



**COUNCIL OF
THE EUROPEAN UNION**

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NOTE

from : General Secretariat
to: Delegations

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Subject : Proposal for a Council (Euratom) Directive setting out the basic obligations and
general principles on the safety of nuclear installations

Delegations will find attached the text of the proposal as revised following the meeting of the Working Party on Atomic Questions on 5 February 2004, taking into account delegations' comments.

Proposal for a
COUNCIL (Euratom) DIRECTIVE

Setting out the basic obligations and general principles on the 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 Commission¹, 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, in accordance with Article 31 of the Treaty, and after obtaining the opinion of the European Economic and Social Committee²,

Having regard to the opinion of the European Parliament³,

Whereas:

- (1) Article 2(b) of the Treaty stipulates that the Community shall, as provided in this Treaty, establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied.
- (2) Article 30 of the Treaty stipulates that basic standards shall be laid down within the Community for the protection of the health of workers and the general public against the dangers arising from ionising radiations. Article 32 provides for the basic standards to be supplemented in accordance with the procedure laid down in Article 31.
- (3) Directive 96/29/Euratom of the Council⁴ lays down basic safety standards for the protection of the health of the general public and of workers against the dangers arising from ionising radiation.

¹ OJ C [...], [...], p. [...].

² OJ C [...], [...], p. [...].

³ OJ C [...], [...], p. [...].

⁴ OJ L 159, 29.6.1996, p. 1.

- (4) The accident at the Chernobyl nuclear power station in 1986 highlighted the need for the Community to supplement the basic standards in force at the time with provisions applying in case of a radiological emergency. Accordingly, Council Decision 87/600/Euratom⁵ established arrangements for the early exchange of information in the event of a radiological emergency while Council Directive 89/618/Euratom⁶ imposed obligations on the Member States on informing the general public in the event of a radiological emergency.
- (5) The basic standards were further supplemented by Directive 92/3/Euratom on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community⁷ and by Council Regulation (Euratom) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States⁸.
- (6) Directive 2003/122/Euratom⁹ on the control of high activity sealed radioactive sources and orphan sources sets out specific requirements to ensure that such sources are kept under control including when they become disused sources.
- (7) Although the radiation protection system created by the basic standards in force ensures a high level of protection for the health of the population based on current scientific knowledge on this subject, this must be supplemented to ensure that a high level of safety of nuclear installations is maintained. Keeping up a high level of safety from conception to decommissioning by maintaining effective defences against radiological risks and preventing accidents which could have radiological consequences is a *sine qua non* in order fully to attain the objectives of health protection set out in Article 2(b) of the Treaty.
- (8) The Member States have already implemented measures enabling them to achieve a high level of nuclear safety within the EU. The evaluation of nuclear safety in candidate countries, carried out by the Council, has ascertained that these countries have already achieved a comparable level of safety or will be in a position to do so, subject to the full implementation of the recommendations resulting from the evaluation.
- (9) International Atomic Energy Agency's (IAEA) standards and approaches constitute an internationally recognised framework of best practice on which national safety requirements are primarily based [...] and to the improvement of which Member States have made considerable contributions.

⁵ OJ L 371, 30.12.1987, p. 76.

⁶ OJ L 357, 7.12.1989, p. 31.

⁷ OJ L 35, 12.2.1992, p. 24.

⁸ OJ L 148, 19.6.1993, p. 1.

⁹ OJ L 346, 31.12.2003, p.57.

