COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 20 November 1978

proposal for a Directive (Euratom) of the Council amending the Directive laying down the Basic Safety Standards for the health protection of the general public and workers against the dangers of ionizing radiation

(Submitted by the Commission to the Council)

EXPLANATORY MEMORANDUM

The Basic Safety Standards for the health protection of the general public and workers against the dangers of ionizing radiation were revised in 1976 (Council Directive of 1 June 1976, published in O. J. No L 187 of 12 July 1976). Since then, the International Commission on Radiological Protection – a scientific body which is recognized as an authority throughout the world and to which the Euratom Commission and, subsequently, the Commission of the European Communities have always referred for the purpose of laying down the Basic Safety Standards for the health protection of the general public and workers against the dangers of ionizing radiation – has issued Publication 26, published in June 1977.

This publication contains a certain number of recommendations which, while not calling into question the fundamental principles of radiation protection or the manner in which the latter is organized, define new concepts and units and provide those whose task it is to protect the health of individuals against any possible exposure risk with a number of new values; these values are conceived in a more coherent way, since they take account of new metabolic data, and are calculated in a more logical manner, since they take account for the first time of the additivity of the radiation to which the various organs or tissues in question are exposed.

In fact, the values proposed differ only slightly from previous ones. Some of them, particularly those relating to the transuranic elements, are generally more strict. Others are slightly less so. The result is a new, more coherent system of calculation which corresponds more closely to actual biological and metabolic processes; if the latest scientific knowledge is to be made use of, this system should be adopted without delay.

Other international organizations, notably the IAEA, the OECD, the WHO and the ILO, are working out – on the basis of Publication 26 mentioned above – a joint recommendation addressed to the States members of these organizations and incorporating the ICRP recommendations.

That being so, the Commission cannot dissociate itself from these other international organizations. Neither can it accept that the laws of the Member States of the European Communities should be out of step with the latest scientific and technical knowledge. This view is shared by the Economic and Social Committee which, at its plenary session on 12.7.78, regretted the fact that there was an appreciable time lag before workers and the general public benefited from this scientific and technical progress and deplored the slowness with which national laws were modified to take account of the ICRP principles, which, be it said, the Directive of 1 June 1976 takes up in more legal terms.

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The main changes contained in the proposal for a directive may be summarized as follows:

Title I introduces three new units but, in doing so, gives users the option of using the old units for some time to come. The Commission, indeed, is aware of the dangers - particularly in the area of medicine and of monitoring - of a sudden and premature introduction of units with which most users are still largely unfamiliar.

Title II remains fundamentally unchanged. Titles III and IV take account of the approach described above. In addition, the dose limits for workers and the public remain the same, except that the formula D = 5 (N-18), the maximum permissible dose during one quarter and the dose limit of 5 rem/30 years per head of the population as a whole are dispensed with. The non-retention of the latter limits does not, however, imply a relaxation. In fact, the basic standards lay down that any exposure must be justified and that protection measures must be made as effective as possible. What is more, it is precisely because these two principles of optimization and justification are also - and for the first time - applicable to the medical field that it would have been impossible and illogical to lay down a dose limit for the population as a whole.

Titles V, VI and VII on the organization of radiation protection measures remain virtually unchanged.

As regards Annex III, it will contain the figures for maximum permissible intake laid down by the ICRP. The other annexes remain virtually unchanged.

With a view to keeping the annexes in question in line with scientific and technical progress and to obtaining the most appropriate figures as quickly as possible, the final articles of the Directive provide for the setting up of a standing committee on amendment and updating, referred to as 'the Committee'. It is anticipated that Member States will have to take special measures to incorporate the values laid down by the Committee into their own national legislation as rapidly as possible.

That is why the Commission is forwarding to the Council of Ministers of the Member States of the European Community the enclosed proposal for a directive, which makes some slight, but not fundamental, amendments to the Directive of 1 June 1976.

Doc. Nr 5020/78 e

Revised May, 1978

II

(Acts whose publication is not obligatory)

COUNCIL

Proposed revision (Oct 1977)

of the Council Directive

of 1 June 1976

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

(76/579 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, worked out 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 ,

Having regard to the opinion of the Economic and Social Committee ,

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 radiations, 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 the Council, on 2 February 1959, adopted Directives laying down such basic standards (1) and whereas these were last amended by Directive 76/579/Euratom (2);

Whereas the usefulness of some modifications of the last Directive has become apparent in the light of new scientific knowledge of radiation protection

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

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

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(1) OJ No 11, 20.2.1959, p.221/59.
(2) OJ No L 187 of 12.7.1976

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

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

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, 6bis and 12.

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

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

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

$$1 \text{ Ci} = 3.7 \times 10^{10} \text{ Bq (exactly)}$$
$$1 \text{ Bq} = 2.7027 \times 10^{-11} \text{ Ci}$$

Absorbed dose (D): the quotient of $d\bar{\epsilon}$ by dm, where $d\bar{\epsilon}$ 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.

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

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

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

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

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

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 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

$$L_\Delta \text{ becomes } L_\infty$$

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

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

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

Irradiation: any irradiation of persons by ionizing radiation. A distinction is made between:

- external irradiation: irradiation resulting from sources outside the body;
- internal irradiation: irradiation resulting from sources inside the body;
- total irradiation: the sum of external and internal irradiation.

Continuous exposure: External irradiation where the sources of radiation subjects the body to prolonged irradiation although its intensity may vary with time or internal irradiation due to continuous intake although its level may vary with time.

Single exposure: External irradiation of short duration, or internal irradiation following 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.

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: the special name of the unit of dose equivalent when the absorbed dose is expressed in grays. In this Directive the values to be used when the dose equivalent is expressed in rems are also given

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

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

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 $g.cm^{-3}$. It is not necessary to determine the dose equivalent in the outer layer of thickness 0.07 mm.

Effective dose: the weighted mean of the average doses in the various organs or tissues evaluated by the method set out in Annex II, Section E.

Whole body irradiation: irradiation regarded as uniform through the whole body.

Partial body irradiation: irradiation predominantly of part of the body or of one or more organs or tissues, or irradiation which is not regarded as uniform through the whole 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 childbearing, 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 childbearing, which is taken to be 30 years.

Annual genetically significant dose to a population: the average of the individual annual gonad doses, weighted in the case of each individual dose for the expected 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 contamination includes both external skin contamination and internal contamination irrespective of method of intake.

Dose limits: The limits that are established 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 irradiation 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 irradiation 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 7, 8, 9 and 11.

Derived limit of concentration of radionuclides in the air inhaled expressed in units of activity per unit volume is the annual mean concentration in the air which, inhaled over a 2000 hours' work, 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 and any possibility of contamination.

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

Natural background radiation: consists of all ionizing radiation from natural terrestrial and cosmic sources, to the extent that the irradiation 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 an annual dose greater than 1/10th of the limits of the annual dose laid down for workers.

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 of 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 experts: persons 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 authority.

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 a limit of annual dose 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 in which a dose limit 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, and in which a dose limit for exposed workers is exceeded, and in which the limits for planned special exposures may also be exceeded. Emergency exposures shall apply only to volunteers.

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 when the amounts 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 paragraph (a);

(d) apparatus emitting ionizing radiations and containing radioactive substances in amounts greater than 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

$$1\ \mu\text{Sv}\ h^{-1}\ (0.1\ \text{mrem}\ h^{-1})$$

(e) apparatus other than television receivers emitting ionizing radiation but not containing any radioactive substances, provided that:
   (1) it is of a tye 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

$1\ \mu\text{Sv h}^{-1}$ (0.1 mrem h^{-1});

(f) television receivers which do not cause, at any point situated at a distance of 0.05 m from the accessible surface of the receiver, a dose rate exceeding

$5\ \mu\text{Sv h}^{-1}$ (0.5 mrem h^{-1}).

Article 5

Apart from the prohibitions provided for by national law, and irrespective of the degree of danger involved, a system of prior authorization must be applied in respect of:

(a) the administration of radioactive substances to persons for purposes of diagnosis, treatment or research;

(b) the use of radioactive substances in toys and the importation of toys containing radioactive substances;

(c) the addition of radioactive substances in the production and manufacture of foodstuffs, medicinal products, cosmetics and products for household use (except for the instruments and timepieces referred to in Article 4 (c) and the importation for commercial purposes of such goods if they contain radioactive substances.

TITLE III - LIMITATION OF DOSES FOR CONTROLLABLE EXPOSURES

Article 6

The limitation of individual and collective doses resulting from controllable exposures shall be based on the following general principles:

(a) Every activity resulting in an exposure to ionizing radiation shall be justified by the advantages which it produces.

(b) All exposures shall be kept as low as reasonably achievable.

(c) Without prejudice to Article 10, the sum of the doses and committed doses received shall not exceed the dose limits for exposed workers, members of the public, apprentices and students, as the case may be, as specified in this title.

