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NOTE

from:	General Secretariat of the Council
to:	Delegations
No. Cion prop.:	14450/11 ATO 112 SOC 791 SAN 183
Subject:	Proposal for a Council Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation - Draft presented under Article 31 Euratom Treaty for the opinion of the European Economic and Social Committee

Based on the suggestions received, the Presidency prepared the attached text to be discussed at the next WPAQ meeting on 21 May 2012.

Definitions and recitals will be revised as discussion advances on the operative part of the Directive.

The changes are in **bold underline**; deletions are marked with ~~strikethrough~~.

ANNEX

Proposal for a

COUNCIL DIRECTIVE

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

Draft presented under Article 31 Euratom Treaty for the opinion of the European Economic and Social Committee

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 and 32 thereof,

Having regard to the proposal from the Commission, drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States, and after having consulted the European Economic and Social Committee,

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

Having regard to the opinion of the European Parliament,

Whereas:

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

(2) In order to perform its task, the Community laid down basic standards for the first time in 1959 pursuant to Article 218 of the Treaty by means of the Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation[1]. The Directives have been revised several times, most recently in 1996 by Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation[2] which repealed the earlier Directives.

(3) Directive 96/29/Euratom establishes the basic safety standards. The provisions of that Directive apply to normal and emergency situations and have been supplemented by more specific legislation.

(4) Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure and repealing Directive 84/466/Euratom[3], Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency[4], Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas[5] and Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources[6] cover different specific aspects complementary to Directive 96/29/Euratom.

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

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

(6) The Group of Experts appointed by the Scientific and Technical Committee has advised that the basic safety standards, established according to Articles 30 and 31 of Euratom Treaty should take into account the new recommendations of the International Commission on Radiological Protection (ICRP), in particular those in Publication 103 (2007)[1], and should be revised in the light of new scientific evidence and operational experience.

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

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

(9) The current annual dose limits for occupational and public exposure are maintained. However, there should be no further need for averaging over 5 years, except in special circumstances specified in national legislation.

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

(11) Industries processing naturally occurring radioactive material extracted from the earth's crust subject workers and, if material is released into the environment, the public to increased radiation exposure.

(12) Protection against natural radiation sources, rather than being addressed separately in a specific title, should be fully integrated within the overall requirements. In particular, industries processing materials containing naturally occurring radionuclides should be managed within the same regulatory framework as other practices.

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

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

(14) Recent epidemiological findings from residential studies demonstrate a lung cancer risk from exposure to indoor radon at levels of the order of 100 Bq m^{-3}. The new concept of exposure situations allows the provisions of Commission Recommendation 90/143/Euratom on the protection of the public against indoor exposure to radon[1] to be incorporated in the binding requirements of the Basic Safety Standards while leaving enough flexibility for implementation.

(15) The exposure of aircrew to cosmic radiation should be managed as a planned exposure situation. The operation of spacecraft should come under the scope of this Directive and should be managed as a specially authorised exposure.

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

(17) In the medical area, important technological and scientific developments have led to a notable increase in the exposure of patients. In this respect, the Directive should emphasise the need for justification of medical exposure, including the exposure of asymptomatic individuals, and should strengthen the requirements concerning information to be provided to patients, the recording and reporting of doses from medical procedures, the use of diagnostic reference levels and the availability of dose-indicating devices.

(18) Accidental and unintended medical exposures are a source of continuing concern. Their prevention and follow-up, should they occur, need to be fully addressed. In this respect, the role of quality assurance programmes, including risk analysis in radiotherapy, to avoid such incidents should be emphasised, and recording, reporting, analysis and corrective action should be required in such cases.

[1] OJ L 80, 27.3.1990, p. 26.

(19) The so-called 'medico-legal' exposures introduced in Directive 97/43/Euratom have now been clearly identified as the deliberate exposure of individuals for other than medical purposes, or 'non-medical imaging exposures'. Such practices need to be placed under appropriate regulatory control and should be justified in a similar way as for medical exposures. However, a different approach is needed on the one hand for procedures implemented by medical staff using medical equipment and on the other hand for procedures implemented by non-medical staff using non-medical equipment. In general, the annual dose limits and corresponding constraints for public exposure should apply.

(20) Member States should be required to submit certain practices involving a hazard from ionising radiation to a system of regulatory control or to prohibit certain practices. Member States should benefit from the application of a graded approach to regulatory control, which should be commensurate with the magnitude and likelihood of exposures resulting from the practices, and commensurate with the impact that regulatory control may have in reducing such exposures or improving the safety of installations.

(21) There is benefit in having the same activity concentration values both for the exemption of practices from regulatory control and for the clearance of materials from regulated practices. After a comprehensive review, it has been concluded that the values recommended in IAEA document RS-G-1.7[1] can be used both as default exemption values, replacing the activity concentration values laid down in Annex I to Directive 96/29/Euratom, and as general clearance levels, replacing the values recommended by the Commission in Radiation Protection No 122[2].

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

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

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

(23) Specific clearance levels, above the default values for exemption and clearance, as well as corresponding Community guidance[1] remain important tools for the management of large volumes of materials arising from the dismantling of **authorised** ~~licensed~~ facilities.

(24) Member States should ensure that outside workers receive the same protection as exposed workers employed by undertakings performing practices with radiation sources. The specific arrangements for outside workers in Directive 90/641/Euratom should be extended to cover work in supervised areas as well.

(25) With regard to the management of emergency exposure situations, the current approach based on intervention levels should be replaced by a more comprehensive system comprising threat analysis, an overall emergency management system, emergency response plans for identified threats, and pre-planned strategies for the management of each postulated event.

(26) The introduction of reference levels in emergency and existing exposure situations allows for the protection of the individual as well as consideration of other societal criteria in the same way as dose limits and dose constraints for planned exposure situations.

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

(28) The International Atomic Energy Agency together with the World Health Organisation, the Food and Agricultural Organisation, the International Labour Organisation, the Nuclear Energy Agency of the Organisation for Economic Cooperation and Development, and the Pan-American Health Organisation are revising the International Basic Safety Standards in the light of the ICRP's new Publication 103.

(29) The roles and responsibilities of the national services and experts involved in ensuring that the technical and practical aspects of radiation protection are managed with a high level of competence need to be clarified.

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

(30) More precise requirements should be introduced for the issuing discharge authorisations and for the monitoring of discharges. Commission Recommendation 2004/2/Euratom of 18 December 2003 on standardised information on radioactive airborne and liquid discharges into the environment from nuclear power reactors and reprocessing plants in normal operation[1]introduced standardised information for the reporting of data on discharges from nuclear power plants and reprocessing facilities.

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

(32) The basic safety standards established under the Euratom Treaty are meant to apply in a uniform way.

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

HAS ADOPTED THIS DIRECTIVE:

[1] OJ L 2, 6.1.2004, p. 36

CHAPTER I

SUBJECT MATTER AND SCOPE

Article 1

Subject matter

1. This Directive establishes the basic safety standards for the protection of the health of workers, ~~general~~ **members of the** public, patients and other individuals subject to medical exposure against the dangers arising from ionising radiation for the purpose of their uniform implementation by Member States.
2. **[**This Directive applies to the protection of the environment as a pathway from radiation sources to the exposure of **members of the public** ~~man~~, complemented where appropriate with specific consideration of the exposure of biota in the environment as a whole.**]**
3. This Directive sets out requirements for the **safe management and** control ~~of the safety and security~~ of radioactive sources and the provisions of appropriate information in an emergency exposure situation.
4. This Directive sets out requirements for the **purpose of** prevention of exposure of workers and members of the public to ionising radiation arising from orphan sources and from inadequate control of high-activity sealed radioactive sources and for the harmonisation of controls in place in the Member States by defining specific requirements ensuring that each such source is kept under control.
5. This Directive defines at Community level common objectives with regard to measures and procedures for informing the public for the purpose of improving the operational health protection provided in the event of an emergency.

Article 2

Scope

1. This Directive applies to any planned, existing or emergency exposure situation which involves a risk from exposure to ionising radiation which cannot be disregarded from the radiation protection point of view with regard to the health protection of workers, members of the public, or patients and other individuals subject to medical exposure or with regard to the protection of the environment.
2. This Directive applies to all practices involving radiation sources, namely:
   (a) the **manufacture,** production, processing, **conversion,** handling, use, storage, holding, transport, ~~shipment,~~ import to, and export from the Community and the disposal of radioactive material;
   (b) the operation of electrical equipment emitting ionising radiation and ~~the operation of any electrical equipment~~ **containing components** operating at a potential difference of more than 5 kV **and were charged particles may accelrate in the resulting electrical field**;
   (c) practices **or 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**, only in relation to the exposure of crews**;
      ii) activities **leading to** exposure to radon in workplaces; **and,** exposure **of either workers or members of the public in:**
      iii) ~~the~~ activities in industries processing materials with naturally occurring radionuclides, or activities related to such processing.
   (d) any other practice specified by the Member State.
3. This Directive applies to the management of existing exposure situations, in particular the exposure of ~~the~~ **members of the** public to indoor radon, the external exposure from building materials and cases of lasting exposure resulting from the after-effects of an emergency or a past activity.

