COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.09.1996
COM(96) 465 final

96/0230 (CNS)

Proposal for a

COUNCIL DIRECTIVE

on Health Protection of Individuals Against the Dangers of Ionizing Radiation in Relation to Medical Exposures, Replacing the Directive 84/466/Euratom

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. BACKGROUND

1.1. In 1984 the Council adopted Directive 84/466/Euratom Laying Down Basic Measures for the Radiation Protection of Persons Undergoing Medical Examination or Treatment[1]. The Council thereby acknowledged that medical practices utilizing ionizing radiation were developing rapidly and this led to the finding that, apart from the largely unavoidable exposure to natural radiation sources, medical exposure was by far the major source of exposure to ionizing radiation for the citizens of the European Community. The Directive laid down basic measures with the objective of improving the radiation protection of patients without jeopardizing the benefits - whether early recognition, diagnosis or therapy - obtainable from radiation.

1.2. The Directive completed, on the particular point of protection of patients, the Council Directive Laying Down the Basic Safety Standards for the Health Protection of the General Public and Workers Against the Dangers of Ionizing Radiation[2] which applies to any activity which involves a hazard arising from ionizing radiation.

Article 2(b) of the Euratom Treaty provides in fact for the establishment within the Community of uniform basic safety standards to protect the health of workers and of the general public against the dangers of ionizing radiation. These basic safety standards were first adopted in 1959 by means of a Council Directive[3] and have subsequently been amended on several occasions to take account of developments in scientific knowledge in the field of radiation protection.

A proposal for a revision of the Basic Safety Standards Directive was submitted to the Council in 1993[4]. An amended proposal which takes account of the opinion of the European Parliament, was put forward in 1994[5]. This Directive (96/29/EURATOM)[6], adopted by Council on 13 May 1996, however, does not deal with radiation protection as regards medical exposures.

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1 O.J. L 265 of 05.10.1984

2 O.J. L 246 of 17.09.1980 and O.J. L 265 of 05.10.1984

3 O.J N° 11 of 20.02.1959

4 O.J. C 245 of 09.09.1993

5 O.J. C 224 of 12.08.1994

6 O.J. L 159 of 29 June 1996

1.3. Since 1984 the use of ionizing radiation in medical practice has continued to develop and the number of related installations to increase. The objective, set out in Directive 84/466/Euratom, of eliminating unnecessary exposures in this specific field remains therefore valid today, particularly as measures aimed at reducing exposures without losing the efficacy of the related practice could be the most cost effective in this field when compared to other sectors of the utilization of ionizing radiation and since alternative techniques involving no exposure to ionizing radiation become more and more available and in some cases are first choice. Nevertheless, the requirements of the 1984 Directive need to be reformulated taking into account the scientific/technical progress, the revision of the Basic Safety Standards Directive and the experience acquired in the implementation of the 1984 Directive. This will ensure that the unity of radiation protection doctrine and methods in relation to medical exposures is maintained.

1.4. The above considerations show that it is appropriate for the Community to revise Directive 84/466/Euratom and to give updated guidance in the particular field of medical exposure to ionizing radiation.

As regards the cost of implementing the Directive, in some cases the introduction of quality assurance and quality control measures may require some cost for the holders of the radiological installations concerned. However, these costs will bring benefits in terms of reduced exposures. Increased attention to the justification of each individual radiological examination is likely to reduce their number and the associated cost for society. A direct cost benefit analysis is impossible, without agreeing on a value of the mansievert averted by the introduction of measures pursuant to the provisions of the proposed Directive. Several figures for such values can be found in the literature, ranging from 5,000 to several million ECU/mansievert according to the circumstances. No international agreement could be reached so far on these figures.

1.5. At international level, the proposal is consistent with the 1990 Recommendations of the International Commission on Radiological Protection (ICRP)[7] and with the International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, jointly sponsored by six international organisations[8], issued in December 1994 which deal with all aspects of radiation protection including medical exposures.

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[7] International Commission on Radiological Protection,
1990 Recommendations of the International Commission on Radiological Protection, Publication N° 60, Pergamon Press, Oxford and New York (1991)

[8] International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, jointly sponsored by: Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Organisation, Nuclear Energy Agency of the Organisation for Economic Co-operation and Development, Pan American Health Organization, World Health Organization - Interim Edition
Safety Series N° 115, International Atomic Energy Agency, Vienna, 1994.