The principles set out in (a) and (b) above apply to all exposures to radiation and include medical exposures. The principle set out in (c) does not apply to the exposure of individuals as a result of medical examination and treatment undergone by them.

Chapter I - Limitation of doses for exposed workers

Article 6bis

1. Workers under 18 years of age may not carry out any activity which would result in their being exposed workers.

2. During pregnancy or the nursing period, women must not be employed in work involving a risk of high exposure; if necessary, a special watch will be kept for bodily radioactive contamination.

Article 7 - Whole body irradiation

1. The dose limit for whole body irradiation of exposed workers shall be 50 mSv (5 rems) in a year.

2. For women of reproductive capacity, the dose to the abdomen shall not exceed 13 mSv (1.3 rems) in a quarter.

3. As soon as pregnancy is declared, measures shall be taken to ensure that exposure of the woman concerned in the context of her employment is such that the dose to the foetus, accumulated over the period of time between declaration of pregnancy and the date of delivery, remains as small as is reasonably practicable and in no case exceeds 10 mSv (1 rem). In general, this limitation can be achieved by employing the woman in working conditions appropriate to category B workers.

Article 8

In the case of partial body irradiation:

(a) the dose limit for the effective dose evaluated by the method set out in Annex II, Section E, shall be 50 mSv (5 rems) in a year; the average dose in each of the organs or tissues involved shall not exceed 500 mSv (50 rems) in a year.

(b) In addition:

- the dose limit for the lens of the eye shall be 300 mSv (30 rems) in a year;
- the dose limit for the skin shall be 500 mSv (50 rems) in a year, and shall apply to the dose averaged over any area of 100 cm^2;
- the dose limit for the hands, forearms, feet and ankles shall be 500 mSv (50 rems) in a year.

Chapter II - Limitation of doses for apprentices and students

Article 9

1. The dose limits for apprentices and students aged 18 years or over who are training for employment involving exposure to ionizing radiation or who, in the course of their studies, are obliged to use sources, shall be equal to the dose limits for exposed workers laid down in Articles 7 and 8.

2. The dose limits for apprentices and students aged between 16 and 18 years who are training for employment involving exposure to ionizing radiation or who, in the course of their studies, are obliged to use sources, shall be equal to 3/10ths of the limits of annual dose for exposed workers laid down in Articles 7 and 8.

3. The dose limits for apprentices and students aged 16 years or over who are not subject to the provisions of paragraphs 1 and 2 and for apprentices and students aged less than 16 years, shall be the same as the dose limits for members of the public specified in Article 11. However, the contribution to the annual doses that they are liable to receive by virtue of the training shall not exceed one-tenth of the dose limits specified in Article 11 and each single exposure shall not exceed one-hundredth of those dose limits.

Chapter III - Planned special exposures

Article 10

1. Only workers of category A defined in Article 23 may be subjected to planned special exposures. Each planned special exposure must be the subject of an appropriate permit.

   Such a permit shall be given only in exceptional situations during normal operations when alternative techniques which do not involve such exposures cannot be used. Account shall be taken of the age and health of the workers involved.

2. The doses or committed doses received as a result of planned special exposures must not in any year exceed twice the limits of annual dose laid down in Articles 7 and 8 or, in a lifetime, five times those dose limits.

3. Planned special exposures must not be authorized:

   (a) if, during the previous 12 months, the worker has received an exposure giving rise to doses in excess of the limits of annual dose laid down in Articles 7 and 8, or

   (b) if the worker has previously received accidental or emergency exposures, the sum of the doses from which exceeds five times the limits of annual dose laid down in Articles 7 and 8; or

   (c) if the worker is a woman of reproductive capacity.

4. The exceeding of dose limits as a result of planned special exposure shall not in itself, be a reason for excluding the worker from his usual occupation. Subsequent conditions of exposure shall be subject to the agreement of the approved medical practitioner.

5. All planned special exposures must be entered in the medical record provided for in Article 35, in which the estimated value of the dose of the activities taken into the body shall also be entered.

6. Before receiving a planned special exposure, the worker shall be given appropriate information about the risks involved and the precautions to be taken during the operation.

Chapter IV - Limitation of doses for the population

Article 11 - Dose limits for members of the public

1. The following dose limits shall apply without prejudice to Article 12.

2. In the case of the whole body irradiation the dose limit shall be 5 mSv (0.5 rem) in a year.

3. In the case of partial body irradiation:

   (a) the dose limit for the effective dose evaluated by the method set out in Annex II, Section E, shall be 5 mSv (0.5 rem) in a year; the average dose in each of the organs or tissues involved shall not exceed 50 mSv (5 rems) in a year.

   (b) In addition:

   - the dose limit for the lens of the eye shall be 30 mSv (3 rems) in a year.
   - the dose limit for the skin shall be 50 mSv (5 rems) in a year, and shall apply to the dose averaged over any area of 100 cm^2.
   - the dose limit for the hands, forearms, feet and ankles shall be 50 mSv (5 rems) in a year.

Article 12 - Exposure of the population as a whole

1. Each Member State shall see that the contribution to the irradiation of the population as a whole from each activity is kept to the minimum amount necessitated by that activity, taking account of the principles set out in Article 6.

2. The total of all such contributions shall be kept under review and in particular the genetic dose resulting from all these contributions shall be estimated.

3. Member States shall regularly transmit the results of these reviews and estimates to the Commission.

TITLE IV - DERIVED LIMITS

Article 13

1. The setting of derived limits in this Title shall not exclude the use of other methods of verifying compliance with the dose limits.

2. 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.

Article 14 - External irradiation only

In the case of external irradiation of the whole body or of a substantial fraction of the body, the dose limits fixed in Articles 7, 8 and 11 shall be deemed to be complied with if the deep dose equivalent index does not exceed the dose limit laid down for the whole body irradiation, and if the shallow dose equivalent index does not exceed the dose limit laid down for the skin.

In the case of irradiation by neutrons or protons the dose limits shall be deemed to have been complied with if the doses assessed using the conversion factors laid down in Annex II, Sections C and D, do not exceed the dose limits fixed for whole body irradiation.

Article 15 - Internal irradiation only

The values of intake and concentration of radionuclides in the air, to be used in implementing the requirements of Articles 7, 8 and 11, shall be those laid down in Annex III.

(a) The tables listed in Annex III (1) give:

- the limits of annual intake by inhalation of radionuclides for exposed workers;
- the derived limits of concentration of radionuclides in the air inhaled for exposed workers. They must be considered as average values for one year;
- the limits of annual intake by inhalation and by ingestion of radionuclides for members of the public.

(b) Where contamination is caused by a mixture of radionuclides the methods given in Annex III (2) shall be used.

Article 16 - Combinations of external and internal irradiation

In the case of combinations of external irradiation of the whole body or of a substantial fraction of the body, and internal contamination by one or more radionuclides, the limits of Articles 7, 8 and 11, shall be deemed to have been met if both the following conditions are satisfied:

$$(a)\quad \frac{H_{I,d}}{H_L} + \sum_j \frac{I_j}{I_{j,L}} \leqslant 1 \ ,$$

Where

$H_{I,d}$ is the annual deep dose equivalent index, H_L is the limit of annual dose for the whole body, I_j is the annual intake of the radionuclide j, and $I_{j,L}$ is the limit of annual intake of that radionuclide; and

(b) the limitations in the doses laid down in Articles 8(b) and 11(3)(b) as appropriate are applied.

Article 17

The derived limits relating to apprentices and students shall be derived from the limitations of dose laid down in Article 9.

TITLE V - ACCIDENTAL AND EMERGENCY EXPOSURES OF WORKERS

Article 18

All accidental and emergency exposures shall be entered in the medical record of the worker, provided for in article 35. Whereever possible doses and committed doses received voluntarily or involuntarily in the course of accidental and emergency exposures must be recorded separately on the exposure record provided for in article 30. The procedures set out in Article 36 shall also be applied.

TITLE VI - FUNDAMENTAL PRINCIPLES GOVERNING OPERATIONAL PROTECTION OF EXPOSED WORKERS

Article 19

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

(a) classification of places of work into different areas;

(b) classification of workers into different categories;

(c) implementation of control measures and monitoring relating to these different areas and to the different categories of workers.

These principles of protection shall also apply to the apprentices and students referred to in Article 9 (1) and (2).

Chapter I - Measures for the restriction of exposure

Section 1 - Classification and demarcation of areas

Article 20

For the purposes of radiation protection, each Member State shall make arrangements as regards all places of work where there is a risk of exposure to ionizing radiation.

In working areas where the exposure is not liable to exceed one-tenth of the limits of annual dose for exposed workers, it shall not be necessary to make special arrangements for the purposes of radiation protection.

In working areas where the exposure is liable to exceed one-tenth of the limits of annual dose laid down for exposed workers, the arrangements must be appropriate to the nature of the installation and sources and to the magnitude and nature of the hazards. The scope of the precautions and monitoring, as well as their type and quality, must be appropriate to the

hazards associated with the work involving exposure to ionizing radiation.