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

Article 3

Exclusion from the scope

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

CHAPTER II

DEFINITIONS[1]

Article 4

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

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

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

where

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

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

In this Directive, absorbed dose denotes the dose averaged over a tissue or an organ. The unit for absorbed dose is the gray [92];

[1] **[**The definitions are rearranged in alphabetic order without shoving **bold underline** or ~~strikeouts~~ due to this rearrangement, the old number is shown at the end of each definition**]**

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

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

(4) Activation means process through which a stable nuclide is transformed into a radionuclide by irradiating with particles or high-energy photons the material in which it is contained [52];

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

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

The unit of activity is ~~the B~~**b**ecquerel **(Bq)** [94];

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

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

(8) ~~B~~**b**ecquerel (Bq) **is** ~~means~~ the special name of the unit of activity. One ~~B~~**b**ecquerel is equivalent to one nuclear transition per second: 1 Bq = 1 s-1 [95];

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

(10) Carers and comforters means individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone medical exposure [33];

(11) Clearance levels means values established by the competent authority or in national legislation, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of this Directive [65];

(12) Clinical audit means a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and the application of new standards if necessary [79];

(13) Clinical responsibility means responsibility of a practitioner for individual medical exposures, notably: justification; optimisation; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical exposure procedures; obtaining information, if appropriate, on previous examinations; providing existing medical radiological information and/or records to other practitioners and/or the referrer, as required; and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate [78];

(14) Committed effective dose (E(τ)) **is** ~~means~~ the sum of the committed organ or tissue equivalent doses HT(τ) resulting from an intake, each multiplied by the appropriate tissue weighting factor wT. It is defined by:

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

In specifying E(τ), τ is given in the number of years over which the integration is made. For the purpose of complying with dose limits specified in this Directive, τ is a period of 50 years following intake for adults and up to age 70 for children. The unit for committed effective dose is ~~the~~ sievert **(Sv)** [39];

(15) Committed equivalent dose (H(τ)) **is** ~~means~~ the integral over time (τ) of the equivalent dose rate (in tissue or organ T) that will be received by an individual as a result of an intake. It is given by:

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

for an intake at time t0 where

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

τ is the time over which the integration is performed.

In specifying $H_T(\tau)$, τ is given in **number of** years **over which the integration is made**. ~~When~~ **For the purpose of complying with dose limits specified in this Directive,** τ is ~~not given,~~ a period of 50 years ~~is assumed~~ for adults and up to age 70 for children. The unit for committed equivalent dose is ~~the~~ sievert **(Sv)** [96];

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

(17) Consumer product means a device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionising radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale [57];

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

(19) Controlled area means an area subject to special rules for the purpose of protection against ionising radiation or preventing the spread of radioactive contamination and to which access is controlled [67];

(20) Diagnostic reference levels means dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment [51];

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

(22) Disused sealed source means a sealed source which is no longer used or intended to be used for the practice for which authorisation was granted [59];

(23) Dose constraint means a constraint set as a prospective upper bound of an individual dose, used to define the range of options considered in the process of optimisation for a given radiation source in planned exposure situation [28];

(24) Dose limit: the value of the effective dose **(where applicable, committed effective dose)** or the equivalent dose in a specified period which may not be exceeded for an individual. ~~The dose limit applies to the sum of exposures from all authorised practices~~ [27];

(25) Dosimetry service means a body or an individual having the competence for calibration, reading or interpretation of individual monitoring devices, or for measurement of radioactivity in the human body or in biological samples, or for assessment of doses, whose capacity to act in this respect is recognised by the competent authorities [46];

(26) Effective dose (E) **is** ~~means~~ the sum of the weighted equivalent doses in all the tissues and organs of the body from internal and external irradiation. It is defined by the expression;

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

where

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

w_R is the radiation weighting factor and

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

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

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

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

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

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

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

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

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

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

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

where

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

– w_R is the radiation weighting factor.

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

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

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

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

(36) Existing exposure situation means an exposure situation that already exists when a decision on its control has to be taken and which does not call or no longer calls for urgent measures to be taken [14];

(37) Exposed worker means person, either self-employed or working under an employer, and who is subject to exposure at work carried out within a practice regulated by this Directive and who is liable to receive doses exceeding one or other of the dose limits for public exposure [35];

(38) Exposure means the act of exposing or condition of being exposed to ionising radiation emitted outside the body (external exposure) or within the body (internal exposure) [5];

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

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

(41) ~~G~~**g**ray (Gy) is **the** unit of absorbed dose. One gray is equal to one joule per kilogram: 1Gy = 1 J kg-1 [93];

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

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

(44) High-activity sealed source means a sealed source in which the amount of radioactive material **is equal to or** exceeds the values laid down in Annex II [43];

(45) Individual detriment means clinically observable deleterious effects in individuals or their descendants, the appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance [74];

(46) Inspection means an investigation by any competent authority to verify compliance with national provisions [60];

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

(48) Interventional radiology means the use of X-ray imaging techniques~~, in addition to those involving ultrasound or magnetic resonance imaging or other non-ionising radiation techniques,~~ to introduce and guide devices in the body for diagnostic or treatment purposes [75];

(49) Ionising radiation means the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less (a frequency of 3x1015 Hertz or more) capable of producing ions directly or indirectly [2];

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

(51) Medical exposure means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health or well-being, as well as exposure incurred by carers and comforters and by volunteers in biomedical research [1];

(52) Medical physics expert means an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence to act is recognised by the competent authorities [40];

(53) Medical radiological installation means a facility containing medical radiological equipment [80];

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

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

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

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

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

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

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

(61) Occupational exposure means exposure of workers incurred in the course of their work [24];

(62) Occupational health service means a health professional or body having competence for the medical surveillance of exposed workers and whose capacity to act in that respect is recognised by the competent authorities [41];

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

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

(65) Orphan source means a ~~sealed~~ **radioactive** source which is neither exempted nor under regulatory control, e.g. because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation [11];

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

(67) Physical **protection means the measures taken by the undertaking aimed at preventing unauthorised access to or loss or theft of a radioactive source [New];**

(68) Planned exposure situation means an exposure situation that arises from the planned operation or introduction of a radiation source or from activities which alter exposure pathways, so as to cause the exposure or potential exposure of people or the environment. Planned exposure situations may include both normal exposures and potential exposures [16];

(69) Potential exposure means exposure that is not expected with certainty but may result from an event or sequence of events of a probabilistic nature, including equipment failures and operating errors [17];

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

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

(72) Practitioner means a medical doctor, dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements [50];

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

(74) Protective measures means measures, other than remedial measures, for the purpose of avoiding or reducing doses that might otherwise be received in an emergency exposure situation or an existing exposure situation [85];

(75) Public exposure means exposure of **members of the public** ~~individuals~~, excluding any occupational or medical exposure [23];

(76) Quality assurance means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. Quality control is a part of quality assurance [63];

(77) Quality control means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled [99];

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

(79) Radiation protection expert means an individual having the knowledge, training and ex erience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose capacity to act is recognised by the competent authorities [42];

(80) ~~Radiation protection means the protection of people from harmful effects of exposure to~~ ionising ~~radiation, and the means for achieving this~~ [18];

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

(82) Radiation source means an entity that may cause radiation exposure — such as by emitting ionising radiation or by releasing radioactive material ~~— and can be treated as a single entity for protection and safety purposes~~ [8];

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

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

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

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

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

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

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

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

(91) Reference level means in an emergency exposure situation or in an existing exposure situation, the level of dose or risk above which it is judged inappropriate to allow exposures to occur, and below which optimisation of protection should continue to be implemented [34];

(92) Referrer means a medical doctor, dentist or other health professional who is entitled to refer individuals for medical radiological procedures to a practitioner, in accordance with national requirements [73];

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

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

(95) Remedial measures means the removal of a source or the reduction of its magnitude (in terms of activity or amount) **or the interuption of exposure pathways or the reduction of their impact** for the purposes of avoiding or reducing doses that might otherwise be received in an existing exposure situation [84];

(96) Representative person means an individual receiving a dose that is representative of the more highly exposed individuals in the population [82];

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

(98) ~~Response~~ strategy ~~means a set of different protective measures to respond to postulated or actual events so as to manage an emergency exposure situation in accordance with the stated objectives. Within an emergency response plan, response strategies are established for each postulated event and scenario [100];~~

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

(100) Sealed source means a radioactive source in which the radioactive material is permanently sealed in a capsule or closely bonded in a solid form [87];

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

(102) Storage means the holding of radioactive **material** ~~sources~~ or radioactive waste in a facility ~~that provides adequate containment,~~ with the intention of retrieval [21];

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

(104) Supplier means **an undertaking** ~~any natural or legal person who~~ suppl**ying**~~ies~~ or mak**ing**~~es~~ available a ~~sealed~~ **radioactive** source [88];

(105) Source container means **an assembly of components guaranteering** the containment of a sealed source, where this is not an integral part of the source but is meant for shielding the source during its use, transport, handling, etc. [89];

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

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

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

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

CHAPTER III

SYSTEM OF RADIATION PROTECTION

Article 5

General principles

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

(a) Justification: decisions introducing ~~or altering~~ **[a new type of]** a radiation source, **introducing or** altering an exposure pathway or **decisions on** actual exposures shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from them ~~offsets~~ **outweighs** the detriment that they may cause.

(b) Optimisation: ~~in all exposure situations, radiation protection~~ **Radiation protection of members of the public, workers, apprentices and students** shall be optimised with the aim of keeping the magnitude and likelihood of exposure and the number of individuals exposed as low as reasonably achievable, taking into account economic and societal factors~~, whereby~~**; the** optimisation of the protection of individuals undergoing medical exposure shall **be applied only to the magnitude of individual doses** ~~be commensurate with the medical purpose of the exposure~~ as described in Article 55. This principle shall be applied **not only** in terms of effective dose ~~as well as~~ **but also, where apropriate, in terms of** organ doses, as a precautionary measure to allow for uncertainties as to health detriment below the threshold **for tissue reactions**~~, deterministic effects~~.

(c) Dose limitation: in planned exposure situations, the sum of doses to an individual from all **authorised practises** ~~regulated radiation sources~~ may not exceed the dose limits laid down for occupational exposure or public exposure. Dose limits shall not apply to medical exposures.

SECTION 1

TOOLS FOR OPTIMISATION

Article 6

Dose constraints for occupational and public exposure

1. **For the purpose of prospective optimisation of protection, the competent authority shall ensure, where appropriate, that dose constraints be established for occupational and public exposure:**

~~1.~~ **(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 authorities. In the case of outside workers the dose constraint shall be established in cooperation between the employer and the undertaking.

~~2.~~ **(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 authorities shall **ensure that** ~~set~~ the constraint**s** are **compatible** ~~so as to ensure compliance~~ with the dose limit for the sum of doses to the same individual from all authorised practices.

