

# COMMISSION OF THE EUROPEAN COMMUNITIES

COM(80) 821 final

Brussels, 8 December 1980

Proposal for a  
COUNCIL DIRECTIVE

laying down basic measures for the radiation protection  
of persons undergoing medical examinations or treatment

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(presented by the Commission to the Council)

COM(80) 821 final



EXPLANATORY MEMORANDUM

1. Pursuant to Article 2b and 30 of the Euratom Treaty the health protection of the general public and workers against the dangers of ionizing radiation was instituted in the Member States of the European Community with the enactment of Council Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation (1).
2. Pursuant to Article 31 of the Euratom Treaty, the abovementioned basic safety standards were worked out by the Commission of the European Communities with the aid of persons appointed by Scientific and Technical Committee from among scientific experts, and in particular public health experts, in the Member States. These standards are broadly in line with the scientific recommendations of the International Commission on Radiological Protection (ICRP), however, they take into account the experience acquired by the Member States in the field of radiation protection and the legal implications which follow from the text of the standards in question, it being understood that this text must be formulated in a legal language which can be integrated without difficulty into the different national legislative systems.
3. Whereas the Commission and the abovementioned experts recognize :
  - that ionizing radiation has enabled very great progress to be made in the diagnostic, therapeutic and preventive aspects of medicine and that, moreover new techniques are under development, notably in nuclear medicine, high energy therapy and the use of computerized diagnosis systems,
  - that, while it is certainly not desired to raise objections to the proper use of ionizing radiation for legitimate reasons and under good radiation protection conditions, it is nevertheless important to eliminate unnecessary radiation exposures and to avoid examinations where the need is not established or repetition is fruitless.

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(1) Council Directive of 2 February 1959 - O.J. No 11 of 20 February 1959  
 Council Directive of 5 March 1962 - O.J. No 57 of 9 July 1962  
 Council Directive of 27 October 1966 - O.J. No 216 of 26 November 1966  
 Council Directive of 1 June 1976 - O.J. No L 187 of 12 July 1976

they have emphasized the fact that apart from natural background radiation, medical exposure to radiation is at present by far the major source of exposure to ionizing radiation and have stressed the fact that this situation has been repeatedly reviewed by the World Health Organization, the United Nations Scientific Committee on the Effects of Atomic Radiation and the International Commission on Radiological Protection. These bodies have already taken major steps in this direction.

4. ICRP publication No 26 which has been available since July 1977, states that medical exposures - as well as all other non-natural exposures - must be justified, on the one hand and optimized on the other, i.e. kept at the minimum indispensable level, compatible with medical requirements. It should be noted that the ICRP has not laid down limits for medical exposures as it has for other non-natural exposures. However, it recommends that periodic checks be carried out with a view to ensuring that exposure levels are acceptable.

5. Accordingly, Article 6 and 12 of the Euratom basic safety standards were revised in 1976, stipulate that

' the exposure of persons and the number of persons exposed to ionizing radiation must be kept as low as is reasonably practicable'

and that

' the contribution to the genetic dose from medical examination and treatment shall be kept to the minimum value consistent with medical requirements'.

Similarly, Article 6 of the proposal for a Council Directive (Euratom) 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 (1) stipulates that

' every activity resulting in an exposure to ionizing radiation shall be justified by the advantages which it produces,

all exposures shall be kept as low as reasonably achievable'.

It is expressly stipulated that these two principles also apply to medical exposures.

Article 12 obliges the Member States to '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'.

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(1) O.J. No C 86, Volume 22, of 2 April 1979

6. The aim of the present proposal for a Directive is to give an operational character to the general provisions contained in the basic safety standards, the Directive will make it possible to increase significantly the radiation protection of patients and of the general public without jeopardizing the benefits - whether diagnostic, preventive or therapeutic - obtainable from radiation. On the contrary, measures which avoid inappropriate or excessive radiation exposure improve the quality and effectiveness of medical uses of radiation. Furthermore, such measures will generally result in savings to the social security organizations, which in turn have to ensure that they do not encourage the multiplication of medical examinations.

A reduction of medical radiation exposures is all the more justified because simple measures would make it possible to reduce considerably the exposure of patients, doctors and other personnel, reducing expenditure at the same time.

7. It must be recognized also that the number of radiological installations and the variety of uses of ionizing radiation are increasing. Any resultant increase in public exposure must be prevented.

Given the growing use of ionizing radiation and the proliferation of techniques, particularly in nuclear medicine, radiotherapy and radio-diagnosis, it is necessary to ensure that users have the necessary competence and experience to avoid inappropriate uses of these techniques. In addition, any unnecessary proliferation of radiological installations must be avoided. All installations in operation have to be kept under control in regard both to their technical quality and their radiological safety, in addition, any inadequate or obsolete equipment should be replaced.

