II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 15 July 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

(80/836/Euratom)

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 establishing the European Atomic Energy Community prescribes that the basic standards for the protection of the health of the general public and workers against the dangers arising from ionizing radiation, as provided for in particular in Article 30 thereof, must be laid down in order to enable each Member State, in accordance with Article 33, to lay down the appropriate provisions, by legislation, regulation or administrative action, to ensure compliance with the basic standards, to take the necessary measures with regard to teaching, education and vocational training and to lay down such provisions in harmony with the provisions applicable in this field in the other Member States;

Whereas on 2 Feburary 1959, the Council adopted Directives laying down such basic standards (3), which were last amended by Directive 76/579/Euratom (4);

Whereas the usefulness of some review of these Directives has become apparent in the light of the development of scientific knowledge concerning radiation protection;

Whereas the protection of the health of workers and the general public requires that any activity involving danger arising from ionizing radiation must be made subject to regulation;

Whereas the basic standards must be adapted to the conditions under which nuclear energy is used; whereas they vary according to whether they are concerned with the individual safety of workers exposed to ionizing radiation or with the protection of the general public;

Whereas the protection of the health of workers exposed to ionizing radiation requires, on the one hand, the organization of measures to prevent exposure and procedures for measuring exposure and, on the other hand, an adequate degree of medical surveillance;

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(1) OJ No C 140, 5. 6. 1979, p. 174.
(2) OJ No C 128, 21. 5. 1979, p. 31.
(3) OJ No 11, 20. 2. 1959, p. 221/59.
(4) OJ No L 187, 12. 7. 1976, p. 1.

Whereas the protection of the health of the general public entails a system of surveillance, inspection and, in the case of accident, intervention;

Whereas the studies conducted on the risks of ionizing radiation are of an exemplary nature, particularly in relation to those carried out on other risks; whereas the positive results achieved in radiation protection are important; whereas it is clear that Community harmonization of basic standards has a role to play;

Whereas the Member States are obliged to take the measures necessary to comply with Directive 76/579/Euratom before 3 June 1980; whereas some of the basic standards laid down in this Directive and in the aforementioned Directive are common to both Directives; whereas amendments to national laws in this field at excessively short intervals should be avoided; whereas it is necessary, therefore, to authorize Member States not to comply with the aforementioned Directive and to prescribe a sufficiently long period to comply with this Directive for Member States that do not take advantage of this authorization and a shorter period for those that do take advantage of it,

HAS ADOPTED THIS DIRECTIVE:

TITLE I

DEFINITIONS

Article 1

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

(a) **Physical terms, quantities and units**

Ionizing radiation: radiation consisting of photons or of particles capable of producing ions directly or indirectly.

Activity (A): the quotient of dN by dt, where dN is the number of spontaneous nuclear transformations which occur in a quantity of a radionuclide in the time interval dt.

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

This definition does not apply to the words 'activity' and 'activities' in Articles 2, 3, 4, 6 and 13.

Becquerel (Bq): the special name of the SI unit of activity.

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

In this Directive the values to be used when the activity is expressed in curies are also given.

$$1\ Ci = 3{\cdot}7 \times 10^{10}\ Bq \text{ (exactly)}$$
$$1\ Bq = 2{\cdot}7027 \times 10^{-11}\ Ci$$

Absorbed dose (D): the quotient of $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is the mean energy imparted by ionizing radiation to matter in a volume element and dm is the mass of matter in that volume element.

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

Gray (Gy): the special name of the SI unit of absorbed dose.

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

In this Directive the values to be used when the absorbed dose is expressed in rads are also given.

$$1\ rd = 10^{-2}\ Gy$$
$$1\ Gy = 100\ rads$$

Linear energy transfer or restricted linear collision stopping power (L_Δ): the quotient of dE by dl, where dl is the distance traversed by a charged particle in a medium and dE is the mean energy loss due to collisions with energy transfers less than a given value 'Δ'.

$$L_\Delta = \left(\frac{dE}{dl}\right)_\Delta$$

For radiation protection calculations, all the transferred energies are included, so that

$$L_\Delta = L_\infty$$

(Particle) fluence (Φ): the quotient of dN by da, where dN is the number of particles which enter a sphere of cross-sectional area da.

$$\Phi = \frac{dN}{da}$$

(Particle) fluence rate (φ): the quotient of $d\Phi$ by dt, where $d\Phi$ is the increment of particle fluence in the time interval dt.

$$\varphi = \frac{d\Phi}{dt}$$

(b) **Radiological, biological and medical terms**

Exposure: any exposure of persons to ionizing radiation. A distinction is made between:

— external exposure: exposure resulting from sources outside the body;

— internal exposure: exposure resulting from sources inside the body;

— total exposure: the sum of external and internal exposure.

