Basic safety standards for protection against the dangers arising from exposure to ionising radiation

2011/0254(NLE) - 30/05/2012 - Legislative proposal

PURPOSE: to lay down laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

PROPOSED ACT: Council Directive.

BACKGROUND: exposure to ionising radiation results in a health detriment. In normal situations doses are very low so that there is no clinically observable tissue effect, but there still is a possible late effect, **cancer** in particular.

Euratom legislation has always followed the recommendations of the International Commission on Radiological Protection (ICRP). This highly respected scientific organisation has recently issued new guidance on the system of radiation protection (Publication 103, 2007).

The problem at EU level can be summarised as follows: (i) scientific progress is not fully reflected in present legislation; (ii) there are inconsistencies between the existing pieces of legislation; (iii) the scope of the present legislation does not fully cover natural radiation sources or the protection of the environment.

This translates into four specific objectives:

1. to introduce the necessary subject-matter amendments in order to respond to the latest scientific data and operational experience;
2. to clarify the requirements and to ensure coherence within the body of European legislation;
3. to ensure coherence with the international recommendations;
4. to cover the whole range of exposure situations and categories of exposure.

IMPACT ASSESSMENT: several options were analysed:

- ***Option 1***: Maintaining the status quo of existing legislation
- ***Option 2***: Revision of Basic Safety Standards and Medical Directive
- ***Option 3***: Revision and consolidation of Basic Safety Standards and Medical Directive and integration of the Outside Workers Directive, the Public Information Directive and the High Activity Sealed Sources Directive (non-legislative measures to address natural radiation issues and the protection of non-human species, see Annex XI),
- ***Option 4***: Revision of the Basic Safety Standards Directive and broadening the scope to cover public exposure to natural radiation
- ***Option 5*** : Revision of the Basic Safety Standards Directive and broadening the scope to cover protection of non-human species
- ***Option 6***: Revision and consolidation of the Basic Safety Standards Directive and Medical Directive, integration of the Outside Workers Directive, the Public Information Directive and the High Activity Sealed Sources Directive and broadening the scope to cover public exposure to natural radiation and protection of non-human species.

Option 6, which combines Options 4 and 5, covers all aspects of the objective of broadening the scope of radiation protection legislation. Their combination, in Option 6, together with undertaking an effort for consolidation similar to Option 3, is most effective in achieving all objectives. The analysis of the options in terms of efficiency **supports the conclusion that Option 6 should be pursued**, as the most effective, efficient and coherent policy option.

LEGAL BASIS: Articles 31 and 32 of the Treaty establishing the European Atomic Energy Community.

It should be noted that prior to proposing the current text, the Article 31 Group of Experts gave its opinion on the revised Basic safety standards Directive, there was still discussion whether a Directive on radioactive substances in water intended for human consumption should be based on Euratom Treaty or EC Treaty. In these circumstances it was decided to proceed with the proposal for a revised Basic Safety Standards Directive as agreed upon in February 2010 by Article 31 Group of Experts (as presented by the Commission in its summary dated 29 September 2011 - initial legislative proposal published). The current proposal constitutes the definitive text published by the Commission.

CONTENT: the recast of five Directives yields a voluminous single Directive, with over 100 articles and numerous annexes. In view of the extent and complexity of the changes, a formal recast procedure is not pursued.

A description of the main features of each chapter may be summarised as follows:

Subject matter and scope: this chapter defines the scope of the new Directive: the general purpose of the Directive across different categories of exposure and different exposure situations and specific purposes resulting from integration of the requirements for high-activity sealed radioactive sources and for public information, and the exclusion of non-controllable exposures).

The scope is broadened to include:

- the exposure of space crew to cosmic radiation;
- domestic exposure to radon gas in indoor air;
- external exposure to gamma radiation from building materials, and
- the protection of the environment beyond environmental pathways leading to human exposure.

