

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 3 September 1984

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

(84/466/Euratom)

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 ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Whereas the Council has adopted Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation, as last amended by Directive 80/836/Euratom ⁽³⁾;

Whereas these 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 reviewed repeatedly 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 to prevent excessive medical exposure;

Whereas, on the other hand, ionizing radiation has enabled great progress to be made in the diagnostic, therapeutic and preventive aspects of medicine, particularly since new techniques are under development, notably in nuclear medicine, high-energy therapy and the use of computer-controlled tomography; whereas, although there is certainly no desire 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 exposure;

Whereas measures which make it possible to improve the radiation protection of patients and of the general public in no way jeopardize the benefits — whether early recognition, diagnosis or therapy — obtainable from radiation; whereas, on the contrary, measures which avoid inappropriate or excessive radiation levels improve the quality and effectiveness of medical uses of radiation;

Whereas it must also be recognized 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;

⁽¹⁾ OJ No C 149, 14. 6. 1982, p. 102.

⁽²⁾ OJ No C 230, 8. 9. 1980, p. 1.

⁽³⁾ OJ No L 246, 17. 9. 1980, p. 1.

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

Whereas the Member States will also take into account the results achieved to date by the five-year Euratom research and training programme in the field of biology and health protection adopted by the Council,

HAS ADOPTED THIS DIRECTIVE:

Article 1

All medical exposures must be medically justified and kept as low as reasonably achievable, as defined in (a) and (b) of the first paragraph of Article 6 of Directive 80/836/Euratom.

Article 2

1. Without prejudice to Directives 75/362/EEC⁽¹⁾ and 75/363/EEC⁽²⁾, as amended by Directive 82/76/EEC⁽³⁾, and Directives 78/686/EEC⁽⁴⁾ and 78/687/EEC⁽⁵⁾, Member States shall take all appropriate measures to ensure that any ionizing radiation used in medical procedures is effected under the responsibility of doctors or dental practitioners or other practitioners who are entitled to perform such medical procedures in accordance with the national legislation and who, during their training, have acquired competence in radiation protection and received adequate training appropriate to the techniques used in medical and dental diagnostic radiology, in radiotherapy or in nuclear medicine.

2. Complementary training must be provided, if necessary, for the persons referred to in paragraph 1 who are already in practice where their competence in radiation protection has not been approved by the competent authorities.

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

Article 3

The competent authorities shall draw up an inventory of medical and dental radiological equipment and nuclear medical installations and shall establish criteria of acceptability for radiological installations and

nuclear medical installations. All installations in use must be kept under strict surveillance with regard to radiological protection and the quality control of appliances.

The competent authorities shall implement the necessary measures to improve inadequate or defective features of installations subject to such surveillance. They shall ensure as soon as possible that all installations which no longer meet the criteria specified in the first paragraph are taken out of service or replaced. Direct fluoroscopic examinations without the use of image intensification shall be carried out only in exceptional circumstances.

Article 4

Each Member State shall take such steps as it may consider necessary to discourage the unnecessary proliferation of equipment for radiotherapy, radiodiagnosis and nuclear medicine.

Article 5

A qualified expert in radiophysics shall be available to sophisticated departments of radiotherapy and nuclear medicine.

Article 6

Practical recommendations to which Member States may refer are set out in the Annex to this Directive.

Article 7

Member States shall take the measures necessary to comply with this Directive before 1 January 1986.

Member States shall inform the Commission of the provisions they have adopted to comply with this Directive.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 3 September 1984.

For the Council

The President

P. BARRY

(1) OJ No L 167, 30. 6. 1975, p. 1.
 (2) OJ No L 167, 30. 6. 1975, p. 14.
 (3) OJ No L 43, 15. 2. 1982, p. 21.
 (4) OJ No L 233, 24. 8. 1978, p. 1.
 (5) OJ No L 233, 24. 8. 1978, p. 10.

ANNEX

PRACTICAL RECOMMENDATIONS

1. (a) No radiological procedure should be carried out unless medically indicated ⁽¹⁾;
 - (b) individual or collective preventive radiological examinations, including nuclear medicine examinations, should be carried out only if they are medically and epidemiologically justified;
 - (c) encouragement should be given to alternative techniques likely to prove at least as effective from a diagnostic or therapeutic point of view and to involve a lesser risk to health.
2. Measures should be taken to ensure that existing radiological and nuclear medical information and/or records can be forwarded quickly, possibly by the patient himself, to the persons referred to in Article 2 (1) of the Directive treating or examining the patient.

Member States should take such necessary steps as they consider necessary to provide the persons referred to in Article 2 (1) of the Directive with information on any radiological examinations and/or treatment undergone by the patient in the past, provided the latter agrees.

In order to avoid unnecessary radiological examinations, the persons referred to in Article 2 (1) of the Directive should see if they can obtain the necessary information by consulting the results of previous examinations. This applies particularly to procedures followed for medico-legal or insurance purposes. Special care should be taken to ensure that such procedures are justified.

With reference to Article 4 of the Directive, Member States should endeavour to ensure that optimum use is made of the most advanced installations of radiotherapy, radiodiagnosis and nuclear medicine.

⁽¹⁾ The scope of Directive and of these recommendations does not extend to the use of ionizing radiation in the field of scientific research.