- (10) Despite a degree of harmonisation, today the nuclear safety measures still vary widely from one Member State to another. At present, this diversity of measures does not allow the Community to satisfy itself that the health protection requirements of Article 2(b) of the Treaty are applied in the best possible way. The European Atomic Energy Community by joining the Convention on Nuclear Safety, which entered into force on 24 October 1996, committed itself to respect an internationally recognised high level of nuclear safety. In order for the Community to ensure that the principles of this Convention are respected at Community level and that “uniform safety standards” as required by Article 2(b) of Euratom Treaty are applied, the basic standards for radiation protection should be supplemented by common safety principles.
- (11) National responsibility for the safety of nuclear installations is the fundamental principle on which nuclear safety regulation has been developed by the international community, as endorsed by the Convention on Nuclear Safety and its Parties including the European Atomic Energy Community; the prime responsibility for the safety of a nuclear installation rests therefore with the licence holder under the control of its national regulatory body and is not reduced by the provisions of this Directive.
- (12) As well as during the active life of a nuclear installation, dangers from ionising radiation may also arise as a result of decommissioning operations. In order to deal with the risks attached to the disposal of radioactive materials, it is necessary to ensure the safe decommissioning of nuclear installations including the long-term management of radioactive waste and of spent fuel.
- (13) In order to attain the Community objectives regarding radioprotection mentioned above, it is essential to define the basic obligations and general principles on the safety of nuclear installations.
- (14) It is necessary that adequate financial resources are available to support the safety of nuclear installations, even beyond their operational lifetime. Safe decommissioning of nuclear installations, including the long-term management of radioactive waste and spent nuclear fuel, calls for substantial financial resources. In order to avoid any danger to human health, it is necessary that sufficient financial resources will be available in Member States to complete decommissioning activities at nuclear installations in conformity with national safety requirements. To this end, Member States should put in place specific rules for the establishment of such financial resources throughout the productive service life of the installations.

- (15) This Directive is consistent with the logic of the regime established by the Convention on Nuclear Safety, which entered into force on 24 October 1996 and to which all the Member States are parties. By the Commission decision 1999/819/Euratom the European Atomic Energy Community acceded to the Convention on 31 January 2000¹⁰. Since the scope of this Convention is limited to nuclear power plants, this Directive extends the principles laid down therein to all nuclear installations where consideration of safety is required.
- (16) In the same context, the International Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management¹¹, which entered into force on 18 June 2001, specifies in Article 26 that each contracting party shall take appropriate steps to ensure the safety of decommissioning of a nuclear facility. Such steps shall ensure that ... qualified staff and adequate financial resources are available. Article 22(ii) of the Convention calls on each Contracting Party to take the appropriate steps to ensure that adequate financial resources are available to support the safety of facilities for spent fuel and radioactive waste management during their operating lifetime and for decommissioning.
- (17) In order to monitor application of rules set up in conformity with this Directive [...]the manner in which safety authorities carry out their duties *should* be reviewed with a Peer review mechanism and [...] Member States *should submit reports on the measures taken to fulfil their obligations under this Directive* [...].
- (18) With a view to making the best use of national regulatory authorities experience and contributing to the furthering of a common approach to nuclear safety these reviews should be conducted under the aegis of a Committee of Regulatory Authorities, and synergies should be sought with relevant activities carried out under the Convention on Nuclear Safety.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Subject matter and scope

1. In order to ensure the protection of the general public and of workers against the dangers of ionising radiation from nuclear installations, this Directive supplements the basic standards laid down under Article 30 of the EAEC Treaty as regards the safety of such installations by setting out relevant basic obligations and general principles.

¹⁰ OJ L 318, 11.12.1999, p. 20.

¹¹ OJ C [...], [...], p. [...].

2. This Directive applies to all nuclear installations, including after the end of their operation, for which consideration of safety is required under the legislative and regulatory framework of the Member State concerned [.]

Article 2
Definitions

For the purposes of this Directive:

- (1) "Nuclear installation" means any civilian facility and its associated land, buildings and equipment where radioactive materials [.] are produced, processed, used, handled, ~~or~~ stored or disposed of temporarily or permanently. This definition applies until the moment the facility is released from any radiological restrictions imposed upon it. This definition does not cover mineral extraction facilities and facilities only holding minor amounts of radioactive materials such as sealed radioactive sources for medical, research and industrial purposes.¹²
- (2) "Nuclear safety" means the state achieved through measures taken with a view to the prevention of accidents or mitigation of accident consequences, resulting in protection of workers and public from undue radiation hazards arising from nuclear installations.
- (3) "Common safety principles" means all the provisions set out in Articles 3 to 12 of this Directive;
- (3a) "Radioactive material" means any material that emits ionising radiation;
- (3b) "Ionising radiation" means the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nanometer or less or a frequency of 3×10^{15} Hertz or more capable of producing ions directly or indirectly;
- (4) "Regulatory body" means, for each Member State, any body or bodies, given the legal authority by the Member State to grant licences and to regulate the siting, design, construction, commissioning, operation or decommissioning of nuclear installations;
- (5) "Licence" means any authorisation granted by the regulatory body to the applicant to confer the responsibility for the siting, design, construction, commissioning, operation or decommissioning of nuclear installations;

