



**COUNCIL OF
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ATO 63

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: COUNCIL DIRECTIVE establishing a Community framework for the
nuclear safety of nuclear installations

COUNCIL DIRECTIVE 2009/.../EURATOM

of

**establishing a Community framework for
the nuclear safety of nuclear installations**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 and 32 thereof,

Having regard to the proposal from the Commission, drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States, and after having consulted the European Economic and Social Committee¹,

Having regard to the opinion of the European Parliament²,

¹ Opinion of 10 June 2009 (not yet published in the Official Journal).

² Opinion of the European Parliament of 22 April 2009 (not yet published in the Official Journal).

Whereas:

- (1) Article 2(b) of the Treaty provides for the establishment of uniform safety standards to protect the health of workers and of the general public.
- (2) Article 30 of the Treaty provides for the establishment of basic standards within the Community for the protection of the health of workers and the general public against the dangers arising from ionizing radiations.
- (3) Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation¹ establishes the basic safety standards. The provisions of that Directive have been supplemented by more specific legislation.
- (4) As recognised by the Court of Justice of the European Communities (hereinafter referred to as "the Court of Justice") in its case-law², the Community shares competences, together with its Member States, in fields covered by the Convention on Nuclear Safety³.
- (5) As recognised by the Court of Justice in its case-law, the provisions of Chapter 3 of the Treaty, related to health and safety, form a coherent whole conferring upon the Commission powers of some considerable scope in order to protect the population and the environment against risks of nuclear contamination.

¹ OJ L 159, 29.6.1996, p. 1.

² C-187/87 (1988 ECR p. 5013), C-376/90 (1992 ECR I-6153) and C-29/99 (2002 ECR I-11221).

³ OJ L 318, 11.12.1999, p. 21.

- (6) As recognised by the Court of Justice in its case-law, the tasks imposed on the Community by Article 2(b) of the Treaty to lay down uniform safety standards to protect the health of the population and of workers does not mean that, once such standards have been defined, a Member State may not provide for more stringent measures of protection.
- (7) Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency¹ established a framework for notification and provision of information to be used by the Member States in order to protect the general public in case of a radiological emergency. Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency² imposed obligations on the Member States to inform the general public in the event of a radiological emergency.
- (8) National responsibility of Member States for the nuclear safety of nuclear installations is the fundamental principle on which nuclear safety regulation has been developed at the international level, as endorsed by the Convention on Nuclear Safety. That principle of national responsibility, as well as the principle of prime responsibility of the licence holder for the nuclear safety of a nuclear installation under the supervision of its national competent regulatory authority, should be enhanced and the role and independence of the competent regulatory authorities should be reinforced by this Directive.
- (9) Each Member State may decide on its energy mix in accordance with relevant national policies.

¹ OJ L 371, 30.12.1987, p. 76.

² OJ L 357, 7.12.1989, p. 31.

- (10) When developing the appropriate national framework under this Directive, national circumstances will be taken into account.
- (11) The Member States have already implemented measures enabling them to achieve a high level of nuclear safety within the Community.
- (12) While this Directive concerns principally the nuclear safety of nuclear installations, it is also important to ensure the safe management of spent fuel and radioactive waste, including at storage and disposal facilities.
- (13) Member States should assess, where appropriate, the relevant fundamental safety principles set by the International Atomic Energy Agency¹ which should constitute a framework of practices that Member States should have regard to when implementing this Directive.
- (14) It is useful to build on the process where the national safety authorities of the Member States having nuclear power plants on their territory have been working together in the context of Western European Nuclear Regulators' Association (WENRA) and have defined many safety reference levels for power reactors.

¹ IAEA Safety Fundamentals: Fundamental safety principles, IAEA Safety Standard Series No SF-1 (2006).

