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.