¹² Mutually aligned with the definition in the draft "Waste" Directive.

- (6) [.]
- (7) "Decommissioning" means all steps leading to the release of a nuclear installation, other than a disposal facility, from regulatory control. These steps include the processes of decontamination and dismantling;
- (8) "Radioactive waste" means radioactive material in gaseous, liquid or solid form for which no further use is foreseen by the member State or by a natural or legal person whose decision is accepted by the Member State, and which is controlled as radioactive waste by a regulatory body under the legislative and regulatory framework of the Member State;
- (9) "Practice" means a human activity that can increase the exposure of individuals to radiation from an artificial source, or from a natural radiation source where natural radionuclides are processed for their radioactive, fissile or fertile properties, except in the case of an emergency exposure;¹³

Article 3

[.] *Regulatory body*

1. Each Member State shall establish a regulatory body *and ensure that* in discharging its duties on nuclear safety the *functions of the* regulatory body *are* effectively separated from *those of* any other body or organisation, whether private or public, concerned with the promotion or utilisation of nuclear energy. The regulatory body shall be provided with adequate authority, competence and financial and human resources to fulfil its assigned responsibilities.
- [.]
2. The regulatory body shall supervise and regulate *nuclear* safety *of* nuclear installations and *ensure the implementation of* safety regulations. It shall grant licences and monitor application of the regulations on siting, design, construction, commissioning, operation or decommissioning of nuclear installations.

¹³ Definition identical to that of Directive 96/29 on Basic standards.

Article 4

Responsibility for the safety of the nuclear installations

1. The responsibility of the safety of nuclear installations shall rest with the Member State having jurisdiction over the nuclear installation concerned.
 - 1a. Each Member State shall establish and maintain a legislative and regulatory framework to govern the safety of nuclear installations. The legislative and regulatory framework shall provide for:
 - (a) the establishment of applicable national safety requirements and regulations;
 - (b) a system of licensing with regard to nuclear installations and the prohibition of the operation of a nuclear installation without a licence
 - (c) a system of regulatory inspection and assessment of nuclear installations to ascertain compliance with applicable regulations and the terms of licences;
 - (d) the enforcement of applicable regulations and of the terms of licences, including suspension, modification or revocation.
2. Member States shall take the necessary measures to ensure that the prime responsibility for the safety of a nuclear installation rests with the holder of the relevant license under the control of their regulatory bodies [.] . The safety measures and controls to be implemented in a nuclear installation shall be decided solely by the regulatory body and the licence holder.
3. Member States take the appropriate measures to ensure that each holder of a license meets its responsibilities.

Article 5

Safety in nuclear installations

Member States shall ensure that all reasonably achievable measures are implemented to ensure a high level of safety in nuclear installations. In particular, Member States shall take all the appropriate steps:

- (a) to establish and maintain effective arrangements in nuclear installations against potential radiological hazards in order to protect individuals and society from harmful effects of ionising radiation from such installations;

- (b) to prevent accidents with radiological consequences and to mitigate such consequences should they occur;
- (c) [.]
- (d) to ensure the long term management of all radioactive materials, including radioactive waste and spent nuclear fuel, produced in the course of operation and decommissioning, in accordance with the basic standards for the protection of the general public and of workers against dangers arising from ionising radiation;
- (e) to ensure effective information to and, where appropriate, consultation of their population, as well as the competent authorities of the States in the vicinity of nuclear installations under the jurisdiction of the Member State concerned, insofar as they are likely to be affected in the event of a radiological emergency at that installation, on issues related to safety of such nuclear installations.