- (15) Following the Council's invitation to set up a High Level Group at EU level, as recorded in its Conclusions of 8 May 2007 on nuclear safety and safe management of spent nuclear fuel and radioactive waste, the European Nuclear Safety Regulators Group (ENSREG) was established by Commission Decision 2007/530/Euratom of 17 July 2007 on establishing the European High Level Group on Nuclear Safety and Waste Management¹ to contribute to the achievement of the Community objectives in the field of nuclear safety.
- (16) It is useful to establish a unified structure for reports of Member States to the Commission on the implementation of this Directive. Given its members' wide experience ENSREG could make a valuable contribution in this respect, thereby facilitating consultation and cooperation of national regulatory authorities.
- (17) On 15 October 2008 at its 5th meeting ENSREG adopted ten principles to be used when drafting a nuclear safety Directive, as noted in its minutes dated 20 November 2008.
- (18) Advances in nuclear technology, lessons learnt from operating experience and safety research and improvements in regulatory frameworks could have the potential to further improve safety. In keeping with the commitment to maintain and improve safety, Member States should take those factors into account when extending their nuclear power programme or deciding to use nuclear power for the first time.

¹ OJ L 195, 27.7.2007 p. 44.

- (19) The establishment of a strong safety culture within a nuclear installation is one of the fundamental safety management principles necessary for achieving its safe operation.
- (20) Maintenance and further development of expertise and skills in nuclear safety should be based, *inter alia*, on a process of learning from past operating experience and employing developments in methodology and science, as appropriate.

- (21) In the past, self-assessments have been carried out in Member States in close connection with international peer reviews under the auspices of the IAEA as International Regulatory Review Team or Integrated Regulatory Review Service missions. These self-assessments were carried out and these missions were invited by Member States on a voluntary basis in the spirit of openness and transparency. Self-assessments and accompanying peer reviews of the legislative, regulatory and organisational infrastructure should be aimed at strengthening and enhancing the national framework of Member States, whilst recognising their competencies in ensuring nuclear safety of nuclear installations on their territory. The self-assessments followed by international peer reviews are neither an inspection nor an audit, but a mutual learning mechanism that accepts different approaches to the organisation and practices of a competent regulatory authority, while considering regulatory, technical and policy issues of a Member State that contribute to ensuring a strong nuclear safety regime. The international peer reviews should be regarded as an opportunity to exchange professional experience and to share lessons learned and good practices in an open and cooperative spirit through advice by peers rather than control or judgement. Recognising a need for flexibility and appropriateness in regard to different existing systems in Member States, a Member State should be free to determine the segments of its system being subject to the specific peer review invited, with the aim of continuously improving nuclear safety.

- (22) In accordance with point 34 of the Interinstitutional Agreement on better law-making¹, Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures and to make them public,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER 1

OBJECTIVES, DEFINITIONS AND SCOPE OF APPLICATION

Article 1 *Objectives*

The objectives of this Directive are:

- (a) to establish a Community framework in order to maintain and promote the continuous improvement of nuclear safety and its regulation;
- (b) to ensure that Member States shall provide for appropriate national arrangements for a high level of nuclear safety to protect workers and the general public against the dangers arising from ionizing radiations from nuclear installations.

¹ OJ C 321, 31.12.2003, p. 1.

Article 2

Scope

1. This Directive shall apply to any civilian nuclear installation operating under a licence as defined in Article 3(4) at all stages covered by this licence.
2. This Directive does not prevent Member States from taking more stringent safety measures in the subject-matter covered by this Directive, in compliance with Community law.
3. This Directive supplements the basic standards referred to in Article 30 of the Treaty as regards the nuclear safety of nuclear installations and is without prejudice to Directive 96/29/Euratom.

Article 3

Definitions

For the purposes of this Directive the following definitions shall apply:

- 1) "nuclear installation" means:
 - (a) an enrichment plant, nuclear fuel fabrication plant, nuclear power plant, reprocessing plant, research reactor facility, spent fuel storage facility; and
 - (b) storage facilities for radioactive waste that are on the same site and are directly related to nuclear installations listed under point (a);

- 2) "nuclear safety" means the achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers and the general public from dangers arising from ionizing radiations from nuclear installations;
- 3) "competent regulatory authority" means an authority or a system of authorities designated in a Member State in the field of regulation of nuclear safety of nuclear installations as referred to in Article 5;
- 4) "licence" means any legal document granted under the jurisdiction of a Member State to confer responsibility for the siting, design, construction, commissioning and operation or decommissioning of a nuclear installation;
- 5) "licence holder" means a legal or natural person having overall responsibility for a nuclear installation as specified in a licence.

