

ENSREG - TECHNICAL INPUT TO A REVISED NUCLEAR SAFETY DIRECTIVE

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CHAPTER I

OBJECTIVES, SCOPE OF APPLICATION AND DEFINITIONS

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;
- (c) to ensure that Member States shall provide for appropriate national arrangements so that nuclear installations are designed, sited, constructed, commissioned, operated and decommissioned in a way to avoid unplanned radioactive releases and minimise other releases.

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 Euratom Treaty as regards the nuclear safety of nuclear installations and is without prejudice to the existing Community legislation for the protection of the health of the workers and the general public against the dangers arising from ionizing radiation, in particular the Directive 96/29/Euratom.

Article 3
Definitions

For the purposes of this Directive the following definitions shall apply: [To be developed – see explanatory note]

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CHAPTER II
OBLIGATIONS
SECTION 1
GENERAL 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 provide in particular for:
 - (a) nuclear safety arrangements, covering all stages of the lifecycle of nuclear installations. The determination on how they are adopted and through which instrument they are applied rests with the competence of the Member States.
 - (b) a system of licensing and prohibition of operation of nuclear installations without a licence;
 - (c) 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 the effective independence of the competent regulatory authority from undue influence in its decision making. For

this purpose, Member States shall ensure that the competent regulatory authority:

- (a) is functionally separate from any other public or private entity concerned with the promotion, or utilisation of nuclear energy, including electricity production.
 - (b) has its own appropriate budget allocations, with autonomy in the implementation of the allocated budget. The financing mechanism and the budget allocation process shall be clearly defined in the national framework;
 - (c) takes regulatory decisions, founded on safety-related criteria.
 - (d) does not seek or take direct instructions from any other public or private entity concerned with the promotion, or utilisation of nuclear energy, including electricity production when carrying out the regulatory tasks.
 - (e) shall comprise an appropriate number of personnel with the necessary qualifications, experience and expertise.
 - (f) has procedures in place for preventing and duly resolving any conflicts of interests.
3. Member States shall ensure that the competent regulatory authority is given the legal powers necessary to fulfil its obligations in connection with the national framework described in Article 4(1) with due priority to safety. This includes the following main regulatory tasks:
- (a) to define national nuclear safety requirements;
 - (b) to require the licence holder to comply with national nuclear safety requirements and the terms of the relevant licence;
 - (c) to require demonstration of this compliance, including the requirements under paragraphs 2 to 5 of Article 6;
 - (d) to verify this compliance through regulatory assessments and inspections;
 - (e) to carry out 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 the 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. This process shall include comprehensive hazards and accident analysis.
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 adequacy of defence-in-depth provisions 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 with appropriate qualifications, expertise and skills 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 requires all parties to make arrangements for education and training for their staff having responsibilities relating to the nuclear safety of nuclear installations and to on-site emergency preparedness and response arrangements, in order to obtain, maintain and to further develop up-to-date expertise and skills in nuclear safety.

Article 8

Transparency

1. Member States shall ensure that information in relation to the nuclear safety of nuclear installations is made available to the workers and the general public, up-to date and in a timely manner, with specific consideration for those living in the vicinity of a nuclear installation.

This obligation includes ensuring that the competent regulatory authority and the license holders, within their fields of responsibilities, develop, publish and implement a transparency strategy covering, inter alia,

information on normal operating conditions of nuclear installations, non-mandatory consultation activities with the workers and the general public and communication in case of incidents and accidents.

2. Information shall be made available to the public in accordance with applicable EU-legislation, national legislation and international obligations, provided that this does not jeopardise other overriding interests, such as security, recognised in national legislation or international obligations.
3. Member States shall ensure that the public is given the opportunity to participate effectively in the licensing process of nuclear installations in accordance with national legislation and international obligations.

SECTION 2

SPECIFIC OBLIGATIONS

Article 9

Safety Objectives for Nuclear Power Plants

1. Member States shall ensure that the national framework requires that nuclear power plants and, if applicable, research reactor facilities are designed, sited, constructed, commissioned, operated and decommissioned with the objective of avoiding potential radioactive releases by:
 - a. practically eliminating the occurrence of all accident sequences which would lead to early or large releases;
 - b. for accidents that have not been practically eliminated, implementing design measures so that only limited protective measures in area and time are needed for the public and that sufficient time is available to implement these measures, and that the frequency of such accidents is minimised.
2. Member States shall ensure that the national framework requires that the objective set out in paragraph 1 applies to existing nuclear installations referred to in paragraph 1 to the extent reasonably achievable.

Article 10

Design, Siting, Construction, Commissioning, Operation, Decommissioning

In order to achieve the general safety objective set out in Article 9, Member States shall ensure that the national framework requires that nuclear installations as set out in Article 9 are:

a. sited with the objective that due consideration is provided to minimise the impact of external hazards;

b. designed, constructed, commissioned, operated and decommissioned based on a defence-in-depth concept with the objectives that

- radiation doses to workers and the general public do not exceed prescribed limits and are kept as low as reasonably achievable;

- the occurrence of abnormal events is minimised;

- the potential for escalation to accident situations is reduced by enhancing plant capability to control abnormal events;

- harmful consequences of abnormal events and design basis accidents, should they occur, are mitigated to ensure that they induce no off-site radiological impact, or only minor radiological impact;

- the impact of external hazards is minimised.

Article 11

On-site emergency preparedness and response

Member States shall ensure that the national framework requires licensees to prepare an on-site emergency plan and to establish the necessary organisational structure for clear allocation of responsibilities, authorities, and arrangements for co-ordinating plant activities and co-operating with external response agencies throughout all phases of an emergency.

The site emergency plan shall be based upon an assessment of events and situations that may require protective measures on- or off-site. The plan shall be co-ordinated with all other involved bodies.

CHAPTER III

PEER-REVIEWS AND REPORTING

Article 12

Peer Reviews

1. 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 competent regulatory 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.

2. Member States, with the support of the competent regulatory authorities, within the framework of ENSREG, shall arrange periodically and at least every six years, a system of topical peer reviews and agree on a time-frame and modalities of implementation. For this purpose Member States shall:
 - a) jointly and in close coordination with the Commission select one or more specific topics related to the nuclear safety;
 - b) based on these topics, perform national assessments and publish the outcomes;
 - c) jointly define a methodology for, and arrange and carry out a peer review, to which the Commission is invited as an observer, of the outcomes of those national assessments;
 - d) publish the results of the peer reviews.
3. Each Member State subject to the peer review laid down in paragraph 2 shall arrange for the mode of implementation of relevant technical recommendations from the peer-review process on its territory.

Article 13

Reporting

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

CHAPTER IV FINAL PROVISIONS

Article 14 Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by XXX at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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. The obligations for transposition and implementation of Articles..... of this Directive shall not apply to Cyprus, Ireland, Luxembourg and Malta, for as long as they do not decide to develop any activity related to nuclear installations under their jurisdiction.
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 and of any subsequent amendments to those provisions.

Article 15 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 16 Addressees

This Directive is addressed to the Member States.