COMMISSION OF THE EUROPEAN COMMUNITIES

COM(93) 349 final

Brussels, 20 July 1993

Amended proposal for a

COUNCIL DIRECTIVE

LAYING DOWN THE BASIC SAFETY STANDARDS

FOR THE PROTECTION OF THE HEALTH

OF WORKERS AND THE GENERAL PUBLIC

AGAINST THE DANGERS ARISING FROM IONIZING RADIATION

(presented by the Commission pursuant to Article 149(3) of the EEC-Treaty)

COMMISSION OF THE EUROPEAN COMMUNITIES

RRIGENDUM

COM(93) 349 final/2

Brussels, 16 August 1993

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Amended proposal for a COUNCIL DIRECTIVE

laying down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation

(presented by the Commission in accordance with Article 119 of the EAEC Treaty)

COMMISSION OF THE EUROPEAN COMMUNITIES

CORRIGENDUM
au titrre des documents
com (93)349 final (20.7.93) et
com (93)349 final/2 (16.8.93)
(concerne les 9 langues)

COM(93) 349 final/3

Brussels, 6 October 1993

Proposal for a

COUNCIL DIRECTIVE

laying down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. Article 2(b) of the Euratom Treaty provides for the establishment within the Community of uniform basic safety standards to protect the health of workers and of the general public against the dangers of ionizing radiation. These basic safety standards were first adopted in 1959 by means of a Council Directive⁽¹⁾ and have subsequently been amended on several occasions to take account of developments in scientific knowledge in the field of radiation protection. The version of the basic standards currently in force dates back to 1980, with amendments mainly affecting their technical annexes being made in 1984⁽²⁾.

Council Directive 84/467/EURATOM of 3.9.1984 amending Directive 80/836/Euratom as regards the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation (OJ L 265 of 5.10.1984, p. 4).

⁽¹⁾ Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation (0J of 20.2.1959).

⁽²⁾ Council Directive 80/836/EURATOM of 15.7.1980 amending the Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation (0J L 246 of 17.9.1980, p.1).

2. Until 1986, the only legal instruments adopted by the Community in the radiation protection field, based on Article 31 of the EURATOM Treaty, were these basic safety standards together with a Directive laying down basic measures for the protection of persons undergoing medical examination or treatment⁽³⁾. Since then, following the accident at Chernobyl, a number of additional measures have been introduced to reinforce and complement existing Community provisions for the protection of health against ionizing radiation⁽⁴⁾.

Council Directive 89/618/EURATOM of 27.11.1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency (OJ L 357 of 7.12.1989, p. 31).

Council Directive 90/641/EURATOM of 4.12.1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas (OJ L 349 of 13.12.1990, p. 21).

Council Directive 92/3/EURATOM of 3.2.1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community (OJ L 35 of 12.2.1992).

Council Regulation 87/3954/EURATOM of 22.12.1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency (OJ L 371 of 30.12.1987, p. 11).

⁽³⁾ Council Directive 84/466/EURATOM of 3.9.1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment (OJ L 265 of 5.10.1984, p.1).

⁽⁴⁾ Council Decision 87/600/EURATOM of 14.12.1987 on Community arrangements for the early exchange of information in the event of a radiological emergency (OJ L 371 of 30.12.1987, p.76).

(4 continued)

Commission Regulation 89/944/EURATOM of 12 April 1989, laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency (OJ L 101 of 13.4.1989, p. 17).

Council Regulation 89/2218/EURATOM of 18.7.1989 amending Regulation 87/3954/EURATOM laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency (OJ L 211 of 22.7.1989, p.1).

Council Regulation 89/2219/EEC of 18.7.1989 on the special conditions for exporting foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency (OJ L 211 of 22.7.1989, p.4).

Council Regulation 90/737/EEC of 22 March 1990 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station (OJ L 82 of 29.3.1990, p. 1).

Commission Regulation 90/770/EURATOM of 29 March 1990 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency (OJ L 83 of 30.3.1990, p. 78).

Council Regulation 93/1493/EURATOM of 8 June 1993 on shipments of radioactive substances between Member States (OJ L 148 of 19.6.1993, p. 1).

Commission Regulation 93/1518/EEC of 21 June 1993 (replacing C.R. 92/598/EEC of 9 March 1992) establishing a list of products excluded from the application of Council Regulation 90/737/EEC on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station (OJ L 150 of 22.6.1993, p. 30).

There is also a Commission Recommendation issued in 1990 which draws the attention of the Member States to the risks of exposure to radon inside dwellings(5).

⁽⁵⁾ Commission Recommendation 90/143/EURATOM of 21.2.1990 on the protection of the public against indoor exposure to radon (OJ L 80 of 27.3.1990, p. 26).

- 3. The Community's basic safety standards have always taken into account to a large extent the ICRP's recommendations, which represent the state-of-the-art as regards radiation protection and also form the basis for the recommendations of other international organisations with responsibilities in this area. The ICRP published its latest recommendations at the beginning of 1991 in its Publication 60 (replacing Publication 26, which appeared in 1977). The Commission, for its part, has reviewed the provisions in the existing Directive in the light not only of the ICRP's recommendations but also of the experience gained in implementing those provisions. The revision is, moreover, in line with the undertaking made to the Council in 1987 at the time of the adoption of Regulation 87/3954 (see footnote 4). While the basic structure of the existing Directive has been retained, the following aims have been pursued in the revision:
 - to provide radiation protection based on the most up-to-date scientific knowledge, which should be utilised to the benefit of workers and the general public;
 - to provide a sound technical and scientific basis and a uniform approach to radiation protection, and to ensure technical consistency with the recommendations of international organisations, such as IAEA, NEA-OECD, WHO and ILO;
 - to update the provisions of the existing Directive, bearing in mind the basic structure on which the regulations in the Member States are modelled;
 - with a view to the completion of the Single Market, to preserve a high degree of harmonisation in the radiation protection measures provided for under the Euratom Treaty;
 - to strengthen the provisions on control of radioactive materials in accordance with the undertaking made to the Council in 1992, at the time of the adoption of Directive 92/3/EURATOM on the supervision and control of shipment of radioactive waste between Member States and into and out of the Community.

- 4. Taking into account all these factors, the most important amendments contained in the proposal for a new Directive are as follows:
 - use of the definitions, quantities and units as well as the radiation and tissue weighting factors set out in the latest ICRP recommendations:
 - the inclusion of more restrictive dose limits taken from the latest ICRP recommendations, which take account of the most recent estimates of cancer risk associated with exposure to ionizing radiation, together with the complex concept of health detriment;
 - the introduction of provisions concerning radiation protection in certain cases of occupational exposure to natural radiation sources;
 - the prohibition of certain unjustified uses of radioactivity;
 - expansion of the provisions concerning protective measures to be taken in the event of a radiological accident;
 - introduction of the "dose constraint" concept in relation to a given source;
 - changes to the radioactivity levels associated with the authorisation/reporting provisions laid down in the Directive;
- 5. The impact of the proposed modifications on business is expected to be limited, as a consequence of their evolutive character with respect to an existing Directive. The introduction of provisions concerning radiation protection in certain cases of occupational exposure to natural radiation sources is made in a flexible way, especially to allow their progressive application.
- The following section consists of comments on the various Titles in the proposed new Directive, explaining its rationale, scope and aims.

- 6.1 Compared with the existing Directive, the scope of the proposed Directive is to be widened (Title II). It now covers explicitly the placing on the market and the exportation of radioactive substances as well as the operation of electrical equipment emitting ionizing radiation and containing components operating at a potential difference of more than 5 kV. It also covers exposure to natural radiation sources at work.
- 6.2 The system of reporting and prior authorisation of practices (Title III) has been modified: the requirements for the application of this system have been laid down more explicitly than in the existing Directive, and in particular, the conditions in which these requirements may be waived have been thoroughly reconsidered. This will contribute to a further harmonisation of authorisation procedures within the Community, which will also have an impact on the achievement of the Community's internal market.
- 6.3 Title IV maintains the three basic principles of radiation protection (Justification, optimisation (ALARA) and dose limitation), specifying that the dose limits shall not apply to medical, accidental or emergency exposures or, in general, to exposures from natural radiation sources at work.

As regards the dose limits, the following steps have been taken:

- for workers, the new limit on effective dose is 20 mSv per year averaged over five consecutive years (100 mSv in five years) with the further provision that the effective dose shall not exceed 50 mSv in any single year).
- for members of the public, the new limit for the effective dose is 1 mSv per year. However, in special circumstances, a higher value may be authorised in a single year, provided that the average over five consecutive years does not exceed 1 mSv per year.
- Member States will be allowed to introduce exceptional derogations from the dose limits in accordance with the procedure laid down in Title X.

As regards the protection of pregnant women exposed at work, the relevant provisions have been modified in order to protect the foetus as if it were a member of the public.

In the case of nursing mothers, the competent authorities must, if necessary, establish dose constraints so as to provide the child with better protection against radioactive contamination.

- 6.4 Title V deals with methods used for the calculation of effective dose and refers to Annexes II and III.
- 6.5 In the proposed Directive, as in the existing version, the fundamental principles governing operational protection of exposed workers are set out in Title VI. They are also applicable to apprentices and students, since these two groups may engage in activities involving exposure. Compared with the existing Directive, the classification of areas (controlled and supervised) according to the level of risk associated with them has been preserved, whilst the criteria for making this classification have been simplified and additional responsibilities have been assigned to the employer/operator.