3. With regard to potential exposures, optimisation shall include adequate management of the safety and **physical protection** ~~security~~ of sources and facilities. Where appropriate**, dose constraint may be replaced by or complemented with** risk constraints **defined for this purpose** ~~may be established~~.

4. Dose ~~constraints~~ shall be **defined** ~~established~~ in terms of individual effective or equivalent doses over a year or any other appropriate shorter time period.

5. Where dose constraints are introduced to restrict any **prolonged** protracted accumulated exposure, ~~these~~ shall be **defined** ~~established~~ in terms of annual effective doses or ~~equivalent doses to an~~ organ **doses**.

Article 7

Dose constraints for medical exposure

Dose ~~constraints~~ shall not apply for the medical exposure of patients **or asymptomatic individuals**.

For carers ~~and~~ comforters and for volunteers participating in medical and biomedical research (for whom no direct medical benefit is expected from the exposure), dose constraints shall**, where apropriate,** be established in terms of the individual dose that complies with good medical practices ~~is unlikely to be exceeded~~ for the ~~period of the~~ examination, treatment or research project in question.

Article 8

Reference levels

1. ~~Reference~~ levels shall be established for emergency and existing exposure situations as a level of effective dose or organ dose above which it is judged inappropriate to allow exposures **to occur** ~~in emergency or existing exposure situations~~. **Optimisation of protection shall give priority to exposures above the reference level.** Optimised protective strategies shall be planned and implemented with the objective of reducing individual doses below the reference levels.

2. The values chosen for reference levels shall depend upon the type of exposure situation. ~~Optimisation of protection shall give priority to exposures above the reference level.~~ The choices of reference levels shall take into account both radiological protection requirements and societal criteria. **For public exposure** ~~T~~**t**he choice of reference levels for the effective dose shall take into account the three bands of reference levels set out in ~~point 1 of~~ Annex I.

3. **For existing exposure situations involving exposure to radon, the reference levels shall be set in terms of radon gas concentration in air as specified in Article 73 for members of the public and Article 53 for workers.**

SECTION 2

DOSE LIMITATION

Article 9

Age limit for exposed workers

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

Article 10

Dose limits for occupational exposure

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

1. The limit on the effective dose for occupational exposure shall be 20 mSv in any single year. However, in special circumstances or for certain exposure situations specified in national legislation, a higher effective dose of up to 50 mSv per year may be authorised in a single year, provided that the average dose over any five consecutive years does not exceed 20 mSv per year.

   For emergency workers ~~a higher effective dose may be authorised, in accordance with~~ Article 52 **shall apply**.

2. In addition to limits of effective dose laid down in paragraph 1, the following limits on equivalent dose shall apply:

   (a) the limit on the equivalent dose for the lens of the eye shall be 20 mSv in a year or, where applicable, the same value as specified for the limit on effective dose;

   (b) the limit on the equivalent dose for the skin shall be 500 mSv in a year;, this limit shall apply to the dose averaged over any area of 1 cm², regardless of the area exposed;

   (c) the limit on the equivalent dose for the **extremities** ~~hands, forearms, feet and ankles~~ shall be 500 mSv in a year.

Article 11

*Protection of pregnant **and breastfeeding workers** ~~women~~*

1. **The protection of the unborn child shall be comparable with that provided for members of the public.** As soon as a pregnant **worker** ~~woman~~ informs the undertaking **or, in the case of an outside worker, the employer,** of her condition, in accordance with national legislation or national practice, ~~the protection of the unborn child shall be comparable with that provided for members of the public.~~ **The undertaking, respectively the employer, shall ensure that** ~~T~~**t**he employment conditions for the pregnant **worker** ~~woman shall therefore be~~ **are** such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy.
2. **A worker who is breastfeeding shall not be employed in work involving a significant risk of intake of radionuclides or of contamination.** As soon as a **worker** ~~breastfeeding woman~~ informs the undertaking **or, in case of an outside worker the employer, that she is breastfeeding an infant, the undertaking shall take appropriate measures**~~of her condition, she shall not be employed in work involving a significant risk of intake of radionuclides~~.

Article 12

Dose limits for apprentices and students

1. The dose limits for apprentices aged 18 years or over and students aged 18 years or over who, in the course of their studies, are obliged to work with radiation sources shall be the same as the dose limits for occupational exposure laid down in Article 10.
2. The limit on the effective dose for apprentices aged between 16 and 18 years and for students aged between 16 and 18 years who, in the course of their studies, are obliged to work with radiation sources shall be 6 mSv per year.

2a. In addition to limits of effective dose laid down in ~~the first sub~~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 year;

(b) the limit on the equivalent dose for the skin shall be 150 mSv in a year, averaged over any area of 1 cm², regardless of the area exposed;

(c) the limit on the equivalent dose for the **extremities** ~~hands, forearms, feet and ankles~~ shall be 150 mSv in a year.

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

Article 13

Dose limits for public exposure

1. Dose limits for public exposure shall apply to the sum of annual exposures of a member of the public resulting from all authorised practices.

2. The limit on the effective dose for public exposure shall be 1 mSv in a year.

3. In addition to the dose limit referred to in ~~the first sub~~paragraph **2**, the following limits on the equivalent dose shall apply:

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

(b) the limit on the equivalent dose for the skin shall be 50 mSv in a year, averaged over any 1 cm² area of skin, regardless of the area exposed.

Article 14

Estimation of the effective and equivalent dose

[For the estimation of effective and equivalent doses, the following values and relationships shall be used:

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

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

CHAPTER IV

REQUIREMENTS FOR RADIATION PROTECTION EDUCATION, TRAINING AND INFORMATION

Article 15

General responsibilities for the education, training and provision of information

Member States shall establish an adequate legislative and administrative framework **ensuring** ~~for providing~~ appropriate radiation protection education, training and information to all individuals whose tasks require specific competences in radiation protection. The training, retraining and information of relevant individuals shall be repeated at appropriate intervals and documented. Member States shall **make arrangment for** ~~establish~~ education, training and retraining to allow the recognition of radiation protection experts, medical physics experts, ~~occupational health services,~~ and dosimetry services **in relation to conducted practices and other national circumstances**.

Article 16

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

1. Member States shall require the undertaking ~~or the employer~~[1] to inform exposed workers, apprentices and students who are subject to occupational exposure on:
   (a) the health risks involved in their work;

[1] *New definition of undertaking*

(b) the general radiation protection procedures and precautions to be taken, in particular those connected with the operational and working conditions of both the practice in general and each type of workstation or work to which they may be assigned;

(c) the emergency response plans and procedures;

(d) the importance of complying with the technical, medical and administrative requirements;

(e) In the case of outside workers, their employer shall provide the information required in (a9, (b) and (d).

2. Member States shall require the undertaking or**, in case of outside workers,** the employer**,** to inform women on the importance of making an early declaration of pregnancy in view of the risks of exposure for the unborn child ~~and the risk of contaminating a nursing infant after intake of radionuclides~~.

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

3. Member States shall require that the undertaking or**, in case of outside workers,** the employer**,** provides appropriate radiation protection training and information programmes for **exposed workers, apprentices and students who are subject to occupational exposure** ~~their personnel~~.

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

Article 17

Information and training of workers potentially exposed to orphan sources

Member States shall ensure that the management of ~~and workers~~ in installations where orphan sources are most likely to be found or processed, in particular large metal scrap yards and major metal scrap recycling plants, and in significant nodal transit points~~, are~~:

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

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

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

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

(e) **ensure** that **workers in their installations receive similar information as above** ~~informed of~~ and **are** trained in the action to be taken on site in the event of the detection or suspected detection of a source.

Article 18

Information and training for emergency workers

1. Member States shall ensure that emergency workers ~~and any other persons who might be involved in the organisation of emergency assistance in the event of an emergency~~ 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.
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 emergency workers receive regular training as provided for in the emergency management system set out in Article 97. Where appropriate, this training shall include practical exercises.
4. Members States shall ensure that, in addition to the emergency response training referred to in paragraph 3 of this Article, the organisation responsible for the protection of emergency workers as referred to in Article 30(1)(b) provides these workers with appropriate radiation protection training and information.

Article 19

Education, information and training in the field of medical exposure

1. ~~Member States shall ensure that p~~**P**ractitioners and the individuals involved in the practical aspects of medical exposure procedures **shall** have adequate education, information and theoretical and practical training for the purpose of medical radiological practices, as well as relevant competence in radiation protection.
   For this purpose Member States shall ensure that appropriate curriculum are established and shall recognise the corresponding diplomas, certificates or formal qualifications.
2. Individuals undergoing relevant training programmes may participate in practical aspects of medical exposure procedures as set out in Article 56(4).
3. Member States shall ensure that continuing education and training after qualification is provided and, in the special case of the clinical use of new techniques, training is provided on these techniques and the relevant radiation protection requirements.
4. ~~Member States shall ensure that mechanisms are in place for the timely dissemination of information relevant to radiation protection for medical exposure regarding lessons learned from significant events.~~[1]
5. Member States shall ensure ~~the introduction of a course on~~ **that** radiation protection **is included** in the basic curriculum of medical and dental schools.

CHAPTER V

JUSTIFICATION AND REGULATORY CONTROL OF PRACTICES

Article 20

Justification of practices

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

[1] *Moved to Article 62(f)*

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

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

4. Types of practices involving medical exposure shall be justified both as a class of practices and at the level of each exposure as specified in Article 54.

[Article 21

Justification of practices with apparatus or products emitting ionising radiation

1. Member States shall require any undertaking intending to manufacture or import or export a new type of apparatus or product emitting ionising radiation to provide the competent authorities with relevant information such as that listed in Annex III, Section A, in order to enable the authorities, on the basis of assessment of information set out in Annex III, Section B, to decide whether the intended use of the apparatus or product can be justified.