1.6. The protection of workers, including medical and paramedical staff, and of members of the public - other than the individuals whose protection is the object of the proposed Directive - is not affected by the Directive on medical exposures and is ensured by the Basic Safety Standards Directive mentioned above. Health and safety requirements including radiation protection aspects regarding the design, manufacture, placing on the market, of the medical devices utilized, are covered by Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices[9].

1.7. Since the coming into effect of the Treaty on European Union a specific competence in the field of the public health was introduced in the EC Treaty. With Articles 3(o) and 129, the Community was set the task of making "a contribution to the attainment of a high level of health protection". The provisions of Article 129 led to the development of a framework for Community action in the field of public health placing an emphasis on the prevention of disease and the promotion of health.

Moreover, Article 129 provides "that health protection requirements shall form a constituent part of the Community's other policies". The present proposal gives effect to the provision, by laying down requirements for the protection of persons undergoing medical examinations or treatments involving their exposure to ionizing radiation.

2. MODIFICATIONS PROPOSED

Taking into account the above mentioned factors and since some recommendations of the annex of the existing Directive are given a legally binding character, the whole text of the existing Directive has been reformulated.

With respect to the Directive presently in force, the main modifications introduced are as follows.

2.1. The scope of the Directive has been more clearly defined as regards exposures of individuals as part of medico-legal insurance or legal procedures. It has also been enlarged to include volunteers in research and individuals helping in the support and comfort of patients.

2.2. The 1984 Directive imposed the application of the principle of justification and optimisation to medical exposures. The proposal expands these provisions and sets out several specific requirements.

2.3. In addition to the requirement that any use of ionizing radiation in medical procedures is effected under the responsibility of a practitioner, as it is in the 1984 Directive, the proposal foresees that practical aspects of the medical procedure could be delegated to other individuals authorized by the competent national authorities. The requirements for the training of the practitioners and other individuals are explicitly set out. Such requirements include continuing education and training.

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[9] O.J. L 169 of 12.07.1993

2.4. The proposal expands the existing requirements on quality control of the installations and supplements them by requiring the establishment of quality assurance programmes which also include assessments of the doses received by the patient.

2.5. Additional requirements are introduced which apply to paediatric exposures, health screening programmes, practices involving high doses, the exposure of pregnant and breast feeding women, the exposure of helping persons and of volunteers.

2.6. The proposal introduces the concept of potential exposures, together with the requirement of keeping their probability and magnitude as low as reasonably achievable.

2.7. Finally, Member States are requested to ensure the establishment of processes for auditing the implementation of the requirements of the Directive.

Proposal for a Council Directive
on Health Protection of Individuals Against the Dangers
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Replacing the Directive 84/466/Euratom

THE COUNCIL OF THE EUROPEAN UNION,

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[10],

Having regard to the opinion of the Economic and Social Committee[11],

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 96/29/Euratom of 13 May 1996.

Whereas, on 3 September 1984 the Council adopted Directive 84/466 Euratom Laying Down the Basic Measures for the Radiation Protection of Persons Undergoing Medical Examination or Treatment;

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[10] ...

[11] O.J. C 212 of 22.07.1996

Whereas, as in 1984, medical exposures continue to constitute the major source of exposure to artificial ionizing radiation of the European Union citizens; whereas the use of ionizing radiation has enabled great progress to be made in many aspects of medicine; whereas practices causing medical exposures need to be carried out in optimised radiation protection conditions.

Whereas, recognizing the development of scientific knowledge in the field of radiation protection applied to medical exposures, the International Commission on Radiological Protection reviewed the subject in its 1990 Recommendations[12]; whereas the International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources[13] recommend measures in the field;

Whereas such developments make it necessary to revise Directive 84/466/Euratom;

Whereas the Basic Safety Standards Directive ensures the protection of the workers administering the medical exposures and of the members of the public; whereas the same Directive ensures that the total of contributions to the exposure of the population as a whole, is kept under review;

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[12] International Commission on Radiological Protection, 1990
Recommendations of the International Commission on Radiological Protection, Publication N° 60, Pergamon Press, Oxford and New York (1991).

[13] International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, jointly sponsored by the Food and Agriculture Organization of the United Nations, the International Atomic Energy Agency, the International Labour Organization, the Nuclear Energy Agency of the Organization for Economic Cooperation and Development, the Pan American Health Organization, and the World Health Organisation - Interim Edition Safety Series N° 115, International Atomic Energy Agency, Vienna 1994.