CHAPTER 2

OBLIGATIONS

Article 4

Legislative, regulatory and organisational framework

1. Member States shall establish and maintain a national legislative, regulatory and organisational framework (hereinafter referred to as "the national framework") for nuclear safety of nuclear installations that allocates responsibilities and provides for coordination between relevant state bodies. The national framework shall establish responsibilities for:
 - (a) the adoption of national nuclear safety requirements. The determination on how they are adopted and through which instrument they are applied rests with the competence of the Member States;
 - (b) the provision of a system of licensing and prohibition of operation of nuclear installations without a licence;
 - (c) the provision of a system of nuclear safety supervision;
 - (d) enforcement actions, including suspension of operation and modification or revocation of a licence.

2. Member States shall ensure that the national framework is maintained and improved when appropriate, taking into account operating experience, insights gained from safety analyses for operating nuclear installations, development of technology and results of safety research, when available and relevant.

Article 5

Competent regulatory authority

1. Member States shall establish and maintain a competent regulatory authority in the field of nuclear safety of nuclear installations.
2. Member States shall ensure that the competent regulatory authority is functionally separate from any other body or organisation concerned with the promotion, or utilisation of nuclear energy, including electricity production, in order to ensure effective independence from undue influence in its regulatory decision making.

3. Member States shall ensure that the competent regulatory authority is given the legal powers and human and financial resources necessary to fulfil its obligations in connection with the national framework described in Article 4(1) with due priority to safety. This includes the powers and resources to:
- (a) require the licence holder to comply with national nuclear safety requirements and the terms of the relevant licence;
 - (b) require demonstration of this compliance, including the requirements under paragraphs 2 to 5 of Article 6;
 - (c) verify this compliance through regulatory assessments and inspections; and
 - (d) carry out regulatory enforcement actions, including suspending the operation of nuclear installation in accordance with conditions defined by the national framework referred to in Article 4(1).

Article 6

Licence holders

1. Member States shall ensure that the prime responsibility for nuclear safety of a nuclear installation rests with the licence holder. This responsibility cannot be delegated.

2. Member States shall ensure that the national framework in place requires licence holders, under the supervision of the competent regulatory authority, to regularly assess and verify, and continuously improve, as far as reasonably achievable, the nuclear safety of their nuclear installations in a systematic and verifiable manner.
3. The assessments referred to in paragraph 2 shall include verification that measures are in place for prevention of accidents and mitigation of consequences of accidents, including verification of the physical barriers and licence holder's administrative procedures of protection that would have to fail before workers and the general public would be significantly affected by ionizing radiations.
4. Member States shall ensure that the national framework in place requires licence holders to establish and implement management systems which give due priority to nuclear safety and are regularly verified by the competent regulatory authority.
5. Member States shall ensure that the national framework in place requires licence holders to provide for and maintain adequate financial and human resources to fulfil their obligations with respect to nuclear safety of a nuclear installation, laid down in paragraphs 1 to 4.

Article 7

Expertise and skills in nuclear safety

Member States shall ensure that the national framework in place requires arrangements for education and training to be made by all parties for their staff having responsibilities relating to the nuclear safety of nuclear installations in order to maintain and to further develop expertise and skills in nuclear safety.

Article 8

Information to the public

Member States shall ensure that information in relation to the regulation of nuclear safety is made available to the workers and the general public. This obligation includes ensuring that the competent regulatory authority informs the public in the fields of its competence. Information shall be made available to the public in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, *inter alia*, security, recognised in national legislation or international obligations.

Article 9

Reporting

1. Member States shall submit a report to the Commission on the implementation of this Directive for the first time by ...^{*}, and every three years thereafter, taking advantage of the review and reporting cycles under the Convention on Nuclear Safety.

* OJ please insert the date: five years after the entry into force of this directive.

2. On the basis of the Member States' reports, the Commission shall submit a report to the Council and the European Parliament on progress made with the implementation of this Directive.
3. Member States shall at least every ten years arrange for periodic self-assessments of their national framework and competent regulatory authorities and invite an international peer review of relevant segments of their national framework and/or authorities with the aim of continuously improving nuclear safety. Outcomes of any peer review shall be reported to the Member States and the Commission, when available.

CHAPTER 3

FINAL PROVISIONS

Article 10

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ...*. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive and of any subsequent amendments to those provisions.

* OJ please insert the date: two years after the entry into force of this directive.

Article 11
Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 12
Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President