A distinction shall be made between:

(a) controlled areas.

Any area in which doses are liable to exceed three-tenths of the limits of annual dose laid down for exposed workers shall constitute or be included in a controlled area.

Annex IV lists examples of establishments and plants in which the presence of generators and sources liable to be the cause of exposure generally justifies the demarcation of one or more controlled areas.

(b) supervised areas.

Any area which is not considered as a controlled area and in which doses are liable to exceed one-tenth of the limits of annual dose laid down for exposed workers shall be considered as a supervised area.

Article 21

Controlled areas must be demarcated.

Taking into account the nature and extent of the radiation hazards:

(a) radiological environmental surveillance shall be organized in controlled and supervised areas, and, in particular, activities, doses and dose rates as the case may be shall be monitored and results recorded;

(b) in controlled and supervised areas, working instructions appropriate to the radiation hazard shall be laid down;

(c) the hazards inherent in the sources shall be indicated in controlled areas;

(d) signs indicating sources shall be displayed in controlled and supervised areas.

Qualified experts shall be concerned in the discharge of these duties.

Article 22

The minimum requirement for a controlled area shall be the control of access by appropriate warning signs.

Section 2 - Classification of exposed workers

Article 23

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

- category A: those who are liable to receive a dose greater than three-tenths of a limit of annual dose.

- category B: those who are not liable to receive this dose.

Article 24

Exposed workers must be informed of the health risks involved in their work, the precautions to be taken, and the importance of complying with the technical and medical requirements.

Apprentices and students referred to in Article 9 (1) and (2) shall also be given adequate training in the field of radiation protection and appropriate information regarding the risks involved in their work.

Section 3 - Examination and testing of protective devices and measuring instruments

Article 25

The examination and testing of protective devices and measuring instruments shall be the responsibility of qualified experts.

The examination and testing shall comprise:

(a) prior critical examination of plans for installations from the point of view of radiation protection;

(b) the acceptance of new installations from the point of view of radiation protection;

(c) regular checking of the effectiveness of protective devices and techniques;

(d) regular checking that measuring instruments are serviceable and correctly used.

Chapter II - Assessment of exposure

Article 26

The nature and frequency of assessment of exposure shall be such as to facilitate compliance with this Directive in each case.

Section 1 - Collective monitoring

Article 27

Taking into account the radiological hazards, measurements shall be carried out:

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

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

Where appropriate, the results of these measurements shall be used for estimating individual doses.

Section 2 - Individual monitoring

Article 28

The assessment of the individual doses must be systematic for workers of category A. This assessment shall be based on individual measurements or, in cases where these are impossible or inadequate, on an estimate arrived at either from individual measurements made on other exposed workers, or from the results of the collective monitoring provided for in Article 27.

Article 29

In the case of accidental or emergency exposure, the absorbed dose shall be assessed, whether a whole or a partial body irradiation has occurred.

Article 29bis

The results of individual monitoring shall be submitted to the approved medical practitioner with a view to their interpretation under his responsibility in relation to the health of the workers.

Section 3 - Recording of results

Article 30

The following shall be kept in the archives for a period of at least 30 years:

(a) the results of collective monitoring measurements used to assess individual doses;

(b) the exposure record containing documents relating to the assessment of individual doses;

(c) in the case of accidental or emergency exposure, the reports relating to the circumstances and to the action taken.

For the documents referred to in (b) and (c), the period of 30 years shall start at the time of cessation of work involving exposure to ionizing radiation.

Chapter III - Medical surveillance of exposed workers

Article 31

The medical surveillance of exposed workers shall be based on the principles that govern occupational medicine generally. It shall include, as appropriate, pre-employment medical examinations and periodic review of health, the frequency and the form of the latter being determined by the worker's state of health, the conditions of work and the incidents that may accompany it.

Article 32

No worker may be employed for any period as an exposed worker if the medical findings are unfavourable.

Section 1 - Medical surveillance of workers of category A

Article 33

The medical surveillance of workers of category A shall be the responsibility of approved medical practitioners.

It shall include:

(a) a pre-employment medical examination
The purpose of this examination shall be to determine the worker's fitness for the first post for which he is being considered. It shall include an inquiry into his medical history including all known previous exposures to ionizing radiation resulting either from his employment or from medical examination and treatment, and also the clinical and other investigations necessary for assessing his general state of health.

(b) general medical surveillance
The approved medical practitioner must have access to any information he requires in order to ascertain the state of health of workers under surveillance and to assess the existing environmental conditions in the working premises, in so far as they might affect the fitness of workers for the tasks assigned to them.

(c) periodic reviews of health
The health of workers shall be subject to review as a matter of routine to determine whether they remain fit to perform their duties. The nature of this review shall depend on the type

and extent of exposure to ionizing radiation and on the individual worker's state of health. The state of health of each worker shall be reviewed at least once a year and more frequently if the worker's exposure conditions or state of health so require.

The approved medical practitioner may indicate the need for medical surveillance after cessation of work for as long as he considers it necessary to safeguard the health of the person concerned.

Article 34

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

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

Article 35

1. A medical record shall be opened for each worker of category A and kept up to date so long as he remains a worker of that category. Thereafter it shall be retained in the archives for a period of at least 30 years.
2. The medical record shall include information regarding the nature of the employment, the results of the pre-employment medical examination and periodic reviews of health, the record of doses that is used to check that the values laid down in Articles 7, 8 and 10 have not been exceeded, and the record of doses received in the course of accidental and emergency exposures.

Section 2 - Special surveillance of exposed workers

Article 36

Special surveillance shall be provided in each case where the dose limits laid down in Articles 7 and 8 are exceeded. Subsequent conditions of exposure shall be subject to the agreement of the approved medical practitioner.

Article 37

In addition to the routine review of health provided for in Article 33 , provisions shall be made for any further examinations, decontamination measures or urgent remedial treatment considered necessary by the approved medical practitioner.

Section 3 - Appeals

Article 38

Each Member State shall lay down the procedure for appeal against the findings and decisions made in pursuance of articles 32 and 36.

Chapter IV

Article 39

1. Each Member State shall take all necessary measures to ensure the effective protection of exposed workers. It shall make provisions relating to the classification of places of

work, to the classification of workers, to the implementation of arrangements aimed at restricting exposure and to monitoring. It shall also establish a system or systems of inspection to supervise the examinations and monitoring specified in this Directive and to initiate surveillance and intervention measures whereever necessary.

2. Each Member State shall make the necessary arrangements to recognize the capacity of the experts responsible for the examination and control of the various protective devices and measuring instruments and to approve medical practitioners responsible for the medical surveillance of category A workers. To this end, each Member State shall arrange for the training of such specialists.

3. Each Member State shall make sure that the means necessary for proper protection are placed at the disposal of the departments responsible. The creation of a specialized radiation protection unit shall be required for all establishments in which there is a serious risk of exposure or contamination. This unit, which may be shared by several establishments, shall be distinct from production and operation units.

4. Each Member State shall facilitate appropriate access within the Community to all relevant information concerning the posting of each exposed worker and the doses received.

5. For the guidance of medical practitioners responsible for the medical surveillance of exposed workers, each Member State shall draw up a list, which need not be exhaustive, of the criteria which should be taken into account when judging a worker's fitness to be exposed to ionizing radiation.

TITLE VII - FUNDAMENTAL PRINCIPLES GOVERNING OPERATIONAL PROTECTION OF THE POPULATION

Article 40

1. Operational protection means all arrangements and surveys for detecting and reducing the factors which, in the production and use of ionizing radiation or in the course of any operation involving exposure to its effects, are liable to create an unjustifiable risk of exposure for the population. The extent of the precautions taken shall depend upon the magnitude of the risk of exposure, especially in the event of an accident, and upon demographic data. Operational protection has application in the medical field as well as in other fields.

2. Protection shall include the examination and testing of protective arrangements and the dose determinations to be carried out for the protection of the population.

Article 41

The examination and testing of protective arrangements shall include:

(a) examination and approval of proposed installations involving a radiation hazard, and of the proposed sitting of installations in the State;

(b) acceptance into service of new nuclear installations with regard to protection against any radiation or contamination liable to extend beyond the perimeter of the installations taking into account demographic, meteorological, geological, hydrological and ecological conditions;

(c) checking the effectiveness of technical protective devices;

(d) acceptance, from the point of view of surveillance of radiological hazards, of equipment for measuring radiation and contamination;

(e) checking that measuring instruments are serviceable and correctly used;

(f) whenever necessary, the establishment of emergency plans and their approval;

(g) the establishment and application of waste discharge formulae and provisions to be made for measurement.

The tasks listed in (a) to (g) shall be carried out in accordance with rules laid down by the competent authorities on the basis of the extent of the radiation hazard involved.

Article 42

1. The health surveillance of the population shall be based, in particular, on the assessment of the doses received by critical groups of the population and by the population as a whole, both in normal circumstances and in the event of an accident.