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

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

Article 22

Prohibition of practices

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

2. **[**Without prejudice to the Directive 1999/2/EC[1] of the European Parliament and of the Council**]**, practices involving the activation of material resulting in an increase in activity **at the time of placing on the market which cannot be disregarded as far as radiation protection is concerned** ~~in the associated products~~ shall be deemed not to be justified. **Nevertheless, the competent authority may evaluate specific types of practices within this class with regard to their justification.**

Article 23

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

1. Member States shall ensure the identification~~, by means of surveys or by any other appropriate means,~~ of practices involving non-medical imaging exposure, as set out in Annex IV.
2. Member States shall ensure that special attention is given to the justification of practices involving non-medical imaging exposure, in particular:
   (a) all types of practices involving non-medical imaging exposure, as listed in Annex IV, shall be justified in advance before being generally accepted;
   (b) each particular application of a generally accepted type of practice shall be justified ~~in advance~~;
   (c) all individual non-medical imaging exposure procedures as listed in section A of Annex IV implemented by medical staff using medical radiological equipment shall be justified in advance taking into account the specific objectives of the procedure and the characteristics of the individual involved;
   (d) the general and particular justification of practices involving non-medical imaging exposure, as specified in (a) and (b), **may** ~~shall~~ be subject to ~~periodic~~ review by the competent authority.
3. Where a Member State has determined that a particular practice involving non-medical imaging exposure is justified it shall ensure that:
   (a) **the** ~~each~~ practice is subject to authorisation;

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

(b) requirements for the practice, including criteria for individual implementation, are established by the competent authority, in cooperation with other relevant agencies and professional bodies as appropriate;

(c) dose constraints are established for **procedures implemented by non-medical staff using non-medical equipment (section B in Annex IV).** ~~each practice. Such~~ These dose constraints shall be ~~well~~ below the dose limit for members of the public~~, including, whenever practicable, for procedures implemented by medical staff using medical equipment (section A in Annex IV); for other practices, the dose constraint shall~~ **and** satisfy the requirements of Article 6(2);

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

(e) the informed consent of the individual to be exposed is sought, allowing for cases where the law enforcement bodies may proceed without consent according to national legislation;

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

Article 24

Identification of practices involving naturally occurring radioactive material

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

Article 25

Notification

1. Member States shall require all practices, including those practices identified in accordance with Article 2**4**~~3~~, to be notified, except for justified practices involving the following:

(a) **radioactive** materials ~~containing radioactive substances~~ where the quantities of the activity involved do not exceed in total the exemption values set out in **Table B, column 3, of** Annex VI or higher values that, for specific applications, are authorised by the competent authorities and satisfy the general exemption and clearance criteria set out in Annex VI; or

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

(ba) apparatus containing radioactive substances provided that:

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

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

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

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

(c) any cathode ray tube intended for the display of visual images~~,~~ or other electrical apparatus operating at a potential difference not exceeding 30 kV, or any other **electrical** apparatus ~~or product~~ which is of a type approved by the competent authorities of the Member State, provided that~~:~~

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

~~(ii) if it~~ contains radioactive ~~substances, these substances are embedded in a capsule or fixed to a solid holder; and~~

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

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

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

4. In situations identified by Member States where there is concern that a practice identified in accordance with Article 24 may lead to the presence of naturally occurring radionuclides in water liable to affect the quality of drinking water supplies[1] or affect any other exposure pathways, so as to be of concern from a radiation protection point of view, the competent authority may require that the practice be subject to notification irrespective of the provisions of paragraph 1(b).

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

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

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1 *[reference to Drinking Water Directive]*

Article 26

Regulatory control

1. Member States shall require any notified practice to be subject to regulatory control commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the impact that regulatory control may have in reducing such exposures or improving the **radiological** safety of installations.
2. **The competent authority may exempt** ~~N~~**n**otified practices ~~may be exempted~~ from **the requirement of** authorisation **on the basis of the general criteria specified in Annex VI**.
3. ~~In~~ In the case of moderate amounts of material as specified by Member States, the activity concentration values laid down in Annex VI, Table B, column 2, may be used for the purpose of exemption.
4. Notified practices which are not exempted **from authorisation** shall be subject to **regulatory control** ~~authorisation~~ through registration or licensing.

Article 27

Authorisation

1. ~~In~~ cases ~~where a limited risk of exposure does not necessitate the examination of individual cases and the practice is undertaken in accordance with conditions laid down in national legislation, competent authorities may limit regulatory control to registration of the practice and an appropriate frequency of inspections.~~
2. Member States shall require licensing for the following practices:
   (a) the operation and decommissioning of any facility of the nuclear fuel cycle and the exploitation and closure of uranium mining;
   (b) the deliberate addition of radioactive substances in the production **or** ~~and~~ manufacture of consumer products or other products, including medicinal products, and the import or export of such products;
   (c) the manufacture, **import, export,** use or taking possession of a high-activity sealed source;

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

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

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

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

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

(b) the use of radiation generators or radioactive sources for industrial radiography, the processing of products or research, and the use of accelerators, except electron microscopes;

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

(d) the manufacture and operation of electrical equipment emitting ionising radiation ~~and operating at a potential difference of more than 30 kV,~~ as well as the import or export of such equipment;

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

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

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

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

Article 28

Authorisation procedure

1. For authorisation purposes, Member States shall require the provision of information commensurate with the nature of the practice and the risks involved.
2. The information referred to in paragraph 1 shall**,** for the purpose of granting a licen**c**se **or, where apropriate, for the purpose of registration,** cover at least**, if applicable,** the following:
   (a) responsibilities and organisational arrangements for protection and safety;
   (b) staff competences, including information and training;
   (c) design features of the installation and radiation sources;
   (d) anticipated occupational and public exposures in normal operation;
   (e) safety assessment of the activities and the installation in order to:
      (i) identify ways in which potential exposures or accidental and unintended medical exposures could occur;
      (ii) estimate, to the extent practicable, the probabilities and magnitude of potential exposures;
      (iii) assess the quality and extent of protection and safety provisions, including engineering features as well as administrative procedures;
      (iv) define the operational limits and conditions of operation;
   (f) emergency procedures ~~and communication links~~;
   (g) maintenance, testing, inspection and servicing so as to ensure that the radiation source and the installation continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime;
   (h) management of radioactive waste and arrangements for the disposal of such waste in accordance with applicable regulatory requirements;
   (i) management of disused sealed sources;
   (j) quality assurance.

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

Article 29

Release from regulatory control

1. The disposal, recycling or reuse of radioactive materials arising from any authorised practice is subject to authorisation.
2. The materials for disposal, recycling or reuse may be released from **regulatory control** ~~the requirements of this Directive~~ provided that the concentrations of activity per unit mass:
   (a) do not exceed the values set out in Annex VI, part 1 of Table A; or
   (b) comply with specific clearance levels and associated requirements for specific materials or for materials originating from specific types of practices; these specific clearance levels, in addition to the general clearance levels referred to in (a), shall be established by the national competent authority following the general exemption criteria set out in Annex VI and taking into account technical guidance provided by the Community.

3. For the clearance of materials containing naturally occurring radionuclides, the values for the concentrations of activity per unit mass shall be those laid down in Annex VI, part 2 of Table A. Nevertheless the following requirements shall apply:

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

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

   (c) for authorised practices subject to notification as specified under Article 25(3), the corresponding requirements for the placing on the market of building materials shall be complied with.

4. place in normal operation when radioactivity is not a consideration, shall not be permitted. The competent authority may authorise in specific situations the mixing of radioactive residues**, for instance those** containing ~~naturally occurring~~ radioactive material with other materials ~~to promote the reuse and recycling of these materials and to reduce public exposure~~ **if:**

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

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

CHAPTER VI

PROTECTION OF WORKERS, APPRENTICES AND STUDENTS

Article 30

Responsibilities

1. The relevant requirements for occupational exposure in this **Directive** ~~Chapter and in Articles 9, 10, 11 and 12,~~ shall apply to the protection of workers**, apprentices and students** in any exposure situation where their exposure ~~at work or as the result of work~~ is the legal responsibility of an undertaking **or an employer responsible for the** ~~another legal person, including, for instance~~:

   (a) **protection** ~~the employer~~ of outside workers;

   (b) ~~the organisation responsible for the~~ protection of emergency workers;

   (c) **protection of workers** ~~the organisation responsible~~ for the remediation of contaminated land, buildings and other constructions;

   (d) ~~the employer who has legal responsibility for the exposure~~**protection** of workers to radon at work, in the situation specified in Article 53(4).

2. The responsibility of an undertaking for occupational exposure shall extend ~~to apprentices and students who in the course of their studies are obliged to work with radiation sources and~~ to individuals who are self-employed or work on a voluntary basis or for a charity organisation.

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

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

Article 31

Operational protection of workers

The operational protection of exposed workers shall be based on:

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

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

(c) **identification and** classification of workers into different categories;

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

(e) medical surveillance**;** ~~.~~

(f) education and training of workers, in accordance with Article 16.

Article 32

*Consultations with **a** radiation protection expert*

Member States shall require the undertaking to consult**, where apropriate,** a radiation protection expert on the examination and testing of protective devices and measuring instruments, in particular for:

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

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

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

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

Article 33

Arrangements in workplaces

1. For the purposes of radiation protection, arrangements shall be made as regards all workplaces where **workers are liable to receive an** ~~there is a possibility of~~ exposure to ionising radiation in excess of an effective dose of 1 mSv per year or an equivalent dose of 15 mSv per year for the lens of the eye or 50 mSv per year for the skin and extremities.
   Such arrangements shall be appropriate to the nature of the installations and sources and to the magnitude and nature of the risks.
2. For practices **or workplaces** involving **exposure to terrestrial natural radiation sources,** ~~naturally occurring radioactive material~~ where the effective dose to workers is liable to exceed 6 mSv per year, the **relevant** requirements set out in this Chapter shall apply. Where the effective dose to workers is less than or equal to 6 mSv per year **and liable to be above 1 mSv per year,** the competent authorities shall at least require **the** undertaking~~s~~ to keep exposures under review, taking into account the potential for protection to be improved or the potential for doses to increase over time or as a result of changes in the process or the work arrangements.
3. For **an** undertaking~~s~~ operating aircraft where the effective dose to the crew from cosmic radiation is liable to exceed 6 mSv per year, the relevant requirements set out in this Chapter shall apply. Where the effective dose to the crew is less than or equal to 6 mSv per year and liable to be above 1 mSv per year, the competent authorities shall at least require **the** undertaking~~s~~ to keep exposures under review, taking into account the potential for doses to change over time or as a result of changes in the work arrangements. The undertaking~~s~~ shall take appropriate measures, in particular:
   (a) to assess the exposure of the crew concerned;
   (b) to take into account the assessed exposure when organising working schedules with a view to reducing the doses of highly exposed crew;
   (c) to inform the workers concerned of the health risks their work involves and their individual dose.