Continuous exposure: prolonged external exposure the intensity of which may, however, vary with time, or internal exposure due to continuous intake although its level may vary with time.

Single exposure: external exposure of short duration, or internal exposure resulting from the intake of radionuclides over a short period.

Quality factor (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. The values of the quality factors to be used in evaluating dose equivalent for different types of radiation shall be those laid down in Annex II.

Effective quality factor ($\overline{Q}$): 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

$$\overline{Q} = \frac{1}{D} \int_0^\infty Q \frac{dD}{dL_\infty} dL_\infty$$

Dose equivalent (H): the product of the absorbed dose (D), the quality factor (Q) and the product of all other modifying factors (N). Where the word 'dose' is used alone the meaning is always that of 'dose equivalent'.

Sievert (Sv): the special name of the SI unit of dose equivalent.

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

In this Directive the values to be used when the dose equivalent is expressed in rems are also given.

$$1\ rem = 10^{-2}\ Sv$$
$$1\ Sv = 100\ rems$$

Deep dose equivalent index ($H_{I,d}$) *at a point:* the maximum dose equivalent within the 28-cm-diameter core of a 30-cm-diameter sphere centred at this point and consisting of material equivalent to soft tissue with a density of $1\ g \cdot cm^{-3}$.

Shallow dose equivalent index ($H_{I,s}$) *at a point:* the maximum dose equivalent within the volume between 0·07 mm and 1 cm from the surface of a 30-cm-diameter sphere centred at this point and consisting of material equivalent to soft tissue with a density of $1\ g \cdot cm^{-3}$. It is not necessary to determine the dose equivalent in the outer layer of thickness 0·07 mm.

Effective dose: the sum of the weighted average dose equivalents in the various organs or tissues.

Whole body exposure: exposure regarded as uniform throughout the body.

Partial body exposure: exposure predominantly of part of the body or of one or more organs or tissues, or exposure which is not regarded as uniform throughout the body.

Committed dose: the dose to an organ or to a tissue over a period of 50 years, resulting from an intake of one or more radionuclides.

Genetic dose: the genetic dose to a population is the dose which, if it were received by each person from conception to the mean age of reproduction, would result in the same genetic burden to the whole population as do the actual doses received by the individuals of this population. The genetic dose can be assessed as the annual genetically significant dose multiplied by the mean age of reproduction, which is taken to be 30 years.

Annual genetically significant dose: the average dose to a population of the individual annual gonad doses, weighted in the case of each individual dose for the probable number of children conceived subsequent to irradiation.

Collective dose: the collective dose (S) to a population or group is given by the summation

$$S = \sum_i H_i P_i$$

where H_i is the dose to the whole body or to a specified organ averaged over the P_i members of the i^{th} subgroup of the population or group.

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

Dose limits: the limits laid down in this Directive for the doses resulting from the exposure of exposed workers, apprentices and students, and members of the public, excluding the doses resulting from natural background radiation and exposure of individuals as a result of medical examination and treatment undergone by them. The dose limits apply to the sum of the doses received from external exposure during the period considered and the committed doses resulting from the intake of radionuclides during the same period.

Intake: the activity entering the body from the external environment.

Limit of annual intake: for a given individual, the activity which, when introduced into the body, results in a committed dose equal to the appropriate limit of annual dose laid down in Articles 8, 9, 10 and 12.

Derived limit of concentration of radionuclides in inhaled air: the annual mean concentration in the air expressed in units of activity per unit volume which, inhaled over 2 000 hours of work per year, gives an intake equal to the limit of annual intake.