2. Surveillance shall be carried out:

   (a) on the critical groups of the population and, in particular, in all places where such groups may occur;

   (b) over the whole area for which the dose limit is that laid down for the whole population.

3. Taking into account the radiological hazards, the dose determinations to be carried out for the protection of the population shall include:

   (a) assessment of external exposure, indicating, where appropriate, the quality of the radiation in question;

   (b) assessment of radioactive contamination, indicating the nature and the physical and chemical state of the radioactive contaminants and determination of their activity and their concentration;

   (c) assessment of the doses that the critical groups of the population are liable to receive in normal or exceptional circumstances, and specification of the characteristics of these groups;

   (d) assessment of the genetic dose and of the annual genetically significant dose, taking demographic characteristics into account.

   Doses due to exposure to various sources must be added together wherever possible.

   (e) The frequency of assessments shall be such as to facilitate compliance with this Directive.

   (f) Records relating to measurements of external exposure and radioactive contamination and the assessment of the doses received by the population, shall be kept in the archives and shall include accidental and emergency exposures.

Article 43

1. Each Member State shall establish a system of inspection to supervise the protection of the health of the population, to interpret in terms of the effects on health the results of the assessments required by Article 42 (3), and to test compliance with the dose limits laid down in Article 11.

2. Each Member State shall initiate action in regard to surveillance and intervention wherever necessary.

3. Each Member State shall take measures to ensure and effectively coordinate the health surveillance of the population, shall decide the frequency of assessments and shall take all necessary steps to identify the critical groups of the population, taking into account the effective pathway of transmission of the radioactive material. These measures may, if necessary, be taken by one Member State jointly with other Member States.

4. In relation to possible accidents, each Member State:

   (a) shall stipulate intervention levels, measures to be taken by the competent authorities and surveillance procedures with respect to the population groups that are liable to receive a dose in excess of the dose limits laid down in Article 11.

   (b) shall determine and provide the necessary resources both in personnel and in equipment

to enable action to be taken to safeguard and maintain the health of the population. These measures may, if necessary, be taken by one Member State jointly with other Member States.

5. Any accident involving exposure of the population to radiation must be notified as a matter of urgency, when the circumstances so require, to neighbouring Member States and to the Commission of the European Communities.

Article 44

Any amendments required to adapt the harmonized standards to scientific progress shall be adopted in accordance with the procedure laid down in Article 46.

Article 45

1. A Committee responsible for adapting the Annexes in this Directive to technical progress (hereinafter called 'the Committee') is hereby set up. It shall consist of representatives of the Member States and be chaired by a representative of the Commission.

2. The Committee shall draw up its rules of procedure.

Article 46

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee by the chairman, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit which may be determined by the chairman according to the urgency of the matter. It shall decide by a majority of 41 votes, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged where these are in accordance with the opinion of the Committee.

   (b) Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion has been given, the Commission shall forthwith propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

   (c) If, within three months of the proposal being submitted to it, the Council has not acted, the measures proposed shall be adopted by the Commission

Article 47

1. Each Member State shall put into effect the necessary measures to conform to this Directive within a period of two years from the date of notification.

2. Each Member State shall inform the Commission of the arrangements it has made to comply with this Directive.

Article 48

This Directive is addressed to the Member States.

Done at Brussels,

For the Council

The President

ANNEX I

lues of activities not to be exceeded, in compliance with Article 4 (a), for the radio-
elides (*) listed in the left-hand column are indicated by an X in the various columns
the following table:

Radionuclides	Group I 5 kBq 1.4×10^{-7} Ci	Group II 50 kBq 1.4×10^{-6} Ci	Group III 500 kBq 1.4×10^{-5} Ci	Group IV 5000 kBq 1.4×10^{-4} Ci
1 H — 3				X
4 Be — 7			X	
6 C — 14			X	
8 O — 15				X
9 F — 18			X	
11 Na — 22		X		
11 Na — 24			X	
14 Si — 31			X	
15 P — 32			X	
16 S — 35			X	
17 Cl — 36		X		
17 Cl — 38			X	
18 Ar — 37				X
18 Ar — 41			X	
19 K — 42			X	
19 K — 43			X	
20 Ca — 45		X		
20 Ca — 47			X	
21 Sc — 46		X		
21 Sc — 47			X	
21 Sc — 48			X	
23 V — 48			X	
24 Cr — 51			X	
25 Mn — 52			X	
25 Mn — 54		X		
25 Mn — 56			X	
26 Fe — 52			X	
26 Fe — 55			X	
26 Fe — 59			X	
27 Co — 56		X		
27 Co — 57			X	
27 Co — 58			X	
27 Co — 58m				X
27 Co — 60		X		
28 Ni — 59				X
28 Ni — 63			X	

(*) The alphabetical list of elements appears at the end of this Annex

Radionuclides	Group I 10^{-7} Ci	Group II 10^{-6} Ci	Group III 10^{-5} Ci	Group IV 10^{-4} Ci
28 Ni —65			X	
29 Cu —64			X	
30 Zn —65			X	
30 Zn —69m			X	
30 Zn —69				X
31 Ga —72			X	
32 Ge —71				X
33 As —73			X	
33 As —74			X	
33 As —76			X	
33 As —77			X	
34 Se —75			X	
35 Br —82			X	
36 Kr —85m			X	
36 Kr —85				X
36 Kr —87			X	
37 Rb —86			X	
38 Sr —85m				X
38 Sr —85			X	
38 Sr —89		X		
38 Sr —90		X		
38 Sr —91			X	
38 Sr —92			X	
39 Y —90			X	
39 Y —91m				X
39 Y —91		X		
39 Y —92			X	
39 Y —93			X	
40 Zr —93				X
40 Zr —95		X		
40 Zr —97			X	
41 Nb —93m			X	
41 Nb —95			X	
41 Nb —97				X
42 Mo —99			X	
43 Tc —96m				X
43 Tc —96			X	
43 Tc —97m			X	
43 Tc —97			X	
43 Tc —99m				X
43 Tc —99			X	
44 Ru —97			X	
44 Ru —103			X	
44 Ru —105			X	
44 Ru —106		X		

	Radionuclides	Group I 10^{-7} Ci	Group II 10^{-6} Ci	Group III 10^{-5} Ci	Group IV 10^{-4} Ci
45	Rh — 103m				X
45	Rh — 105			X	
46	Pd — 103			X	
46	Pd — 109			X	
47	Ag — 105			X	
47	Ag — 110m		X		
47	Ag — 111			X	
48	Cd — 109			X	
48	Cd — 115m		X		
48	Cd — 115			X	
49	In — 113m				X
49	In — 114m		X		
49	In — 115m			X	
50	Sn — 113			X	
50	Sn — 125			X	
51	Sb — 122			X	
51	Sb — 124		X		
51	Sb — 125		X		
52	Te — 125m			X	
52	Te — 127m		X		
52	Te — 127			X	
52	Te — 129m		X		
52	Te — 129			X	
52	Te — 131m			X	
52	Te — 132			X	
53	I — 124		X		
53	I — 125		X		
53	I — 129				X
53	I — 130			X	
53	I — 131		X		
53	I — 132			X	
53	I — 133		X		
53	I — 134			X	
53	I — 135			X	
54	Xe — 131m				X
54	Xe — 133				X
54	Xe — 135			X	
55	Cs — 131				
55	Cs — 134m				X
55	Cs — 134		X		
55	Cs — 135				X
55	Cs — 136			X	
55	Cs — 137		X		
56	Ba — 131			X	
56	Ba — 140		X		

	Radionuclides	Group I 10^{-7} Ci	Group II 10^{-6} Ci	Group III 10^{-5} Ci	Group IV 10^{-4} Ci
57	La — 140			X	
58	Ce — 141			X	
58	Ce — 143			X	
58	Ce — 144		X		
59	Pr — 142			X	
59	Pr — 143			X	
60	Nd — 147			X	
60	Nd — 149			X	
61	Pm — 147			X	
61	Pm — 149			X	
62	Sm — 151			X	
62	Sm — 153			X	
63	Eu — 152m (9 h)			X	
63	Eu — 152 (13 a)		X		
63	Eu — 154		X		
63	Eu — 155			X	
64	Gd — 153			X	
64	Gd — 159			X	
65	Tb — 160		X		
66	Dy — 165			X	
66	Dy — 166			X	
67	Ho — 166			X	
68	Er — 169			X	
68	Er — 171			X	
69	Tm — 170		X		
69	Tm — 171			X	
70	Yb — 175			X	
71	Lu — 177			X	
72	Hf — 181		X		
73	Ta — 182		X		
74	W — 181			X	
74	W — 185			X	
74	W — 187			X	
75	Re — 183			X	
75	Re — 186			X	
75	Re — 188			X	
76	Os — 185			X	
76	Os — 191m				X
76	Os — 191			X	
76	Os — 193			X	
77	Ir — 190			X	
77	Ir — 192		X		
77	Ir — 194			X	
78	Pt — 191			X	
78	Pt — 193m				X

