

Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation

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COUNCIL DIRECTIVE 96/29/EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation

THE COUNCIL OF THE EUROPEAN UNION,

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

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

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

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

Whereas Article 2b of the Treaty provides for the establishment of uniform basic safety standards to protect the health of workers and of the general public;

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 Article 33 of the Treaty requires each Member State 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 Article 218 of the Treaty by means of Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiations (3); whereas the Directives were revised in 1962 by Directive of 5 March 1962 (4), in 1966 by Directive 66/45/Euratom (5), in 1976 by Directive 76/579/Euratom (6), in 1979 by Directive 79/343/Euratom (7), in 1980 by Directive 80/836/Euratom (8) and in 1984 by Directive 84/467/Euratom (9);

Whereas the basic standards directives have been supplemented by Council Directive 84/466/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment (10); Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency (11); Council Regulation (Euratom) No 3954/87 of 22 December 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 (12); Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency (13); Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas (14); Council Directive 92/3/Euratom of 3 February 1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community (15); and Council Regulation (Euratom) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States (16);

Whereas the development of scientific knowledge concerning radiation protection, as expressed in particular in Recommendation No 60 of the International Commission on Radiological Protection, makes it convenient to revise the basic standards and to lay them down in a new legal instrument; Whereas the basic standards are of special significance as to ionizing radiation risks with regard to other Directives concerned with other types of risks and it is important to make progress in applying them in a uniform manner within the Community;

Whereas it is desirable to take into account in the scope of the basic standards the practices or work activities which may result in a significant increase in exposure for workers and members of the public, which cannot be disregarded from the radiation protection point of view, due to ionizing radiation from artificial radiation sources or natural radiation sources, as well as appropriate protection in cases of intervention;

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

Whereas a system of radiation protection for practices should continue to be based on the principles of justification of exposure, optimization of protection and dose limitation; whereas, limitations of doses must be fixed taking into account the particular situation of the different groups of persons exposed such as workers, apprentices, students and members of the public;

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

Whereas the Member States should be required to identify work activities involving significantly increased levels of exposure for workers or members of the public to natural radiation sources which cannot be disregarded from a radiation protection point of view; whereas the Member States should take appropriate protective measures in respect of the work activities declared to be of concern;

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

Whereas the Member States should be prepared for the likelihood of potential radiological emergencies on their territory and should cooperate with other Member States and with third countries in order to facilitate the preparedness and management of those situations;

Whereas the basic standards directives as last revised by Directive 84/467/Euratom should be repealed with effect from the date that this Directive becomes applicable,

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

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

where

d

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, in which particles are accelerated, emitting ionizing radiation with an energy higher than 1 mega-electron volt (MeV).

Accidental exposure: an exposure of individuals as a result of an accident. It does not include emergency exposure.

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 of activity is the becquerel.

Apprentice: a person receiving training or instruction within an undertaking with a view to exercising a specific skill.

Approved dosimetric service: a body responsible for the calibration, reading or interpretation of individual monitoring devices, or for the measurement of radioactivity in the human body or in biological samples, or for assessment of doses, whose capacity to act in this respect is recognized by the competent authorities.

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

Approved occupational health services: a body or bodies to which may be assigned responsibility for the radiation protection of exposed workers and/or medical surveillance of category A workers. Its capacity to act in that respect is recognized by the competent authorities.

Artificial sources: radiation sources other than natural radiation sources.

Authorization: a permission granted in a document by the competent authority, on application, or granted by national legislation, to carry out a practice or any other action within the scope of this Directive.

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

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

Clearance levels: values, established by national competent authorities, and expressed in terms of activity concentrations and/or total activity, at or below which radioactive substances or materials containing radioactive substances arising from any practice subject to the requirement of reporting or authorization may be released from the requirements of this Directive.

Committed effective dose: $E(\hat{\delta})$: the sum of the committed organ or tissue equivalent doses $HT(\hat{\delta})$ resulting from an intake, each multiplied by the appropriate tissue weighting factor w_T . It is defined by:

$$E(\hat{\delta}) = \sum w_T HT(\hat{\delta})$$

In specifying $E(\hat{\delta})$, $\hat{\delta}$ 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 $HT(\hat{\delta})$: the integral over time (t) of the equivalent dose rate in tissue or organ T that will be received by an individual as a result of an intake. It is given by:

$$HT(\hat{\delta}) = \int_{t_0}^{t_0 + \hat{\delta}} \dot{C}_T(t) dt \text{ for an intake at time } t_0 \text{ where}$$

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>END OF GRAPHIC<

$T(t)$ is the relevant equivalent dose rate in organ or tissue T at time t,

- $\hat{\delta}$ is the time over which the integration is performed.

In specifying $HT(\hat{\delta})$, $\hat{\delta}$ is given in years. When $\hat{\delta}$ 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.

Competent authorities: any authority designated by a Member State.

Controlled area: an area subject to special rules for the purpose of protection against ionizing radiation or of preventing the spread of radioactive contamination and to which access is controlled.

Disposal: the emplacement of waste in a repository, or a given location, without the intention of retrieval. Disposal also covers the approved direct discharge of wastes into the environment, with subsequent dispersion.

Dose constraint: a restriction on the prospective doses to individuals which may result from a defined source, for use at the planning stage in radiation protection whenever optimization is involved.

Dose limits: maximum references 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 covered by this Directive that apply to the sum of the relevant doses from external exposures in the specified period and the 50-year committed doses (up to age 70 for children) from intakes in the same period.

Effective dose (E): 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:

$$E = \sum w_T H_{T,R} = \sum w_T \sum w_R D_{T,R}$$

where

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

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

Emergency exposure: an exposure of individuals implementing the necessary rapid action to bring help to endangered individuals, prevent exposure of a large number of people or save a valuable installation or goods, whereby one of the individual dose limits equal to that laid down for exposed workers could be exceeded. Emergency exposure shall apply only to volunteers.

