Basic information

1996/0230(CNS) CNS - Consultation procedure Directive	Procedure completed
Public health: protection of individuals against ionizing radiation in medical exposures (repl. Direct. 84/466/Euratom) Repealed by 2011/0254(NLE) **Subject** 4.20.01 Medicine, diseases	

Key players

European Parliament	**Committee responsible**	**Rapporteur**	**Appointed**
	ENVI Environment, Public Health and Consumer Protection	AMADEO Amedeo (NI)	30/10/1996
Council of the European Union	**Council configuration**	**Meetings**	**Date**
	Culture	2022	1997-06-30

Key events

Date	Event	Reference	Summary
26/09/1996	Legislative proposal published	COM(1996)0465	Summary
23/10/1996	Committee referral announced in Parliament		
16/04/1997	Vote in committee		Summary
16/04/1997	Committee report tabled for plenary, 1st reading/single reading	A4-0146/1997	
13/05/1997	Debate in Parliament		Summary
19/06/1997	Modified legislative proposal published	COM(1997)0315	Summary
30/06/1997	Act adopted by Council after consultation of Parliament		
30/06/1997	End of procedure in Parliament		
09/07/1997	Final act published in Official Journal		

Technical information

Procedure reference	1996/0230(CNS)

Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Directive
Amendments and repeals	Repealed by 2011/0254(NLE)
Legal basis	EC Treaty (before Amsterdam) E 031
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/4/08328

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A4-0146/1997 OJ C 150 19.05.1997, p. 0003	16/04/1997	
Text adopted by Parliament, 1st reading/single reading		T4-0231/1997 OJ C 167 02.06.1997, p. 0046-0089	14/05/1997	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(1996)0465 OJ C 341 13.11.1996, p. 0017	26/09/1996	Summary
Modified legislative proposal	COM(1997)0315 OJ C 247 13.08.1997, p. 0005	19/06/1997	Summary

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Directive 1997/0043
OJ L 180 09.07.1997, p. 0022 Summary

Public health: protection of individuals against ionizing radiation in medical exposures (repl. Direct. 84/466/Euratom)

1996/0230(CNS) - 14/05/1997 - Text adopted by Parliament, 1st reading/single reading

By adopting the report by Mr Amedeo AMADEO (NI, I) on the dangers of ionizing radiation, the European Parliament approved this proposal for a directive with the following amendments: -the proposed directive should supplement Directive 96/29/Euratom on the basic safety standards as regards medical exposures (rather than 80/836/Euratom), -exposures on medico-legal grounds where there is no direct health benefit for the person undergoing the exposures should be avoided, -every radiological unit must have the possibility of consulting a medical physicist for the necessary advice on the exposure, -the exposures covered by the directive should include exposure resulting from events such as equipment failure or faults or human error and with a probability of occurrence that can be assessed in advance, -Member States should ensure that equipment and installations which do not meet predetermined acceptability criteria are taken out of service or replaced, -a medical physicist should check the suitability of the equipment on the basis of the exposure/diagnostic benefit ratio, laying down the maximum and minimum reference criteria, -quality assurance, as defined in the directive, implies the optimum quality of the equipment (Parliament defines what should be meant by 'optimum quality': in the case of radiodiagnostic procedure, the production of adequate diagnostic information with minimum exposure of patients and workers, and in the case of radiotherapeutic procedures, the optimum exposure of patients and workers), -the prescriber and the examining doctor should have specific responsibilities in accordance with the provisions laid down by the Member State, -pregnant women should not undergo exposure (particularly for medical purposes) affecting the pelvic and abdominal regions (unless their health will otherwise be seriously affected).

Public health: protection of individuals against ionizing radiation in medical exposures (repl. Direct. 84/466/Euratom)

1996/0230(CNS) - 26/09/1996 - Legislative proposal

OBJECTIVE: to revise Directive 84/466/Euratom and to specify requirements to be satisfied in order to protect persons who undergo medical examinations or treatment entailing their exposure to ionizing radiation. SUBSTANCE: the Commission proposes the following amendments to the existing directive (84/466/Euratom): - the scope of the directive is more clearly defined with respect to the exposure of individuals as part of medico-legal, insurance or legal procedures. It is extended to include individuals who participate in research as volunteers or who support and comfort patients; - the provisions requiring the application of the principle of justification and optimization to medical exposures have been expanded (specific requirements); - besides requiring that any use of ionizing radiation in medical procedures is effected under the responsibility of a practitioner, the proposal permits practical aspects of the medical procedure to 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. In addition, the proposal: - expands the existing requirements on quality control of the installations and requires the establishment of quality assurance programmes which also include assessments of the doses received by the patient; - introduces new requirements concerning paediatric exposures, health screening programmes, procedures involving high doses, the exposure of pregnant and breast-feeding women and the exposure of helpers and volunteers; - introduces the concept of potential exposures and requires their probability and magnitude to be kept as low as reasonably possible; - requests the Member States to ensure the establishment of processes for auditing the implementation of the requirements of the Directive.