	Radionuclides	Group I 10^{-7} Ci	Group II 10^{-6} Ci	Group III 10^{-5} Ci	Group IV 10^{-4} Ci
78	Pt —193			X	
78	Pt —197m				X
78	Pt —197			X	
79	Au —196			X	
79	Au —198			X	
79	Au —199			X	
80	Hg —197			X	
80	Hg —197m			X	
80	Hg —203			X	
81	Tl —200			X	
81	Tl —201			X	
81	Tl —202			X	
81	Tl —204		X		
82	Pb —203			X	
82	Pb —210	X			
82	Pb —212		X		
83	Bi —206			X	
83	Bi —207		X		
83	Bi —210		X		
83	Bi —212			X	
84	Po —210	X			
85	At —211		X		
86	Rn —220			X	
86	Rn —222			X	
88	Ra —223	X			
88	Ra —224		X		
88	Ra —226	X			
88	Ra —228	X			
89	Ac —227	X			
89	Ac —228		X		
90	Th —227	X			
90	Th —228	X			
90	Th —230	X			
90	Th —231			X	
90	Th —232				X
90	Th —234		X		
90	Th nat (*)				X
91	Pa —230		X		
91	Pa —231	X			
91	Pa —233			X	
92	U —230	X			
92	U —232	X			

(*) One becquerel of natural thorium corresponds to 1 alpha disintegration per second (0.5 disintegrations per second of Th-232 and 0.5 disintegrations per second of Th-228). One curie of natural thorium corresponds to 3.7×10^{10} alpha disintegrations per second (1.85×10^{10} disintegrations per second of Th-232 and 1.85×10^{10} disintegrations per second of Th-228)

Radionuclides	Group I 10^{-7} Ci	Group II 10^{-6} Ci	Group III 10^{-5} Ci	Group IV 10^{-4} Ci
92 U —233	X			
92 U —234	X			
92 U —235				X
92 U —236		X		
92 U —238				X
92 U nat (*)				X
92 U —240+93Np-240			X	
93 Np —237	X			
93 Np —239			X	
94 Pu —238	X			
94 Pu —239	X			
94 Pu —240	X			
94 Pu —241	X			
94 Pu —242	X			
94 Pu —243			X	
94 Pu —244		X		
95 Am—241	X			
95 Am—242m	X			
95 Am—242		X		
95 Am—243	X			
95 Am—244			X	
96 Cm—242	X			
96 Cm—243	X			
96 Cm—244	X			
96 Cm—245	X			
96 Cm—246	X			
96 Cm—247		X		
96 Cm—248	X			
96 Cm—249				X
97 Bk —249		X		
97 Bk —250			X	
98 Cf —249	X			
98 Cf —250	X			
98 Cf —251	X			
98 Cf —252	X			
98 Cf —253		X		
98 Cf —254	X			
99 Es —253		X		
99 Es —254m		X		
99 Es —254	X			

(*) One becquerel of natural uranium corresponds to 1 alpha disintegration per second (0.489 disintegrations per second of U-238, 0.489 disintegrations per second of U-234 and 0.022 disintegrations per second of U-235).

One curie of natural uranium corresponds to 3.7×10^{10} alpha disintegrations per second (1.81×10^{10} disintegrations per second of U-238, 1.81×10^{10} disintegrations per second of U-234 and 8.31×10^{8} disintegrations per second of U-235).

Radionuclides	Group I 10^{-7} Ci	Group II 10^{-6} Ci	Group III 10^{-5} Ci	Group IV 10^{-4} Ci
99 Es - 255	X			
100 Fm - 254			X	
100 Fm - 255		X		
100 Fm - 256		X		

2. In the case of the nuclides In - 115, Nd - 144, Rb - 87, Re - 187 and Sm - 147 the requirement for reporting and obtaining prior authorization may be waived, irrespective of the quantities used.

3. In the case of a mixture of radionuclides belonging to different radiotoxicity groups, the requirements for reporting and obtaining prior authorization may be waived only if the sum of the ratios between the activity of each of the radionuclides and the limit laid down in paragraph 1 for the group to which it belongs is less than or equal to 1.

4. For radioluminescent paint, the requirement for reporting and obtaining prior authorization need not be applied if the overall activity in radioactive substances does not exceed 2000 MBq (54 mCi) of tritium, 100 MBq (2.7 mCi) of Pm - 147 or 0.5 MBq (14 /uCi) of Ra-226, and where this paint is kept or used for the manufacture or repair of the instruments and timepieces referred to in Article 4 (c).

5. Radionuclides not included in this Annex shall, where necessary, be assigned to a toxicity group by the competent authority.

ALPHABETICAL LIST OF THE ELEMENTS

	Atomic Number	Name
Ac	89	Actinium
Ag	47	Silver
Al	13	Aluminium
Am	95	Americium
Ar	18	Argon
As	33	Arsenic
At	85	Astatine
Au	79	Gold
B	5	Boron
Ba	56	Barium
Be	4	Beryllium
Bi	83	Bismuth
Bk	97	Berkelium
Br	35	Bromine
C	6	Carbon
Ca	20	Calcium
Cd	48	Cadmium
Ce	58	Cerium
Cf	98	Californium
Cl	17	Chlorine
Cm	96	Curium
Co	27	Cobalt
Cr	24	Chromium
Cs	55	Caesium/Cesium
Cu	29	Copper
Dy	66	Dysprosium
Er	68	Erbium
Es	99	Einsteinium
Eu	63	Europium
F	9	Fluorine
Fe	26	Iron
Fm	100	Fermium
Fr	87	Francium
Ga	31	Gallium
Gd	64	Gadolinium
Ge	32	Germanium
H	1	Hydrogen
He	2	Helium
Hf	72	Hafnium
Hg	80	Mercury
Ho	67	Holmium
I	53	Iodine
In	49	Indium
Ir	77	Iridium
K	19	Potassium
Kr	36	Krypton
La	57	Lanthanum
Li	3	Lithium
Lu	71	Lutecium
Md	101	Mendelevium
Mg	12	Magnesium
Mn	25	Manganese
Mo	42	Molybdenum
N	7	Nitrogen
Na	11	Sodium
Nb	41	Niobium
Nd	60	Neodymium
Ne	10	Neon
Ni	28	Nickel
No	102	Nobelium
Np	93	Neptunium
O	8	Oxygen
Os	76	Osmium
P	15	Phosphorus
Pa	91	Protactinium
Pb	82	Lead
Pd	46	Palladium
Pm	61	Promethium
Po	84	Polonium
Pr	59	Praseodymium
Pt	78	Platinum
Pu	94	Plutonium
Ra	88	Radium
Rb	37	Rubidium
Re	75	Rhenium
Rh	45	Rhodium
Rn	86	Radon
Ru	44	Ruthenium
S	16	Sulphur
Sb	51	Antimony
Sc	21	Scandium
Se	34	Selenium
Si	14	Silicon
Sm	62	Samarium
Sn	50	Tin
Sr	38	Strontium
Ta	73	Tantalum
Tb	65	Terbium
Tc	43	Technetium
Te	52	Tellurium
Th	90	Thorium
Ti	22	Titanium
Tl	81	Thallium
Tm	69	Thulium
U	92	Uranium
V	23	Vanadium
W	74	Tungsten
Xe	54	Xenon
Y	39	Yttrium
Yb	70	Ytterbium
Zn	30	Zinc
Zr	40	Zirconium

ANNEX II

Relationship between the quality factor Q and linear energy transfer L_∞

L_∞ in water (keV/μm)	Q (*)
3·5 and less	1
7	2
23	5
53	10
175 and above	20
(*) Intermediate values are to be obtained from the curve in Figure 1.	

Values of effective quality factor $\bar{Q}$

Values of effective quality factor $\bar{Q}$ depend on the conditions of irradiation, as well as on the type and energy of the incident radiation. For uniform irradiation of the whole body by external irradiation, the following values are to be applied. The same values will usually be adequate for other irradiation conditions. If other values are needed, they are to be calculated from the values of Q given in A and from the curves in Figure 2.

Radiation	$\bar{Q}$
X-rays, γrays, βrays, electrons and positrons	1
Neutrons of unknown energy	10

C Conversion factors (neutron fluence rate, $cm^{-2}\ s^{-1}$, corresponding to a dose equivalent rate of 1 $\mu Sv\ h^{-1}$ and 1 $mrem\ h^{-1}$) and effective quality factor $\bar{Q}$ as function of neutron energy.(1)

(The factors may also be used to relate neutron fluence rate and dose equivalent index rate.)