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:

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

where

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

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

$H_T = \sum w_R D_{T,R}$ The appropriate w_R values are specified in Annex II. The unit for equivalent dose is the sievert.

Exposed workers: persons, either self-employed or working for an employer, 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 levels equal to 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:
 $1 \text{ Gy} = 1 \text{ J kg}^{-1}$

Health detriment: an estimate of the risk of reduction in length and quality of life occurring in a population following exposure to ionizing radiations. This includes loss arising from somatic effects, cancer and severe genetic disorder.

Intake: the activities of radionuclides entering the body from the external environment.

Intervention: a human activity that prevents or decreases the exposure of individuals to radiation from sources which are not part of a practice or which are out of control, by acting on sources, transmission pathways and individuals themselves.

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

Ionizing radiation: the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nanometer or less or a frequency of 3×10^{15} Hertz or more capable of producing ions directly or indirectly.

Members of the public: individuals in the population, excluding exposed workers, apprentices and students during their working hours and individuals during the exposures referred to in Article 6(4)(a), (b) and (c).

Natural radiation sources: sources of ionizing radiation from natural terrestrial or cosmic origin.

Potential exposure: exposure, that is not expected to be delivered with certainty, with a probability of occurrence that can be estimated in advance.

Practice: a human activity that can increase the exposure of individuals to radiation from an artificial source, or from a natural radiation source where natural radionuclides are processed for their radioactive, fissile or fertile properties, except in the case of an emergency exposure.

Qualified experts: Persons having the knowledge and training needed to carry out physical, technical or radiochemical tests enabling doses to be assessed, and to give advice in order to ensure effective protection of individuals and the correct operation of protective equipment, whose capacity to act as a qualified expert is recognized by the competent authorities. A qualified expert may be assigned the technical responsibility for the tasks of radiation protection of workers and members of the public.

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 concentration of which cannot be disregarded as far as radiation protection is concerned.

Radiological emergency: a situation that requires urgent action in order to protect workers, members of the public or the population either partially or as a whole.

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 more highly exposed to that source.

Reporting: requirement of submitting a document to the competent authority to notify the intention to carry out a practice or any other action within the scope of this Directive.

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

Sievert: the special name of the unit of equivalent or effective dose. One sievert is equivalent to one joule per kilogram:

$$1 \text{ Sv} = 1 \text{ J kg}^{-1}$$

Source: an apparatus, a radioactive substance or an installation capable of emitting ionizing radiation or radioactive substances.

Supervised area: an area subject to appropriate supervision for the purpose of protection against ionizing radiation.

Undertaking: any natural or legal person who carries out the practices or work activities referred to in Article 2 of this Directive and who has the legal responsibility under national law for such practices or work activities.

TITLE II SCOPE

Article 2

1. This Directive shall apply to all practices which involve a risk from ionizing radiation emanating from an artificial source or from a natural radiation source in cases where natural radionuclides are or have been processed in view of their radioactive, fissile or fertile properties, namely:

(a) the production, processing, handling, use, holding, storage, transport, import to and export from the Community 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) any other practice specified by the Member State.

2. In accordance with Title VII it shall also apply to work activities which are not covered by paragraph 1 but which involve the presence of natural radiation sources and lead to a significant increase in the exposure of workers or members of the public which cannot be disregarded from the radiation protection point of view.

3. In accordance with Title IX it shall also apply to any intervention in cases of radiological emergencies or in cases of lasting exposure resulting from the after-effects of a radiological emergency or a past or old practice or work activity.

4. This Directive shall not apply to exposure to radon in dwellings or to the natural level of radiation, i.e. to radionuclides contained in the human body, to cosmic radiation prevailing at ground level or to aboveground exposure to radionuclides present in the undisturbed earth's crust.

TITLE III REPORTING AND AUTHORIZATION OF PRACTICES

Article 3

Reporting

1. Each Member State shall require the carrying out of the practices referred to in Article 2 (1) to be reported, except as provided for in this Article.

2. No reporting need be required for practices involving the following:

(a) radioactive substances where the quantities involved do not exceed in total the exemption values set out in column 2 of Table A to Annex I or, in exceptional circumstances in an individual Member State, different values authorized by the competent authorities that nevertheless satisfy the basic general criteria set out in Annex I; or

(b) radioactive substances where the concentration of activity per unit mass do not exceed the exemption values set out in column 3 of Table A to Annex I or, in exceptional circumstances in an individual Member State, different values authorized by the competent authorities that nevertheless satisfy the basic general criteria set out in Annex I; or

(c) apparatus containing radioactive substances exceeding the quantities or concentration values specified in subparagraphs (a) or (b), provided that:

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

(ii) it is constructed in the form of a sealed source; and

(iii) 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; and

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

(d) the operation of any electrical apparatus to which this Directive applies, other than that referred to in subparagraph (e) provided that:

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

(ii) 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, or other electrical apparatus operating at a potential difference not exceeding 30 kV, provided that this operation 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

(f) material contaminated with radioactive substances resulting from authorized releases which competent authorities have declared not to be subject to further controls.

Article 4

Authorization

1. Except as provided for in this Article, each Member State shall require prior authorization for the following practices:

- (a) operation and decommissioning of any facility of the nuclear fuel cycle and exploitation and closure of uranium mining;
 - (b) the deliberate addition of radioactive substances in the production and manufacture of medicinal products and the import or export of such goods;
 - (c) the deliberate addition of radioactive substances in the production and manufacture of consumer goods and the import or export of such goods;
 - (d) the deliberate administration of radioactive substances to persons and, in so far as radiation protection of human beings is concerned, animals for the purpose of medical or veterinary diagnosis, treatment or research;
 - (e) the use of X-ray sets or radioactive sources for industrial radiography or processing of products or research of the exposure of persons for medical treatment and the use of accelerators except electron microscopes;
2. Prior authorization may be required for practices other than those listed in paragraph 1.
3. Member States may specify that a practice shall not require authorization where:
- (a) in the case of the practices described in paragraph 1 (a), (c) and (e), the practice is exempt from reporting; or
 - (b) in cases where a limited risk of exposure of human beings does not necessitate the examination of individual cases the practice is undertaken in accordance with conditions laid down in national legislation.