Radiotoxicity: the toxicity attributable to ionizing radiation emitted by an incorporated radionuclide and its daughters; radiotoxicity is related not only to the radioactive characteristics of the radionuclide but also to its chemical and physical state and to the metabolism of the element in the body or in the organ.

(c) **Other terms**

Source: an apparatus or substance capable of emitting ionizing radiation.

Sealed source: a source consisting of radioactive substances firmly incorporated in solid and effectively inactive materials, or sealed in an inactive container of sufficient strength to prevent, under normal conditions of use, any dispersion of radioactive substances.

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.

Natural background radiation: all ionizing radiation from natural terrestrial and cosmic sources, to the extent that the exposure which it causes is not significantly increased by man.

Critical assembly: an assembly of fissile materials in which it is feasible to maintain a chain reaction.

Whole population: the entire population, including exposed workers, apprentices, students and members of the public.

Exposed workers: persons subjected, as a result of their work, to an exposure liable to result in annual doses exceeding one-tenth of the annual dose limits laid down for workers.

Reference groups (critical groups) of the population: groups comprising persons whose exposure is reasonably uniform and representative of that of the more highly exposed individuals in the population.

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

Controlled area: an area subject to special rules for the purposes of protection against ionizing radiation and to which access is controlled.

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

Intervention level: a value of absorbed dose or dose equivalent or a derived value fixed in connection with the drawing-up of emergency plans.

Approved medical practitioner: a medical practitioner responsible for the medical surveillance of workers of category A as defined in Article 23, whose capacity to act in this respect is recognized by the competent authorities.

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

Accident: an unforeseen event that causes damage to an installation or disrupts the normal operation of an installation, and is likely to result for one or more persons in a dose exceeding the dose limits.

Planned special exposure: an exposure causing an annual dose to exceed one of the annual dose limits laid down for exposed workers, permitted exceptionally in certain situations during normal operations when alternative techniques which do not involve such exposures cannot be used.

Accidental exposure: exposure which is of a fortuitous and involuntary nature and whereby one of the dose limits laid down for exposed workers is exceeded.

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 installation, whereby one of the dose limits laid down for exposed workers is exceeded, and whereby the limits for planned special exposures may also be exceeded. Emergency exposures shall apply only to volunteers.

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

TITLE II

SCOPE, REPORTING AND AUTHORIZATION

Article 2

This Directive shall apply to the production, processing, handling, use, holding, storage, transport and disposal of natural and artificial radioactive substances and to any other activity which involves a hazard arising from ionizing radiation.

Article 3

Each Member State shall make the reporting of the activities referred to in Article 2 compulsory. Without prejudice to Article 5 and in the light of possible dangers and other relevant considerations, these activities shall be subject to prior authorization in cases decided upon by each Member State.

Article 4

Without prejudice to Article 5, these requirements for reporting and obtaining prior authorization need not be applied to activities involving

(a) radioactive substances where the quantities involved do not exceed in total the values given in Annex I;

(b) radioactive substances of a concentration of less than 100 Bq g^{-1} (0·0027 µCi g^{-1}), this limit being increased to 500 Bq g^{-1} (0·014 µCi g^{-1}) for solid natural radioactive substances;

(c) the use of navigation instruments or timepieces containing radioluminescent paint, but not their manufacture or repair except as provided for in (a);

(d) apparatus emitting ionizing radiation and containing radioactive substances in quantities exceeding the values specified in (a), provided that:

1. it is of a type approved by the competent authority;

2. it possesses advantages in relation to the potential hazard that, in the opinion of the competent authority, justify its use;

3. 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

4. it does not cause, at any point situated at a distance of 0·1 m from the accessible surface of the apparatus and under normal operating conditions, a dose rate exceeding

1 µSv h^{-1} (0·1 mrem h^{-1});

(e) apparatus other than that referred to in (f) emitting ionizing radiation but not containing any radioactive substances, provided that:

1. it is of a type approved by the competent authority;

2. it possesses advantages in relation to the potential hazard that, in the opinion of the competent authority, justify its use; and

3. it does not cause, at any point situated at a distance of 0·1 m from the accessible surface of the apparatus and under normal operating conditions, a dose rate exceeding

1 µSv h^{-1} (0·1 mrem h^{-1});