As regards the classification of exposed workers into category A and category B workers, this is no longer found in the latest ICRP recommendations but the Commission's proposal has retained it since it has proved its value over a period of several years, particularly where the organisation of radiation protection is concerned.

6.6 There are special provisions in the proposed Directive (Title VII) concerning exposure to natural radiation sources at work. Title VII requires that the Member States should first carry out surveys to identify in which areas of their territory and for which practices and working conditions workers are exposed in a significant manner to gamma radiation or radon from natural sources. On the basis of the results of these surveys, the measures described in the new Directive must be taken. As

examples of activities to be the object of such surveys and as a result of which measures may need to be taken, the proposal mentions operations in mines or other underground workplaces, operations with materials containing significant traces of natural radionuclides, and the operation of jet aircraft in flight.

- 6.7 Title VIII sets out the fundamental principles governing operational protection of the population in normal circumstances. Among other things, this Title provides for the establishment in the Member States of a system of inspection to keep under review the radiation protection of the population and check compliance with the national regulations implementing the new Directive. In this connection, a number of obligations are placed on the operator/employer.
- 6.8 Title IX represents an expansion of its earlier counterpart, owing to the experience gained from the accident at Chernobyl. It now covers potential, accidental and emergency exposures. The Member States are required to consider the development of all radiological emergencies on their territory before, during and after the event.

The Member States must also establish relations with other Member States and with third countries to ensure that they are better prepared for any eventuality and that measures taken to deal with any emergency are harmonised.

- 6.9 Title X contains the final provisions, the main points of which are as follows:
 - A procedure has been laid down for modifying the lists of practices included in Articles 3 and 4 and for allowing exceptional derogations from the dose limits.
 - Each Member State shall report to the Commission every two years on the implementation of the Directive, so enabling the Commission to prepare reports for the European Parliament, the Council and the Economic and Social Committee;

- Member States must transpose the Directive into national law within the deadline specified;
- the above deadline is meant to be a single time limit, any time limits appearing in the previous Directives being superseded.

6.10 Annexes

The proposal for a Directive refers to values set out in its three annexes, which have been revised in line with the provisions of the proposed Directive.

in the existing Directive the As regards Annex 1. exemptions from the system of reporting/authorisation have been defined in terms of total activity (values ranging 5 x 10³ and 5 x 10⁶ Bg spread over four radiotoxicity categories, as set out in Annex I to the existing Directive) and in terms of mass specific activity (100 Bq/g for artificial radionuclides and 500 Bg/g for solid natural radionuclides). It was recognised that this type of classification did not fully reflect the potential hazard to workers and to members of the public associated the use, misuse and disposal of radioactive substances. Consequently, the revised version of Annex 1 sets out nuclide-specific activity levels and mass specific activity values, on a provisional basis at this stage.

Annex II includes the radiation and tissue weighting factors in accordance with the latest recommendations of the ICRP. However, re-examination of relationships between dosimetric quantities and progress in radiation research may lead to modification of these values in the future.

The derived limits which appeared in Annex III to the existing Directive need to be revised to take account of the new tissue weighting factors and new metabolic data and to achieve greater consistency with the proposed dose limits. Nevertheless, since a re-assessment of metabolic models is in progress, and it would not be appropriate to suspend the revision of the Basic Standards, nor to embark upon a revision of the tables at this moment, Annex III indicates provisionally the methods to be applied.

Amended proposal for a

COUNCIL DIRECTIVE

laying down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation

THE COUNCIL OF THE EUROPEAN COMMUNITIES

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,

Having regard to the opinion of the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee(2),

Whereas the Treaty provides in Article 2b that uniform basic safety standards to protect the health of workers and of the general public shall be laid down;

^{(1) 0.}J. n° ...

⁽²⁾ O.J. n° C 108, 19.4.1993, p. 48.

Whereas Article 30 of the Treaty defines the basic standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation as:

- (a) maximum permissible doses compatible with adequate safety;
- (b) maximum permissible levels of exposure and contamination;
- (c) the fundamental principles governing the health surveillance of workers;

Whereas each Member State is required by Article 33 to lay down the appropriate provisions, whether by legislation, regulation or administrative action, to ensure compliance with the basic standards which have been established and shall take the necessary measures with regard to teaching, education and vocational training;

Whereas in order to perform its task the Community laid down basic standards for the first time in 1959 pursuant to Art. 218 of the Treaty (3), and has since revised (4)

⁽³⁾ O.J. n. 11, 20.2.1959, p. 211/59

^{(4) -} Council Directive of 5.3.1962 (0.J. of 6.7.1962);

Council Directive 66/45/EURATOM of 27.10.1966 (0.J. of 26.11.1966);

Council Directive 76/579/EURATOM of 1.6.1976 (O.J. L-187 of 12.7.1976);

Council Directive 79/343/EURATOM of 27.3.1979 (0.J. L-83 of 3.4.1979);

Council Directive 80/836/EURATOM of 15.7.1980 (O.J. L-246 of 17.9.1980);

Council Directive 84/467/EURATOM of 3.9.1984 (0.J. L-265 of 5.10.1984).

and supplemented them(5); which is a second of the second of them (5);

Whereas the development of scientific knowledge concerning radiation protection makes it necessary to revise the basic standards and to lay them down in a new legal instrument, replacing Directives 76/579/Euratom and 80/836/Euratom;

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- Directive 90/641/EURATOM of 4.12.1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled aresas (0.J. L-349 of 13.12.90);
- Regulation 87/3954/EURATOM of 22.12.1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency (0.J. L-371 of 30.12.87);
- Directive 92/3/EURATOM of 3.2.1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community (0.J. L-35 of 12.2.92);
- Regulation 93/1493/EURATOM of 8.6.1993 on shipments of radioactive substances between Member States (0.J. L-148 of 19.6.93);
- Recommendation 90/143/EURATOM of 21.2.1990 on the protection of the public against indoor exposure to radon (0.J. L-80 of 27.3.90);
- Council Decision 87/600/EURATOM of 14.12.1987 on Community arrangements for the early exchange of information in the event of a radiological emergency (0.J. L-371 of 30.12.87).

^{(5) -} Directive 84/466/EURATOM of 3.9.1984 laying down basic measures for radiation protection of persons undergoing medical examination or treatment (0.J. L-265 of 5.10.84);

Directive 89/618/EURATOM of 27.11.1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency (0.J. L-357 of 7.12.89);

Whereas this development has given rise to a reappraisal of the risks involved in the use of ionizing radiation, to the recognition of the need to reinforce the protection of health at the workplace against the dangers arising from exposure to natural radiation sources and to an increased awareness of the need to provide for precautionary measures to be applied in the event of an accident;

Whereas the basic standards to be laid down within the Community have to take due account of the requirements of the nuclear common market as set out in Title Two, Chapter IX of the Treaty and the internal market created under the Treaty establishing the European Economic Community, subject to Art. 232 (2) of that Treaty;

Whereas, in order to attain the objectives set out above, it is necessary to define the scope of the basic standards by including the placing on the market of radioactive substances, the operation of certain electrical equipment and exposure to natural radiation sources at the workplace;

Whereas the Member States, in order to ensure compliance with the basic standards, are required to prohibit certain practices involving a hazard from ionizing radiation or, according to the degree of hazard involved, to submit them to a system of reporting and prior authorization;

Whereas a system of radiation protection for practices should be based on the principles of justification of exposure, optimisation of protection and dose limitation taking into account the particular situation of the different groups of persons exposed such as workers, nursing and pregnant women, apprentices, students and members of the public; whereas to this end limitations of doses and limits derived therefrom must be fixed;

Whereas the operational protection of exposed workers, apprentices and students requires the implementation of measures at the workplace; whereas these measures must include the prior evaluation of the hazard involved, the classification of workplaces and workers, monitoring of areas and working conditions as well as medical surveillance;

Whereas it has become apparent that workers should be protected against exposure to natural radiation sources at their workplace; whereas to this end the Member States should be required to carry out surveys to identify the areas, practices and working conditions where workers are exposed, in a significant manner, to such sources; whereas, on the basis of such surveys, the Member States should take the appropriate protective measures;

Whereas the operational protection of the population in normal circumstances requires the establishment of a system of inspection to keep under review the radiation protection of the population and to check compliance with the basic standards;

Whereas, owing to the experience gained from the Chernobyl accident, the Member States should consider the development of all radiological emergencies on their territory before, during and after an accident and should take all necessary measures to reduce their consequences; whereas cooperation between Member States and with third countries has proved capable of assuring increased preparedness;

HAS ADOPTED THIS DIRECTIVE:

TITLE I

DEFINITIONS

Article 1

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

Absorbed dose (D): the energy absorbed per unit mass

 $D = d\overline{\varepsilon}$

Where - de is the mean energy imparted by ionizing 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.

Accelerator: apparatus or installation emitting jonizing radiation with an energy higher than 1 Mev.

<u>Accident</u>: an unintended event that causes damage to a source or that results or could result in exposure of members of the public in excess of the appropriate intervention level or in exposure of workers above the appropriate dose limits.

<u>Accidental exposure</u>: a fortuitous and involuntary exposure of individuals as a result of an accident.

Activation: process through which a stable nuclide is transformed into a radionuclide by irradiating with particles or high-energy gamma rays the material in which it is contained.

Activity(A): the activity A, of an amount of a radionuclide in a particular energy state at a given time, 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:

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

The unit for activity is the becquerel.