Whereas health and safety requirements, including radiation protection aspects, regarding the design, manufacture and placing on the market of the medical devices are dealt with by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[14]. Whereas it is necessary to set out radiation protection requirements for the medical use of radiological installations from the date of the commencement of their operation;

Whereas the concept of medical exposure has to be defined so as to include exposures incurred by volunteers and persons knowingly and willingly helping persons undergoing medical examination or treatment;

Whereas the Committee of Ministers of the Council of Europe adopted on 6 February 1990 Recommendation R(90)3 on Medical Research on Human Beings;

Whereas detailed requirements are needed for the correct application of the justification and optimisation principles in relation to medical exposures;

Whereas responsibilities for administering medical exposures need to be set out;

Whereas appropriate training for the staff involved, the establishment of quality assurance and audit programmes, and inspections by the competent authorities are necessary to ensure that medical exposures are delivered under good radiation protection conditions;

Whereas specific provisions are necessary as regards to special practice, pregnant and breastfeeding women, volunteers in research and helping persons;

Whereas potential exposures need to be taken into account;

HAS ADOPTED THIS DIRECTIVE

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[14] O.J. L 169 of 12.07.1993

Article 1 - Purpose : This Directive lays down the general principles of the radiation protection of individuals undergoing medical exposures and associated practices involving ionizing radiation.
The purpose of this Directive is to supplement Directive 80/836/EURATOM on the Basic Safety Standards as regards medical exposures.

Article 2 - Definitions : For the purpose of this Directive, the following terms have the meaning hereby assigned to them:

- Audit : A systematic and independent examination to determine whether the measures taken and the related results comply with prescribed criteria.

- Clinical Responsibility : Responsibility regarding individual medical exposures attributed to a practitioner, notably : justification ; optimization; clinical evaluation of the outcome; cooperation with other specialists and the staff, as appropriate, regarding practical aspects; obtaining information, if appropriate, of previous examinations; providing existing radiological information and/or records to other practitioners, promptly; giving information on the risks of ionizing radiation to patients, as appropriate.

- Competent Authorities : Any authority responsible in a Member State for the application of any part of this Directive, or any body or bodies designated by the Member State for this purpose.

- Exposure : Process of being exposed to ionizing radiation

- Health Detriment : Clinically observable deleterious effects that are expressed in individuals or their descendants, the appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance.

- Health Screening : A procedure using radiological installations for early diagnosis in asymptomatic population groups, also called mass screening.

- Holder : Any natural or legal person who has the legal responsibility under national law for the use and holding of a given radiological installation.

- Medical Physicist : An expert in radiation physics applied to medical exposures whose training and competence to act is recognised by the competent authorities and who, as appropriate, gives advice on patient dosimetry, on the development and use of complex techniques and equipment and on optimisation, on quality assurance, including quality control, and on matters relating to radiation protection as defined in article 3, as appropriate. This expert might also give advice on radiation protection aspects as regards workers and the public.

- Medical Radiological Practice : Each type of activity resulting in exposure to ionizing radiation for medical purposes.

- Potential exposures : Exposure with a probability of occurrence that can be estimated in advance for accidents and incidents, such as a failure of equipment, a misadministration, a human error or a computer failure.

- Practical Aspects : Any aspect associated with the medical practice such as handling and use of radiological equipment, measurement of technical and physical parameters including radiation doses, calibration and maintenance of equipment, preparation and injection of radio-pharmaceuticals, medical informatics.

- Practitioner : A medical doctor, dentist or other health professional, who is entitled to take overall clinical responsibility for individual medical exposures in accordance with national legislation.

- Prescriber : A medical doctor, dentist or other health professional, who is entitled to refer individuals for medical exposures, in accordance with national legislation.

- Quality Assurance : All those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service. Satisfactory performance in service implies the optimum quality of the entire procedure. In the case of radiodiagnostic procedure, the consistent production of adequate diagnostic information with minimum exposure of both patients and personnel. In the case of a radiotherapeutic procedure optimum exposure of patients and minimum exposure of personnel.

- Quality Control : The set of operations (programming, coordinating, carrying out) intended to maintain or to improve quality . It covers monitoring, evaluation, and maintenance at optimum levels of all characteristics of performance that can be defined, measured, and controlled.

- Radiological : Pertaining to radiodiagnosis, radiotherapy and nuclear medicine.

- Radiodiagnostic : Pertaining to in vivo diagnostic nuclear medicine, diagnostic radiology and interventional radiology.

- Radiotherapeutic : Pertaining to therapeutic nuclear medicine and every other type of radiotherapy.