Article 5

Authorization and clearance for disposal, recycling or reuse

1. The disposal, recycling or reuse of radioactive substances or materials containing radioactive substances arising from any practice subject to the requirement of reporting or authorization is subject to prior authorization.
2. However, the disposal, recycling or reuse of such substances or materials may be released from the requirements of this Directive provided they comply with clearance levels established by national competent authorities. These clearance levels shall follow the basic criteria used in Annex I and shall take into account any other technical guidance provided by the Community.

TITLE IV JUSTIFICATION, OPTIMIZATION AND DOSE LIMITATION FOR PRACTICES

CHAPTER I GENERAL PRINCIPLES

Article 6

1. Member States shall ensure that all new classes or types of practice resulting in exposure to ionizing radiation are justified in advance of being first adopted or first approved by their economic, social or other benefits in relation to the health detriment they may cause.
2. Existing classes or types of practice may be reviewed as to justification whenever new and important evidence about their efficacy or consequences is acquired.
3. In addition each Member State shall ensure that:
 - (a) in the context of optimization all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account;
 - (b) without prejudice to Article 12, the sum of the doses from all relevant practices shall not exceed the dose limits laid down in this Title for exposed workers, apprentices and students and members of the public.
4. The principle set out in paragraph 3 (a) shall apply to all exposures to ionizing radiation resulting from the practices referred to in Article 2 (1). The principle set out in paragraph 3 (b) shall not apply to any of the following exposures:
 - (a) exposure of individuals as part of their own medical diagnosis or treatment;
 - (b) 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;
 - (c) exposure of volunteers participating in medical and biomedical research programmes.

5. Member States shall permit neither the deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics nor the import or export of such goods.

Article 7

Dose constraints

1. Dose constraints should be used, where appropriate, within the context of optimization of radiological protection.
2. Guidance established by each Member State on the appropriate procedures to be applied to individuals exposed in accordance with Article 6 (4) (b) and (c) may include dose constraints.

CHAPTER II LIMITATION OF DOSES

Article 8

Age limit for exposed workers

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

Article 9

Dose limits for exposed workers

1. The limit on effective dose for exposed workers shall be 100 millisieverts ('mSv') in a consecutive five-year period, subject to a maximum effective dose of 50 mSv in any single year. Member States may decide an annual amount.
2. Without prejudice to paragraph 1:
 - (a) the limit on equivalent dose for the lens of the eye shall be 150 mSv in a year;
 - (b) the limit on equivalent dose for the skin shall be 500 mSv in a year. This limit shall apply to the dose averaged over any area of 1 cm², regardless of the area exposed;
 - (c) the limit on equivalent dose for the hands, forearms, feet and ankles shall be 500 mSv in a year.

Article 10

Special protection during pregnancy and breastfeeding

1. As soon as a pregnant woman informs the undertaking, in accordance with national legislation and/or national practice, of her condition, the protection of the child to be born shall be comparable with that provided for members of the public. The conditions for the pregnant woman in the context of her employment shall therefore be such that the equivalent dose to the child to be born will be as low as reasonably achievable and that it will be unlikely that this dose will exceed 1 mSv during at least the remainder of the pregnancy.
2. As soon as a nursing woman informs the undertaking of her condition she shall not be employed in work involving a significant risk of bodily radioactive contamination.

Article 11

Dose limits for apprentices and students

1. The dose limits for apprentices aged 18 years or over and students aged 18 years or over who, in the course of their studies, are obliged to 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.

Without prejudice to this dose limit:

- (a) the limit on equivalent dose for the lens of the eye shall be 50 mSv in a year;
 - (b) the limit on equivalent dose for the skin shall be 150 mSv in a year. This limit shall apply to the dose averaged over any area of 1 cm², regardless of the area exposed;
 - (c) the limit on equivalent dose for the hands, forearms, feet and ankles shall be 150 mSv in a year.
3. The dose limits for apprentices and students who are not subject to the provisions of paragraphs 1 and 2 shall be the same as the dose limits for members of the public specified in Article 13.

Article 12

Specially authorized exposures

1. In exceptional circumstances, excluding radiological emergencies and 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, provided that such exposures are limited in time, confined to certain working areas and within maximum exposure levels defined for the particular case by the competent authorities. The following conditions shall be taken into account:

- (a) only category A workers as defined in Article 21 may be subject to specially authorized exposures;
- (b) apprentices, students, pregnant women and breastfeeding women who are likely to be bodily contaminated shall be excluded from such exposures;
- (c) the undertaking shall carefully justify these exposures in advance and thoroughly discuss them with the voluntary workers, their representatives, the approved medical practitioner, the approved occupational health services or the qualified expert;
- (d) information about the risks involved and the precautions to be taken during the operation shall be provided to the relevant workers in advance;
- (e) all doses relating to such exposures shall be separately recorded in the medical record referred to in Article 34 and the individual record referred to in Article 28.

2. The exceeding of dose limits as a result of specially authorized exposures shall not necessarily constitute a reason by the employer for excluding from his usual occupation or relocating the worker, without the agreement of the worker.

Article 13

Dose limits for members of the public

1. Without prejudice to Article 14, 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.

3. Without prejudice to paragraph 2:

- (a) the limit on equivalent dose for the lens of the eye shall be 15 mSv in a year;
- (b) the limit on equivalent dose for the skin shall be 50 mSv in a year averaged over any 1 cm² area of skin, regardless of the area exposed.

Article 14

Exposure of the population as a whole

Each Member State shall take reasonable steps to ensure that the contribution to the exposure of the population as a whole from practices is kept as low as reasonably achievable, economic and social factors being taken into account.