Neutron energy MeV	Conversion factor (2) (3)		Effective quality factor $\bar{Q}$ (2) (3)
	($cm^{-2}\ s^{-1}$) per ($\mu Sv\ h^{-1}$)	($cm^{-2}\ s^{-1}$) per ($mrem\ h^{-1}$)	
$2.5 \cdot 10^{-8}$ (thermal)	26	260	2.3
$1 \cdot 10^{-7}$	24	240	2
$1 \cdot 10^{-6}$	22	220	2
$1 \cdot 10^{-5}$	23	230	2
$1 \cdot 10^{-4}$	24	240	2
$1 \cdot 10^{-3}$	27	270	2
$1 \cdot 10^{-2}$	28	280	2
$2 \cdot 10^{-2}$	17	170	3.3
$5 \cdot 10^{-2}$	8.5	85	5.7
$1 \cdot 10^{-1}$	4.8	48	7.4
$5 \cdot 10^{-1}$	1.4	14	11
1	0.85	8.5	10.6
2	0.70	7.0	9.3
5	0.68	6.8	7.8
10	0.68	6.8	6.6
20	0.65	6.5	6.0
50	0.61	6.1	5.0
$1 \cdot 10^{2}$	0.56	5.6	4.4
$2 \cdot 10^{2}$	0.51	5.1	3.8
$5 \cdot 10^{2}$	0.36	3.6	3.2
$1 \cdot 10^{3}$	0.22	2.2	2.8
$2 \cdot 10^{3}$	0.16	1.6	2.6
$3 \cdot 10^{3}$	0.14	1.4	2.5

(1) For undirectional broad beams of monoenergetic neutrons at normal incidence.

(2) At the point where the dose equivalent rate is maximum.

(3) Intermediate values are to be obtained from the curves in Figures 3 and 4.

D Conversion factors (proton fluence rate, $cm^{-2}\ s^{-1}$) corresponding to a dose equivalent rate of 1 $\mu Sv\ h^{-1}$ and 1 mrem h^{-1}) and effective quality factor $\bar{Q}$ as function of proton energy (1). (The factors may also be used to relate proton fluence rate and dose equivalent index rate).

Proton energy MeV	Conversion factor (2) (3)		Effective quality factor $\bar{Q}$ (2)
	($cm^{-2}\ s^{-1}$) per ($\mu Sv\ h^{-1}$)	($cm^{-2}\ s^{-1}$) per (mrem h^{-1})	
! to 60	0.040	0.40	1.4
$.10^2$	0.041	0.41	1.4
$.5\ .10^2$	0.042	0.42	1.4
$.10^2$	0.043	0.43	1.4
$.5\ .10^2$	0.21	2.1	1.4
$.10^2$	0.24	2.4	1.5
$.10^2$	0.25	2.5	1.6
$.10^2$	0.24	2.4	1.7
$.10^2$	0.22	2.2	1.8
$.10^3$	0.20	2.0	1.9
$.5\ .10^3$	0.16	1.6	2.0
$.10^3$	0.14	1.4	2.1
$.10^3$	0.11	1.1	2.2

(1) Calculated for unidirectional broad beams of monoenergetic protons as normal incidence

(2) At the point where the dose equivalent rate is maximum

(3) Intermediate values are to be obtained from the curve in figure 5.

E The method of evaluating the effective dose.

The effective dose is equal to

$$\sum_{T} W_T \; H_T$$

Where H_T is the average dose equivalent in the organ or tissue, T and W_T is the weighting factor for the organ or tissue, T.

The values of the weighting factors are shown below:

Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone (surfaces)	0.03
Remainder (1)	0.30

In assessing the contribution from this remainder, the average dose is to be evaluated to each of the five most highly exposed organs or tissues of the remainder (excluding the lens of the eye, the skin, and the hands, forearms, feet and ankles). A weighting factor of 0.06 is to be used for each of these organs or tissues. The exposure of all other organs can then be neglected.

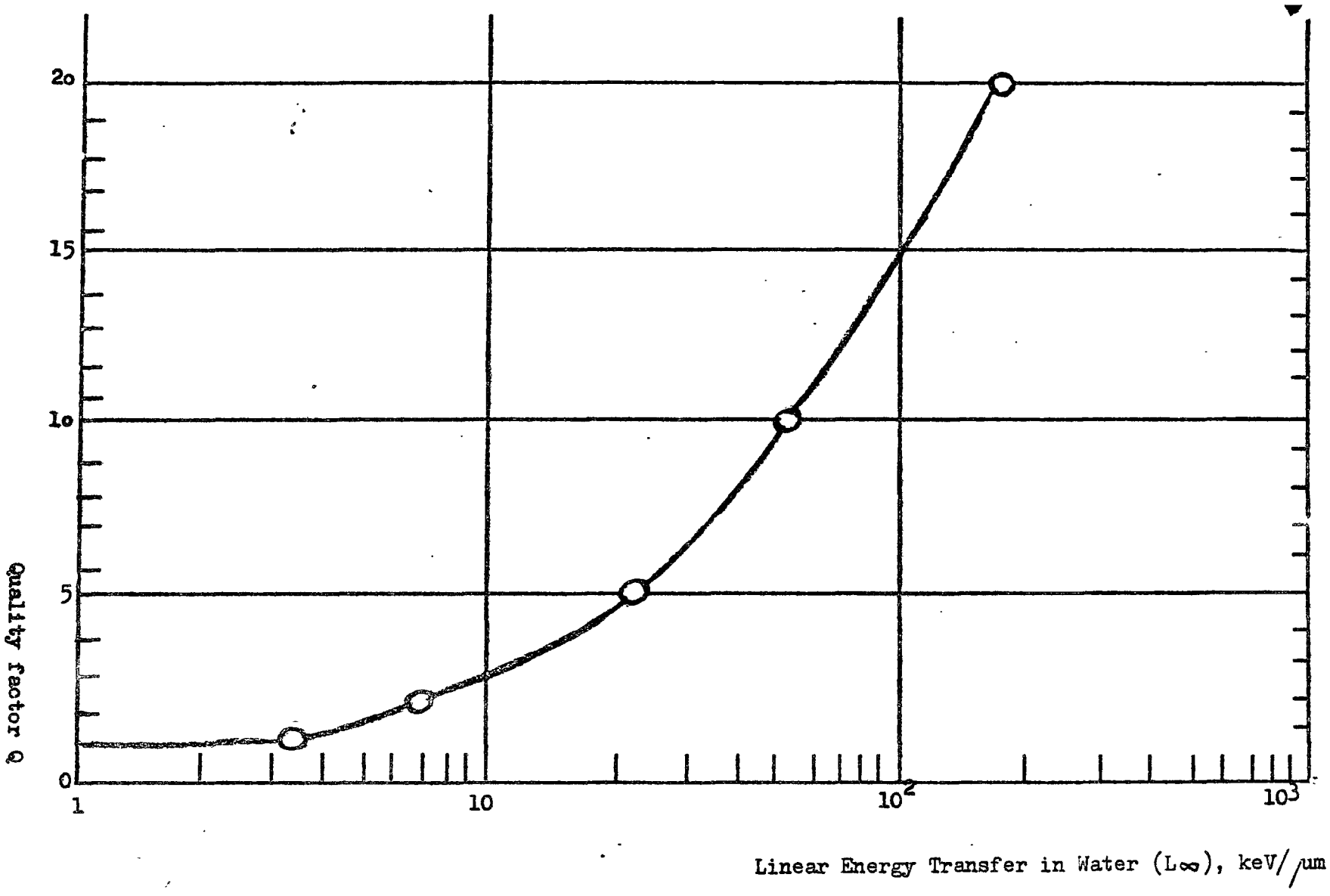

Figure 1: Quality factor as function of Linear Energy Transfer in Water (L_∞)