<u>Apprentice:</u> a person receiving training for employment involving exposure to ionizing radiation and instruction within an undertaking.

Approved medical practitioner: a medical practitioner responsible for the medical surveillance of workers of category A as defined in Article 21, whose capacity to act in this respect is recognised by the competent authorities.

Approved occupational health services: a body or bodies responsible for the radiation protection and medical surveillance of exposed workers as defined in Article 21 whose capacity to act in this respect is recognised by the competent authorities.

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

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

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

$$E(\tau) = \sum_{i} w_{i}H_{i}(\tau)$$

In specifying $E(\tau)$, τ is given in the number of years over which the integration is made. The unit for committed effective dose is the sievert.

Committed equivalent dose $(H_T(r_c))$: the integral over time (t) of the equivalent dose rate in tissue or organ T that will be received by an individual resulting from an intake. It is given by:

for an intake at time $\boldsymbol{t_{\text{O}}}$ where

- $H_T(t)$ is the relevant equivalent dose rate in organ or tissue T at time t
- ~ is the time over which the integration is performed.

In specifying H_{T} (τ), τ is given in years. When 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.

<u>Consignee</u>: any natural or legal person to whom a radioactive substance is shipped.

<u>Controlled area</u>: an area subject to special rules for the purpose of protection against ionizing radiation or of preventing the spread of radioactive contamination, to which access is controlled and restricted to workers who have received appropriate instructions.

<u>Dose constraint</u>: a restriction on the doses to individuals resulting from defined sources for the purposes of optimisation of protection.

<u>Dose limits</u>: the limits laid down in Title IV for the doses resulting from the exposure of workers, apprentices and students, and members of the public to ionizing radiation from the practices covered by this Directive.

<u>Effective dose (E):</u> the sum of the weighted equivalent doses in all the tissues and organs of the body specified in Annex II from internal and external irradiation. It is defined by the expression:

$$E = \sum_{T} w_{T}H_{T} = \sum_{T} w_{T} \sum_{T} w_{R} D_{T,R}$$

where

- $D_{T,R}$ is the organ absorbed dose from radiation R,
- WR is the radiation weighting factor and
- WT is the tissue weighting factor for tissue or organ T.

The appropriate w_T and w_R values are specified in Annex II. The unit for effective dose is the sievert.

Emergency exposure: an exposure justified in abnormal conditions in the interests of bringing help to endangered individuals, preventing exposure of a large number of people or saving a valuable undertaking or source, whereby one of the dose limits laid down for exposed workers could be exceeded.

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

where

- $D_{T,R}$ is the absorbed dose in tissue or organ T from radiation R and
- 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 \mathbf{w}_{R} values are specified in Annex II. The unit for equivalent dose is the sievert.

<u>Exposed workers</u>: persons, aged 18 years or more, subject to an exposure incurred at work from practices covered by this Directive and liable to result in doses exceeding one or other of the dose limits for members of the public.

Exposure: the process of being exposed to ionizing radiation.

Gray (Gy): the special name of the unit of absorbed dose. One gray is equal to one Joule per kilogram:

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

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<u>Harm</u>: clinically observable deleterious effects that are expressed in individuals or their descendants. It includes the probability of such effects.

<u>Holder</u>: any natural or legal person who, before carrying out a shipment of radioactive substances, has the legal responsability under national law for such materials and intends to carry out a shipment to a consignee.

<u>Intake</u>: the activities of radionuclides entering the body from the external environment.

<u>Intervention</u>: a human activity that decreases the overall exposure of individuals to radiation by removing existing sources, modifying existing exposure pathways or reducing the number of individuals exposed to an existing source.

<u>Intervention level</u>: a value of equivalent dose, effective dose or a derived value, at which intervention measures should be considered. The dose or derived value is solely that associated with the exposure pathway to which the intervention measure is to be applied.

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<u>lonizing radiation</u>: the transfer of energy in space in the form of electro-magnetic waves or particles with quantities of energy higher than 12.4 eV corresponding to a wavelength of 100 nanometer or a frequence of 3x10(15) Hertz.

<u>Members of the public:</u> individuals in the population, excluding exposed workers, apprentices and students during their working hours.

<u>Natural radiation sources</u>: sources of ionizing radiation from natural terrestrial or cosmic origin.

Other relevant sources: any radioactive substance not being a sealed source intended for direct or indirect use of the ionizing radiation it emits for medical, veterinary, industrial, commercial, research or agricultural applications.

<u>Placing on the market</u>: any supply, whether in return for payment or free of charge, other than for storage followed by exportation from the territory of the Community or by disposal. Importation of a radioactive substance or products containing such substances into the territory of the Community shall be deemed to constitute placing on the market for the purposes of this Directive.

<u>Potential exposure</u>: exposure which has a probability of occurrence and magnitude that may be predicted for an event such as an accident or failure of equipment.

<u>Practice</u>: a human activity that can increase the overall exposure of individuals to radiation from a source.

Qualified expert: a person having the knowledge and training needed to carry out physical, technical, or radiochemical tests and to assess doses, and to give advice in order to ensure effective protection of individuals and correct operation of protective equipment, whose capacity to act as a qualified expert is recognised by the competent authorities.

<u>Radiological emergency</u>: the consequence of an accident for which Member States decide to take measures of a widespread nature in order to protect the public.

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Radioactive contamination: the contamination of any material, surface or environment or of an individual by radioactive substances. In the specific case of the human body, this radioactive contamination includes both external skin contamination and internal contamination, irrespective of route of intake.

Radioactive substance: any substance that contains one or more radionuclides, the activity or the concentration of which cannot be disregarded as far as radiation protection is concerned.

Reference group of the population: a group comprising individuals whose exposure to a source is reasonably uniform and representative of that of the individuals in the population who are the most highly exposed to that source.

<u>Sealed source:</u> a source whose structure is such as to prevent, under normal conditions of use, any dispersion of the radioactive substances into the environment.

<u>Shipment</u>: the transport operations from the place of origin to the place of destination, including loading and unloading, of radioactive substances.

<u>Sievert (Sv)</u>: the special name of the unit of equivalent and effective dose. One sievert is equivalent to one joule per kilogram:

$$1 \text{ SV} = 1 \text{ J Kg}^{-1}$$

<u>Source</u>: an apparatus, substance or installation capable of emitting ionizing radiation or radioactive substances, other than natural radiation sources.

<u>Supervised area</u>: an area in which the working conditions are kept under review but special arrangements such as those enforced in controlled areas are not normally needed.

TITLE II

SCOPE

Article 2

This Directive shall apply to any practice or intervention which involves a hazard from ionizing radiation, notably:

- a) the production, processing, handling, use, holding, storage, transport, placing on the market, exportation and disposal of radioactive substances;
- b) the operation of any electrical equipment emitting ionizing radiation and containing components operating at a potential difference of more than 5 kV;
- c) exposure to natural radiation sources at work
 - (i) in uranium mines; and
 - (ii) in other workplaces as specified in Title VII.

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REPORTING AND AUTHORISATION

Article 3

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- 1. Each Member State shall make it compulsory for each person who or undertaking which carries out the practices referred to in Article 2 to report those practices.
- 2. However, no reporting shall be required for the following practices:

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- (a) the use of radioactive substances or their subsequent disposal if the quantities involved do not exceed in total the values given in column 2 of table A in Annex I; or
- (b) the use of radioactive substances or their subsequent disposal if the concentrations of activity per unit mass do not exceed the values given in column 3 of table A in Annex I; or
- (c) the use of apparatus containing radioactive substances exceeding the quantities or concentration values specified in (a) or (b), provided that:
 - 1. it is of a type approved by the competent authority of the Member State; and

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- it is constructed in the form of sealed sources ensuring effective protection against any contact with the radioactive substances and against any leakage of them; and
- 3. It does not cause, in normal operating conditions, a dose rate exceeding $1 \, \mu \text{SV}$ h⁻¹ at a distance of 0.1 m from any accessible surface of the apparatus; or

- (d) the operation of any electrical equipment to which this Directive applies, provided that:
 - it is of a type approved by the competent authority of the Member State; and
 - 2. It does not cause, in normal operating conditions, a dose rate exceeding $1 \, \mu \text{SV} \, h^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus; or
- (e) the operation of any cathode ray tube intended for the display of visual images provided that it does not cause, in normal operating conditions, a dose rate exceeding 1 μ Sv h⁻¹ at a distance of 0.1 m from any accessible surface of the apparatus; or
- (f) the occupancy of dwellings and other exposures to natural sources, without prejudice to Article 2 (c).
- 3. The list of practices, laid down in paragraph 2, may be revised in accordance with the procedure laid down in Article 56.

Article 4

Authorization

- 1. Prior authorization shall be required for the following practices:
- (a) the construction, operation and decommissioning of any undertaking of the nuclear fuel cycle;
- (b) the disposal of radioactive substances or the recycling of materials containing radioactive substances, arising from any industrial, medical, veterinary or research undertaking, unless conditions laid down by the competent authorities are met;

- (c) the deliberate addition of radioactive substances in the production and manufacture of medicinal products and consumer goods and the placing on the market of such goods;
- (d) the deliberate administration of radioactive substances to persons and animals for the purpose of medical or veterinary diagnosis, treatment or research;
- (e) the use of X-ray sets or radiation sources containing radioactive substances for industrial radiography or processing of products and the use of accelerators except electron microscopes:
- (f) the use of accelerators, X-ray sets or radioactive sources for the exposure of persons for medical treatment or research.
- 2. Prior authorization may be required for other practices than those listed in paragraph 1, to be determined in accordance with the procedure laid down in Article 56.
- 3. Authorizations may be issued for a continued practice and cover the use of several radiation sources over a specified period of time. They may be renewable.