The total of all such contributions shall be regularly assessed.

TITLE V ESTIMATION OF EFFECTIVE DOSE

Article 15

For the estimation of effective and equivalent doses the values and relationships referred to in this Title shall be used. The competent authorities may authorize the use of equivalent methods.

Article 16

Without prejudice to the provisions of Article 15:

- (a) For external radiation, the values and relationships given in Annex II shall be used to estimate the relevant effective and equivalent doses;
- (b) For internal exposure from a radionuclide or from a mixture of radionuclides, the values and relationships 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 FOR PRACTICES

Article 17

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

- (a) prior evaluation to identify the nature and magnitude of the radiological risk to exposed workers and implementation of the optimization of radiation protection in all working conditions;
- (b) classification of workplaces into different areas, where appropriate, by reference to an assessment of the expected annual doses and the probability and magnitude of potential exposures;
- (c) classification of workers into different categories;
- (d) implementation of control measures and monitoring relating to the different areas and working conditions, including, where necessary, individual monitoring;
- (e) medical surveillance.

CHAPTER I MEASURES FOR THE RESTRICTION OF EXPOSURE

Section 1 Classification and delineation of areas

Article 18

Arrangements in workplaces

1. For the purposes of radiation protection, arrangements shall be made as regards all workplaces where there is a possibility of exposure to ionizing radiation in excess of 1 mSv per year on an equivalent dose of 10 of the dose limits for the lens of the eyes, skin and extremities laid down in Article 9 (2). Such arrangements must be appropriate to the nature of the installations and sources and to the magnitude and nature of the risks. The scope of the precautions and monitoring, as well as their type and quality, must be appropriate to the risks associated with the work involving exposure to ionizing radiation.
2. A distinction shall be made between controlled areas and supervised areas.
3. The competent authorities shall establish guidance on the classification of controlled and supervised areas which is relevant to the particular circumstances.
4. The undertaking shall keep under review the working conditions in controlled and supervised areas.

Article 19

Requirements for controlled areas

1. The minimum requirements for a controlled area are as follows:
 - (a) the controlled area shall be delineated and access to it shall be restricted to individuals who have received appropriate instructions and shall be controlled in accordance with written procedures provided by the undertaking. Wherever there is a significant risk of the spread of radioactive contamination, specific arrangements shall be made, including access and exit of individuals and goods;
 - (b) taking into account the nature and extent of radiological risks in the controlled area, radiological surveillance of the working environment shall be organized in accordance with the provisions of Article 24;
 - (c) signs indicating type of area, nature of the sources and their inherent risks shall be displayed;
 - (d) working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.
2. The implementation of these duties will be carried out under the responsibility of the undertaking following consultations with the approved occupational health services or the qualified experts.

Article 20

Requirements for supervised areas

1. The requirements for a supervised area are as follows:
 - (a) as a minimum, taking into account the nature and extent of radiological risks in the supervised area, radiological surveillance of the working environment shall be organized in accordance with the provisions of Article 24;
 - (b) if appropriate, signs indicating type of area, nature of the sources and their inherent risks shall be displayed;

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

2. The implementation of these duties will be carried out under the responsibility of the undertaking following consultations with the qualified experts or the approved occupational health services.

Section 2 Classification of exposed workers, apprentices and students

Article 21

Categorization of exposed workers

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

(a) category A: those exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than >3

>10

of the dose limits for the lens of the eye, skin and extremities laid down in Article 9 (2);

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

Article 22

Information and training

1. Member States shall require the undertaking to inform exposed workers, apprentices and students who, in the course of their studies, are obliged to use sources on:

(a) the health risks involved in their work:

- 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 practice in general and each type of work station or job to which they may be assigned,

- the importance of complying with the technical, medical and administrative requirements;

(b) in the case of women, the need for early declaration of pregnancy in view of the risks of exposure for the child to be born and the risk of contaminating the nursing infant in case of bodily radioactive contamination.

2. Member States shall require the undertaking to arrange for relevant training in the field of radiation protection to be given to exposed workers, apprentices and students.

Section 3 Assessment and implementation of arrangements for the radiological protection of exposed workers

Article 23

1. The undertaking shall be responsible for assessing and implementing arrangements for the radiological protection of exposed workers.

2. Member States shall require the undertaking to consult the qualified experts or the approved occupational health services on the examination and testing of protective devices and measuring instruments comprising in particular:

(a) prior critical examination of plans for installations 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

Article 24

1. The radiological surveillance of the working environment referred to in Articles 19 (1) (b) and 20 (1) (a) shall comprise, where appropriate:

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

(b) the measurement of air activity concentration and surface density of contaminating radioactive substances, indicating their nature and their physical and chemical states.

2. The results of these measurements shall be recorded and shall be used, if necessary, for estimating individual doses, as provided for in Article 25.

Section 2 Individual monitoring

Article 25

Monitoring - General

1. Individual monitoring shall be systematic for exposed category A workers. This monitoring shall be based on individual measurements which are established by an approved dosimetric service. In cases where category A workers are liable to receive significant internal contamination an adequate system for monitoring should be set up; the competent authorities may provide general guidance for identifying such workers.

2. Monitoring for category B workers shall be at least sufficient to demonstrate that such workers are correctly classified in category B. Member States may require individual monitoring and if necessary individual measurements, established by an approved dosimetric service, for category B workers.

3. In cases where individual measurements are impossible or inadequate, the individual monitoring shall be based on an estimate arrived at either from individual measurements made on other exposed workers or from the results of the surveillance of the workplace provided for in Article 24.

Section 3 Monitoring in the case of accidental or emergency exposure

Article 26

In the case of accidental exposure the relevant doses and their distribution in the body shall be assessed.

Article 27

In the case of emergency exposure, individual monitoring or assessment of the individual doses shall be carried out as appropriate to the circumstances.

