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.