Article 5

Prohibited practices

The deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics, the deliberate activation of such goods and their placing on the market shall be prohibited.

Article 6

Shipment of radioactive substances

- 1. Each Member State shall make arrangements to ensure that shipments of radioactive substances within its territory can be made only to consignees which have complied with all applicable provisions implementing this Directive and with relevant national requirements for use, treatment, handling, safe storage or disposal of such radioactive substances.
- 2. A holder of sealed sources who intends to carry out a shipment of such sources to a consignee in another Member State, or to arrange for such a shipment to be carried out, shall obtain a prior written declaration by the consignee of the sealed sources to the effect that the consignee has complied, in the Member State of destination, with all applicable provisions implementing this Directive and with relevant national requirements for use, treatment, handling, safe storage or disposal of that class of source.

The declaration shall be sent by the consignee to the competent authorities of the Member State to which the shipment is to be made. Receipt of the declaration shall be acknowledged thereon by the competent authority and the declaration shall then be sent by the consignee to the holder.

- 3. A holder of sealed sources or other relevant sources who has carried out a shipment of such sources to a consignee in another Member State, or arranged for such a shipment to be carried out, shall, within 21 days of the end of each calendar quarter, provide the competent authorities in the Member State of destination with the following information in respect of deliveries during the quarter:
 - names and addresses of consignees;
 - the total activity per isotope delivered to each consignee and the number of such deliveries made;
 - the highest single quantity of each isotope delivered to each consignee;
 - the type of substance: sealed source or other relevant source.

TITLE IV

SYSTEM OF RADIOLOGICAL PROTECTION FOR PRACTICES

CHAPTER I

GENERAL PRINCIPLES

Article 7

- 1. Each Member State shall establish and require the application of a system of radiological protection for practices based on the following general principles:
- (a) all practices resulting in exposure to ionizing radiation shall be justified in advance by, and kept under review as to the benefits which they produce;
- (b) all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account; generic dose constraints for particular types of practice shall be established by the competent authorities:
- (c) without prejudice to Article 13, the sum of the doses from all relevant practices shall not exceed the dose limits laid down in this Title for exposed workers, apprentices, students and members of the public.
- 2. The principles set out in paragraph 1 (a) and (b) shall apply to all exposures to ionizing radiation including medical exposures. The principle set out in paragraph 1 (c) shall not apply to any of the following exposures:

- (a) the exposure of individuals as part of their own medical diagnosis or treatment;
- (b) emergency exposures, without prejudice to Article 55;
- (c) exposures from natural sources other than in uranium mines and as specified in Title VII;
- (d) the exposure of individuals knowingly and willingly helping (other than as part of their occupation) in the support and comfort of patients undergoing medical diagnosis or treatment, either in a hospital or at home, without prejudice to paragraph 3;
- (e) the exposure of volunteers participating in medical and biomedical research programmes, without prejudice to paragraph 3.
- 3. Each Member State shall establish guidance on appropriate procedures to be applied to the individuals referred to at 2 (d) and 2 (e) above. It shall also establish appropriate constraints to be applied to the doses received by the volunteers referred to at 2 (e) above.

CHAPTER II

LIMITATION OF DOSES FOR EXPOSED WORKERS

Article 8

Age limit for exposed workers

Without prejudice 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.

Dose limits for exposed workers

- 1. The limit on effective dose for exposed workers shall be 20 mSv per year averaged over five consecutive years (100 mSv in five years), with the further provision that the effective dose shall not exceed 50 mSv in any single year. This limit applies to the sum of the relevant doses from external exposure in the specified period and the 50-year committed equivalent dose from intakes in the same period.
- 2. Without prejudice to paragraph 1, the following limits for the lens of the eye, skin and extremities apply:
- the limit for equivalent dose for the lens of the eye shall be 150 mSv in a year;
- the limit for 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;
- the limit for equivalent dose for the hands, forearms, feet and ankles shall be 500 mSv in a year.

Article 10

Protection of pregnant women

As soon as a pregnant woman, in accordance with national legislation and/or national practice, informs the management of her condition, the foetus shall be protected as far as possible as though it were a member of the public. The exposure of the pregnant woman in the context of her employment shall be as low as reasonably achievable and the conditions of her work shall be such as to ensure that the equivalent dose to the foetus does not exceed 1 mSv during the remainder of the pregnancy.

Protection of nursing mothers

- 1. Nursing mothers shall not be employed in work involving a risk of radioactive contamination.
- 2. Special attention will be paid to the possibility of bodily radioactive contamination. If necessary, the competent authorities shall establish relevant dose constraints.

CHAPTER III

LIMITATION OF DOSES 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 use sources shall be the same as the dose limits for exposed workers laid down in Article 9.
- 2. The limit for 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 use sources, shall be 6 mSv per year. The dose limits for the lens of the eye, skin and extremities shall be equal to three-tenths of the dose limits for exposed workers laid down in Article 9 (2).
- 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 specified in Article 14.

CHAPTER IV

SPECIALLY AUTHORIZED EXPOSURES

- 1. In exceptional circumstances, evaluated case by case, the competent authorities may, where some specific operation so requires, authorize individual occupational exposures of some identified workers exceeding the dose limits set out in Article 9, but within maximum exposure levels defined for the particular case by the competent authorities. The following conditions shall apply:
- a) only workers of category A defined in Article 23 may be subject to specially authorized exposures:
- b) pregnant and nursing women are excluded from such exposures;
- c) these exposures shall be carefully justified and thoroughly discussed with the management, the relevant workers, their representatives, the approved occupational health services or approved medical practitioner and the qualified expert;
- d) information about the risks involved and the precautions to be taken during the operation shall be provided;
- e) all doses related to such exposures shall be separately recorded in the health record.
- 2. The exceeding of dose limits as a result of specially authorized exposures shall not necessarily be a reason for excluding the worker from his usual occupation.

CHAPTER V

LIMITATION OF DOSES FOR THE POPULATION

Article 14

Dose limits for members of the public

- 1. Without prejudice to Article 15, the dose limits for members of the public shall be as laid down in paragraphs 2 and 3.
- 2. The limit for effective dose shall be 1 mSv in a year. However, in special circumstances, a higher effective dose may be authorized in a single year, provided that the average over five consecutive years does not exceed 1 mSv per year. This limit applies to the sum of the relevant doses from external exposure in the specified period and the 50-year committed equivalent dose (to age 70 years for children) from intakes in the same period.

3. In addition:

- The limit for the equivalent dose for the lens of the eye shall be 15 mSv in a year;
- the limit for 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;
- the limit for the equivalent dose for the hands, forearms, feet and ankles shall be 50 mSv in a year.

Exposure of the whole population

- 1. Each Member State shall ensure that the contribution to the exposure of the whole population from each practice is kept as low as reasonably achievable, taking account of the principles set out in Article 7 (1) (a) and (b).
- 2. The total of all such contributions shall be regularly assessed.
- 3. Each Member State shall regularly transmit the results of these assessments to the Commission.

CHAPTER VI

Article 16

If exceptional circumstances so require, dose limits different from those fixed in this Title may be authorised in accordance with the procedure laid down in Article 56. Such authorization shall be duly justified and limited in its scope, duration and geographical applicability.

TITLE V

ESTIMATION OF EFFECTIVE DOSE

Article 17

For the estimation of effective dose the methods referred to in this Title or any other appropriate methods shall be used.

- 1. For external radiation, the values given in Annex II may be used to estimate the relevant equivalent and effective doses.
- 2. For internal exposure from a radionuclide or from a mixture of radionuclides, the methods given in Annexes II and III may be used to estimate the effective doses.

TITLE VI

FUNDAMENTAL PRINCIPLES GOVERNING OPERATIONAL PROTECTION OF EXPOSED WORKERS, APPRENTICES AND STUDENTS

Article 19

Operational protection of exposed workers shall be based on the following principles:

- a) prior evaluation to identify the nature and magnitude of the radiation hazard to exposed workers;
- b) classification of workplaces into different areas, where appropriate, by reference to an assessment of the expected annual doses and of the expected frequency and possible consequences of minor mishaps;
- c) classification of workers into different categories;
- d) implementation of control measures and monitoring relating to the different areas and to the different working conditions;
- e) medical surveillance.

CHAPTER I

MEASURES FOR THE RESTRICTION OF EXPOSURE

SECTION 1

CLASSIFICATION AND DELINEATION OF AREAS

Article 20

Arrangements in workplaces

- 1. For the purposes of radiation protection and having regard to Titles II and VII, arrangements shall be made as regards all workplaces where there is a risk of exposure to ionizing radiation in excess of the relevant dose limits for members of the public. Such arrangements must be appropriate to the nature of the undertakings and sources and to the magnitude and nature of the hazards. The scope of the precautions and monitoring, as well as their type and quality, must be appropriate to the hazards associated with the work involving exposure to ionizing radiation.
- 2. A distinction shall be made between controlled areas and supervised areas.
- 3. Specific arrangements shall be made in controlled areas, wherever there is a significant risk of the spread of radioactive contamination.
- 4. The competent authorities shall establish guidance on the classification of controlled and supervised areas which is relevant to the particular circumstances.