Section 4 Recording and reporting of results

Article 28

1. A record containing the results of the individual monitoring, shall be made for each exposed category A worker.

2. For the purposes of paragraph 1 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 pursuant to Articles 12, 25, 26 and 27;

(b) in the case of exposures referred to in Articles 26 and 27, the reports relating to the circumstances and the action taken;

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

3. Exposure referred to in Articles 12, 26 and 27 shall be recorded separately in the dose record referred to in paragraph 1.

Article 29

1. The results of the individual monitoring required by Articles 25, 26 and 27 shall be:

(a) made available to the competent authorities, and to the undertaking;

(b) made available to the worker concerned in accordance with Article 38 (2);

(c) submitted to the approved medical practitioner or approved occupational health services in order to interpret their implications for human health, as provided for in Article 31.

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

3. In the case of an accidental or emergency exposure, the results of individual monitoring shall be submitted without delay.

CHAPTER III MEDICAL SURVEILLANCE OF EXPOSED WORKERS

Article 30

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 31

Medical surveillance

1. Notwithstanding the overall responsibility of the undertaking, the medical surveillance of category A workers shall be the responsibility of approved medical practitioners or approved occupational health services.

This medical surveillance must allow for ascertaining the state of health of workers under surveillance as regards their fitness for the tasks assigned to them. To this end the approved medical practitioner or approved occupational health services must have access to any relevant information they require including the environmental conditions existing in the working premises.

2. Medical surveillance shall include:

(a) a medical examination prior to employment or classification as category A worker.

The purpose of this thorough examination shall be to determine the worker's fitness for a post as category A worker for which he is being considered;

(b) periodic reviews of health.

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

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

Article 32

Medical classification

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

(a) fit;

(b) fit, subject to certain conditions;

(c) unfit.

Article 33

No worker may be employed or classified for any period in a specific post as a category A worker if the medical findings deem him unfit for that specific post.

Article 34

Medical records

1. A medical record shall be opened for each category A worker 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 record shall include information regarding the nature of the employment, the results of the medical examinations prior to employment or classification as category A worker, the periodic reviews of health and the record of doses required by Article 28.

Section 2 Special surveillance of exposed workers

Article 35

1. Special medical surveillance shall be provided in each case where one of the dose limits laid down in Article 9 has been exceeded.

2. Subsequent conditions of exposure shall be subject to the agreement of the approved medical practitioner or approved occupational health services.

Article 36

In addition to the medical surveillance of exposed workers provided for in Articles 30 and 31, provision shall be made for any further action in relation to the health protection of the exposed individual considered necessary by the approved medical practitioner or approved occupational health services such as further examinations, decontamination measures or urgent remedial treatment.

Section 3 Appeals

Article 37

Each Member State shall lay down the procedure for appeal against the findings and decisions made in pursuance of Articles 32, 33 and 35.

CHAPTER IV TASKS OF MEMBER STATES IN RESPECT OF PROTECTION OF EXPOSED WORKERS

Article 38

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 at their request to the results of their individual monitoring, including the results of measurements which may have been used in estimating them, or of the assessments of their doses made as a result of workplace measurements.

3. Each Member State shall make the necessary arrangements to recognize, as appropriate, the capacity of:

- the approved medical practitioners,
- the approved occupational health services,
- the approved dosimetric services,
- the qualified experts.

To this end, each Member State shall ensure that the training of such specialists is arranged.

4. Each Member State shall require that the means necessary for proper radiation protection are placed at the disposal of the units responsible. A specialized radiation protection unit, distinct from production and operation units in the case of an internal unit, authorized to perform radiation protection tasks and provide specific advice shall be required for the installations which the competent authorities consider necessary. This unit may be shared by several installations.

5. Each Member State shall facilitate the exchange amongst competent authorities, or approved medical practitioners, or approved occupational health services, or qualified experts, or approved dosimetric services within the European Community of all relevant information on the doses previously received by a worker in order to perform the medical examination prior to employment or classification as a category A worker pursuant to Article 31 and to control the further exposure of workers.

CHAPTER V OPERATIONAL PROTECTION OF APPRENTICES AND STUDENTS

Article 39

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

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

TITLE VII SIGNIFICANT INCREASE IN EXPOSURE DUE TO NATURAL RADIATION SOURCES

Article 40

Application

1. This Title shall apply to work activities not covered by Article 2 (1) within which the presence of natural radiation sources leads to a significant increase in the exposure of workers or of members of the public which cannot be disregarded from the radiation protection point of view.
2. Each Member State shall ensure the identification, by means of surveys or by any other appropriate means, of work activities which may be of concern. These include, in particular:
 - (a) work activities where workers and, where appropriate, members of the public are exposed to thoron or radon daughters or gamma radiation or any other exposure in workplaces such as spas, caves, mines, underground workplaces and aboveground workplaces in identified areas;
 - (b) work activities involving operations with, and storage of, materials, not usually regarded as radioactive but which contain naturally occurring radionuclides, causing a significant increase in the exposure of workers and, where appropriate, members of the public;
 - (c) work activities which lead to the production of residues not usually regarded as radioactive but which contain naturally occurring radionuclides, causing a significant increase in the exposure of members of the public and, where appropriate, workers;
 - (d) aircraft operation.
3. Articles 41 and 42 shall apply to the extent that the Member States have declared that exposure to natural radiation sources due to work activities identified in accordance with paragraph 2 of this Article needed attention and had to be subject to control.

Article 41

Protection against exposure from terrestrial natural radiation sources

For each work activity declared by them to be of concern, the Member States shall require the setting-up of appropriate means for monitoring exposure and as necessary:

- (a) the implementation of corrective measures to reduce exposure pursuant to all or part of Title IX;
- (b) the application of radiation protection measures pursuant to all or part of Titles III, IV, V, VI and VIII.