Article 34

Classification of workplaces

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

Article 35

Requirements for controlled areas

1. The minimum requirements for a controlled area shall be the following:
   (a) The controlled area shall be delineated and access to it shall be restricted to individuals who have received appropriate instructions and shall be controlled in accordance with written procedures 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 in the adjacent area.
   (b) Taking into account the nature and extent of radiological risks in the controlled area, radiological surveillance of the **workplace** ~~working environment~~ shall be organised in accordance with the provisions of Article 37.
   (c) Signs indicating the type of area, the nature of the sources and their inherent risks shall be displayed.
   (d) Working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.
2. The undertaking shall be responsible for implementation of these duties following consultations with the radiation protection expert.

Article 36

Requirements for supervised areas

1. The requirements for a supervised area shall be the following:
   (a) taking into account the nature and extent of radiological risks in the supervised area, radiological surveillance of the **workplace** ~~working environment~~ shall be organised in accordance with the provisions of Article 37;
   (b) **if appropriate,** signs indicating the type of area, the nature of the sources and their inherent risks shall be displayed;
   (c) **if apropriate,** working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.
2. The undertaking shall be responsible for implementation of these duties following consultations with the radiation protection expert.

Article 37

*Radiological surveillance of the **workplace** ~~working environment~~*

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

Article 38

Categorisation of exposed workers

1. For the purposes of monitoring and surveillance, a distinction shall be made between two categories of exposed workers:
   (a) category A: those exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than 150 mSv per year for skin and extremities;
   (b) category B: those exposed workers who are not classified as category A workers.
2. **The undertaking or, in the case of outside workers, the employer, shall decide on the categorisation of individual workers prior to their taking up work that may give rise to exposure, and shall regularly review this categorisation** ~~The distinction referred to in paragraph 1 shall be made prior to employment for work involving exposure and shall be subject to regular review~~ on the basis of working conditions and medical surveillance. **The distinction shall also take into account potential exposure and the risk for accidents.**
3. For emergency workers, the distinction referred to in paragraph 1 of this Article~~, where appropriate, shall~~ have no effect on the requirements for monitoring set out in Articles 37, 39 – 43 as long as the workers are not involved in an actual emergency exposure situation.

Article 39

Individual monitoring

1. Category A workers shall be systematically monitored based on individual measurements performed by a dosimetry service. In cases where category A workers are liable to receive significant internal exposure or significant exposure of the lens of the eye or extremities an adequate system for monitoring shall be set up. ~~The competent authority shall give special attention to the identification of such workers.~~
2. Monitoring for category B workers shall be at least sufficient to demonstrate that such workers are correctly classified in category B. Member States may require individual monitoring and if necessary individual measurements, performed by a dosimetry service, for category B workers.

3. In cases where individual measurements are impossible or inadequate, the individual monitoring shall be based on an estimate arrived at ~~either~~ from individual measurements made on other exposed workers**,** ~~or~~ from the results of the surveillance of the working environment provided for in Article 37 **or on the basis of approved calculation methods**.

Article 40

Monitoring in the case of accidental exposure

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

Article 41

Recording and reporting of results

1. A record containing the results of individual monitoring shall be made for each exposed worker for whom such monitoring is performed.
2. For the purposes of paragraph 1, the following information on exposed workers shall be retained:
   (a) a record of the exposures measured or estimated, as the case may be, of individual doses pursuant to Articles 3**9**~~7~~, 40, **50,** 51,and 52;
   (b) in the case of exposures as referred to in Articles 40, **51** and 52, the reports relating to the circumstances and the action taken;
   (c) the results of workplace monitoring used to assess individual doses where necessary.
3. The information referred in paragraph 1 shall be retained during the period of their working life involving exposure to ionising radiation and afterwards until they have or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure.
4. Exposure as referred to in Articles 40, 51, and 52 shall be recorded separately in the dose record referred to in paragraph 1.

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

Article 42

Access to the results ***of individual monitoring***

1. The Member States shall require that the results of the individual monitoring set out in Articles 39, 40**, 51** and 52 be:
   (a) made available to the competent authorities, to the undertaking, and to the employer of outside workers;
   (b) made available to the worker concerned in accordance with **paragraph 2** ~~Article 43(1)~~;
   (c) submitted to the occupational health services in order for them to interpret the implications of the results for human health, as provided for in Article 44;
   (d) submitted to the data system for individual radiological monitoring established by the Member State in accordance with **provisions set out n Annex VIII** ~~paragraph 2~~.

1a. Member States shall require the undertaking and the employer to grant workers to have access at their request 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.

2. Member States shall determine the arrangements under which the results of individual monitoring are conveyed.
3. The data system for individual radiological monitoring shall **cover** ~~communicate~~ at least the data listed in Annex VIII, Section A.
4. In the case of an accidental or emergency exposure, **the undertaking shall communicate** the results of individual monitoring ~~shall be communicated~~ without delay.

~~*Article 43*~~

~~1. Member States shall require workers to have access at their request 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 workplace measurements.~~

~~2.~~ **5.** Member States shall facilitate the exchange among competent authorities, occupational health services, radiation protection experts, or dosimetry services within the Union of all relevant information on the doses previously received by a worker in order to perform the medical examination prior to employment or classification as a category A worker pursuant to Article 44 and to control the further exposure of workers.

Article 44

Medical surveillance of exposed workers

1. The medical surveillance of exposed workers shall be based on the principles that govern occupational medicine generally.
2. The medical surveillance of category A workers shall be the responsibility of occupational health services.

   This medical surveillance shall allow for the state of health of workers under surveillance to be ascertained as regards their fitness for the tasks assigned to them. To this end, the occupational health services shall have access to any relevant information they require, including the environmental conditions in the working premises.
3. Medical surveillance shall include:
   (a) A medical examination prior to employment or classification as a category A worker to determine the worker's fitness for a post as a category A worker for which the worker is being considered.

(b) Periodic reviews of health.

The state of health of all category A workers shall be reviewed at least once a year, in order to determine whether they remain fit to perform their duties. The nature of these reviews, which can be performed as many times as the occupational health services consider necessary, shall depend on the type of work and on the individual worker's state of health.

4. The occupational health services may indicate the need for medical surveillance to continue after cessation of work for as long as they consider it necessary to safeguard the health of the person concerned.

Article 45

Medical classification

The following medical classification shall be established with respect to fitness for work as a category A worker:

(a) fit;

(b) fit, subject to certain conditions;

(c) unfit.

Article 46

Prohibition to employ or classify unfit workers

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

Article 47

Medical records

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

2. The medical record shall include information regarding the nature of the employment, the results of the medical examinations prior to employment or classification as a category A worker, the periodic reviews of health and the record of doses required by Article 41.

Article 48

Special medical surveillance

1. In addition to the medical surveillance of exposed workers provided for in Article 44, provision shall be made for any further action considered necessary by the occupational health services for the health protection of exposed individuals, such as further examinations, decontamination measures**.** ~~, or~~ urgent remedial treatment **or other actions identifiesd by the occuoational health services**.
2. Special medical surveillance shall be performed in each case where an annual effective dose of **[**50 mSv**]** in a year or any of the other dose limits laid down in Article 10(2) has been exceeded.
3. Subsequent exposure conditions shall be subject to the agreement of the occupational health services.

Article 49

Appeals

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

Article 50

Protection of outside workers

1. Member States shall ensure that the system for individual radiological monitoring affords outside workers equivalent protection to that for workers employed on a permanent basis by the undertaking.
2. The undertaking shall be responsible, either directly or through contractual agreements with the employer of outside workers, for the operational aspects of the radiation protection of outside workers.
3. In particular, the undertaking shall:
   (a) check that the outside worker concerned has been passed as medically fit for the activities to be assigned to the worker;
   (b) ensure that, in addition to the basic training in radiation protection referred to in Article 16, the outside worker has received specific training in connection with the characteristics of ~~both the controlled area~~ **the workplace** and the activities;
   (c) ensure that the outside worker has been issued with the necessary personal protective equipment;
   (d) ensure that the outside worker receives individual exposure monitoring appropriate to the nature of the activities, and any operational dosimetric monitoring that may be necessary;
   (e) ensure compliance with the system of protection as defined in Chapter III;
   (f) ensure or take all appropriate steps to ensure that after every activity the radiological data from individual exposure monitoring of each outside worker within the meaning of Annex VIII, Section B, point 2, are recorded.
4. Employers of outside workers shall, either directly or through contractual agreements with the undertaking, ensure that the radiation protection of their workers is in accordance with the relevant provisions of this Directive, in particular by:
   (a) ensuring compliance with the system of protection as defined in Chapter III;
   (b) providing the information and training in the field of radiation protection referred to in Article 16;

(c) guaranteeing that their workers are subject to the assessment of exposure and medical surveillance under the conditions laid down in Articles 37, 39 to 48;

(d) ensuring that the radiological data from the individual exposure monitoring of each of their workers within the meaning of Annex VIII, Section B, point 1, are kept up to date in the data system for individual radiological monitoring referred to in Article 42(1)(d).