5. The management shall keep under review the working practices in controlled and supervised areas.

Article 21

Requirements for controlled areas

The minimum requirements for a controlled area are that it shall be delineated and that access to it shall be controlled in accordance with written procedures provided by the management.

Article 22

Discretionary measures for controlled and supervised areas

Taking into account the nature and extent of radiation hazards in the controlled and supervised areas:

- a) signs indicating type of area, nature of the sources and their inherent hazards shall be displayed;
- b) working instructions appropriate to the radiation hazard associated with the sources and the operations involved shall be laid down;
- c) radiological environmental surveillance shall be organized in accordance with the provisions of Article 26.

These duties shall be within the competence of qualified experts.

SECTION 2

CLASSIFICATION OF EXPOSED WORKERS, APPRENTICES AND STUDENTS

Article 23

Categorisation of exposed workers

For the purposes of monitoring and surveillance, a distinction shall be made between two categories of exposed workers:

- category A: those who work routinely in controlled areas and those who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than three-tenths of the dose limits for the lens of the eye, skin and extremities laid down in Article 9 (2);
- category B: those exposed workers not classified as workers of category A, routinely working in supervised areas or occasionally in controlled areas.

Article 24

Information and training

Exposed workers, apprentices and students shall:

- (a) be informed of the health risks involved in their work;
 - be informed of the general radiation protection procedures and precautions to be taken and, in particular, those involved with operational and working conditions in respect of both the undertaking in general and each type of work station or job;

- be informed of the importance of complying with the technical,
 medical and administrative requirements;
- (b) in the case of women, be informed about the specific health risks; this information shall be supplemented in the event of a pregnancy;
- (c) be given training in the field of radiation protection.

SECTION 3

ARRANGEMENTS FOR THE RADIOLOGICAL PROTECTION OF EXPOSED WORKERS

- 1. An assessment of arrangements for the radiological protection of exposed workers shall be made by the management.
- 2. The examination and testing of protective devices and measuring instruments shall be the task of qualified experts and shall comprise:
- a) prior critical examination of plans for sources from the point of view of radiation protection:
- b) the acceptance into service of new or modified 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.

CHAPTER II

ASSESSMENT OF EXPOSURE

SECTION 1

MONITORING OF THE WORKPLACE

- 1. The radiological environmental surveillance, mentioned in Article 22, shall comprise:
- a) the measurement of dose rates, indicating if necessary the nature and the quality of the radiation in question;
- b) the measurement of the air concentration and surface density of contaminating radioactive substances, indicating if necessary their nature and their physical and chemical states.
- 2. The results of these measurements shall be recorded and shall be used, where appropriate, for estimating individual doses, as required in section 2.

SECTION 2

INDIVIDUAL MONITORING

Article 27

Monitoring - General

- 1. Individual monitoring shall be systematic for exposed workers of category A. This monitoring shall be based on individual measurements or, in cases where these are impossible or inadequate, on an estimate arrived at either from individual measurements made on other exposed workers or from the results of the surveillance of the workplace provided for in Article 26.
- 2. The competent authority shall provide general guidance for identifying those workers of category A liable to receive significant internal contamination, in order to set up an adequate system for their monitoring.
- 3. Category B workers shall be individually monitored when entering a controlled area. In other circumstances, where individual measurements have not been made, an estimate of individual doses shall be made from the results of the surveillance of the workplace provided for in Article 26.

Article 28

investigations after accidental exposures

In the case of accidental exposures an investigation shall be conducted with the aim of identifying the circumstances and assessing and recording the relevant doses and their distribution in the body.

Recording of emergency exposures

In the case of emergency exposures, the results of individual monitoring or dose assessments shall be separately and individually recorded.

Article 30

Reporting of results

- 1. The results of individual monitoring required by Articles 27 to 29 shall:
- be made available to the competent authorities, to the management and to the worker as required by Article 41 (2);
- be submitted to the approved occupational health services or approved medical practitioner. In the case of an accident or emergency the results shall be submitted as soon as possible.
- 2. It shall be the responsibility of the management to ensure compliance with the requirements of this Article.

SECTION 3

MONITORING FOR THE PURPOSE OF OPTIMISATION

Article 31

Provision shall be made for monitoring, in addition to that required by Articles 26 to 29, whenever it is needed to confirm optimisation of radiation protection.

SECTION 4

RECORDING OF RESULTS

- 1. A record, referred to as the radiation exposure section of the health record, and containing the results of the individual monitoring, shall be made for each exposed worker of category A.
- 2. The following shall be retained during the working life involving exposure to ionizing radiation of exposed workers, and afterwards until the individual has or would have attained the age of 75 years, but in any case not less than 30 years from the termination of the work involving exposure:
- a) a record of the exposures measured or estimated, as the case may
 be, of individual doses in pursuance of Articles 27 to 29;
- b) in the case of exposures referred to in Articles 28 and 29, the reports relating to the circumstances and to the action taken;

c) any results of workplace monitoring that have been specifically used in the assessment or estimation of the dose to an individual for whom an exposure record is required by virtue of subparagraph (a) above, shall be annexed to that exposure record and retained accordingly.

CHAPTER III

MEDICAL SURVEILLANCE OF EXPOSED WORKERS

Article 33

Taking into account the specific features of radiation protection and without prejudice to Articles 34 to 39, the medical surveillance of exposed workers shall be based on the principles that govern occupational medicine generally.

SECTION 1

MEDICAL SURVEILLANCE OF CATEGORY A WORKERS

Article 34

Medical surveillance

- 1. The medical surveillance of workers of category A shall be the responsibility of approved occupational health services or approved medical practitioners.
- 2. Medical surveillance shall include:

a) a pre-employment medical examination

The purpose of this examination shall be to determine the worker's fitness for the first post within the current employment for which he is being considered and for each new post involving a change in type of risk. It shall include an inquiry into his medical history including all known previous exposures to ionizing radiation resulting either from his employment or from medical examination and treatment, a clinical examination and any other investigations necessary for assessing his general state of health;

b) general medical surveillance

The approved occupational health services or approved medical practitioner must have access to any relevant information they require in order to ascertain the state of health of workers under surveillance and to assess the environmental conditions existing in the working premises insofar as they might affect the fitness of workers for the tasks assigned to them;

c) periodic reviews of health

The health of workers shall be reviewed as many times as the approved occupational health services or approved medical practitioner consider necessary to determine whether they remain fit to perform their duties. The nature of this review shall depend on the type of work and on the individual worker's state of health. The state of health of each worker shall be reviewed at least once a year.

3. The approved occupational health services or approved medical practitioner 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.

Medical classification

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

- fit;
- fit, subject to certain conditions;
- unfit.

Article 36

No worker may be employed for any period as a category A worker if the medical findings are unfavourable.

Article 37

Medical records

- 1. A medical section of the health record shall be opened for each worker of category A and kept up to date so long as he remains a worker of 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 from the termination of the work involving exposure to ionizing radiation.
- 2. The medical section of the health record shall include information regarding the nature of the employment, the results of the pre-employment medical examinations and the periodic reviews of health.

SECTION 2

EXCEPTIONAL MEASURES OF MEDICAL SURVEILLANCE

Article 38

Special medical surveillance

- 1. Special medical surveillance shall be provided in each case of exposure where the effective dose of 50mSv as laid down in Article 9 (1), or any of the other dose limits laid down in Article 9 (2), have been exceeded.
- 2. Subsequent conditions of exposure shall be subject to the agreement of the approved occupational health services or approved medical practitioner.

Article 39

Additional medical surveillance

In addition to the medical surveillance of exposed workers provided for in Articles 33 and 34, provision shall be made for any further examinations, decontamination measures or urgent remedial treatment considered necessary by the approved occupational health services or approved medical practitioner and for any further action in relation to the health protection of the exposed individual.

SECTION 3

APPEALS

Article 40

Each Member State shall lay down the procedure for appeal against the findings and decisions made in pursuance of Articles 35, 36 and 38.

CHAPTER IV

TASKS OF MEMBER STATES IN RESPECT OF PROTECTION OF EXPOSED WORKERS

- 1. Each Member State shall establish a system or systems of inspection to enforce the provisions introduced in compliance with this Directive and to initiate surveillance and intervention measures wherever necessary.
- 2. Each Member State shall require that workers have access on their request to the results of their individual monitoring measurements or assessments of their doses made as a result of workplace measurements or biological monitoring.
- 3. Each Member State shall make the necessary arrangements to recognise the capacity of:
 - the qualified experts;
 - the approved medical practitioners and approved occupational health services.

To this end, each Member State shall arrange for the training of such specialists.

- 4. Each Member State shall require the management of an undertaking to provide the worker with the means necessary for proper radiation protection. If necessary a specialized radiation protection unit shall be set up. This unit, which may be shared by several undertakings, shall be the responsibility of the management and shall not be part of any production or operation unit.
- 5. Each Member State shall facilitate the exchange within the European Community of all relevant information on the doses previously received by a worker, in order to control the further exposure of the worker and to perform the pre-employment medical examination required by Article 34.

CHAPTER V

OPERATIONAL PROTECTION OF APPRENTICES AND STUDENTS

- 1. Articles 10 and 19 shall also apply to the apprentices and students referred to in Article 12 (1) and 12 (2).
- 2. The operational protection of apprentices and students aged 18 years or over shall be equivalent to that of exposed workers of category A or B as appropriate.
- 3. The operational protection of apprentices and students aged between 16 and 18 years shall be equivalent to that of exposed workers of category B.

