

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

2011/0254(NLE) - 05/12/2013 - Final act

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

NON LEGISLATIVE ACT: Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

CONTENT: this Directive brings **together five Council Directives in a single Directive.**

The five Directives are:

- Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. This establishes uniform basic safety standards against the dangers of radiation and applies to all practices which involve a risk from ionising radiation.
- Directive on protection in relation to medical exposure (97/43/Euratom),
- Directive on the control of high-activity sealed radioactive sources and orphan sources (2003/122/Euratom)
- Directive on the operational protection of outside workers (90/641/Euratom),
- Directive on informing the general public (89/618/Euratom).

Objective: the Directive establishes uniform basic safety standards for the protection of the health of individuals subject to **occupational, medical and public exposures** against the dangers arising from ionising radiation.

Scope: the Directive applies to **any planned, existing or emergency exposure situation** which involves a risk from exposure to ionising radiation which cannot be disregarded from a radiation protection point of view or with regard to the environment in view of long-term human health protection.

It applies in particular to:

- the manufacture, production, processing, handling, disposal, use, storage, holding, transport, import to, and export from the Community of **radioactive material**;
- the manufacture and the operation of **electrical equipment emitting ionising radiation** and containing components operating at a potential difference of more than 5 kilovolt (kV);

- human activities which involve the presence of **natural radiation sources** that lead to a significant increase in the exposure of workers or members of the public, in particular: (i) the operation of aircraft and spacecraft, in relation to the exposure of crews; (ii) the processing of materials with naturally-occurring radionuclides;
- the exposure of workers or members of the public to **indoor radon**, the external exposure from building materials and cases of lasting exposure resulting from the after-effects of an emergency or a past human activity;
- the preparedness for, the planning of response to and the management of emergency exposure situations that are deemed to warrant measures to protect the health of members of the public or workers.

Exclusion from the scope: the Directive does not apply to exposure to the natural level of radiation, such as radionuclides contained in the human body and cosmic radiation prevailing at ground level, or exposure of members of the public or workers other than air or spacecrew to **cosmic radiation in flight or in space**.

System of radiation protection: Member States shall establish legal requirements and an appropriate **regime of regulatory control** which, for all exposure situations, reflect a system of radiation protection based on the principles of:

1. **justification:** decisions introducing a practice shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause;
2. **optimisation:** exposure and the number of individuals exposed must be as low as reasonably achievable taking into account the current state of technical knowledge;
3. **dose limitation:** in planned exposure situations, the sum of doses to an individual shall not exceed the dose limits laid down for occupational exposure or public exposure. Dose limits shall not apply to medical exposures.

Optimisation of exposure: the directive lays down **dose constraints** for occupational, public, and medical exposure for the purpose of **prospective optimisation of protection**. Reference levels are established for exposure situations, which must not be exceeded.

Dose limitation: a series of provisions are laid down to **prevent or limit exposure** to certain categories of workers: (i) workers under age 18; (ii) pregnant or breastfeeding women; (iii) apprentices and students.

Specific provisions have been laid down:

- **for occupational exposure:** Member States shall ensure that dose limits for occupational exposure apply to the sum of **annual occupational exposures** of a worker from all authorised practices. The limit on the effective dose for occupational exposure shall be **20 mSv in any single year** (with some exceptions to this rule);
- **for public exposure:** Member States shall set the limit on the effective dose for public exposure at 1 mSv in a year;

- **for medical exposure:** Member States shall ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are **kept as low as reasonably achievable** consistent with obtaining the required medical information, taking into account economic and societal factors.

Other protection measures:

- **Information and training:** the Directive lays down requirements for radiation protection education, training and information. Member States shall establish an **adequate legislative and administrative framework** ensuring the provision of appropriate radiation protection education, training and information to all individuals whose tasks require specific competences in radiation protection.
- **Justification and regulatory control of practices:** Member States should be required to submit certain practices involving a hazard from ionising radiation to a system of regulatory control or to prohibit certain practices. The application of radiation protection principles in relation to **consumer products** requires the regulatory control of practices to start at the stage of design and manufacture of products or at the time of import of such products. Therefore, the manufacture or import of consumer products should be regulated and specific procedures should be introduced. It should be noted that Member States shall **prohibit the deliberate addition of radioactive substances in certain consumer products** (such as foodstuffs, animal feeding stuffs, cosmetics, toys and personal ornaments) and shall prohibit the import or export of such products.
- **Graded approach to regulatory control:** Member States shall require practices to be subject to regulatory control for the purpose of radiation protection, by way of notification, authorisation and **appropriate inspections**, commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the impact that regulatory control may have in reducing such exposures or improving radiological safety.

Exemptions: Member States should be able to grant specific exemption from authorisation for certain practices involving activities above the exemption values.

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