~~5. All outside workers shall be obliged to make their own contribution as far as practicable towards the protection to be afforded to them by the radiological monitoring system referred to in paragraph 1.~~

Article 51

Specially authorised exposures

1. In exceptional circumstances evaluated case by case, excluding emergencies, the competent authorities may, where a specific operation so requires, authorise individual occupational exposures of identified volunteer workers exceeding the dose limits set out in Article 10, provided that such exposures are limited in time, confined to certain working areas and within the maximum exposure levels defined for the particular case by the competent authorities. The following conditions shall be taken into account:

(a) only category A workers as defined in Article 38 **or spacecraft crew** may be subject to such exposures;

(b) apprentices, students, pregnant women, and, if there is a risk of intake of radionuclides, breastfeeding women shall be excluded from such exposures;

(c) the undertaking shall carefully justify such exposures in advance and thoroughly discuss them with the voluntary workers, their representatives, the occupational health services or the radiation protection expert;

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

(e) all doses relating to such exposures shall be separately recorded in the medical record referred to in Article 47 and the individual record referred to in Article 41.

2. The exceeding of dose limits as a result of specially authorised exposures shall not necessarily constitute a reason for excluding workers from their usual occupation or relocating them, without their agreement.
3. The exposure of space**craft** crew above the dose limits shall be managed as a specially authorised exposure.

Article 52

Emergency occupational exposure

1. Emergency response organisations shall ensure that no emergency worker undertakes actions resulting in doses **as a result of these actions** in excess of ~~50~~ **100** mSv, except in specific cases identified in the national emergency plan. In such cases, appropriate reference levels ~~above 50 mSv~~ shall be defined. In exceptional situations, in order to save life, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions, a reference level above 100 mSv may be set**, up to a maximum of 500 mSv**.
2. Emergency response organisations shall ensure that emergency workers who are liable to undertake actions whereby ~~50~~ **100** mSv may be exceeded ~~are volunteers who~~ have been clearly and comprehensively informed in advance of the associated health risks and the available protection measures **and undertake these actions voluntarily**.
3. In the event of an emergency exposure, Member States shall require radiological monitoring**[** and medical surveillance of emergency workers**]**. Individual monitoring or assessment of the individual doses shall be carried out as appropriate to the circumstances.

Article 53

Radon in workplaces

1. ~~Within the action plan referred to in Article 103,~~ Member States shall establish national reference levels for indoor radon concentrations **in workplaces**. Such reference levels shall **be equal to or above the reference level set for any type of existing buildings but shall** not exceed an annual average of 1 000 Bq m^{-3} for workplaces.

2. Under the national action plan **referred to in Article 103**, Member States shall ensure that radon measurements are carried out in **underground** workplaces ~~located on the ground floor or at basement level within radon-prone areas~~ and in specific types of workplaces **in radon prone areas,** as identified in the action plan.
3. Member States shall require undertakings in which the national reference level for existing workplaces is exceeded to take appropriate action in order to reduce radon concentrations or exposures, in accordance with the principle of optimisation set out in Chapter III.
4. Where workplaces or specific rooms within a building continue to exceed the reference level despite the action taken in accordance with paragraph 3, the Member States shall manage this situation as a planned exposure situation and apply the relevant requirements for occupational exposure as specified in Article 3**0**~~1~~(d).

CHAPTER VII

PROTECTION OF PATIENTS AND OTHER INDIVIDUALS SUBJECTED TO MEDICAL EXPOSURE

Article 54

Justification

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

   ~~Account shall also be taken of the individual detriment from the exposure of the medical radiological staff and other individuals.~~

   ~~In particular the following requirements shall be applied:~~

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

~~(b) existing~~ types ~~of practices involving medical exposure shall be reviewed whenever new, important evidence about their efficacy or consequences is acquired;~~

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

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

(e) The referrer and the practitioner shall seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure.

(f)2. Medical exposure for biomedical and medical research shall be examined by an ethics committee, set up in accordance with national procedures and/or by the competent authorities;

(g)~~3.~~ Specific justification for medical radiological procedures to be performed as part of a health screening programme shall be carried out by the **competent authority** ~~health authority~~ in conjunction with appropriate **medical scientific societies** ~~professional bodies~~.

(h)~~4.~~ The exposure of carers and comforters shall show a sufficient net benefit, taking into account the direct health benefits to a patient, the benefits to the carer / comforter and the detriment that the exposure might cause.

(i)~~5.~~ Any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, shall be part of a health screening programme, or shall require specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant professional bodies and competent authorities. Special attention shall be given to the provision of information to the patients, as required by Article 56(3).

~~6. If an exposure~~ cannot ~~be justified in accordance with paragraphs 1-5, it shall be prohibited.~~

Article 55

Optimisation

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

   For all medical exposure of individuals for radiotherapeutic purposes, exposures of target volumes shall be individually planned, taking into account that doses of non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.
2. Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radiodiagnostic examinations, and when appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.
3. Member States shall ensure that for each biomedical and medical research project:
   (a) the individuals concerned participate voluntarily;
   (b) these individuals are informed about the risks of exposure;
   (c) a dose constraint is established for individuals for whom no direct medical benefit is expected from exposure;
   (d) in the case of patients who voluntarily accept to undergo an experimental **medical** ~~diagnostic or therapeutic~~ 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.
4. The optimisation shall include the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical exposure procedures, quality assurance, and the assessment and evaluation of patient and staff doses or administered activities, taking into account economic and social factors.
5. Member States shall ensure that:
   (a) dose constraints are established for the exposure of carers and comforters**, where apropriate**;
   (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 appropriate, provides the patient or legal guardian with written instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable and providing information on the risks of ionising radiation.

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

Article 56

Responsibilities

1. The referrer and the practitioner shall be involved in the justification process as specified by Member States.
2. Member States shall ensure that any medical exposure takes place under the clinical responsibility of a practitioner.
3. The practitioner shall ensure that the patient or legal guardian is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure ~~to enable informed consent~~. **This information should be part of the informed consent process as specified by Member States.** Similar information as well as relevant guidance in accordance with Article 55(5)(b) shall be given to carers and comforters.
4. Practical aspects of medical exposure procedures may be delegated by the undertaking or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognised field of specialisation.

Article 57

Procedures

1. Written protocols for every type of standard medical radiological procedure shall be established for each equipment **for relevant categories of patients**.
2. Member States shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to the referrers.

3. In medical radiological practices, a medical physics expert shall be appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice. In particular:
   (a) in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved;
   (b) in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, a medical physics expert shall be involved;
   (c) for other simple radiodiagnostic procedures, a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.
4. Clinical audits shall be carried out in accordance with national procedures.
5. Member States shall ensure that appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that corrective action is taken where appropriate.

Article 58

Training

Member States shall ensure that training and recognition requirements, as laid down in Articles 81, 15 and 19, are met for the practitioner, the medical physics expert and the individuals referred to in Article 56(4).

Article 59

Equipment

1. Member States shall take such steps as they **may** consider necessary with a view to avoiding unnecessary proliferation of medical radiological equipment.
2. Member States shall ensure that:
   (a) all medical radiological equipment in use is kept under strict surveillance regarding radiation protection;

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

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

(d) acceptance testing, involving the medical physics expert, is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any major maintenance procedure.

3. Competent authorities shall take steps to ensure that the necessary measures are taken by the undertaking to improve inadequate or defective features of medical radiological equipment. They shall also adopt specific criteria for the acceptability of equipment in order to indicate when appropriate corrective action is necessary, including, if appropriate, taking the equipment out of service.

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

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

6. Any equipment used for interventional radiology and computed tomography shall have a device or a feature informing the practitioner of relevant equipment parameters during the medical radiological procedure for assessing the patient dose or a dose indicator. The radiation dose or the dose indicator shall form part of the report on the examination.

Article 60

Special practices

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

   Member Staes ~~Special attention~~ shall **adopt** ~~be given to~~ **specific provisions for** quality assurance programmes and the assessment of dose or administered activity, as mentioned in Article 59(2)(c), for these practices.
2. Member States shall ensure that practitioners and those individuals referred to in Article 56(4) who perform the exposures referred to in paragraph 1 obtain appropriate training in these medical radiological practices as required by Article 19.

Article 61

Special protection during pregnancy and breastfeeding

1. In the case of a woman of childbearing age, the referrer and the practitioner shall inquire as specified by Member States whether she is pregnant or breastfeeding, if relevant.
   If pregnancy cannot be excluded, depending on the type of medical exposure, in particular if abdominal and pelvic regions are involved, ~~special attention shall be given to the justification, particularly~~ the urgency **of the procedure**~~,~~ and ~~to the optimisation of the medical exposure, taking into account~~ the exposure both of the expectant mother and the unborn child **shall be given particular consideration in the justification and optimisation**.

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

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

Article 62

Accidental and unintended exposures

Member States shall ensure that

(a) all reasonable **measures** ~~steps~~ are taken to minimise the probability and magnitude of accidental or unintended **medical** exposures ~~of patients~~ from all medical radiological procedures, taking into account economic and social factors;

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

(c) for all medical exposures the undertaking implements a system for the **record keeping** ~~registration~~ and analysis of events involving or potentially involving accidental or unintended **medical exposures, commensurate with the hazard and probability of the event**;

(ca) arrangements are made to inform the referrer, the patient and, where relevant, the practitioner about an unintended or accidental exposure and the results of the analysis;

(d) the undertaking declares as soon as possible to the competent authorities the occurrence of significant events as defined by the authorities, including the results of the investigation and the corrective measures to avoid such events~~. The competent authorities shall share this information with the competent authorities for post-market surveillance established in Council Directive 93/42/EEC concerning medical devices~~;

(e) ~~arrangements are made to inform the referrer, the practitioner and the patient about an unintended or accidental exposure.~~ **mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events, includiong the results of investigations referred to under (e).**

Article 63

Estimates of population doses

Member States shall ensure that the distribution of individual dose estimates from medical exposure is determined and shall take into account the age distribution and the gender of the exposed population.

