20.2.59 OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES 221/59

DIRECTIVES

laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiations

THE COUNCIL OF THE EUROPEAN ATOMIC ENERGY COMMUNITY,

Having regard to the provisions of the Treaty, and in particular Articles 30 and 31 thereof;

Having regard to the opinion of the group of experts appointed by the Scientific and Technical Committee from among the scientific experts of the Member States;

Having regard to the Opinion of the Economic and Social Committee;

Having regard to the proposal from the Commission;
After consulting the European Parliament;

Whereas basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiations must, as specified in the Treaty, be laid down in order to enable each Member State, in accordance with Article 33 of the Treaty, to lay down the appropriate laws, regulations or administrative provisions to ensure compliance, to take the necessary measures with regard to teaching, education and vocational training, and to lay down such provisions in harmony with those applicable in this field in the other Member States;

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

Whereas it is necessary that basic standards be adapted to the conditions governing the use of nuclear energy and that they vary according to whether occupationally exposed persons or persons belonging to special groups of the population are concerned or protection of the population as a whole is envisaged;

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

Whereas procedure for the protection of the health of workers calls for both medical and physical radiation protection surveillance;

HAS ADOPTED THESE DIRECTIVES:

TITLE I

Definitions

Article 1

For the purposes of these Directives, the following terms have the meaning hereby assigned to them:

§ 1 — Physical and Radiological Terms

'Maximum permissible concentration of a radioactive nuclide': the concentration of this nuclide in air inhaled or in drinking water which delivers the maximum permissible dose under conditions of continuous exposure. It is expressed in units of activity per unit volume.

'Contamination': radioactive contamination, i.e. the contamination of any material or any area by radioactive substances.

In the particular case of workers, such contamination includes both external skin contamination and internal contamination irrespective of method of intake (inhalation, ingestion, absorption through the skin, etc.).

'Disintegration': the process of spontaneous breakdown of a nucleus of an atom resulting in the emission of a particle or a photon or of a particle and a photon.

'Natural background radiation': all ionising radiations from natural terrestrial and cosmic sources.

'Uptake': internal contamination in which radioactive substances participate in the metabolism of the body.

'Exposure': any exposure to ionising radiation; a distinction is made between external radiation, where the source is outside the body, and internal radiation, which is caused by the uptake of radioactive substances.

'Planned abnormal exposure': total exposure to ionising radiation of an occupationally exposed person, studied and accepted beforehand as a risk.

'Nuclide': the atom defined by its mass number, atomic number and energy state.

'Ionising radiations': eletromagnetic radiations (X-ray or gamma-ray photons or quanta), or corpuscular radiations (alpha particles, beta particles, electrons, positrons, protons, neutrons and heavy particles) capable of producing ions.

'Radioactivity': spontaneous disintegration of a nuclide, with the emission of a particle or a photon, to form a different nuclide.

'Radiotoxicity': the toxicity attributable to ionising radiations emitted by an incorporated radioactive element; it depends not only on the radioactive characteristics but also on the metabolism of the element in the body or in the organ, and therefore on its chemical and physical state.

'Source': an apparatus or substance capable of emitting ionising radiations.

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

'Unsealed source': a source consisting of radioactive substances in such a form that dispersion of radioactive substances cannot be prevented and risk of contamination cannot be eliminated.

'Radioactive substances': all substances displaying the characteristics of radioactivity.

§ 2 — Other Terms

'Accident': an unforeseen event which entails risk of exposure exceeding the maximum permissible doses.

'Medical surveillance': all the medical examinations and the measures taken by an approved medical practitioner for health surveillance of workers with a view to protecting them against ionising radiations, and to ensure compliance with the basic standards.

'Physical surveillance': all the surveys, monitoring and tests carried out with a view to protecting the health of workers and of the general public against ionising radiations, and to ensure compliance with the basic standards.

'Qualified expert': a person having the knowledge and training needed both to measure ionising radiations and to give advice in order to ensure the effective protection of individuals and the correct operation of protective facilities, and having qualifications recognised by the competent authority.

'Special groups of the population': these groups include:

(a) persons who enter the controlled area occasionally in the course of their duties, but are not regarded as 'occupationally exposed persons';

(b) persons who handle apparatus emitting ionising radiations or containing radioactive substances in quantities such that the radiations emitted do not result in the maximum permissible dose for this category of person being exceeded;

(c) persons who reside in the vicinity of the controlled area and as a result may be subjected to an exposure higher than that laid down for the population as a whole.

'Approved medical practitioner': a medical practitioner responsible for medical control whose qualifications and competence are recognised and approved by the competent authority.

'Occupationally exposed persons': persons who in a controlled area regularly undertake work exposing them to the dangers arising from ionising radiations.

'Controlled area': a specified area in which there is a source of ionising radiations and where occupationally exposed persons are liable to receive a dose higher than 1·5 rem per year; in this area both physical and medical radiation surveillance are applied.

'Protected area': any area surrounding a controlled area where there is a permanent danger of the maximum permissible dose for the general public being exceeded, and where there is physical radiation protection surveillance.

