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COUNCIL DIRECTIVE

of 27 October 1966

amending the 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

(66/45/Euratom)

THE COUNCIL OF THE EUROPEAN ATOMIC ENERGY COMMUNITY,

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

Having regard to the request of the Federal Republic of Germany of 23 March 1960 for the basic standards to be revised and supplemented;

Having regard to the Opinion of the specialist group appointed by the Scientific and Technical Committee from among scientific experts in 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[1];

Whereas the basic standards must be adjusted in accordance with the most recent scientific data;

Whereas it is necessary to take account of experience acquired from the practical application of the basic standards by the Member States;

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Council Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiations,[2] as amended by the Council Directive of 5 March 1962,[3] shall be amended in accordance with Articles 2 to 20.

Article 2

In Article 1 (1) the seventh and eighth subparagraphs shall be replaced by the following:

'Exposure': any exposure of persons to ionising radiation; a distinction is made between:

— external exposure, where the source is outside the body;

— internal exposure, which is caused by the introduction of radioactive substances into the body; and

— total exposure, which is the sum of external exposure and internal exposure.

'Planned abnormal exposure': external and internal (or external or internal) exposure as a result of which a maximum permissible dose is exceeded in occupationally exposed persons, and for which the risk has previously been studied and accepted. It may be authorised only in cases of absolute necessity.

'Unplanned abnormal exposure': external and internal (or external or internal) exposure which is of a fortuitous nature and which involves exceeding a maximum permissible dose for occupationally exposed persons.

[1] OJ No 96, 2.6.1965, p. 1696/65.

[2] OJ No 11, 20.2.1959, p. 221/59.

[3] OJ No 57, 9.7.1962, p. 1633/62.

Article 3

The Table in Article 1 (4) shall be replaced by the following:

Radiation	RBE[1]
X- and gamma rays, electrons and beta rays of all energies	1
Neutrons	2 to 10·5[2]
Protons	10
Alpha particles	10
Heavy recoil nuclei	20

[1] In the case of irradiation of the lenses of the eyes, the RBE must be multiplied by:
— a factor of 1 when its value is equal to 1;
— a factor of 3 when its value is higher than or equal to 10;
— a factor between 1 and 3, obtained by interpolation, for RBE values between 1 and 10.

[2] See Annex 2.

Article 4

(a) The heading of Article 7 shall be deleted.

(b) Article 7 (1) shall be replaced by the following:

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

The maximum permissible dose for a person of a given age, received by the blood-forming organs and the gonads (or by one or other of those organs), shall be calculated in accordance with the basic formula:

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

where D = dose in rem

N = age in years.'

(c) Article 7 (3) shall be amended to read as follows:

'§ 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 must be avoided wherever possible.'

Subparagraphs (b) to (d) shall remain unaltered.

Article 5

Articles 8 and 9 shall be deleted.

Article 6

Article 10 shall be renumbered Article 8 and be amended to read as follows:

'*Article 8*

Where there is partial exposure of the body, during which the doses received by the blood-forming organs and the gonads or by one or other of those organs do not exceed the limits set by the basic formula, the maximum permissible dose shall be:

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

(b) for external exposure of the skin or bone, with the exception of the extremities specified in (a) above, 8 rem per thirteen weeks and 30 rem per year;

(c) for exposure of other organs individually, 4 rem per thirteen weeks and 13 rem per year.'

Article 7

Article 11 shall be renumbered Article 9.

Article 8

Article 12 shall be renumbered Article 10. The first sentence of that Article shall be amended to read as follows:

'For the population as a whole, the maximum permissible genetically significant dose shall be 5 rem per head, accumulated up to thirty years of age.'

Article 9

Article 13 shall be renumbered Article 11. Paragraph 3 of that Article shall be amended to read as follows:

'The Table in Annex 2 shows the neutron flux as imparting a dose rate of 2·5 millirem/hours as a function of the neutron energy and the corresponding RBE values.'

Article 10

Article 14 shall be renumbered Article 12 and amended to read as follows:

'Article 12

§ 1 — "Maximum permissible contamination of persons" means contamination resulting from the inhalation or ingestion of air or water contaminated to the maximum permissible concentrations calculated in accordance with Annex 3.