CHAPTER VIII

PROTECTION OF MEMBERS OF THE PUBLIC

SECTION 1

PROTECTION OF THE MEMBERS OF THE PUBLIC IN NORMAL CIRCUMSTANCES

Article 64

Principles of protection of members of the public

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

Article 65

Operational protection of members of the public

1. The operational protection of members of the public in normal circumstances from practices subject to licensing shall include all arrangements and surveys for detecting and eliminating factors which, in the course of any operation involving exposure to ionising radiation, are liable to create a risk of exposure for the members of the public which cannot be disregarded from the radiation protection point of view. Such protection shall include the following tasks:
   (a) examination and approval of plans for installations involving an exposure risk, and of the proposed siting of such installations within the territory concerned, from the point of view of radiation protection;
   (b) acceptance into service of new installations involving an exposure risk, subject to adequate protection being provided against any exposure or radioactive contamination liable to extend beyond the perimeter, taking into account, if relevant, demographic, meteorological, geological, hydrological and ecological conditions;
   (c) examination and approval of plans for the discharge of radioactive effluents.

   These tasks shall be carried out in accordance with rules laid down by the competent authorities on the basis of the exposure risk involved.
2. The competent authority shall establish authorised limits for discharging radioactive effluents. These discharge authorisations shall
   (a) take into account the results of the optimisation of public exposure;
   (b) reflect good practice in the operation of similar facilities;
   (c) allow a margin for operational flexibility of a facility.

Article 66

Estimation of doses to the members of the public

1. Member States shall, on the basis of the exposure risk involved, establish a system for the estimation of doses to members of the public from planned exposure situations.

2. The competent authorities shall identify practices where a realistic assessment of doses to members of the public shall be carried out. For other practices Member States may require only a screening assessment with generic data.

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

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

   (b) decide on the frequency of assessments and take all necessary steps to identify the representative person, taking into account the effective pathways for transmission of the radioactive substances;

   (c) ensure, taking into account the radiological risks, that the estimates of doses to members of the public include:

      i) assessment of the doses due to external radiation, indicating, where appropriate, the quality 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 and concentrations of these radionuclides;

      iii) assessment of the doses that the representative person is liable to receive and specification of the characteristics of the representative person;

   (d) require records to be kept and be made available to all stakeholders relating to measurements of external exposure, estimates of intakes of radionuclides and radioactive contamination, 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 the radioactive airborne or liquid discharges into the environment and to report the results of this monitoring to the competent authority.

2. Member States shall require any undertaking responsible for a nuclear power reactor or reprocessing plant to monitor discharges in normal operation in accordance with the standardised information selected for monitoring and reporting to the European Commission as laid down in Commission Recommendation 2004/2/Euratom[1].

Article 68

Tasks for the undertakings

1. Member States shall require the undertaking to carry out the following tasks:
   (a) achieving and maintaining an optimal level of protection;
   (b) checking the effectiveness and maintenance of technical devices;
   (c) acceptance into service, from the point of view of surveillance of radiation protection, of equipment and procedures for measuring and assessing, as appropriate, exposure of members of the public and radioactive contamination of the environment;
   (d) regular calibration of measuring instruments and regular checking that they are serviceable and correctly used.
2. Radiation protection experts and, as appropriate, radiation protection officers shall be involved in the performance of the tasks referred to in paragraph 1.

Article 69

Environmental monitoring programme

Member States shall ensure that an appropriate environmental monitoring programme is in place for estimating the exposure of members of the public.

[1] OJ L 2/36, 6.1.2000.

SECTION 2

EMERGENCY EXPOSURE SITUATIONS

Article 70

Emergency response

1. Member States shall require the undertaking responsible for a practice to notify the competent authorities immediately of any emergency occurring in its facility or related to its activities and to take all appropriate action to reduce the consequences.
2. Member States shall ensure that, in the event of an emergency on its own territory, the undertaking makes an initial provisional assessment of the circumstances and consequences of the emergency and assists with protective measures.
3. Member States shall ensure that provision is made for protective measures with regard to:
   (a) the radiation source, to reduce or stop the direct radiation and emission of radionuclides, or to prevent exposure or contamination resulting from orphan sources;
   (b) the environment, to reduce the transfer of radioactive substances to individuals;
   (c) individuals, to reduce exposure.
4. In the event of an emergency on or outside its territory, the Member State or the emergency response authority shall require:
   (a) the organisation of appropriate protective measures, taking account of the real characteristics of the emergency and in accordance with the optimised protection strategy as part of the emergency response plan, whereby the elements to be included in an emergency response plan are indicated in Section B of Annex IX;
   (b) the assessment and recording of the consequences of the emergency and of the effectiveness of the protective measures.
5. The Member State or the emergency response authority shall, if the situation so requires, ensure that provision is made to organise the medical treatment of victims.

Article 71

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 it and about the action it should take in the event of such an emergency.
2. The information supplied shall include at least the elements set out in Section A of Annex X.
3. The information shall be communicated to the members of the public referred to in paragraph 1 without any request being made.
4. Member States shall update the information and circulate it at regular intervals and whenever significant changes take place. This information shall be permanently available to the public.

Article 72

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 is informed without delay of the facts of the emergency, the steps to be taken and, as appropriate, the health protection measures applicable to these members of the public.
2. The information provided shall cover those points contained in Section B of Annex X which are relevant to the type of emergency.

SECTION 3

EXISTING EXPOSURE SITUATIONS

Article 73

Contaminated areas

1. Strategies for managing contaminated areas shall include, where applicable, the following:
   (a) delineation of the affected regions and identification of the affected members of the public;

(b) consideration of the need for and extent of protective measures applied to the affected regions and members of the public;

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

(d) assessment of the exposure of different groups in the population and assessment of the means available to individuals for controlling their own exposure;

(e) objectives and long-term goals pursued by the strategy and corresponding reference levels.

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

(a) establishment of reference levels consistent with day-to-day life;

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

Article 74

Radon in dwellings and buildings with public access

1. Within the action plan referred to in Article 103, Member States shall establish national reference levels for indoor radon concentrations, which shall not exceed (as an annual average):

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

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

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

2. Under the national action plan, Member States shall
   (a) take action to identify existing dwellings exceeding the reference level and to encourage radon-reducing measures in existing dwellings where the reference levels are exceeded;
   (b) ensure that radon measurements are carried out in buildings with public access within radon-prone areas.
3. Member States shall establish specific building codes to prevent radon ingress from the soil and, as specified in the national action plan, from building materials, and require compliance with such building codes, in particular in radon-prone areas, so as to avoid radon concentrations exceeding the reference level for new buildings.
4. Member States shall provide local and national information on prevailing radon concentrations, on the associated health risks and on the technical means available for reducing existing radon concentrations.

Article 75

Building materials

1. The requirements in Article 75(2) to (6) shall apply to the following:
   (a) building materials which are identified and listed by the relevant competent authority as being of concern from the radiation protection point of view, taking into account the indicative list of materials set out in Annex XI with regard to their emitted gamma radiation; or
   (b) building materials which the authority has assessed to be of concern in the national action plan for radon, as specified in Article 103.
2. For identified types of building materials, the industries placing such materials on the market
   (a) shall determine the concentrations of the radionuclides specified in Annex VII;
   (b) shall provide information to the competent authority on the results of measurements and the corresponding activity concentration index, as defined in Annex VII.
3. The competent authority shall ensure that identified types of building materials are classified, as laid down in Annex VII, on the basis of their intended use and activity concentration index.

4. Identified types of building materials which are not liable to give doses exceeding the reference level of 1 mSv per year for indoor external exposure from building materials, in excess of prevailing outdoor external exposure, shall be exempt from requirements at national level, without prejudice to Article 103. Such building materials shall nevertheless be further monitored to ensure that the activity concentration continues to comply with this reference level. Building materials of category A as specified in Annex VII shall be exempt from any restrictions with regard to their placing on the market in the Union.
5. For identified types of building materials which are liable to give doses exceeding the reference level of 1 mSv per year for indoor external exposure from building materials, in excess of the prevailing outdoor external exposure, the competent authority shall decide on appropriate measures, ranging from registration and general application of relevant building codes to specific restrictions on the envisaged use of such materials.
6. Information on identified types of building materials, relevant to the implementation of building codes, including their radionuclide concentrations, activity concentration index and corresponding classification, shall be made available prior to their placing on the market.

CHAPTER IX

PROTECTION OF THE ENVIRONMENT

Article 76

Environmental criteria

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

Article 77

Authorised limits on discharges

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

Article 78

Accidental releases

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

Article 79

Environmental monitoring

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

CHAPTER X

REQUIREMENTS FOR REGULATORY CONTROL

SECTION 1

INSTITUTIONAL INFRASTRUCTURE

Article 80

Competent authority

1. Member States shall designate the competent authority or authorities to carry out tasks in accordance with this Directive.
2. Member States shall forward to the Commission the name and address of the competent authority or authorities and their respective areas of competence to ensure rapid communication with such authorities.
3. Where a Member State has more than one competent authority for the control of high-activity sealed sources and orphan sources, it shall designate one point of contact for communication with the competent authorities of other Member States.
4. Member States shall forward to the Commission any changes to the information referred to in paragraphs 2 and 3.
5. The Commission shall communicate the information referred to in paragraphs 2, 3 and 4 to all competent authorities and shall publish it periodically in the Official Journal of the European Union, at intervals of no more than two years.

Article 81

Recognition of services and experts

1. Member States shall make the necessary arrangements 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.

2. Member States shall specify the recognition requirements and communicate them to the Commission together with the name and address of the competent authorities in charge of recognition. Member States shall communicate any changes to this information.
3. Member States shall specify other services or experts requiring particular radiation protection qualifications and, where appropriate, the process for the recognition of such qualifications.
4. The Commission shall make the information received in accordance with paragraph 2 available to the Member States.

Article 82

Occupational health services

Occupational health services shall perform medical surveillance of exposed workers with regard to their exposure to ionising radiation and their fitness for the tasks assigned to them.

Article 83

Dosimetry services

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

Article 84

Radiation protection expert

1. The radiation protection expert shall, on the basis of professional judgment, measurements and assessments, give competent advice to the undertaking on matters relating to occupational exposure and public exposure.
2. The advice of the radiation protection expert shall cover, but not be limited to, the following:
   (a) 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;
   (b) the categorisation of controlled and supervised areas;
   (c) the classification of workers;
   (d) the content of workplace and individual monitoring programmes;
   (e) the appropriate radiation monitoring instrumentation to be used;
   (f) the appropriate methods of personal dosimetry;
   (g) the optimisation and establishment of appropriate dose constraints,
   (h) quality assurance;
   (i) the environmental monitoring programme;
   (j) radioactive waste disposal requirements;
   (k) the arrangements for prevention of accidents and incidents;
   (l) preparedness and response in emergency exposure situations;
   (m) training and retraining programmes for exposed workers.
3. Where appropriate, the task of the radiation protection expert may be carried out by a group of specialists who together have the necessary expertise.