Article 42

Protection of air crew

Each Member State shall make arrangements for undertakings operating aircraft to take account of exposure to cosmic radiation of air crew who are liable to be subject to exposure to more than 1 mSv per year. The undertakings shall take appropriate measures, in particular:

- to assess the exposure of the crew concerned,
- to take into account the assessed exposure when organizing working schedules with a view to reducing the doses of highly exposed aircrew,
- to inform the workers concerned of the health risks their work involves,
- to apply Article 10 to female air crew.

TITLE VIII IMPLEMENTATION OF RADIATION PROTECTION FOR THE POPULATION IN NORMAL CIRCUMSTANCES

Article 43

Basic principles

Each Member State shall create the conditions necessary to ensure the best possible protection of the population based on the principles set out in Article 6 and to apply the fundamental principles governing operational protection of the population.

Article 44

Conditions for authorization of practices involving a risk from ionizing radiation for the population
Operational protection of the population in normal circumstances from practices subject to prior authorization means all arrangements and surveys for detecting and eliminating the factors which, in the course of any operation involving exposure to ionizing radiation, are liable to create a risk of exposure for the population which cannot be disregarded from the radiation protection point of view. Such protection shall include the following tasks:

(a) examination and approval of plans for installations involving an exposure risk, and of the proposed siting of such installations within the territory concerned, from the point of view of radiation protection;

(b) acceptance into service of such new installations subject to adequate protection being provided against any exposure or radioactive contamination liable to extend beyond the perimeter, taking into account, if relevant, demographic, meteorological, geological, hydrological and ecological conditions;

(c) examination and approval of plans for the discharge of radioactive effluents.

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

Article 45

Estimates of population doses

The competent authorities shall:

(a) ensure that dose estimates from practices referred to in Article 44 are made as realistic as possible for the population as a whole and for reference groups of the population in all places where such groups may occur;

(b) 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 substances;

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

- assessment of the doses due to external radiation, indicating, where appropriate, the quality of the radiation in question,

- 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,

- assessment of the doses that the reference groups of the population are liable to receive and specification of the characteristics of these groups.

(d) 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.

Article 46

Inspection

As regards health protection of the population each Member State shall establish a system of inspection to enforce the provisions introduced in compliance with this Directive and to initiate surveillance in the area of radiation protection.

Article 47

Responsibilities of undertakings

1. Each Member State shall require the undertaking responsible for practices as referred to in Article 2 to conduct them in accordance with the principles of health protection of the population in the area of radiation protection and in particular to carry out the following tasks within its installations:

(a) achieving and maintaining an optimal level of protection of the environment and the population;

(b) checking the effectiveness of technical devices for protecting the environment and the population;

(c) acceptance into service, from the point of view of surveillance of radiation protection, of equipment and procedures for measuring and assessing, as appropriate, exposure 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. Qualified experts and, as appropriate, the specialized radiation protection unit referred to in Article 38 (4) shall be concerned in the discharge of these duties.

TITLE IX INTERVENTION

Article 48

Application

1. This Title shall apply to intervention in cases of radiological emergencies or in cases of lasting exposure resulting from the after-effects of a radiological emergency or a past or old practice or work activity.
2. The implementation and extent of any intervention shall be considered in compliance with the following principles:
 - intervention shall be undertaken only if the reduction in detriment due to radiation is sufficient to justify the harm and costs, including social costs, of the intervention,
 - the form, scale and duration of the intervention shall be optimized so that the benefit of the reduction in health detriment less the detriment associated with the intervention, will be maximized,
 - dose limits, as laid down in Articles 9 and 13, shall not apply to intervention; however, the intervention levels established in application of Article 50 (2) constitute indications as to the situations in which intervention is appropriate; furthermore, in cases of long term exposure covered by Article 53, the dose limits set out in Article 9 should normally be appropriate for workers involved in interventions.

Section 1 Intervention in cases of radiological emergency

Article 49

Potential exposures

The Member States shall, where appropriate, require:

- that the possibility of radiological emergencies resulting from practices subject to the system of reporting or authorization laid down in Title III be considered,
- that the spatial and temporal distribution of the radioactive substances dispersed in the event of a possible radiological emergency be assessed,
- that the corresponding potential exposures be assessed.

Article 50

Intervention preparation

1. Each Member State shall ensure that account is taken of the fact that radiological emergencies may occur in connection with practices on or outside its territory and affect it.
2. Each Member State shall ensure that appropriate intervention plans, taking account of the general principles of radiation protection for intervention referred to in Article 48 (2) and of the appropriate intervention levels established by the competent authorities, are drawn up at national or local level, including within installations, in order to deal with various types of radiological emergency and that such plans are tested to an appropriate extent at regular intervals.
3. Each Member State shall ensure, where appropriate, that provision is made for the creation and appropriate training of special teams for technical, medical and health intervention.
4. Each Member State shall seek to cooperate with other Member States or non-Member States in relation to possible radiological emergencies at installations on its own territory which may affect other Member States or non-Member States, in order to facilitate the organization of radiological protection in these States.

Article 51

Implementation of intervention

1. Each Member State shall make provision for the immediate notification to its competent authorities by the undertaking responsible for the practices involved of any radiological emergency occurring in its territory and shall require all appropriate action to reduce the consequences.
2. Each Member State shall ensure that in the event of a radiological emergency on its own territory, the undertaking responsible for the practices involved makes an initial provisional assessment of the circumstances and consequences of the emergency and assists with intervention.

3. Each Member State shall ensure that provision is made, if the situation so requires, for intervention 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 exposure and organize the treatment of victims.

4. In the event of a radiological emergency on or outside its territory, each Member State shall require:

- (a) the organization of appropriate intervention, taking account of the real characteristics of the emergency;
- (b) the assessment and recording of the consequences of the radiological emergency and of the effectiveness of the intervention.

5. Each Member State shall, in the event of a radiological emergency occurring at an installation on its territory or being 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.

