

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

SECTION 4

Significant events

Article 96

Notification and recording of significant events

Member States shall require the undertaking to:

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

(b) promptly notify the competent authority of the occurrence of any significant event resulting or liable to result in the exposure of an individual beyond the operational limits or conditions of operation specified in authorising requirements with regard to occupational or public exposure or as defined by the competent authority for medical exposure, including the results of the investigation and the corrective measures to avoid such events.

SECTION 5

Emergency exposure situations

Article 97

Emergency management system

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

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

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

Article 98

Emergency preparedness

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

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

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

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

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

Article 99

International cooperation

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

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

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

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

SECTION 6

Existing exposure situations

Article 100

Programmes on existing exposure situations

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

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

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

Article 101

Establishment of strategies

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

2 Each strategy shall contain

a the objectives pursued;

b appropriate reference levels, taking into account the reference levels laid down in Annex I.

Article 102

Implementation of strategies

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

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

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

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

a evaluate the available remedial and protective measures for achieving the objectives and the efficiency of planned and implemented measures;

b provide information to exposed populations on the potential health risks and on the available means for reducing their exposure;

c provide guidance for the management of exposures at individual or local level;

d with regard to activities that involve naturally occurring radioactive material and are not managed as planned exposure situations, provide information on appropriate means for monitoring concentrations and exposures and for taking protective measures.

Article 103

Radon action plan

1 In application of Article 100(1), Member States shall establish a national action plan addressing long-term risks from radon exposures in dwellings, buildings with public access and workplaces for any source of radon ingress, whether from soil, building materials or water. The action plan shall take into account the issues set out in Annex XVIII and be updated on a regular basis.

2 Member States shall ensure that appropriate measures are in place to prevent radon ingress into new buildings. These measures may include specific requirements in national building codes.

3 Member States shall identify areas where the radon concentration (as an annual average) in a significant number of buildings is expected to exceed the relevant national reference level.

SECTION 7

System of enforcement

Article 104

Inspections

1 Member States shall establish a system or systems of inspection to enforce the provisions adopted pursuant to this Directive and to initiate surveillance and corrective action where necessary.

2 Member States shall ensure that the competent authority establishes an inspection programme taking into account the potential magnitude and nature of the hazard associated with practices, a general assessment of radiation protection issues in the practices, and the state of compliance with the provisions adopted pursuant to this Directive.

3 Member States shall ensure that the findings from each inspection are recorded and communicated to the undertaking concerned. If the findings are related to an outside worker or workers, where appropriate, the findings shall also be communicated to the employer.

4 Member States shall ensure that outlines of the inspection programmes and the main findings from their implementation are available to the public.

5 Member States shall ensure that mechanisms are in place for the timely dissemination to relevant parties, including manufacturers and suppliers of radiation sources and, where appropriate, international organisations, of protection and safety information concerning significant lessons learned from inspections and from reported incidents and accidents and related findings.

Article 105

Enforcement

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

CHAPTER X

FINAL PROVISIONS

Article 106

Transposition

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 6 February 2018.

2 When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

3 Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

Article 107

Repeal

Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom, and 2003/122/Euratom are repealed with effect from 6 February 2018.

References to the repealed Directives shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex XIX.

Article 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 109

Addressees

This Directive is addressed to the Member States.