Article 85

Medical physics expert

1. Within the health care environment, the medical physics expert shall, as appropriate, act or give specialist advice on matters relating to radiation physics as applied to medical exposure.

2. Depending on the medical radiological practice, the medical physics expert shall take responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient, give advice on medical radiological equipment, and contribute in particular to the following:
   (a) optimisation of the radiation protection of patients and other individuals subjected to medical exposure, including the application and use of diagnostic reference levels;
   (b) the definition and performance of quality assurance of the medical radiological equipment;
   (c) the preparation of technical specifications for medical radiological equipment and installation design;
   (d) the surveillance of the medical radiological installations with regard to radiation protection;
   (e) the selection of equipment required to perform radiation protection measurements;
   (f) the training of practitioners and other staff in relevant aspects of radiation protection. Where appropriate, the task of the medical physics expert may be carried out by a medical physics service.

Article 86

Radiation protection officer

1. Member States shall decide in which practices the designation of a radiation protection officer is necessary 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 duties. The radiation protection officer shall report directly to the undertaking.
2. Depending on the nature of the practice, the tasks of the radiation protection officer 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 radioactive sources;

(d) carrying out periodic assessments of the condition of the relevant safety and warning systems;

(e) supervise implementation of the personal monitoring programme;

(f) supervise implementation of the health surveillance programme;

(g) providing new employees with an introduction to local rules and procedures;

(h) giving advice and comments on work plans;

(i) authorising work plans;

(j) providing reports to the local management;

(k) participating in the arrangements for prevention, preparedness and response for emergency exposure situations;

(l) liaising with the radiation protection expert.

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

SECTION 2

CONTROL OF SEALED SOURCES

Article 87

General requirements

1. Member States shall make arrangements for keeping adequate control of sealed sources with regard to their location, use and disuse.
2. Member States shall require the undertaking to keep records of all such sources under its responsibility, their location and their transfer.
3. Member States shall set up a system to enable them to be adequately informed of individual transfers of sealed sources, where necessary, and in any event of transfers of high-activity sealed sources.
4. Member States shall require each undertaking holding a sealed source to notify the competent authority promptly of any loss, theft or unauthorised use of a sealed source.

Article 88

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 **physical protection** ~~security~~ of sources, including when they become disused sources. Such arrangements may provide for the transfer of disused sources to the supplier or their placement in a disposal or storage facility or an obligation for the manufacturer or the supplier to receive them;

(b) adequate provision, by way of a financial security or any other equivalent means appropriate for the source in question, has been made for the safe management of sources when they become disused sources, including the case where the undertaking becomes insolvent or ceases its activities.

Article 89

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

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

(b) work procedures to be followed;

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

Article 90

Record keeping by the undertakings

Member States shall require that the records for high-activity sealed sources include the information set out in Annex XII and that the undertaking provides the competent authorities with a copy of all or part of these records upon request and at least as set out in Annex XIII. The undertaking's records shall be available for inspection by the competent authority.

Article 91

Record keeping by the competent authorities

The competent authorities shall keep records of undertakings authorised to perform practices with high-activity sealed sources and of the high-activity sealed sources they hold. 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 authorities shall keep the records up to date, taking transfers of the sources and other factors into account.

Article 92

*~~Security~~**Control** of high-activity sealed sources*

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

SECTION 3

ORPHAN SOURCES

Article 93

Detection of orphan sources

1. Member States shall require any person encountering an orphan source to promptly notify the emergency organisation or the competent authority and to refrain from any further action on the source until these bodies have given appropriate instructions.
2. Member States shall make arrangements for the establishment of systems to detect 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, such as customs posts.
3. Member States shall ensure that specialised technical advice and assistance is promptly made available to persons who work in the places referred to in paragraph 2 and who are not normally involved in operations subject to radiation protection requirements. The primary aim of advice and assistance shall be the protection of workers and members of the public from radiation and the safety of the source.

Article 94

Metal contamination

Member States shall require that a metal scrap recycling installation promptly notifies the competent authority of any melting of an orphan source and shall require that the contaminated metal not be further processed without authorisation by the competent authority.

Article 95

Recovery, management and disposal of orphan sources

1. Member States shall ensure that the competent authorities are prepared, or have made provision, including assignment of responsibilities, to recover orphan sources and to deal with emergencies due to orphan sources and have drawn up appropriate response plans and measures.
2. Member States shall ensure that campaigns are organised, as appropriate, to recover orphan sources left behind from past practices.

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

Article 96

Financial security for orphan sources

Member States shall ensure that, on the basis of arrangements to be decided by Member States, a financial security system or other equivalent means is established to cover intervention costs relating to the recovery of orphan sources and which may result from implementation of Article 95.

SECTION 4

EMERGENCY EXPOSURE SITUATIONS

Article 97

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.

2. The emergency management system shall be designed to be commensurate with the results of a threat assessment and to be able to respond effectively to emergency exposure situations in connection with practices or unforeseen events, including malevolent acts and the discovery of orphan sources.
3. The emergency management system shall provide for the establishment of emergency response plans with the objective of avoiding deterministic effects in any individual from the affected members of the public and reducing the risk of stochastic effects, taking account of the general principles of radiation protection and the reference levels referred to in Chapter III. The emergency management system shall include the elements listed in Section A of Annex IX.

Article 98

Emergency preparedness

1. Member States shall ensure that emergency response plans are established in advance for the various types of emergencies identified by the threat assessment.
2. Member States shall ensure that emergency response plans are tested, reviewed and revised at regular intervals.
3. The emergency response plans shall, where appropriate, incorporate relevant elements of the emergency management system referred to in Article 97.
4. The emergency response plans shall include the elements defined in Section B of Annex IX.

Article 99

International cooperation

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

2. Member States shall, in the event of an emergency occurring on their territory or likely to have radiological consequences on its territory, establish contact to obtain the cooperation of any other Member State or third country which may be involved.
3. Member States shall promptly exchange information and cooperate with other relevant Member States or third countries and with relevant international organisations regarding the loss, removal, theft or discovery of high-activity sealed sources, other radioactive sources and radioactive material of concern and regarding related follow-up or investigations, without prejudice to relevant confidentiality requirements and relevant national legislation.

SECTION 5

EXISTING EXPOSURE SITUATIONS

Article 100

Programmes on existing exposure situations

1. Member States shall ensure that programmes are established to identify and evaluate existing exposure situations and to determine which occupational and public exposures are of concern from a radiation protection point of view.
2. The requirements for existing exposure situations shall apply to:
   (a) exposure due to contamination of areas by residual radioactive material from:
      (i) past activities that were never subject to regulatory control or were not regulated in accordance with the requirements laid down by this Directive;
      (ii) an emergency, after the emergency exposure situation has been declared ended, as provided for in the emergency management system;
      (iii) residues from past activities for which the undertaking is no longer legally accountable;
   (b) exposure to natural radiation sources, including:
      (i) indoor exposure to radon and thoron, in workplaces, dwellings and other buildings;
      (ii) indoor external exposure from building materials;

(c) exposure to commodities incorporating

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

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

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

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

4. Existing exposure situations which are the legal responsibility of an undertaking and which are of concern from a radiation protection point of view shall be subject to the relevant requirements for planned exposure situations.

Article 101

Establishment of strategies

1. Member States shall arrange for the establishment of strategies to ensure that existing exposure situations are managed appropriately and that the resources made available for their management are commensurate with the risks and with the effectiveness of protective measures.

2. The competent authority charged with establishing a strategy for managing an existing exposure situation shall ensure that the strategy contains:

(a) the objectives pursued by the strategy;

(b) appropriate reference levels, taking into account the bands of reference levels laid down in Annex I.

Article 102

Implementation of strategies

1. Member States shall assign responsibilities to a competent authority for the implementation of strategies for the management of existing exposures, and, as appropriate, to registrants, licensees and other parties involved in the implementation of remedial and protective measures, and shall provide as appropriate for the involvement of stakeholders in decisions regarding the development and implementation of strategies for managing exposures.
2. The form, scale and duration of all protective measures considered for implementation of a strategy shall be optimised.
3. The distribution of residual doses that has resulted from the implementation of a strategy shall be assessed. Further efforts shall be considered with the aim of reducing any exposures that are still above the reference level.
4. Throughout the implementation of a strategy, the competent authority shall regularly:
   (a) evaluate the available remedial and protective measures for achieving the objectives and the efficiency of planned and implemented measures;
   (b) provide information to exposed individuals on the potential health risks and on the available means for reducing their own exposure;
   (c) provide guidance for the management of exposures at individual or local level;
   (d) with regard to activities that involve naturally occurring radioactive material and are not managed as planned exposure situations, provide information to undertakings on appropriate means for monitoring concentrations and exposures and for taking protective measures in the context of overall health and safety requirements.

Article 103

Radon action plan

1. Member States shall establish an action plan to manage long-term risks from radon exposures in dwellings, buildings with public access and workplaces for any source of radon ingress, whether from soil, building materials or water. The action plan shall take into account the issues set out in Annex XVI.

2. Member States shall forward the action plan and information on any identified radon-prone areas to the Commission. Member States shall update the action plan and information on radon-prone areas on a regular basis.

SECTION 6

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

Article 105

Enforcement

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

Article 106

Penalties

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

CHAPTER XI

FINAL PROVISIONS

Article 107

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 00.00.0000 at the latest. The provisions laid down in Chapter IX with regard to the protection of the environment shall be transposed by 00.00.0000.

2. When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.
3. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive and a correlation table between those provisions and this Directive.

Article 108

Repeal

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

Article 109

Entry into force

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

Article 110

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President