Article 52

Emergency occupational exposure

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 exposure 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 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 radiological monitoring and medical surveillance of the special emergency intervention teams.

Section II Intervention in cases of lasting exposure

Article 53

Where the Member States have identified a situation leading to lasting exposure resulting from the after-effects of a radiological emergency or a past practice, they shall, if necessary and to the extent of the exposure risk involved, ensure that:

- (a) the area concerned is demarcated;
- (b) arrangements for the monitoring of exposure are made;
- (c) any appropriate intervention is implemented, taking account of the real characteristics of the situation;
- (d) access to or use of land or buildings situated in the demarcated area is regulated.

TITLE X FINAL PROVISIONS

Article 54

1. This Directive establishes the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation with the aim of their uniform implementation by Member States. If a Member State is to adopt dose limits which are stricter than those laid down in this Directive, it shall inform the Commission and the Member States.

Article 55

Implementation

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 13 May 2000. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main laws, regulations or administrative provisions which they adopt in the field governed by this Directive.

Article 56

Repeals

The Directives of 2 February 1959, the Directive of 5 March 1962, Directives 66/45/Euratom, 76/579/Euratom, 79/343/Euratom, 80/836/Euratom and 84/467/Euratom shall be repealed with effect from 13 May 2000.

Article 57

This Directive is addressed to the Member States.

Done at Brussels, 13 May 1996.

For the Council

The President

S. AGNELLI

(1) OJ No C 128, 9. 5. 1994, p. 209.

(2) OJ No C 108, 19. 4. 1993, p. 48.

(3) OJ No 11, 20. 2. 1959, p. 221/59.

(4) OJ No 57, 6. 7. 1962, p. 1633/62.

(5) OJ No 216, 26. 11. 1966, p. 3693/66.

(6) OJ No L 187, 12. 7. 1976, p. 1.

(7) OJ No L 83, 3. 4. 1979, p. 18.

(8) OJ No L 246, 17. 9. 1980, p. 1.

(9) OJ No L 265, 5. 10. 1984, p. 4.

(10) OJ No L 265, 5. 10. 1984, p. 1.

(11) OJ No L 371, 30. 12. 1987, p. 76.

(12) OJ No L 371, 30. 12. 1987, p. 11. Regulation as amended by Regulation (Euratom) No 2218/89 (OJ No L 211, 22. 7. 1989, p. 19).

(13) OJ No L 357, 7. 12. 1989, p. 31.

(14) OJ No L 349, 13. 12. 1990, p. 21. Directive as amended by the 1994 Act of Accession.

(15) OJ No L 35, 12. 2. 1992, p. 24.

(16) OJ No L 148, 19. 6. 1993, p. 1.

ANNEX I

CRITERIA TO BE CONSIDERED FOR THE APPLICATION OF ARTICLE 3

1. A practice may be exempted from the requirement to report without further consideration, in compliance with Article 3 (2) (a) or (b) respectively, if either the quantity or the activity concentration, as appropriate, of the relevant radionuclides does not exceed the values in column 2 or 3 of Table A.

2. The basic criteria for the calculation of the values in Table A, for the application of exemptions for practices, are as follows:

(a) the radiological risks to individuals caused by the exempted practice are sufficiently low as to be of no regulatory concern; and

(b) the collective radiological impact of the exempted practice is sufficiently low as to be of no regulatory concern under the prevailing circumstances; and

(c) the exempted practice is inherently without radiological significance, with no appreciable likelihood of scenarios that could lead to a failure to meet the criteria in (a) and (b).

3. Exceptionally, as provided in Article 3, individual Member States may decide that a practice may be exempted where appropriate without further consideration, in accordance with the basic criteria, even if the relevant radionuclides deviate from the values in Table A, provided that the following criteria are met in all feasible circumstances:

(a) the effective dose expected to be incurred by any member of the public due to the exempted practice is of the order of 10 μ Sv or less in a year;

and

(b) either the collective effective dose committed during one year of performance of the practice is no more than about 1 man × Sv or an assessment of the optimization of protection shows that exemption is the optimum option.

4. 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.

5. The values laid down in Table A apply to the total inventory of radioactive substances held by a person or undertaking as part of a specific practice at any point in time.

6. Nuclides carrying the suffix '+' or 'sec' in Table A represent parent nuclides in equilibrium with their correspondent 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.

7. 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.

>TABLE>

>TABLE>

ANNEX II

A. Definitions of terms used in this Annex

Ambient dose equivalent $H^*(d)$: the dose equivalent at a point in a radiation field that would be produced by the corresponding expanded and aligned field in the ICRU sphere at a depth, d , on the radius opposing the direction of the aligned field. The special name for the unit of ambient dose equivalent is sievert (Sv).

Directional dose equivalent $H'(d, Z)$: the dose equivalent at a point in a radiation field that would be produced by the corresponding expanded field, in the ICRU sphere at a depth, d , on a radius in a specified direction, Z . The special name for the unit of directional dose equivalent is sievert (Sv).

Expanded and aligned field: a radiation field in which the fluence and its directional and energy distribution are the same as in the expanded field, but the fluence is unidirectional.

Expanded field: a field derived from the actual field, where the fluence and its directional and energy distributions have the same values throughout the volume of interest as in the actual field at the point of reference.

Fluence, \dot{O} : the quotient of dN by da , where dN is the number of particles which enter a sphere of cross-sectional area da :

$$\dot{O} = \frac{dN}{da}$$

>DEN> da

Mean quality factor >START OF GRAPHIC>

>END OF GRAPHIC>

: average value of the quality factor at a point in tissue where the absorbed dose is delivered by particles with different L values. It is calculated according to the expression:

>START OF GRAPHIC>

>END OF GRAPHIC>

$$= \frac{1}{\int Q(L)D(L)dL}$$

>DEN"START OF GRAPHIC>

>END OF GRAPHIC>

$$\int_0^{\infty} Q(L)D(L)dL$$

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

Personal dose equivalent, $H_p(d)$: the dose equivalent in soft tissues, at an appropriate depth, d , below a specified point in the body. The special name for the unit of personal dose equivalent is sievert (Sv).