Article 6

Priority to safety

1. Member States shall take all appropriate measures to ensure that in the course of all practices directly related to nuclear installations due priority is given to nuclear safety.
2. The measures for operational protection of the population in normal circumstances pursuant to Article 44 of Directive 96/29 Euratom shall take account of all aspects of the nuclear safety of installations.

Article 7

Obligations of licence holders

1. Member States shall require the licence holders to operate their installations in accordance with the common safety principles set out in this Directive and with national safety requirements applicable to them and the regulations laid down by the regulatory body and any measures taken by the same regulatory body.
2. Member States shall require the licence holders to establish and implement quality assurance programmes commensurate with the nuclear safety relevance of the installations concerned, subject to at least verification by the regulatory body, with a view to providing confidence that specified requirements for all activities important to nuclear safety are satisfied throughout the life of nuclear installations.

3. Member States shall take the necessary measures for the allocation of responsibility for the decommissioning of nuclear installations, including in those cases where the parties originally responsible are no longer able to meet their commitments.

Article 8

Inspection

Member States shall ensure that nuclear safety inspections are carried out by the regulatory body, or by experts designated by the regulatory body, in nuclear installations throughout their life, including during their decommissioning, and that the licence holder submits to such inspections.

Article 9

Financial resources

1. Member States shall take the appropriate steps to ensure that adequate financial resources are available when needed to support the safety of nuclear installations throughout their life, including during the decommissioning phase.
2. Member States shall ensure that financial resources for decommissioning are built up during the period of operation of the nuclear installations in order to reach a sufficient level of resources and are actually available for the purpose for which they have been established so as to cover, when needed, decommissioning costs, taking into account the strategy for decommissioning.

*Article 10*¹⁴

Nuclear safety expertise

1. Member States shall take the appropriate steps to ensure the availability of nuclear safety experts commensurate to the nuclear safety-related activities carried out under their jurisdiction. Member States shall require in particular that the regulatory body and the licence holders have such staff at their disposal.

¹⁴ The respective roles of Member States and operators regarding the implementation of Articles 10 and 11 should be seen in the light of Article 5 which assigns the *prime* responsibility for nuclear safety to the operators.

2. Each Member States shall ensure that appropriate curricula and opportunities for continuous theoretical and practical training are available, either in the Member State concerned or through transnational cooperation, for the personnel concerned in the safety of nuclear installations.

Article 11

Emergency plans [.]

1. Each Member State shall require the establishment of off-site as well as, in the case of Member States with nuclear installations under their jurisdiction, on-site emergency plans [.] approved by their regulatory body, and regularly tested, to deal with operating incidents and accidents in order to reduce the possible effects on its population of any radiological emergencies resulting from operation of nuclear installations.
2. Each Member State shall take the appropriate steps to ensure that, insofar as they are likely to be affected by a radiological emergency, its own population and the competent authorities of the States in the vicinity of nuclear installations under its jurisdiction are provided with appropriate information for emergency planning and response.¹⁵
3. Member States shall require the licence holder to notify the regulatory body forthwith of any incidents significant to safety and of the corrective measures taken in response.

Article 12

Committee of Regulatory Authorities

1. A Committee of Regulatory Authorities (hereinafter "the Committee") is hereby established [.]
2. The Committee shall be composed of representatives of the regulatory bodies designated by each Member State.

¹⁵ This paragraph reproduces Article 16(2) of CNS. The issue of informing the public is covered under Directive 89/618/Euratom. Also, Council Decision 87/600/Euratom provides for the exchange of information between Member States (*in the event of*) radiological emergencies. It is therefore likely that Member States have already put in place most of the measures necessary to implement this provision.