. TITLE VII

EXPOSURE TO NATURAL RADIATION SOURCES AT WORK

Article 43

Application

- 1. This Title shall apply to exposures to natural radiation sources at work to the extent that the competent authority has declared, following a survey carried out under Article 44 (1), that exposure to these natural radiation sources is subject to control.
- 2. In particular this Title shall apply to:
 - a) operations in identified workplaces where it has been declared that radon or gamma radiation needs attention such as: operations in spas, caves, mines (other than uranium mines) and other underground workplaces;
 - b) identified operations with and storage of materials not usually regarded as radioactive, but which contain significant traces of natural radionuclides;
 - c) identified operation of jet aircraft in flight.
- 3. Without prejudice to the above paragraphs, it does not apply to potassium-40 in the body, cosmic rays at ground level, and radionuclides in the earth's crust.

Surveys and protective measures

- 1. Each Member State shall require surveys to be carried out to identify in which areas of its territory, and for which practices and working conditions, workers are likely to experience significant exposures due to gamma radiation or radon gas and its daughters, or due to operations with materials containing significant amounts of natural radionuclides.
- 2. Member States shall, on the basis of such surveys and for each identified area, practice and working conditions, require, as appropriate:
- a) arrangements for measurements to assess the doses received by the workers;
 - b) the application at the workplace of the principles laid down in Article 7;
 - c) the establishment of regulations, standards or codes of practice for construction of new workplaces;
 - d) the opening of a radon section of the health record for workers.

Article 45

Protection of Aircrew

Each Member State shall make arrangements for the assessment of exposure of aircrew involved in the operation of jet aircraft, identified under Article 43 (2) (c), by their employers and shall, where appropriate, classify aircrew as exposed workers.

TITLE VIII

FUNDAMENTAL PRINCIPLES GOVERNING OPERATIONAL PROTECTION OF THE POPULATION IN NORMAL CIRCUMSTANCES

Article 46

Basic Principle

Each Member State shall take all necessary measures to ensure the protection of the population.

Article 47

Conditions for authorization of practices involving a hazard from ionizing radiation for the population

In cases decided upon by each Member State in the light of the extent of the exposure hazard involved, the competent authorities shall carry out the following tasks concerning practices subject to prior authorization:

- a) examination and approval of plans for undertakings involving an exposure hazard, and of the proposed siting of such undertakings within the territory concerned, from the point of view of radiation protection;
- b) acceptance into service of such new undertakings subject to adequate protection 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 waste.

Estimates of population doses

The competent authorities shall:

- 1. ensure that dose estimates from all sources are made for the whole population of the area concerned and for reference groups of the population in all places where such groups may occur;
- decide on the frequency of assessments and take all necessary steps to identify the reference groups of the population, taking into account the effective pathways of transmission of the radioactive materials;
- 3. ensure that, taking into account the radiological hazards, the estimates of the population doses include:
 - a) assessment of the doses due to external radiation, indicating,
 where appropriate, the quality of the radiation in question;
 - b) 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;
 - c) assessment of the doses that the reference groups of the population are liable to receive and specification of the characteristics of these groups;
- 4. require records to be kept relating to measurements of external exposure, estimates of intakes of radionuclides and radioactive contamination as well as the results of the assessment of the doses received by reference groups and by the population.

Inspection

- 1. Each Member State shall establish a system of inspection to:
- keep under review the radiation protection of the population;
- check compliance with the national regulations implementing this Directive.
- 2. Inspections of shipments of sealed sources and other relevant sources, pursuant to Community or national law, for the purpose of radiation protection shall be performed as part of the control procedures applied in a non-discriminatory manner throughout the territory of the Member State.

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Tasks within undertakings

- 1. Each Member State shall require the management responsible for practices as referred to in Article 2 to conduct them in accordance with the general principles of health protection of the population and in particular to carry out the following tasks within its undertaking:
- a) achieving and maintaining an optimal level of protection;
- b) checking the effectiveness of technical devices for protecting the environment and the population;
- acceptance into service, from the point of view of surveillance of radiation protection, of equipment and procedures for measuring exposure and radioactive contamination of the environment and the population;
- d) regular calibration of measuring instruments and regular checking that they are serviceable and correctly used.
- 2. The tasks provided for in paragraph 1 shall be the responsability of qualified experts.

TITLE IX

POTENTIAL, ACCIDENTAL AND EMERGENCY EXPOSURES

Article 51

Tasks of the competent authorities

- 1. Each Member State shall require that the possibilities of accidents and the potential exposures due to those accidents affecting undertakings or sources within its jurisdiction are considered and that intervention plans are drawn up and are tested, to an appropriate extent, at regular intervals.
- 2. In particular, intervention plans shall take into account the following aspects:
 - a) The general principles of radiation protection for intervention mentioned hereafter shall be respected:
 - the reduction in health detriment due to radiation, resulting from the reduction in dose, should be sufficient to justify the harm and costs, including social costs, of the intervention;
 - the form, scale and duration of the intervention should be optimised so that the benefit of the reduction in health detriment, less the detriment associated with the intervention, will be maximised;
 - dose limits, as laid down in Articles 9 and 14, do not apply to intervention. However, guidance on the situations in which intervention is appropriate will be given by the intervention levels adopted under sub-paragraph (c) below.

- b) Each Member State shall require provision to be made for interventions related to:
 - the source, to reduce or stop the direct radiation and emission of radionuclides;
 - the environment, to reduce the transfer of radioactive substances to individuals;
 - individuals, to reduce the accidental exposure and organize the treatment of victims.
 - c) Each Member State shall adopt intervention levels, taking account of any intervention levels established by Community legislation.
 - d) Each Member State shall arrange, where necessary, for the designation of special teams for technical, medical and health interventions on a national basis and for their training in accordance with Article 7 of Directive 89/618/Euratom. If necessary, these arrangements shall be made in cooperation with competent organizations in other States.
 - e) Each Member State shall provide for the organization of intervention in case of a major accident in or outside its territory.
 - f) Each Member State shall assess and record the consequences of any accident and the effectiveness of the intervention.

Cooperation with other States

- 1. Without prejudice to relevant Community legislation and international agreements, each Member State shall, in the event of a radiological emergency at an undertaking on its territory or likely to have radiological consequences on its territory, establish relations to obtain cooperation with any other Member State or non-member State which may be involved.
- 2. Each Member State shall require emergency plans to be drawn up in its territory in relation to possible radiological emergencies at undertakings outside its own territory, in accordance with the provisions of Article 51.
- 3. Each Member State shall seek to cooperate with other Member States or non-member States in relation to possible radiological emergencies at undertakings on its own territory, in order to facilitate the organization of radiological protection in these States, in accordance with the provisions of Article 51.

Article 53

Potential exposures

Each Member State shall, where appropriate:

 consider the probability and magnitude of potential exposures from practices carried out by persons and undertakings subject to the system of reporting or authorization laid down in Title III;

- seek to assess the spatial and temporal distribution of the radioactive substances dispersed following possible accidents, recognizing the increasing difficulties when the probability of occurrence of the accident decreases;
- establish technical standards for the undertakings or sources, intervention plans for the different kinds of accident and training of special emergency teams.

Tasks of management

- 1. Each Member State shall require the management to draw up plans for intervention within the undertakings under its responsibility.
- 2. Each Member State shall make provision for the immediate notification to its competent authorities, by the management responsible for the practice involved, of accidents occurring on its territory and require all appropriate actions to reduce the consequences.
- 3. Each Member State shall require that in the event of an accident the responsible management shall make an initial provisional assessment of the consequences of the accident and successive assessments based on subsequent measurements of radioactive contamination.

Emergency exposures

- 1. Each Member State shall make provision for situations where workers or intervention personnel involved in different kinds of intervention are liable to be subjected to emergency exposures resulting in doses in excess of the dose limits for exposed workers. To this end, each Member State shall establish exposure levels taking into account the technical obligations and the health risks; these levels shall be operational guides. An exposure above these special levels may be admitted exceptionally to save human lives and only for volunteers who are informed about the risks involved in their intervention.
- 2. Each Member State shall require monitoring and medical surveillance of the persons exposed in the emergency teams.

TITLE X

FINAL PROVISIONS

Article 56

Accelarated procedure

- 1. Where the procedure laid down in this Article is to be followed, the Commission shall submit to the Council a proposal, after consultation of the group of experts instituted under Article 31 of the Euratom Treaty.
- 2. The Council shall, acting by a qualified majority, decide upon the proposal within three months.
- . 3. The Commission shall examine any request for a proposal made by a Member State.

Article 57

Reports on implementation

- 1. Every two years, and for the first time on.....(date to be specified), each Member State shall forward to the Commission a report on the implementation of this Directive, including the results of the assessments made under Article 15.
- 2. On the basis of these reports, the Commission shall prepare a summary report for the European Parliament, the Council and the Economic and Social Committee.

Implementation in Member States law

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive on 31 December 1994. They shall immediately inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

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

Article 59

Repeals

Directives 76/579/Euratom and 80/836/Euratom and Regulation 93/1493/Euratom are repealed with effect from 31 December 1994.

Article 60

This Directive is addressed to the Member States.

Done at Brussels,.....199....

For the Council, The President,

ANNEX 1

Values of quantities and concentrations of radionuclides to be used for the application of Article 3.