§ 2 — The values shown in Annex 3 are applicable for determining the maximum permissible concentrations in inhaled air or in drinking water; they must be considered as average values covering a period of thirteen consecutive weeks.

§ 3 — These values relate to continuous exposure, calculated on the basis of one hundred and sixty-eight hours per week, for occupationally exposed persons. They must be multiplied by a factor of 3 to relate to a working week of forty to forty-eight hours.

§ 4 — The introduction at a single time of a quantity of radioactive nuclides equal to that which would be introduced in thirteen consecutive weeks on the basis of the maximum permissible concentrations as calculated from Annex 3 must be avoided wherever possible.

§ 5 — Outside the controlled areas, for persons belonging to the population group defined in (c) of the fifth subparagraph of Article 1 (2), the maximum permissible concentrations which determine the maximum permissible contaminations shall be laid down as one-tenth of the values shown in the Tables in Annex 3. They must be considered as average values relating to a period of a year.

§ 6 — Where contamination results from a mixture of radioactive nuclides, Table C, D or E in Annex 3, as the case may be, shall apply.'

Article 11

Article 15 shall be deleted.

Article 12

The provisions of the new Articles 13, 14 and 15 shall be as follows:

'Article 13

TOTAL EXPOSURE

In the case of total exposure, the sum of the doses due to external exposure and internal exposure shall be calculated by an appropriate method and shall be within the maximum permissible doses.

Article 14

ABNORMAL EXTERNAL EXPOSURE

§ 1 — "Planned abnormal external exposure"

(a) The dose delivered on one occasion or more in the course of a planned abnormal external exposure shall not exceed 12 rem. This dose shall be added to the dose accumulated up to the time of the abnormal exposure.

(b) If the cumulative dose thus calculated is below the maximum permissible dose calculated according to the basic formula set out in Article 7 (1) and if the quarterly dose exceeds 3 rem, subsequent exposures shall be reduced to a maximum dose of 1·5 rem per quarter until such time as the values derived from applying the provisions of Article 7 (3) are restored.

(c) If the cumulative dose thus calculated exceeds the maximum permissible dose calculated according to the basic formula set out in Article 7 (1), subsequent exposures shall be reduced to a maximum dose of 2·5 rem per year until such time as the cumulative dose conforms again to the basic formula.

(d) No woman of reproductive capacity may be subjected to such an exposure.

§ 2 — "Unplanned abnormal external exposure"

(a) When a dose delivered during an unplanned abnormal external exposure does not exceed 25 rem, paragraph 1 (b) or (c) shall be applicable.

(b) When the dose exceeds 25 rem, Article 25 (3) shall be applicable.

§ 3 — "Partial planned abnormal external exposure"

(a) The dose delivered on one or more occasions in the course of a partial planned abnormal external exposure must not exceed:

— in the case of the extremities (hands, forearms, feet, ankles): 60 rem;

— in the case of the skin (with the exception of that of the extremities): 30 rem;

— in the case of the lenses of the eyes: 15 rem.

The doses received shall be added to the doses accumulated in the current year.

(b) For subsequent exposures of the extremities, the skin (with the exception of that of the extremities) and the lenses of the eyes, the maximum permissible doses to be taken into consideration shall, until such time as the

integrated values derived from applying the provisions of that Article are restored, be reduced to half of the dose laid down in Article 8.

§ 4 — "Partial unplanned abnormal exposure"

(a) When a dose delivered in the course of a partial unplanned abnormal external exposure does not exceed:

— 120 rem in the case of the extremities (hands, forearms, feet, ankles);

— 60 rem in the case of the skin (with the exception of that of the extremities);

— 30 rem in the case of the lenses of the eyes;

paragraph 3 (b) shall be applicable.

(b) When the dose exceeds the values specified in (a), Article 25 (3) shall be applicable.