§ 3 — Units and Symbols

'Curie': the quantity of a radioactive nuclide in which the number of disintegrations per second is $3{\cdot}7 \cdot 10^{10}$; it is the unit of radioactivity. One 'kilocurie' equals 10^{3} curies, one 'millicurie' (mc) equals 10^{-3} curie, and one 'microcurie' equals 10^{-6} curie.

'Rad': the unit of absorbed dose: 1 rad equals 100 ergs per gramme of irradiated material at the place of interest.

'Rem': corresponds to the quantity of ionising radiation which, when absorbed by the human body, produces a biological effect identical to that produced in the same tissue by the absorption of one rad of X-radiation.

The X-rays taken as reference are those producing an average specific ionisation of 100 ion pairs per

micron of water. This corresponds to X-rays of about 250 kV.

'Röntgen': the quantity of X- or gamma radiation which the associated corpuscular emission per 0·001293 gramme of air produces, in air, ions carrying a quantity of electricity of either sign equal to one electrostatic unit.

§ 4 — Activity and Doses

'Activity': the number of disintegrations per unit time; activity is expressed in 'curies'.

'Absorbed dose': the amount of energy imparted to matter by ionising particles per unit mass of irradiated material at the place of interest, whatever type of ionising radiation is used. The unit of absorbed dose is the 'rad'.

'Exposure dose': of X- or gamma rays at a given place: the measure of radiation in terms of its ability to produce ionisation. The unit of exposure dose of X- or gamma rays is the 'röntgen' (r).

'Personal dose': the dose of ionising radiations received by any individual during a given period of time.

'Integral absorbed dose': the total quantity of energy imparted by ionising particles to material throughout the region of interest.

The unit of integral absorbed dose is the 'gramme-rad'.

'Relative biological effectiveness' (RBE): the ratio of a dose of X-rays taken as reference to the dose of the ionising radiation in question which produces the same biological effect. The accepted values of the RBE of various types of radiation are given in the following Table:

Radiation	RBE	Biological effect
X- and gamma rays, electrons and beta rays of all energies	1	Whole-body irradiation (blood-forming organs critical)
Fast neutrons and protons up to 10 MeV	10	Whole-body irradiation (cataract formation critical)
Alpha particles emitted by natural radio elements	10	Cancer formation
Heavy recoil nuclei	20	Cataract formation

'Biological effective dose' or 'RBE dose': determined by multiplying the absorbed rad dose by the RBE factor. The RBE dose is expressed in 'rem'.

'Maximum permissible doses compatible with adequate safety': the doses of ionising radiation which, in the light of present knowledge, are not expected to cause bodily injury to a person at any time during his life or to the population as a whole.

Such doses are assessed on the basis of the radiation received by individuals or by the population as a whole, excluding natural background radiation and radiation received in the course of medical examination and treatment.

'Accumulated dose': expresses the sum of all the doses, integrated in time, which an individual has received from any source, with the exception of those due to natural background radiation and to medical examination and treatment.

'Population dose': the dose of ionising radiations received by a population during a given period of time and weighted in relation to demographic data.

TITLE II

Scope

Article 2

These Directives 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 danger arising from ionising radiations.

Article 3

Each Member State shall make the reporting of the activities referred to in Article 2 compulsory and, in cases to be determined by the Member State in relation to the degree of danger arising from such activities, shall make the activities subject to, a procedure for prior authorisation.

Article 4

This procedure for reporting and for obtaining prior authorisation may be waived in the case of:

(a) radioactive substances with a total activity of less than 0·1 microcurie. This value is applied to the most highly toxic radioactive nuclides. Other values are determined in each case by reference to the relative radiotoxicity and the information given in the Tables in Annex I to these Directives;

(b) radioactive substances of a concentration of less than 0·002 microcurie per gramme and solid natural radioactive substances of a concentration of less than 0·01 microcurie per gramme;

(c) apparatus emitting ionising radiations of a type accepted by the competent authorities, provided that the radioactive materials are effectively protected against any contact or leakage and that the dose emitted, at any time and at any external point 0·1 metres from the surface of the apparatus does not exceed 0·1 millirem per hour.

Article 5

Apart from the cases provided for by national legislation, a prior authorisation shall always be required for:

(a) the use of radioactive substances for medical purposes;

(b) the addition of radioactive substances in the manufacture of foodstuffs, and in pharmaceutical goods, cosmetics and products for household use, and in the handling of such foodstuffs, pharmaceutical goods and products;

(c) the use of radioactive substances in the manufacture of toys.

TITLE III

Maximum permissible doses compatible with adequate safety

Article 6

§ 1 — Exposure of persons and the number of persons exposed to ionising radiations must be kept to a minimum.

§ 2 — Persons under the age of eighteen must not be employed in work involving occupational exposure to the risk of ionising radiation.

§ 3 — During pregnancy or the nursing period, women must not be employed in work involving a risk of high exposure.