3. The Committee shall:
- (a) establish guidance on the conduct of the peer reviews referred to in Article 13,
 - (b) establish an annual planning for the peer reviews of Member States' regulatory bodies as well as the programme of each individual review,
 - (c) issue an opinion on the review reports prepared by the review teams as referred to in Article 13(5),
 - (d) draw up a summary report of each peer review,
 - (e) establish guidance on the content, form, structure and timing of the national reports referred to in Article 14, with a view to ensuring, to the extent possible, consistency with the reports to be drawn up pursuant to Article 5 of the Convention on Nuclear Safety,
 - (f) advise the Commission on its summary reports referred to in Article 14(3).
4. Further to the tasks set out in paragraph 3, the Committee may provide advice on other nuclear safety matters.
5. The Committee shall adopt its rules of procedure and designate a chairman from among its members.

Article 13

Peer review procedure

1. In order to ensure the maintenance of a high level of nuclear safety in Member States, the Commission shall organise reviews of regulatory bodies with a view to contributing to the furthering of a common approach to nuclear safety. Member States shall ensure that regulatory bodies cooperate in these reviews.
2. These reviews shall be carried out, according to a Peer review mechanism, by experts designated by the Member States. To this end, Member States shall communicate to the Commission a list of experts, indicating their fields of expertise.
3. The experts shall obtain prior approval from the Member State whose regulatory authority is subject to the review before they may carry out the reviews provided for in paragraph 1. Experts shall not be allocated for reviews within their Member State of origin.

[.]

4. Not less than three months prior to the review, the Commission shall inform the Member State concerned of the programme of the review, the date on which it is to begin and the identity of the persons in charge of the review.
5. Within three months following the review, the review team shall draw up, by consensus, a report. The Commission shall convene the Committee for a presentation of the review report. The Committee shall give an opinion on the report, which may contain recommendations to the Member State concerned. Unless otherwise agreed with the Member State concerned the review report and the opinion of the Committee shall be confidential.
6. The Commission shall forward the review report, accompanied by the opinion of the Committee, to the Member State concerned. The Member State concerned, shall, within six months of receipt, present its observations, if any, including, where relevant, the measures which it may have taken or intends to take in response to the review.
7. The Committee shall draw up a summary report of each review which shall be made available to the public.

*Article 14*¹⁶

National reports and summary reports

1. Member States shall submit a report to the Commission on the measures taken to fulfil their obligations under this Directive and on the safety situation in nuclear installations under their jurisdiction. Member States may indicate which parts of the report shall be considered confidential. The Commission shall forward these reports to the Committee.
2. The first report shall be submitted within [three] years from the date provided for in Article 17 paragraph 1 and thereafter at the same intervals as the reports to be drawn up pursuant to Article 5 of the Convention on Nuclear Safety in accordance with the guidelines drawn up by the Committee.¹⁷

[.]

¹⁶ It follows from the current draft provisions that, if the Directive is *adopted* in xxx4, the Member States should *transpose* it by xxx6, when the first *reviews* could also take place. Member States, and the Commission, would submit the first *reports* in xxx9.

¹⁷ Such timing, consistent with the CNS, should also apply to the *first* report.

3. The Commission shall *following consultation of the Committee*, submit regular *summary* reports¹⁸ to the Council and to the European Parliament in conformity with the timetable arising from paragraph 2 on the application of this Directive and on the overall progress made on nuclear safety in the Community, based on the reports submitted by the Member States and the review reports and subject to the confidentiality requirements concerned.

Article 15

More stringent measures

Member States may apply more stringent measures than those laid down in this Directive. [.]

*Article 16*¹⁹

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before [two years after the date referred to in Article 18].
2. Where these measures are adopted by the Member States, 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 references shall be laid down by Member States.
3. 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, together with a table showing how the provisions of this Directive correspond to the national provisions adopted.

Article 17

Entry into force

This Directive shall enter into force the twentieth day after its publication in the Official Journal of the European Union.

¹⁸ Formulation used in para. 59 of the conclusions of the Laeken European Council (Dec. 2001)
¹⁹ Adapted from Directive 2003/122/Euratom on the control of high-activity sealed radioactive sources and orphan sources (OJ L 346, 31.12.2003, p. 57).

Article 18

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the Council

The President