- Reference Level : A tool for optimization of radiation protection in medical radiodiagnostic practices by specifying dose levels and, in the case of radiopharmaceuticals levels of activity, for typical examinations for a standard sized patient, taking into account good practice regarding diagnostic and technical performance. An investigation may be needed if these levels are exceeded and corrective action should be taken, if appropriate.

Article 3 - Scope:

1. This Directive shall apply to all medical exposures and associated practices:
   a) the exposure of individuals as part of their own medical diagnosis or treatment;

   b) the exposure of individuals as part of medico-legal, insurance or legal procedures;

   c) the exposure of individuals as part of health screening;

   d) the exposure of individuals knowingly and willingly helping (other than as part of their own occupation) in the support and comfort of patients undergoing medical diagnosis or treatment;
   e) the exposure of individuals in medical and biomedical research programmes.

2. This Directive shall not apply to the design and the placing on the market of medical devices covered by the Directive 93/42/EEC.

Article 4 - Justification:

1. All individual medical exposures shall be justified taking into account the specific objectives of the exposure and the efficacy and availability of alternative techniques.

   The prescriber and the practitioner will always check if previous diagnostic information or medical records relevant to the planned exposure are available and consult these data to avoid unnecessary examinations.

2. All new medical radiological practices shall be justified in advance by their potential benefits in relation to alternative practices having the same objective but not involving exposure to ionizing radiation and in relation to the health detriment they might cause; existing practices shall be reviewed whenever new, important evidence about their efficiency or consequences is acquired.

3. Member States shall take measures to avoid unnecessary proliferation of installations for radiodiagnostic and radiotherapeutic purposes.

4. Special attention shall be given for those exposures where there is no direct health benefit for the person undergoing the exposure and especially for exposures on medico-legal, insurance and legal grounds.

5. The prescriber as well as the practitioner shall be involved in the justification process, at the appropriate level.

6. Exposures for biomedical and medical research shall be examined by an officially approved ethics committee and/or the competent authorities, taking into account the principles set out by the Recommendation R(90)3 of the Committee of Ministers of the Council of Europe.

7. In the case of fluoroscopy, examinations without image intensification are not justified and shall therefore be prohibited and examinations without an automatic dose rate control shall be limited to exceptional circumstances.

Article 5 - Optimisation:

1. All medical exposures for radiodiagnostic purposes shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information, taking into account economic and social factors. Member States shall promote the establishment and use of reference levels for medical exposures and shall ensure, on the basis of European reference levels where available, the availability of guidance for this purpose.

2. For radiotherapeutic purposes, exposures of target tissues shall be individually planned; exposures of non target tissues shall be as low as reasonably achievable, without under-exposing the target tissues.

3. Written guidelines for every type of standard radiological practice shall be established for each item of radiological equipment.

4. The optimisation process shall include selection of equipment and both acceptance testing before the first use of the installation for clinical purposes, and thereafter performance testing on a regular basis, and after any major maintenance procedure.

5. In radiotherapeutic practices, a medical physicist shall be closely involved. In diagnostic nuclear medicine practices, a medical physicist shall be involved as approriate. For other radiodiagnostic practices, a medical physicist shall be available for consultation on optimisation and quality assurance, including quality control, as appropriate, and also to give advice on matters relating to radiation protection concerning medical exposures, as required.

6. Member States shall ensure that for each biomedical and medical research project involving healthy volunteers, a maximum individual dose level is established. These volunteers will be informed about the risks of exposure to ionizing radiation.

7. In the special case of patients, who voluntarily accept to undergo an experimental therapeutic or diagnostic practice, optimum dose levels should be established on an individual basis by the practitioner.

Article 6 - Responsibilities:

1. Member States shall ensure that any medical exposure is effected under the clinical responsibility of a practitioner.

2. The practical aspects for the procedure or part of it may be delegated, as appropriate, to one or more individuals entitled by the competent authorities to act in this respect in the relevant field of specialisation, such as medical physics, radiation and nuclear medicine technology, medical-nuclear engineering, radiopharmacy, radiography and medical informatics.

3. Member States shall lay down procedures to determine responsibilities in case of medico-legal, insurance or legal examinations.

Article 7 - Training:

1. Member States shall ensure that the practitioners and individuals mentioned in Article 6 have adequate theoretical and practical training appropriate to the techniques they use in medical or dental diagnostic radiology, in nuclear medicine or in radiotherapy, as well as relevant competence in radiation protection.