Article 15

ABNORMAL INTERNAL EXPOSURE

§ 1 — "Planned abnormal internal exposure"

(a) A planned abnormal internal exposure shall be permitted only if it cannot be avoided by taking all the necessary safety measures. Should such exposure prove unavoidable, the quantity of radioactive nuclides introduced into the body at one time or more than once must not exceed the quantity which would result from exposure, over a period of one year, to the maximum permissible concentrations as shown in Annex 3 for occupationally exposed persons.[1]

(b) Every planned abnormal internal exposure must be entered in the physical control records (Article 22 (2)) and in the medical file of the worker concerned (Article 26), together with the estimated value of the absorbed dose and of the uptake resulting from that exposure.

(c) In the case of subsequent internal exposure, the maximum permissible concentrations to be taken into consideration must be at the most equal to half the values calculated in accordance with Annex 3 and must remain so for such time as would be required to accumulate, by continuous exposure under the same conditions, the quantity of radionuclides introduced into the body as a result of the planned abnormal internal exposure.

(d) No woman of reproductive capacity may be subjected to such an exposure.

§ 2 — "Unplanned abnormal internal exposure"

(a) When the quantity of radioactive nuclides introduced into the body during an unplanned abnormal internal exposure is less than double the quantity as laid down in paragraph 1 (a), the provisions of paragraph 1 (c) shall be applicable.

(b) When the contamination exceeds the limit laid down in (a) of this paragraph, Article 25 (3) shall be applicable.'

Article 13

Article 16 shall be replaced by the following:

'*Article 16*

The values of maximum permissible exposure and contamination applicable to conditions other than those obtaining in the case of occupationally exposed persons shall be calculated from the maximum permissible doses as laid down in Part III.'

Article 14

Article 25 (3) shall be replaced by the following:

'§ 3 — *Special surveillance*

(a) Special surveillance shall be arranged in the event of abnormal exposure.

(b) Routine medical examinations shall be supplemented by any examinations, decontamination measures and urgent remedial treatment considered by the medical practitioner to be necessary.

(c) The medical practitioner shall decide whether the worker should remain at work, be moved away, or be isolated and whether urgent medical treatment should be given.'

Article 15

Annex 1 shall be replaced by the following:

[1] This quantity X (in curies) may be calculated from the maximum permissible concentrations in air for occupationally exposed persons for forty to forty-eight hours per week by the following formula:

$$X = 2500 \cdot q$$

q being three times the value shown in the Tables in Annex 3. The coefficient 2500 is obtained on the basis of an inhalation of 10 m^3 of air per day for five days per week and fifty weeks per year.

'ANNEX 1

§ 1 — Activities below which the requirements for reporting and obtaining prior authorisation may be waived:

Nuclides of very high radiotoxicity: 10^{-7} curies;

Nuclides of high radiotoxicity: 10^{-6} curies;

Nuclides of moderate radiotoxicity: 10^{-5} curies;

Nuclides of low radiotoxicity: 10^{-4} curies;

§ 2 — The principal radioactive nuclides are classified as follows, according to their relative radiotoxicity:

(a) *Very high radiotoxicity:*

Ac^{227} Am^{241} Am^{242m} Am^{243} Cf^{249} Cf^{250} Cf^{251} Cf^{252} Cf^{254} Cm^{242} Cm^{243} Cm^{244} Cm^{245} Cm^{246} Cm^{248} Es^{254} Es^{255} Np^{237} Pa^{231} Pb^{210} Po^{210} Pu^{238} Pu^{239} Pu^{240} Pu^{241} Pu^{242} Ra^{223} Ra^{226} Ra^{228} Th^{227} Th^{228} Th^{230} U^{230} U^{232} U^{233} U^{234}

(b) *High radiotoxicity:*

Ac^{228} Ag^{110m} Am^{242} At^{211} Ba^{140} Bi^{207} Bi^{210} Bk^{249} Ca^{45} Cd^{115m} Ce^{144} Cf^{253} Cl^{36} Cm^{247} Co^{56} Co^{60} Cs^{134} Cs^{137} Es^{253} Es^{254m} Eu^{152} (13 years) Eu^{154} Fm^{255} Fm^{256} Hf^{181} I^{124} I^{126} I^{131} I^{133} In^{114m} Ir^{192} Mn^{54} Na^{22} Pa^{230} Pb^{212} Pu^{244} Ra^{224} Ru^{106} Sb^{124} Sb^{125} Sc^{46} Sr^{89} Sr^{90} Ta^{182} Tb^{160} Te^{127m} Te^{129m} Th^{234} Tl^{204} Tm^{170} U^{236} Y^{91} Zr^{95}