System of radiation protection: this title includes the general principles of radiation protection: justification, optimisation and dose limitation. It explains the more prominent role of dose constraints and reference levels in the process of optimisation, with Annex I giving the bands of reference levels proposed by the ICRP for existing and emergency exposure situations. The dose limits are not modified, except for **a uniform definition of the annual occupational dose limit** (no averaging over 5 years) and a lower organ dose limit for the lens of the eye, as recommended by the ICRP. The new Directive no longer includes the technical measurements entering into the definition of the effective dose and other factors entering into the assessment of doses, but refers to ICRP Publication 103 for this purpose. In addition, the Directive no longer includes the long lists of radionuclide-specific dose coefficients (doses per unit intake by ingestion or inhalation), but will refer to a forthcoming consolidated publication of the ICRP which can be downloaded free of charge.

Requirements for radiation protection education, training and information: this chapter brings together the miscellaneous requirements governing education and training in the different Directives and includes provisions for recognition of the 'Radiation Protection Expert' and 'Medical Physics Expert'.

Justification and regulatory control of practices: the application of the principle of justification remains a national responsibility. Specific attention is given to the justification of practices involving the deliberate exposure of humans for non-medical imaging (e.g. security screening in airports).

The regime for regulatory control is now presented as a three-tier system (notification, registration, licensing), replacing the earlier two-tier system of reporting and 'prior authorisation'. A more detailed list of which types of practice are subject to either registration or licensing is given.

Protection of workers, apprentices and students: this title includes, with little amendment, the provisions on occupational exposure in Directive 96/29/Euratom. It also includes the specific requirements in the Outside Workers Directive, and introduces a clear allocation of responsibilities between the employer and the undertaking where the practice is conducted. The data system for individual radiological monitoring of exposed workers and the minimum set of data to be communicated for outside workers has been updated**.**

This chapter now also covers occupational exposure in all exposure situations, which provides more explicit protection for emergency workers as well as for workers exposed to high levels of **indoor radon** in their workplace.

Protection of patients and other individuals subjected to medical exposure: this chapter includes the relevant requirements from the Medical Directive, but strengthens them, in particular with regard to:

- the application of the justification principle;
- information to patients on the health risks and benefits;
- information on doses;
- diagnostic reference levels;
- involvement of the Medical Physics Expert;
- prevention of accidental and unintended medical exposures.

Protection of members of the public: this chapter includes the public exposure requirements in Directive 96/29/Euratom, with more explicit consideration of the issuing of discharge authorisations for radioactive effluent

The section on emergency exposure situations includes the requirements of the Public Information Directive.

The section on existing exposure situations addresses indoor exposure to radon, with a somewhat lower maximum reference level for existing dwellings than in Commission Recommendation 90/143/Euratom, in line with ICRP and WHO recommendations. It also includes requirements for the classification of building materials on the basis of a radioactivity index and a uniform reference level for the annual dose resulting from residence in a building constructed with such materials.

Protection of the environment: this chapter, in line with the broader scope of the Directive as in the International Basic Safety Standards, aims to provide a means to demonstrate compliance with environmental criteria. It is up to national authorities to assess the doses to representative animals and plants in terms of protection of the ecosystem.

Appropriate technical measures also need to be taken to avoid the environmental consequences of an accidental release and to monitor existing levels of radioactivity in the environment, from the perspectives of both environmental protection and human health.

Requirements for regulatory control: this chapter includes all the responsibilities of the regulatory authorities in all exposure situations. The first section on 'institutional infrastructure' calls for a clear definition of the responsibilities of different authorities. The Commission is to receive periodically

updated information and publish this in the Official Journal. This section also defines the responsibilities of the 'Radiation Protection Expert', the 'Radiation Protection Officer' (in the current BSS these concepts were merged within the function of 'Qualified Expert') and the 'Medical Physics Expert'.

Final provisions: a 2-year transposition deadline is deemed sufficient. Specific new features, such as the protection of the environment, can be transposed later. In line with the Euratom Treaty, the Basic Standards are to be uniformly applied in the Member States, though without prejudice to those requirements for which flexibility is clear from the wording of the text. However, dose limits, default exemption values, the reference level for building materials, etc. are explicitly intended for uniform transposition and application.

BUDGETARY IMPLICATIONS: there are no implications for the EU budget.