- 1. Table A below presents the values of quantities and concentrations of activity per unit mass not to be exceeded in compliance with Articles 3 (a) and (b) respectively for the principal radioactive nuclides concerned.
- 2. For radionuclides not listed in Table A, the competent authority shall assign appropriate values for the quantities and concentrations of activity per unit mass where the need arises. Values thus assigned shall be complementary to those in Table A.
- 3. The values laid down in Table A apply to the total inventory of radioactive substances held by a person or undertaking at any point in time.
- 4. The values laid down in Table A column 3 for the concentration of activity per unit mass pertain to the use of moderate amounts of radioactive substances; they shall not be applied to other practices involving low levels of radioactivity unless it can be demonstrated that the same values are justified; levels laid down by the competent authorities for the general or specific authorization of waste disposal or of recycling shall be constrained so as to ensure that materials released to the environment shall not exceed the values specified in Table A.

- 5. Nuclides carrying the suffix '+' or 'sec' in Table A represent parent nuclides in equilibrium with their corresponding daughter nuclides as listed in Table B. In this case the values given in Table A refer to the parent nuclide alone but already take account of the daughter nuclide(s) present.
- 6. In all other cases of mixtures of more than one nuclide the requirement for reporting may be waived if the sum of the ratios for each nuclide of the total amount present divided by the value listed in Table A is less than or equal to 1. This summation rule also applies to activity concentrations where the various nuclides concerned are contained in the same matrix.

1. Table A: Values of quantities and of concentrations of activity per unit mass not to be exceeded in compliance with Article 3 (2) (a) and (b) respectively, for the principal radioactive nuclides listed below:

Nuclide	Quantity (Bq)	Concentration (kBq/kg)
H-3	108	106
Be-7	10 ⁸	10 ²
C-14	10 ⁶	104
0-15	10 ⁹	10 ³
F-18	10 ⁵	10
Na-22	10 ⁵	1
Na-24	105	1
Si-31	10 ⁵	10 ²
P-32	105	10 ²
P-33	107	105
S-35	10 ⁷	105
C1-36	10 ⁵	103
C1-38	10 ⁵	1
Ar-37	10 ¹²	10 ⁷
Ar-41	10 ⁹	103
K-42	106	10
K-43	10 ⁵	10
Ca-45	106	10 ⁴ .
Ca-47	105	10
Sc-46	10 ⁶	1
Sc-47	10 ⁶	10
Sc-48	10 ⁵	1
V-48	10 ⁵	. 1
Cr-51	10 ⁷	10 ²
Fe-52	105	10
Fe-55	10 ⁶	104
Fe-59	10 ⁶	1
Mn-51	105	10
Mn-52	105	1
Mn-52m	105	1

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Nuclide	Quantity (Bq)	Concentration (kBq/kg)
Mn-53	108	104
Mn-54	10 ⁶	10
Mn-56	10 ⁵	· 1
Co-55	10 ⁵	1
Co-56	10 ⁵	1
Co-57	10 ⁵	10
Co-58	10 ⁵	10
Co-58m	107	10 ⁴
Co-60	104	1
Co-60m	10 ⁶	103
Co-61	105	10
Co-62m	10 ⁵	1
Ni-59	10 ⁷	104
Ni-63	10 ⁷	105
Ni-65	105	10
Cu-64	106	10
Zn-65	105	10
Zn-69	105	102
Zn-69m	106	10
Ge-71	109	10 ³
Ga-72	105	1
As-73	106	103
As-74	105	10
As-76	10 ⁵	10
As-77	10 ⁵	10 ²
Se-75	10 ⁶	10-
Br-82	105	1
Kr-74	109	103
Kr-76	10 ¹⁰	103
Kr-77	109	103
Kr-79	10 ¹⁰	104
Kr-79 Kr-81	10 ¹¹	105
	1011	105
Kr-83m		
Kr-85	10 ¹⁰	10 ⁶

Nuclide	Quantity (Bq)	Concentration (kBq/kg)
Kr-85m	10 ¹⁰	104
Kr-87	109	103
Kr-88	109	10 ³
Sr-85	106	10
Sr-85m	106	10
Sr-87m	106	10
Sr-89	105	10 ²
Sr-90+	104	10
Sr-91	105	10
Sr-92	105	1
Y-90	10 ⁵	10
Y-91	105	10 ²
Y-91m	10 ⁷	10.
Y-92	105	10
Y-93	105	. 10
Rb-86	105	10
Zr-93+	106	103
Zr-95	10 ⁶	10
Zr-97+	105	10
Nb-93m	107	10 ³
Nb-94	10 ⁶	1 .
Nb-95	10 ⁶	10
Nb-97	105	10
Nb-98	105	1
Tc-96	106	1
Tc-96m	108	10 ²
Tc-97	107	103
Tc-97m	106	103
Tc-99	106	104
Tc-99m	10 ⁷	10
Mo-90	105	10
Mo-93	107	10 ³
Mo-99	105	10
Mo-101	105	1

Nuclide	Quantity (Bq)	Concentration (kBq/kg)
Ru-97	10 ⁷	10
Ru-103	106	10
Ru-105	105	10
Ru-106+	10 ⁵	10
Rh-103m	108	10 ³
Rh-105	106	10 ²
Pd-103	10 ⁷	103
Pd-109	105	10 ²
Cd-109	10 ⁶	103
Cd-115	10 ⁵	10
Cd-115m	105	102
Ag-105	106	10
Ag-110m	10 ⁶	1
Ag-111	105	10 ²
In-111	106	10
In-113m	105	10
In-114m	105	10 ²
ln-115m	105	10
Sn-113	106	10 ²
Sn-125	105	10
Sb-122	105	10
Sb-124	105	1
Sb-125	106	10
I-123	107	10
I-125	105	102
I-126	10 ⁵	10
I-129	104	102
I-130	105	1
I-131	105	10
I-132	105	1
1–133	105	10
I-134	10 ⁵	1
1–135	10 ⁵	1

Nuclide	Quantity (Bq)	Concentration (kBq/kg)
Cs-129	10 ⁶	10
Cs-131	10 ⁶	102
Cs-132	10 ⁶	10
Cs-134m	10 ⁵	10 ²
Cs-134	105	1
Cs-135	10 ⁶	104
Cs-136	10 ⁵	. 1
Cs-137+	10 ⁵	10
Cs-138	104	1
Te-123m	10 ⁶	10
Te-125m	10 ⁶	10 ²
Te-127	10 ⁵	102
Te-127m	106	10 ³
Te-129	105	10
· Te-129m	10 ⁵	102
Te-131	105	10
Te-131m	10 ⁶	1 .
Te-132	106	10
Te-133	105	10
Te-133m	10 ⁵	. 1
Te-134	105	. 10
Xe-131m	1010	105
Xe-133	1010	104
Xe-135	1010	104
Ce-139	10 ⁶	10
Ce-141	10 ⁶	102
Ce-143	10 ⁵	10
Ce-144+	10 ⁵	10
Ba-131	10 ⁶	10
Ba-140+	10 ⁵	1
La-140	105	1
Pr-142	10 ⁵	10
Pr-143	106	10 ²

	T	· ·
Nuc i i de	Quantity (Bq)	Concentration (kBq/kg)
Pm-147	10	104
Pm-149	105	10 ²
Nd-147	105	10
Nd-149	105	10
Sm-151	10 ⁷	105
Sm-153	105	102
Eu-152	106	1
Eu-152m	105	10
Eu-154	106	1
Eu-155	106	10 ²
Gd-153	106	10
Gd-159	105	10 ²
Tb-160	105	1
Dy-165	105	102
Dy-166	106	102
Ho-166	105	10
Er-169	106	104
Er-171	105	10
Tm-170	106	102
Tm-171	10 ⁷	104
Yb-175	106	102
Lu-177	106	102
Ta-182	105	1
Hf-181	105	10
W-181	107	102
W-185	106	104
W-187	105	10
Re-186	105	. 10 ²
Re-188	105	10
0s-185	106	10
0s-191	106	102
Os-191m '	106	103
0s-193	105	102
Ir-190	106	1 · .

Nuclide	Quantity (Bq)	Concentration (kBq/kg)
lr-192	10 ⁵	10
lr-194	10 ⁵	10
Pt-191	10 ⁶	10
-Pt-193m	106	102
Pt-197	10 ⁵	102
Pt-197m	105	102
Hg-197	106	10 ²
Hg-197m	10 ⁵	102
Hg-203	10 ⁶	10
Au-198	10 ⁵	10
Au-199	106	102
T1-200	106	1
TI-201	106	10
T1-202	106	10
T1-204	105	102
Bi-206	105	1
Bi-207	106 .	1
Bi-210	105	102
Bi-212+	105	1
Pb-203	106 :	10
Pb-210+	103	10
Pb-212+	105	1
Po-203	105	, 1
Po-205	106	1
Po-207	106	1
Po-210	103	10 i
At-211	106	102
Rn-220+	107	104
Rn-222+	108	1
Ra-223+	104	10
Ra-224+	104	1
Ra-225	104	102

Nuc I i de	Quantity (Bq)	Concentration
•		(kBq/kg)
Ra-226+	103	1
Ra-227	105	10
Ra-228+	104	10
Th-226+	106	102
Th-227	104	10
Th-228+	104	1
Th-229+	103	10
Th-230	103	10
Th-231	10 ⁷	102
Th-232sec	102	1
Th-234+	105	10
Ac-227+	103	10
Ac-228	10 ⁵	10 '
Pa-230	106	10
Pa-231	10 ³	10
Pa-233	106	10
U-230+	104	102
U-231	106	10 ²
U-232+	10 ³	1
U-233	104	10 ²
U-234	10 ⁴	10 ²
U-235+	104	102
U-236	104	102
U-237	10 ⁵	10
U-238+	104	10
U-238sec	10 ³	1
U-239	105	102
U-240	106	103
U-240+	105	1
Np-237+	103	10
Np-239	10 ⁶	10