Public health: protection of individuals against ionizing radiation in medical exposures (repl. Direct. 84/466/Euratom)

1996/0230(CNS) - 30/06/1997 - Final act

OBJECTIVE: to replace Directive 84/466/EURATOM and define the requirements to be complied with to protect individuals undergoing medical examination or treatment involving exposure to ionizing radiation. COMMUNITY MEASURE: Council Directive 97/43/EURATOM on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/EURATOM. SUBSTANCE: the Directive supplements Directive 96/29/EURATOM laying down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation, and lays down the general principles concerning the protection of individuals against such radiation when undergoing medical examination or treatment. 1) scope of the Directive: the Directive applies to exposure: -of patients as part of their own medical diagnosis or treatment, -of individuals as part of occupational health surveillance, -of individuals as part of health screening programmes, - of healthy individuals or patients voluntarily participating in medical or biomedical, diagnostic or therapeutic research programmes, - of individuals as part of medico-legal procedures, -of individuals knowingly and willingly helping in the support and comfort of individuals undergoing medical exposure. 2) The Directive contains provisions requiring the application of the principle of justification and optimization of exposure for medical purposes. Precise conditions are laid down: -as regards justification: .medical exposure must show a sufficient net benefit, weighing the benefits against the individual detriment that the exposure might cause, taking into account the benefits and risks of other techniques, .individual exposure for medical purposes must be justified in advance, taking into account the specific objectives of the exposure. The prescriber and the practitioner must try to obtain previous diagnostic information relevant to the planned exposure, .if exposure cannot be justified, it is prohibited; -as regards optimisation: .all doses due to medical exposure for radiological purposes must be kept as low as reasonably achievable, and in the case of exposure for radiotherapeutic purposes, exposures of target volumes must be secured, while exposure of non-target tissues must be kept as low as possible, .the choice of equipment, the production of diagnostic information, therapeutic outcome and quality control must be taken into account. 3) the Directive defines responsibility for exposure of individuals for medical purposes: any use of ionizing radiation for medical purposes must be carried out under the responsibility of a practitioner. The Directive allows the practical aspects of the medical procedure to be delegated to other persons approved by the competent national authorities. The compulsory training of practitioners and the other persons concerned is explicitly laid down. The Directive also: - requires the quality of installations to be monitored, and quality assurance programmes to be drawn up, which must also comprise patient dose assessments. Measures are also laid down to prevent proliferation of radiological equipment in the Member States. If the competent authorities consider that equipment does not meet requirements, they must communicate the fact, and measures are to be taken to have the equipment taken out of service; - lays down new procedures whereby written protocols are to be adopted for each type of equipment in conjunction with each type of standard radiological practice; - introduces new requirements concerning the exposure of children, screening programmes, acts involving high doses for the patient (including radiotherapy), exposure during pregnancy and breastfeeding, and exposure of helpers and volunteers; - introduces the concept of potential exposure: Member States must take steps to reduce to a minimum the probability and size of accidental or unintentional doses. As regards prevention of

accidents, special attention is devoted to equipment used for radiotherapy and other diagnostic equipment; - calls on Member States to establish audit procedures concerning the application of the provisions of the Directive and to arrange for inspections to be carried out by the competent authorities to ensure that exposure takes place under satisfactory conditions. TRANSPOSITION OF THE DIRECTIVE INTO NATIONAL LAW: 13.05.2000. Directive 84/466/EURATOM is repealed as of the same date.

Public health: protection of individuals against ionizing radiation in medical exposures (repl. Direct. 84/466/Euratom)

1996/0230(CNS) - 19/06/1997 - Modified legislative proposal

In its amended proposal, the Commission incorporated 10 of the 12 amendments adopted by the European Parliament in plenary. The amendments incorporated concerned the following points: -the purpose of the Directive is to supplement Directive 96/29/EURATOM on basic safety standards as regards medical exposures, -insertion of a definition of 'potential exposures' and modification of the definition of 'medical physicist', deleting the reference to his responsibilities regarding the protection of workers and the public, -insertion of provisions concerning the optimum quality of the functioning of radiological equipment, -reference to national provisions with regard to the responsibilities of the prescriber and practitioner, -prohibition of exposures without direct health benefit for the person undergoing them, -insertion of a paragraph on taking out of service or replacing equipment and installations which do not comply with acceptability criteria, -strengthening of the role of medical physicists in checking equipment used in radiotherapy, -inclusion of exposures for radiotherapeutic purposes in the article on training of medical and paramedical staff, -improved protection of pregnant women in the case of exposure of the pelvic and abdominal regions. However, the Commission did not accept the amendment seeking to make it possible for every radiological unit to consult a medical physicist. Nor did it accept the amendment concerning the 'examining doctor' (rather than 'practitioner').