(c) *Moderate radiotoxicity:*

A^{41} Ag^{105} Ag^{111} Am^{244} As^{73} As^{74} As^{76} As^{77} Au^{196} Au^{198} Au^{199} Ba^{131} Be^{7} Bi^{206} Bi^{212} Bk^{250} Br^{82} C^{14} Ca^{47} Cd^{109} Cd^{115} Ce^{141} Ce^{143} Cl^{38} Co^{57} Co^{58} Cr^{51} Cs^{131} Cs^{136} Cu^{64} Dy^{165} Dy^{166} Er^{169} Er^{171} Eu^{152} (9 h) Eu^{155} F^{18} Fe^{52} Fe^{55} Fe^{59} Fm^{254} Ga^{72} Gd^{153} Gd^{159} Hg^{197} Hg^{197m} Hg^{203} Ho^{166} I^{130} I^{132} I^{134} I^{135} In^{115m} Ir^{190} Ir^{194} K^{42} K^{43} Kr^{85m} Kr^{87} La^{140} Lu^{177} Mn^{52} Mn^{56} Mo^{99} Na^{24} Nb^{93m} Nb^{95} Nd^{147} Nd^{149} Ni^{63} Ni^{65} Np^{239} Os^{185} Os^{191} Os^{193} P^{32} Pa^{233} Pb^{203} Pd^{103} Pd^{109} Pm^{147} Pm^{149} Pr^{142} Pr^{143} Pt^{191} Pt^{193} Pt^{197} Pu^{243} Rb^{86} Re^{183} Re^{186} Re^{188} Rh^{105} Rn^{220} Rn^{222} Ru^{97} Ru^{103} Ru^{105} S^{35} Sb^{122} Sc^{47} Sc^{48} Se^{75} Si^{31} Sm^{151} Sm^{153} Sn^{113} Sn^{125} Sr^{85} Sr^{91} Sr^{92} Tc^{96} Tc^{97} Tc^{97m} Tc^{99} Te^{125m} Te^{127} Te^{129} Te^{131m} Te^{132} Th^{231} Tl^{200} Tl^{201} Tl^{202} Tm^{171} U^{240} + Np^{240} V^{48} W^{181} W^{185} W^{187} Xe^{135} Y^{90} Y^{92} Y^{93} Yb^{175} Zn^{65} Zn^{69m} Zr^{97}

(d) *Low radiotoxicity:*

A^{37} Cm^{249} Co^{58m} Cs^{134m} Cs^{135} Ge^{71} H^{3} I^{129} In^{113m} In^{115} Kr^{85} Nb^{97} Nd^{144} Ni^{59} O^{15} Os^{191m} Pt^{193m} Pt^{197m} Rb^{87} Re^{187} Rh^{103m} Sm^{147} Sr^{85m} Tc^{96m} Tc^{99m} Th nat.* Th^{232} U nat.** U^{235} U^{238} Xe^{131m} Xe^{133} Y^{91m} Zn^{69} Zr^{93}

§ 3 — In the case of the nuclides In^{115}, Nd^{144}, Rb^{87}, Re^{187}, Sm^{147} the requirements for reporting and obtaining prior authorisation may be waived, irrespective of the quantities used.

§ 4 — In the case of a mixture of radioactive nuclides belonging to different radiotoxicity groups, the requirements for reporting and obtaining prior authorisation may be waived if the sum of the ratios between the activity of each of the radioactive nuclides and the limit laid down in paragraph 1 for the group to which it belongs is less than 1.

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* By custom, one curie of natural thorium corresponds to:
$3{\cdot}7 \cdot 10^{10}$ dis/sec of Th^{232} and
$3{\cdot}7 \cdot 10^{10}$ dis/sec of Th^{228}.

** By custom, one curie of natural uranium corresponds to:
$3{\cdot}7 \cdot 10^{10}$ dis/sec of U^{238},
$3{\cdot}7 \cdot 10^{10}$ dis/sec of U^{234} and
$1{\cdot}7 \cdot 10^{9}$ dis/sec of U^{235}.'