Nuclide	Quantity (Bq)	Concentration (kBq/kg)
Np-240	105	1
Pu-234	108	102
Pu-235	108	102
Pu-236	104	102
Pu-237	10 ⁷	102
Pu-238	103	10
Pu-239	103	10
Pu-240	103	10
Pu-241	105	103
Pu-242	103	10
Pu-243	106	10 ²
Pu-244	. 103	10
Am-241	103	10
Am-242	106	102
Am-242m+	103	102
Am-243+	103	10
Cm-242	10 ⁵	103
Cm-243	103	10
Cm-244	104	102
Cm-245	103	10
Cm-246	103	10
Cm-247	103	10
Cm-248	10 ³	10
Bk-249	10 ⁶	104
Cf-246	106	103
Cf-248	104	102
Cf-249	10 ³	10
Cf-250	104	102
Cf-251	10 ³	10
Cf-252	104	102
Cf-253	10 ⁶	104
Cf-254	103	10

Quantity (Bq)	Concentration
	(kBq/kg)
105	103
104	102
105	10
10 ⁷	104
106	103
	10 ⁵ 10 ⁴ 10 ⁵ 10 ⁷

Table B: List of nuclides in secular equilibrium as referred to in pt. 5

Parent nuclide	Daughter nuclides
Sr-80+	Rb-80
Sr-90+	Y-90
Zr-93+	Nb-93m
Zr-97+	Nb-97
Ru-106+	Rh-106
Cs-137+	Ba-137
Ce-134+	La-134
Ce-144+	Pr-144
Ba-140+	La-140
Bi-212+	TI-208,Po-212
Pb-212+	Bi-212,T1-208,Po-212
Rn-220+	Po-216
Rn-222+	Po-218,Pb-214,Bi-214
Ra-223+	Rn-219,Po-215,Pb-211,Bi-211
Ra-224+	Rn-220,Po-216,Pb-212,Bi-212,Tl-208,
	Po-212
Ra-226+	Rn-222,Po-218,Pb-214,Bi-214,Pb-210,
	Bi-210,Po-210
Ra-228+	Ac-228
Th-226+	Ra-222,Rn-218, Po-214
Th-228+	Ra-224,Rn-220,Po-216,Pb-212,Bi-212,
·	TI-208,Po-212
Th-229+	Ra-225,Ac-225,Fr-221,At-217,Bi-213,
	Po-213,Pb-209
Th-232sec	Ra-228,Ac-228,Th-228,Ra-224,Rn-220,
	Po-216,Pb-212,Bi-212,TI-208,Po-212

Parent nuclide	Daughter nuclides
Th-234+	Pa-234m
Ac-227+	Fr-223,Ra-223,Rn-219,Po-215,Pb-211,
	BI-211
U-230+	Th-226,Ra-222,Rn-218,Po-214
U-232+	Th-228,Ra-224,Rn-220,Po-216,Pb-212,
	Bi-212,TI-208,Po-212
U-235+	Th-231
U-238+	Th-234,Pa-234m
U-238sec	Th-234,Pa-234m,U-234,Th-230,Ra-226,
	Rn-222,Po-218,Pb-214,Bi-214,Pb-210,
	Bi-210,Po-210
U-240+	Np-240
Np-237+	Pa-233
Am-242m+	Am-242
Am-243+	Np-239

ANNEX II

A. Definitions of terms used in this ANNEX

Effective quality factor (Q): average value of the quality factor where the dose absorbed is delivered by particles with different L values. It is calculated according to the expression:

<u>Quality factor</u> (Q): a function of linear energy transfer (L) used to weight absorbed doses in such a way as to indicate their significance for radiation protection purposes.

Radiation weighting factor (w_R) : a dimensionless factor which is used to weight the absorbed dose. The appropriate W_R values are specified in this Annex.

<u>Tissue weighting factor</u> (w_T) : a dimensionless factor used to weight the equivalent dose. The appropriate values are specified in this Annex.

Unrestricted Linear energy transfer (Loo): the unrestricted linear energy transfer is defined as

where dE is the mean energy lost by a particle of energy E in traversing a distance dl. In the Directive L_{∞} is denoted by L.

B. Values of radiation weighting factor, w_R

Values of radiation weighting factor, \mathbf{w}_{R} , depend on the type and quality of the external radiation field or on the type and quality of the radiation emitted by an internally deposited radionuclide.

When the radiation field is composed of types and energies with different values of \mathbf{w}_R , the absorbed dose must be sub-divided into blocks, each with its own value of \mathbf{w}_R and added to give the total equivalent dose. Alternatively, it may be expressed as a continuous distribution in energy where each element of absorbed dose from the energy element between E and E + dE is multiplied by the value of \mathbf{w}_R from the relevant entry in the Table below.

Type and energy range	Radiation weighting factor, w _R
Photons, all energies	1
Electrons and muons, all energies	1
Neutrons, energy < 10 keV	5
10 keV to 100 keV	10
> 100 keV to 2 MeV	20
> 2 MeV to 20 MeV	10
> 20 MeV	5
Protons, other than recoil	
Protons, energy > 2 MeV	5
Alpha particles, fission	•
fragments, heavy nuclei	20

In calculations involving neutrons, difficulties may arise in applying step function values. In these cases it may be preferable to use the continuous function described by the following mathematical relationship:

$$w_R = 5 + 17e^{-(\ln(2E))2/6}$$

where E is the neutron energy in MeV.

A direct comparison of the two approaches is given in Figure 1.

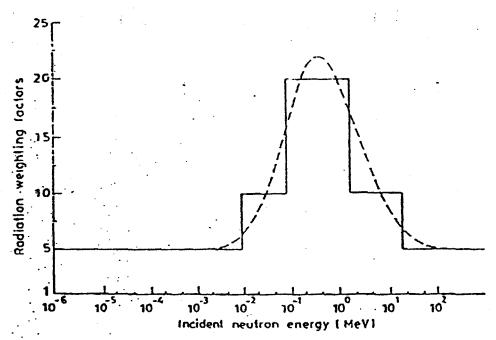


Fig. 1. Radiation weighting factors for neutrons. The smooth curve is to be treated as an approximation.

For radiation types and energy which are not included in the table, an approximation of w_R may be obtained by calculation of Q at a 10 mm depth in a 30 cm diameter, tissue-equivalent sphere with a density of 1 cm⁻³ and a mass composition of 76.2% oxygen, 11.1% carbon, 10.1% hydrogen and 2.6% nitrogen:

$$\overline{Q} = \frac{1}{D} \int_{0}^{\infty} Q(L)D(L)dL$$

where D(L)dL is the absorbed dose at 10 mm between linear energy transfer L and L + dL; and Q(L) is the quality factor of L at 10 mm. The Q-L relationships are given in B.

C. Relationship between the quality factor, Q(L), and unrestricted linear energy transfer, L

Unrestricted linear energy	Q(L)
transfer, L in water (keV μ m $^{-1}$)	
< 10	1
10 - 100	0.32L - 2.2
> 100	300/VL

D. Values of tissue weighting factor, $w_T^{(1)}$

⁽⁽¹⁾⁾ The values have been developed from a reference population of equal numbers of both sexes and a wide range of ages. In the definition of effective dose they apply to workers, to the whole population, and to either sex.

· Values of tissue weighting factor, w_T , are shown below:

issue or organ	Tissue weighting factors, w _T
Gonads	0.20
Bone marrow (red)	0.12
Colon	0.12
Lung	0.12
Stomach	0.12
Bladder	0.05
Breast	0.05
Liver	0.05
Oesophagus	0.05
Thyroid	0.05
Skin	0.01
Bone surface	0.01
Remainder	0.05 ((2))((3))

⁽⁽²⁾⁾ For the purposes of calculation, the remainder is composed of the following additional tissues and organs: adrenals, brain, upper large intestine, small intestine, kidney, muscle, pancreas, spleen, thymus and uterus. The list includes organs which are likely to be selectively irradiated. Some organs in the list are known to be susceptible to cancer induction. If other tissues and organs subsequently become identified as having a significant risk of induced cancer they will then be included either with a specific W_T or in this additional list constituting the remainder. The latter may also include other tissues or organs selectively irradiated.

⁽⁽³⁾⁾ In those exceptional cases in which a single one of the remainder tissues or organs receives an equivalent dose in excess of the highest dose in any of the twelve organs for which a weighting factor is specified, a weighting factor of 0.025 should be applied to that tissue or organ and a weighting factor of 0.025 to the average dose in the rest of the remainder as defined above.

ANNEX 111

Arrangements for assessing the effective doses due to intakes

The limits on effective dose set out in Articles 9, 12 and 14 apply to the sum of the effective dose received in the specified period and the committed effective dose due to intakes in the same period. The relationship between intake and committed effective dose depends on the age of the individual, on the physical and chemical form of the radioactive material and on the route of intake.

These relationships can then be used to estimate the relevant effective doses. If derived limits are used for external exposure and for intakes, the limit on effective dose can be applied by the following expression for each of the relevant age groups:

(This Annex will contain for all relevant radionuclides dose coefficients (Sv/Bq) for inhalation and ingestion for different age categories regarding the population and for workers. For the exposures to noble gases coefficients in the unit Svy^{-1}/Bqm^{-3} will be given).

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