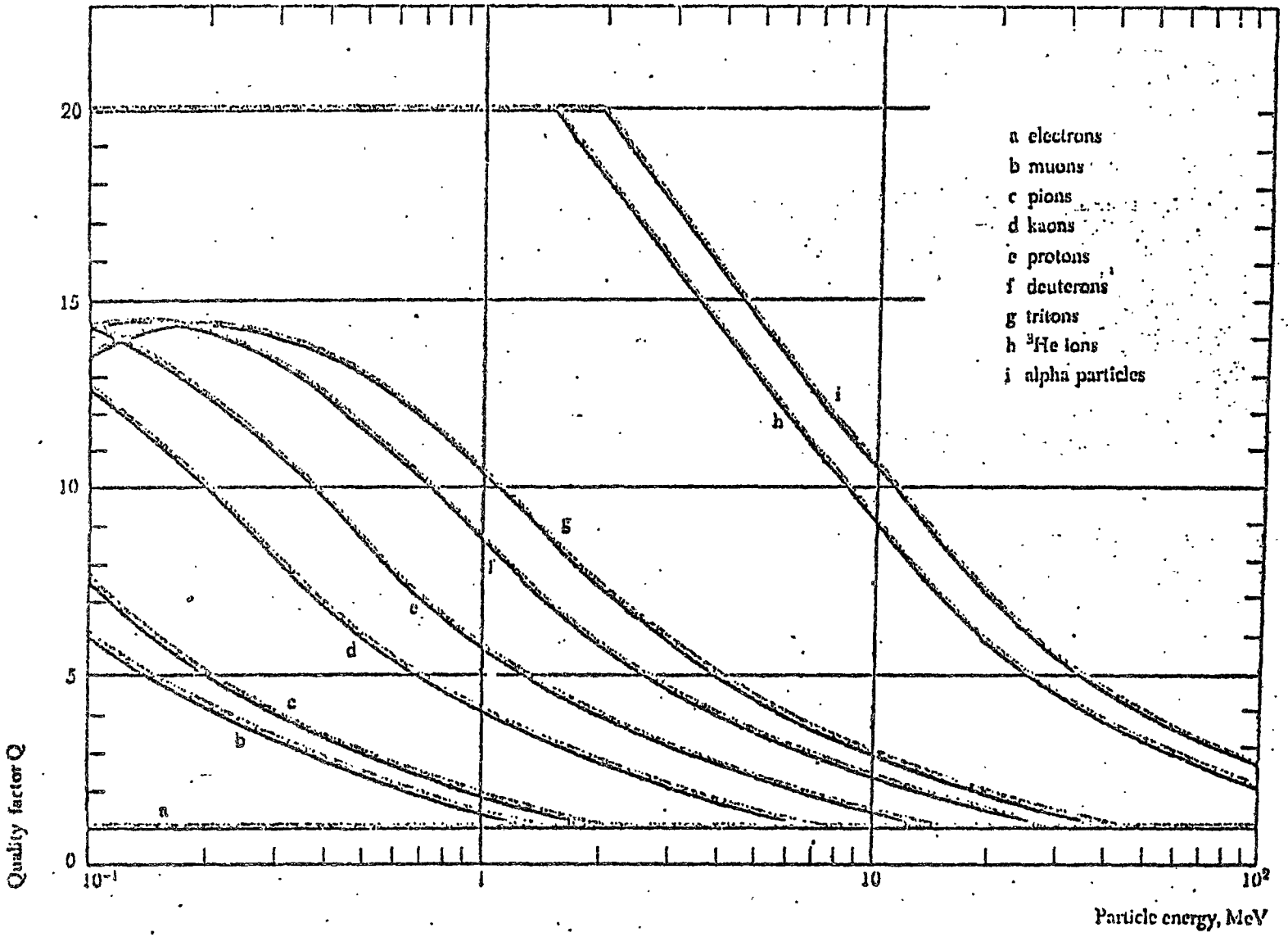
a electrons
b muons
c pions
d kaons
e protons
f deuterons
g tritons
h ^{3}He ions
i alpha particles
Quality factor Q
Particle energy, MeV
0
5
10
15
20
10^{-1}
1
10
10^2

Figure 2:

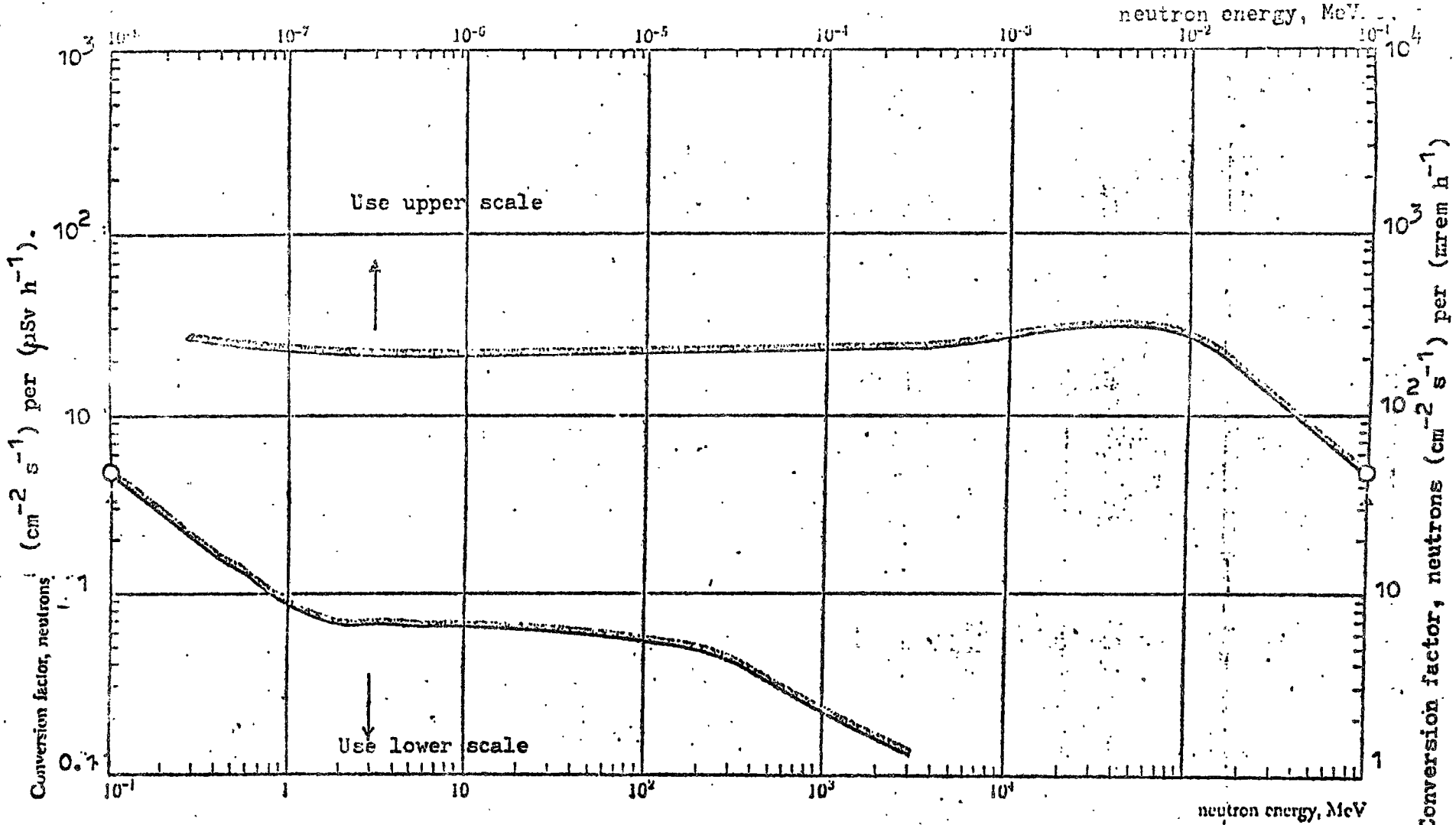

Figure 3: Factors for converting neutron fluence rate to dose equivalent rate

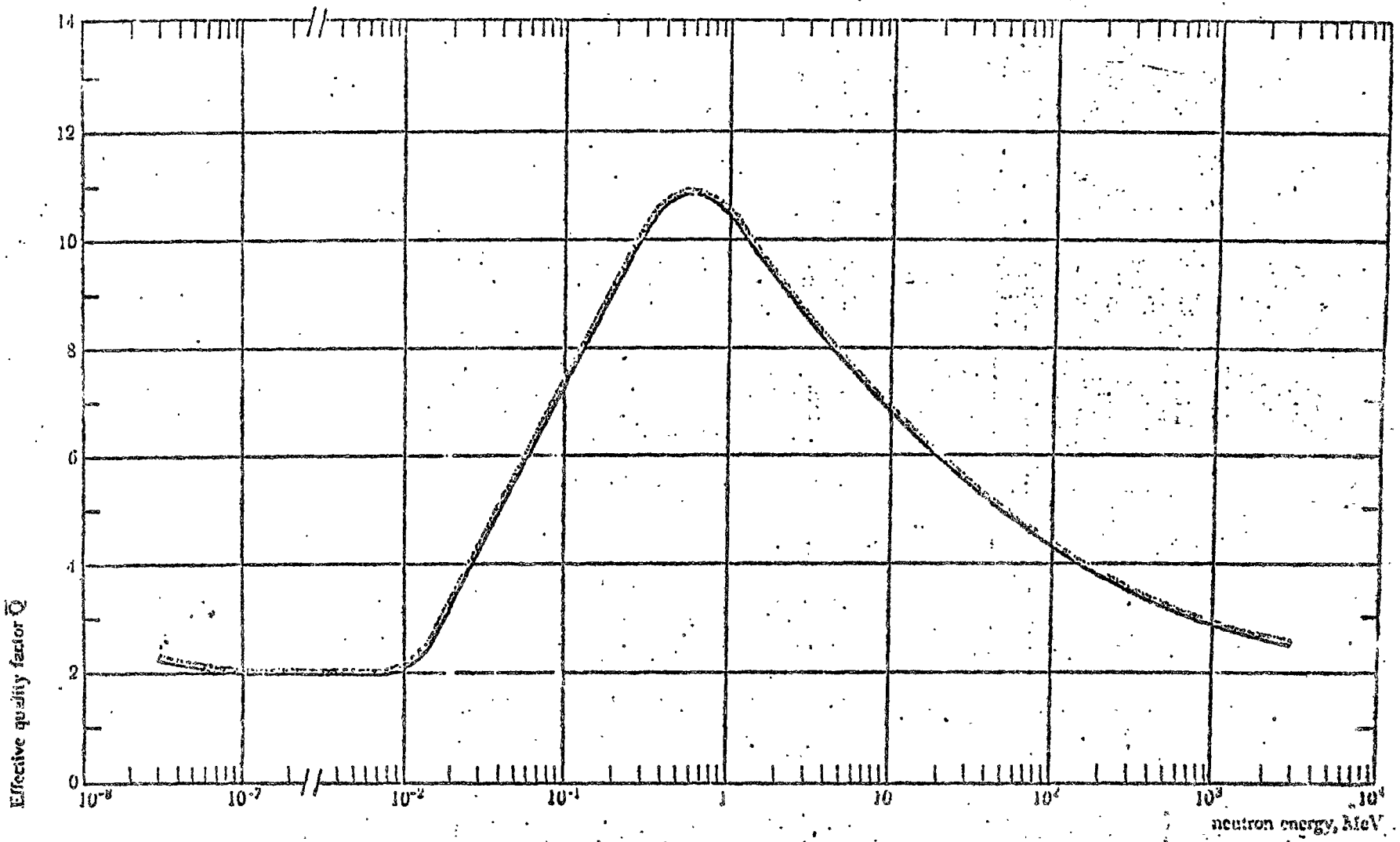

Figure 4: Effective quality factors for neutrons

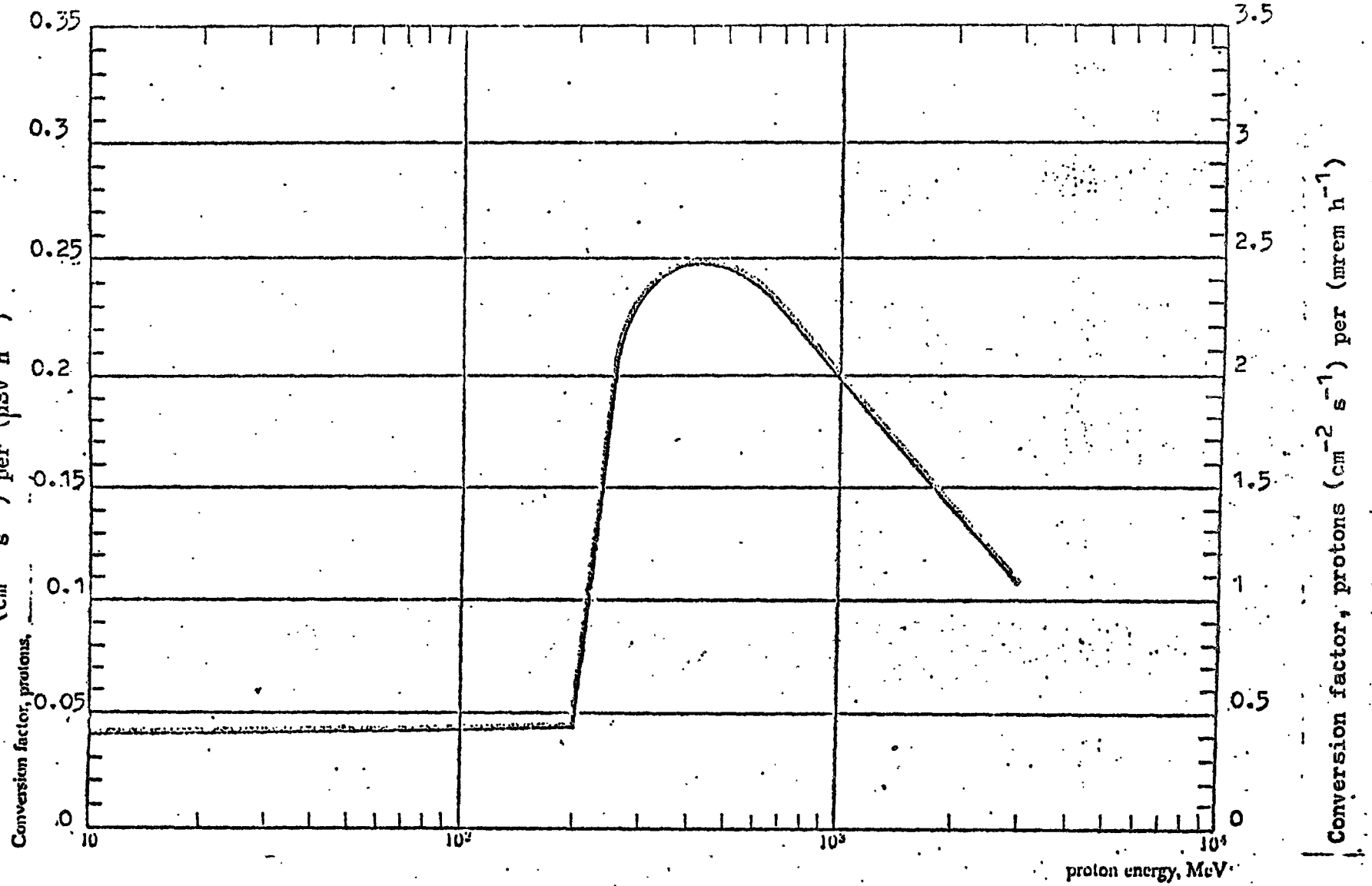

Figure 5: Factors for converting proton fluence rate to dose equivalent rate

Annex III

1 Limits of annual intake by inhalation, and derived limits of concentration of radionuclides in the air inhaled for exposed workers, and limits of annual intake by inhalation and ingestion for members of the public.

The figures in Tables 1a and 1b correspond with the limits of annual dose laid down in Articles 7, 8 and 11 for exposed workers and members of the public.

The figures in Table 2 are those laid down in the Directive of June 1976. They do not correspond exactly to the limits of annual dose laid down in Articles 7 8 and 11, but as an interim measure compliance with these values shall be deemed to achieve compliance with the limits of annual dose laid down in Articles 7, 8 and

The values of Tables 1 and 2 relate to adults. In the case of children account must be taken of anatomical and physiological characteristics which may require modification to these values.

Table 1a

Radionuclides	Form	Exposed Workers		Members of the Public	
		Limit of annual intake by inhalation kBq	Derived limit of the concentration in air for an exposure of 2000 h/y kBq m^{-3}	Limit of annual intake by inhalation kBq	Limit of annual intake by ingestion kBq
	1 to 3 depending on the "solubility" of the radionuclide				

Table 1b

Radionuclides	Form	Exposed Workers		Members of the Public	
		Limit of annual intake by inhalation	Derived limit of the concentration in air for an exposure of 2000 h/y	Limit of annual intake by inhalation	Limit of annual intake by ingestion
		µCi	µCi cm^{-3}	µCi	µCi
	1 to 3 depending on the solubility of the radionuclide				

Table 2

Radionuclides		Exposed workers		Members of public	
		Limits of annual intake by inhalation	Derived limits of concentration in the air for exposure of 2000 h per year	Limits of annual intake by inhalation	Limits of annual intake by ingestion
		µCi	Ci m^{-3}	µCi	µCi
	Soluble or insoluble				

2 Mixture of radionuclides

(a) If the composition of the mixture is not known but the presence of certain radionuclides can be positively excluded, use shall be made of the lowest limit laid down for the radionuclides that may be present;

(b) if the exact composition of the mixture is not known, but the radionuclides in it have been identified, use shall be made of the lowest limit laid down for the radionuclides present;

(c) if the concentration and toxicity of one radionuclide in the mixture predominate, the limit of annual intakes to be used are those given for the radionuclide concerned in Section 1;

(d) when dealing with a radionuclide mixture of known composition one of the following conditions shall be met:

$$\sum_j \frac{I_j}{I_{j,L}} < 1$$

or

$$\sum_j \frac{C_j}{C_{j,L}} < 1$$

where I_j is the annual intake of radionuclide j and I_{jL} is the limit of annual intake of that radionuclide, C_j is the annual average concentrati in air of radionuclide j and C_{jL} is the derived limit of concentration o that radionuclide in air.

ANNEX IV

ESTABLISHMENTS AND PLANTS REFERRED TO IN THE SECOND PARAGRAPH OF ARTICLE 20(a)

1. Establishments and plants including reactors and critical assemblies.

2. Establishments and plants including accelerators and X-ray generators.

3. Establishments and plants including sealed sources used in radiotherapy, gammagraphy, and industrial irradiators.

4. Industrial plants involving work with thorium and natural or enriched uranium:
   - uranium refining plants,
   - ore concentration plants.

5. Plants for manufacturing fuel elements.

6. Plants for processing irradiated fuels.

7. Uranium and thorium mine workings.

8. Radioactive waste processing plants and storage sites.

9. High activity laboratories and plants.