CHAPTER I

Maximum permissible doses for occupationally exposed persons

Article 7

WHOLE-BODY EXPOSURE

§ 1 — The maximum permissible dose for a person occupationally exposed shall be expressed in rem and shall be calculated by reference to age and to an average annual dose of 5 rem.

The maximum permissible dose for an occupationally exposed person, of a given age, shall be calculated in accordance with the basic formula:

$$D = 5\,(N-18)$$

where

D = dose in rem

N = age in years.

Dose D is the dose actually received in the blood-forming organs, the gonads and the lenses of the eyes.

§ 2 — Protective devices shall be based on an average weekly dose of 0·1 rem.

§ 3 — The maximum cumulative dose in any period of thirteen consecutive weeks shall not exceed 3 rem. The following shall be taken into account in calculating the dose:

(a) Persons aged eighteen and over may receive a cumulative dose of 3 rem (distributed over thirteen consecutive weeks), provided that the basic formula is complied with and that the dose accumulated over one year never exceeds 12 rem.

A single dose of 3 rem may be permitted only as an exception.

(b) When the dose previously accumulated is known with certainty and is below the dose calculated according to the basic formula, doses may be accumulated at the rate of 3 rem per 13 weeks as long as the maximum permissible dose calculated according to the basic formula has not been reached.

(c) When the dose previously accumulated is not known with certainty, it shall be assumed to be equal to the maximum permissible dose calculated according to the basic formula.

(d) When the dose previously accumulated is known with certainty and corresponds to standards applying at a time when the recommended maximum permissible doses were higher than those derived from the basic formula, the method of calculation shall be as stipulated in (c).

Article 8

PLANNED ABNORMAL EXPOSURE

In the case of a planned abnormal exposure, a dose of 12·5 rem may be permitted for occupationally exposed persons. This dose may be received only once in a lifetime; it shall be included in the maximum permissible total dose calculated according to the basic formula. Any excess in relation to that maximum permissible total dose calculated according to the basic formula shall be disregarded.

Women of reproductive age may not be subjected to a planned abnormal exposure.

Article 9

ACCIDENTAL WHOLE-BODY EXPOSURE

Where there is accidental exposure of an occupationally exposed person, a dose between 3 and 25 rem, provided that it is received only once in a lifetime, shall be included in the maximum permissible cumulative dose corresponding to the age of the individual and calculated in accordance with the basic formula. Any excess in relation to that maximum permissible total dose shall be disregarded.

Article 10

PARTIAL EXPOSURE

Where there is partial exposure of the body, during which the doses received by the blood-forming organs, the gonads and the lenses of the eyes together do not exceed the limits set by the basic formula, the maximum permissible dose shall be laid down as follows:

(a) for external exposures of the extremities (hands and forearms, feet and ankles), 15 rem per 13 weeks and 60 rem per year;

(b) for external exposures of the whole skin, 8 rem per 13 weeks and 30 rem per year;

(c) for exposures of internal organs with the exception of the blood-forming organs, the grounds and the lenses of the eyes, 4 rem per 13 weeks and 15 rem per year.

CHAPTER II

Maximum permissible doses for special groups of the population

Article 11

(a) For persons belonging to the special groups of the population within the meaning of (a) and (b) of the fifth subparagraph of § 2 of Article 1, the maximum permissible dose shall be laid down as 1·5 rem per year; the dose in question is the dose actually received by the blood-forming organs, the gonads and the lenses of the eyes.

(b) For persons belonging to the special group of the population within the meaning of (c) of the fifth subparagraph of § 2 of Article 1, the maximum permissible dose shall be laid down as 0·5 rem per year; the dose in question is the dose actually received by the blood-forming organs, the gonads and the lenses of the eyes.

CHAPTER III

Maximum permissible dose for the population as a whole

Article 12

For the population as a whole, the maximum permissible dose shall be 5 rem per head, accumulated up to thirty years of age. This dose shall take into account, by weighting, the doses received by occupationally exposed persons and by special groups of the general public. It shall not take into account exposure to natural background radiation and exposure in the course of medical examination and treatment.

TITLE IV

Maximum permissible exposure and contamination

Article 13

§ 1 — 'Maximum permissible exposure' means the external exposure distributed in the body over a period of time and which imparts, in the light of present knowledge, the maximum permissible dose to the individual or to the general public.

§ 2 — Exposures shall, according to the case, be expressed in terms of exposure dose, dose measured in the air, or in particle flux.

§ 3 — The Table in Annex 2 to these Directives shows the corresponding neutron flux in respect of the maximum permissible dose for occupationally exposed persons.

Article 14

§ 1 — 'Maximum permissible contaminations' means such contaminations that the quantities of radioactive nuclides present in air inhaled or in drinking water do not exceed the maximum permissible concentrations laid down in the Table in Annex 3 to these Directives.

§ 2 — Concentrations shall be expressed in activity per unit volume.

§ 3 — The Table in Annex 3 gives the concentrations which correspond to the maximum permissible dose for occupationally exposed persons.