2. Member States shall ensure the provision of continuing education and training after qualification and, in the special case of the clinical introduction of new techniques, the prior organisation of training related to these techniques and the relevant radiation protection requirements.

3. For this purpose Member States shall ensure the establishment of appropriate curricula and shall recognise the corresponding diplomas, certificates or formal qualifications, in accordance with the existing Council Directives[15].

4. Member States shall ensure that adequate referral criteria for medical exposure, including radiation doses are provided to the prescribers of medical exposures.

5. Member States shall ensure that a course on radiation protection is introduced in the basic curriculum of schools for practitioners.

Article 8 - Inventory:

1. Member States shall ensure the drawing up of an inventory of radiological installations.

2. This inventory shall be one of the tools used for inspection purposes by the competent authorities.

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[15] Council Directive of 27 June 1977 (77/452/CEE)
Council Directive of 25 July 1978 (78/686/CEE)
Council Directive of 14 December 1981 (81/1057/CEE)
Council Directive of 16 September 1985 (85/433/CEE)
Council Directive of 24 January 1989 (89/48/CEE)
Council Directive of 24 July 1992 (92/51/CEE)
Council Directive of 5 April 1993 (93/16/CEE)

Article 9 - Surveillance:

Member States shall ensure that all radiological installations in use are kept under strict surveillance regarding radiation protection and quality control. This shall be achieved at two levels:

a) The Member States shall ensure that quality assurance programmes including quality control measures and patient dose assessment are established by the holder of the installation.
The competent authorities shall be informed about these programmes if they so request.

b) Competent authorities shall at regular intervals perform inspections of radiological installations. They shall ensure that necessary measures are taken by the holder of the installation to improve inadequate or defective features of the installation.
They shall ensure that all installations which do not or no longer meet specific criteria adopted by competent authorities for this purpose are taken out of service.

Article 10 - Special Practices

1. Member States shall ensure that medical and paramedical staff performing

- frequent paediatric medical exposures
- exposures as part of a health screening programme
- examinations involving high doses to the patient and the medical staff, such as interventional radiology and Computed Tomography

receive specific training on the relevant radiological practices and on the relevant radiation protection aspects.

2. Member States shall ensure that appropriate radiological installations are used in each case for paediatric practices, health screening and high dose techniques and that specific quality assurance programmes, including quality control measures and patient dose

assessment, are adopted for these practices.

Article 11 - Medical exposures to pregnant and breastfeeding women.

1. In the case of a female patient of childbearing age, the prescriber and the practitioner shall inquire whether the patient is pregnant, or breastfeeding, if relevant.

2. If pregnancy cannot be excluded, depending on the type of medical exposures, special attention shall be given to the justification, particularly the urgency, and to the optimisation of the medical exposure both for the mother and the unborn child.

3. In nuclear medicine for breastfeeding women, depending on the type of medical examination or treatment, special attention shall be given to the justification, particularly the urgency, and to the optimisation of the medical exposure both for the mother and the child.

Article 12 - Potential exposures

Member States shall ensure that the probability and magnitude of potential exposures of patients from medical practices are taken into consideration and kept as low as reasonably achievable, economic and social factors being taken into account.

Article 13 - Helping persons

1. Member States shall ensure that appropriate guidance for exposures of individuals, who are knowingly and willingly helping, other than as part of their occupation, in the support and comfort of in-patients or out-patients undergoing medical diagnosis or treatment, is established.

2. In the case of a patient undergoing a treatment with radionuclides Member States shall ensure that the practitioner provides the patient or legal guardian before leaving the hospital or clinic, with written instructions as appropriate on the reduction of doses to persons in contact with the patient and with information on the risks of ionizing radiation.

Article 14 - Estimates of population doses

Member States shall ensure that individual dose and collective dose estimates from practices referred to in article 3 are made for the whole population and for relevant reference groups of the population.

Article 15 - Audit

In order to assure the implementation of the preceeding articles, Member States shall ensure that appropriate processes for audit are adopted.

Article 16 - Transposition into Member State law

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive on 1 January 1999. They shall immediately inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at time of their official publication. The procedure for such reference shall be adopted by Member States.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

Article 17 - Repeals

Directive 84/466/Euratom is repealed with effect from 1 January 1999.

Article 18 -

This Directive is addressed to the Member States.

ISSN 0254-1475

COM(96) 465 final

DOCUMENTS

EN 15 05 12

Catalogue number : CB-CO-96-474-EN-C

ISBN 92-78-09091-3

Office for Official Publications of the European Communities

L-2985 Luxembourg

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