Quality factor (Q): a function of linear energy transfer (L) used to weight absorbed doses at a point in such a way as to take into account the quality of a radiation.

Radiation weighting factor (w_R): a dimensionless factor used to weight the tissue or organ absorbed dose. The appropriate (w_R) values are given in B.

Tissue or organ absorbed dose (D_T): the quotient of the total energy imparted in a tissue or organ and the mass of that tissue or organ.

Tissue weighting factor (w_T): a dimensionless factor used to weight the equivalent dose in a tissue or organ (T). The appropriate (w_T) values are specified in D.

Unrestricted linear energy transfer (L_{un}): a quantity defined as:

$$L_{un} = \frac{dE}{dl}$$

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

ICRU sphere: a body introduced by the International Commission on Radiation Units (ICRU) to approximate the human body as regards energy absorption from ionizing radiation; it consists of a 30 cm diameter tissue equivalent sphere with a density of 1 g cm⁻³ and a mass composition of 76,2 % oxygen, 11,1 % carbon, 10,1 % hydrogen and 2,6 % nitrogen.

B. Values of radiation weighting factor, w_R

Values of radiation weighting factor, 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 w_R, the absorbed dose must be subdivided into blocks, each with its own value of 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 w_R from the relevant entry in the Table below.

>TABLE>

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.

>REFERENCE TO A GRAPHIC>

Figure 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 calculating the mean quality factor >START OF GRAPHIC>

>END OF GRAPHIC>

at a depth of 10 mm in a ICRU sphere.

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

>

TABLE POSITION>

D. Values of tissue weighting factor, w_T (1*)

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

>TABLE>

E. Operational quantities for external radiation

Operational quantities for external radiation are used for individual monitoring for radiation protection purposes:

1. Individual monitoring:

personal dose equivalent H_p(d),

d: depth in mm in the body.

2. Area monitoring:

ambient dose equivalent $H^*(d)$,

directional dose equivalent $H'(d, Z)$,

d: depth in mm under the surface of the sphere given in A,

Z: angle of incidence.

3. For strongly penetrating radiation a depth of 10 mm, for weakly penetrating radiation a depth of 0,07 mm for the skin and 3 mm for the eye is recommended.

(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.

ANNEX III

A. Throughout the Directive, unless otherwise specified, requirements on doses apply to the sum of the relevant doses from external exposure in a specified period and the relevant 50-year committed doses (up to age 70 for children) from intakes in the same period. The specified period is that given in Articles 9 and 13 in relation to the dose limits.

In general the effective dose E incurred by an individual in the group of age g will be determined according to the following formula:

$$E = E_{\text{external}} + \sum_j h(g)_{j,\text{ing}} J_{j,\text{ing}} + \sum_j h(g)_{j,\text{inh}} J_{j,\text{inh}}$$

Where E_{external} is the relevant effective dose from external exposure; $h(g)_{j,\text{ing}}$ and $h(g)_{j,\text{inh}}$ are the committed effective dose per unit-intake for ingested or inhaled radionuclide j (Sv/Bq) by an individual in the group of age g ; $J_{j,\text{ing}}$ and $J_{j,\text{inh}}$ respectively are the relevant intake via ingestion or inhalation of the radionuclide j (Bq).

B. Except for radon progeny and thoron progeny, values of the committed effective dose for unit intake for ingestion and inhalation are given for members of the public and for apprentices and students aged between 16 and 18 years in Tables (A) and (B) to this Annex.

Except for radon progeny and thoron progeny, values of the committed effective dose for unit intake for ingestion and inhalation are given for exposed workers and for apprentices and students aged 18 years or more in Table (C) to this Annex.

For exposure of members of the public, Table (A) for ingestion includes values corresponding to different gut transfer factors f_1 for infants and for older persons. Also for exposure of members of the public, Table (B) for inhalation includes values for different lung retention types with appropriate f_1 values for the component of the intake cleared to the gastrointestinal tract. If information is available on these parameters, the appropriate value shall be used; if not, the most restrictive value shall be used. For occupational exposure, Table (C) includes values for ingestion corresponding to different gut transfer factors f_1 and values for inhalation for different lung retention types with appropriate f_1 values for the component of the intake cleared to the gastrointestinal tract.

Table (D) presents gut transfer factors f_1 by element and compounds for workers and where appropriate members of the public for intake by ingestion. Table (E) presents lung absorption types and gut transfer factors f_1 , also by element and compounds and also for exposed workers and for apprentices and students aged 18 years or more, for intake by inhalation.

For members of the public the lung absorption types and gut transfer factors f_1 , shall take into account the chemical form of the element on the basis of available international guidance. In general, if no information is available on these parameters, the most conservative value should be used.

C. For radon progeny and thoron progeny the following conventional conversion factors apply, effective dose per unit potential alpha-energy exposure (Sv per J.h.m⁻³):

Radon at home: 1,1

Radon at work: 1,4

Thoron at work: 0,5

Potential alpha energy (of radon progeny and thoron progeny): The total alpha energy ultimately emitted during the decay of radon progeny and thoron progeny through the decay chain, up to but not including ^{210}Pb for progeny of ^{222}Rn and up to stable ^{208}Pb for progeny of ^{220}Rn . The unit is J (Joule). For the exposure to a given concentration for a given time the unit is $\text{J}\cdot\text{h}\cdot\text{m}^{-3}$.

D. Tables:

(A) Ingestion dose coefficients for members of the public.

(B) Inhalation dose coefficients for members of the public.

(C) Inhalation and ingestion dose coefficients for workers.

(D) Values for f_1 for the calculation of ingestion dose coefficients.

(E) Lung absorption types and f_1 values for chemical forms of the elements for the calculation of inhalation dose coefficients.

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