Finally, the use of radioisotopes even for in-vitro tests should take place under properly controlled conditions, not only in the interests of radiation protection and the quality of the tests, but also for the sake of environmental protection.

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PROPOSAL FOR A COUNCIL DIRECTIVE

Laying down basic measures for the  
radiation protection of persons  
undergoing medical examinations or treatment

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission, drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical Committee,

Having regard to the opinion of the European Parliament,

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

Whereas the Council has adopted a Directive laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation;

Whereas the standards also relate to problems of radiation protection connected with the use of ionizing radiation for diagnostic and therapeutic purposes;

Whereas, on the one hand, apart from natural background radiation, medical exposure to radiation is at present by far the major source of exposure to ionizing radiation; whereas this problem has been repeatedly reviewed by the World Health Organization, the United Nations Scientific Committee on the Effects of Atomic Radiation and the International Commission on Radiological Protection, which have already recommended measures with a view to preventing excessive medical exposure;

Whereas, on the other hand, ionizing radiation has enabled very great progress to be made in the diagnostic, therapeutic and preventive aspects of medicine and whereas, moreover, new techniques are under development, notably in nuclear medicine, high energy therapy and the use of computer-controlled tomography; whereas, although it is certainly not desired to raise objections to the proper use of ionizing radiation for legitimate reasons and under good radiation protection conditions, it is nevertheless important to eliminate unnecessary radiation exposures;

Whereas measures which make it possible to increase significantly the radiation protection of patients and of the general public in no way jeopardize the benefits - whether diagnostic, preventive, or therapeutic - obtainable from radiation; whereas, on the contrary, measures which avoid inappropriate or excessive radiation exposure improve the quality and effectiveness of medical uses of radiation;

Whereas it must be recognized also that the number of radiological installations and the variety of uses of ionizing radiation are increasing; whereas any resultant unjustified increase in public exposure must be prevented;

Whereas given the growing use of ionizing radiation and the proliferation of techniques, it is necessary to ensure that users have the necessary competence and experience to avoid inappropriate uses of these techniques; whereas any unnecessary proliferation of radiological installations must be avoided;

Whereas it is therefore appropriate that other provisions be enacted to complement those contained in the abovementioned Directive, laying down suitable measures relating to the radiation protection of patients,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

Member States shall take all appropriate measures to ensure that radiological procedures are carried out under the responsibility of doctors or dentists engaged in radiology, who have a recognized competence in radiation protection and who have received an adequate training in radiation protection which is approved by the administrative authority and which is appropriate to the techniques used in medical and dental diagnostic radiology, in radiotherapy or in nuclear medicine.

Assistants shall receive instruction in the techniques applied and in suitable radiation protection procedures; they shall receive training appropriate to their work.

#### Article 2

- a) No radiological examination shall be carried out for preventive purposes without medical indication.
- b) Individual or collective preventive radiological examinations shall be carried out only if they are biologically, clinically or epidemiologically justified.
- c) Radiological examinations carried out at the request of insurance companies shall depend on a previous medical decision. Such examinations may be refused by the individuals concerned.
- d) Direct fluoroscopic examinations without the use of image intensification shall be carried out only when justified by exceptional circumstances.

Article 3

Member States shall take the steps necessary to ensure that doctors or dentists engaged in radiology referred to in Article 1 have acquired adequate and effective training in radiation protection.

Training facilities shall also be available for doctors or dentists engaged in radiology already authorized to use ionizing radiation but who have not acquired the necessary competence in radiation protection.

Article 4

The doctors or dentists engaged in radiology and assistants referred to in Article 1 and 3 shall make the necessary arrangements to ensure that exposures permitted for diagnostic purposes are kept under control and as low as reasonably achievable.

Article 5

a) Member States shall set up a system allowing any practitioner who may be consulted to ascertain what previous radiological examinations a patient has undergone.

b) Appropriate measures shall ensure that existing radiological information or records can be made available quickly and without complex formalities to other medical or dental practitioners treating the patient.

Article 6

Member States shall draw up an inventory of medical and dental radiological equipment and shall establish criteria of acceptability for radiological installations, without prejudice to the Community provisions on harmonization relating to medical electroradiological equipment.

All installations in use shall be kept under appropriate surveillance in regard to procedures relevant to radiological protection.

Member States shall implement the necessary measures with a view to improving inadequate or defective features of installations subject to such surveillance. In extreme cases Member States may require that certain installations be removed from service.



Article 7

Member States shall determine the actual requirements of the population with a view to optimizing the use of sophisticated departments of radiotherapy, radiodiagnosis and nuclear medicine. A trained specialist in medical physics shall be at any time available to such department.

Article 8

Member States shall take the steps necessary for compliance with this Directive before 1 February 1983.

Member States shall inform the Commission of provision they have made to comply with this Directive.

Article 9

This Directive is addressed to the Member States.

