

Subsidiary Legislation made under s. 2.

Subsidiary
2012/022

**HEALTH PROTECTION (NUCLEAR SAFETY
FRAMEWORK) REGULATIONS 2012**

(LN. 2012/022)

Commencement **1.3.2012**

Amending enactments	Relevant current provisions	Commencement date
LN. 2017/157	rr. 3, 4(2), 6A, Sch.	15.8.2017

EU Legislation/International Agreements involved:

Directive 2009/71/EURATOM

Directive 2014/87/EURATOM

ARRANGEMENT OF REGULATIONS.

Regulation

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SCHEDULE

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In exercise of the powers conferred upon it by section 2 of the Health Protection (Ionising Radiation) Act 1995, and for the purpose of transposing into the law of Gibraltar Council Directive 2009/71/EURATOM of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations, the Government has made the following Regulations>

Title and commencement.

1. These Regulations may be cited as the Health Protection (Nuclear Safety Framework) Regulations 2012 and come into operation on the day of publication.

Interpretation.

2. In these Regulations “Directive” means Council Directive 2009/71/EURATOM of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations, as the same may be amended from time to time.

Directive to have effect.

3.(1) Subject to subregulation (2), the Directive, as set out in the Schedule, has effect in Gibraltar.

(2) Subregulation (1) is subject to the provision in Article 10(1a) of the Directive.

Competent regulatory authority.

4.(1) The Minister with responsibility for health protection shall be the competent regulatory authority for the purposes of the Directive.

(2) The Government may by Order published in the Gazette, appoint a competent authority in place of the appointment made in subregulation (1) and where it does so the appointment must fulfil the criteria set out in Article 5 of the Directive.

Regulations are without prejudice.

5. These Regulations are without prejudice to the Radiation (Emergency Preparedness and Public Information) Regulations 2004 (which transpose Directive 96/29/EURATOM).

Information to the public.

6. The Minister shall be responsible for providing information to the public in accordance with Article 8 of the Directive.

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Restriction on the issue of licences.

6A. No licence may be issued to a civilian nuclear installation unless-

- (a) a national framework, as defined in Article 4(1) of the Directive, has been established;
- (b) a competent authority has been appointed under regulation 4(2).

Penalties.

7. A person who operates a nuclear installation without a licence issued by the competent regulatory authority commits an offence and is liable on summary conviction to imprisonment for 3 months or a fine at level 5 on the standard scale, or both.

SCHEDULE**COUNCIL DIRECTIVE 2009/71/EURATOM**

of 25 June 2009 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 Committee,

Having regard to the opinion of the European Parliament,

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 radiation (3) 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-law, the Community shares competences, together with its Member States, in fields covered by the Convention on Nuclear Safety.
- (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.

- (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 emergency (6) 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 emergency (7) 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.
- (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

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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 Agency (1) 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.
- (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 Management 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 fifth meeting ENSREG adopted 10 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.

- (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 Inter institutional Agreement on better law-making, 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,

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HAS ADOPTED THIS DIRECTIVE:

CHAPTER 1

OBJECTIVES, SCOPE 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.

Article 2

Scope

- 1. This Directive shall apply to any civilian nuclear installation subject to a 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 the existing Community legislation for the protection of the health of the workers and the general public against the dangers arising from ionising radiation, and in particular Council Directive 2013/59/Euratom.

Article 3

Definitions

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

- 1. 'nuclear installation' means:

- (a) a nuclear power plant, enrichment plant, nuclear fuel fabrication 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.
6. ‘accident’ means any unintended event, the consequences or potential consequences of which are significant from the point of view of radiation protection or nuclear safety;
7. ‘incident’ means any unintended event, the consequences or potential consequences of which are not negligible from the point of view of radiation protection or nuclear safety;
8. ‘abnormal operations’ means an operational process deviating from normal operation which is expected to occur at least once during the operating lifetime of a facility but which, in view of appropriate design provisions, does not cause any significant damage to items important to safety or lead to accident conditions;
9. ‘design basis’ means the range of conditions and events taken explicitly into account in the design, including upgrades, of a nuclear installation, according to established criteria, so that the installation can withstand them without exceeding authorised limits by the planned operation of safety systems;
10. ‘design basis accident’ means accident conditions against which a nuclear installation is designed according to established design criteria, and

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for which the damage to the fuel, where applicable, and the release of radioactive material are kept within authorised limits;

11. 'severe conditions' means conditions that are more severe than conditions related to design basis accidents; such conditions may be caused by multiple failures, such as the complete loss of all trains of a safety system, or by an extremely unlikely event.

CHAPTER 2

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 ('national framework') for the nuclear safety of nuclear installations. The national framework shall provide in particular for:

- (a) the allocation of responsibilities and coordination between relevant state bodies;
- (b) national nuclear safety requirements, covering all stages of the lifecycle of nuclear installations;
- (c) a system of licensing and prohibition of operation of nuclear installations without a licence;
- (d) a system of regulatory control of nuclear safety performed by the competent regulatory authority;
- (e) effective and proportionate enforcement actions, including, where appropriate, corrective action or suspension of operation and modification or revocation of a licence.

The determination on how national nuclear safety requirements referred to in point (b) are adopted and through which instrument they are applied remains within the competences of the Member States.

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.

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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 from undue influence of the competent regulatory authority in its regulatory decision-making. For this purpose, Member States shall ensure that the national framework requires that the competent regulatory authority:

- (a) is functionally separate from any other body or organisation concerned with the promotion or utilisation of nuclear energy, and does not seek or take instructions from any such body or organisation when carrying out its regulatory tasks;
- (b) takes regulatory decisions founded on robust and transparent nuclear safety-related requirements;
- (c) is given dedicated and appropriate budget allocations to allow for the delivery of its regulatory tasks as defined in the national framework and is responsible for the implementation of the allocated budget;
- (d) employs an appropriate number of staff with qualifications, experience and expertise necessary to fulfil its obligations. It may use external scientific and technical resources and expertise in support of its regulatory functions;
- (e) establishes procedures for the prevention and resolution of any conflicts of interest;
- (f) provides nuclear safety-related information without clearance from any other body or organisation, provided that this does not jeopardise other overriding interests, such as security, recognised in relevant legislation or international instruments.

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). For this purpose, Member States shall ensure that the national framework entrusts the competent regulatory authorities with the following main regulatory tasks, to:

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- (a) propose, define or participate in the definition of national nuclear safety requirements;
- (b) require that the licence holder complies and demonstrates compliance with national nuclear safety requirements and the terms of the relevant licence;
- (c) verify such compliance through regulatory assessments and inspections;
- (d) propose or carry out effective and proportionate enforcement actions.

*Article 6**Licence holders*

Member States shall ensure that the national framework requires that:

- (a) the prime responsibility for the nuclear safety of a nuclear installation rests with the licence holder. That responsibility cannot be delegated and includes responsibility for the activities of contractors and sub-contractors whose activities might affect the nuclear safety of a nuclear installation;
- (b) when applying for a licence, the applicant is required to submit a demonstration of nuclear safety. Its scope and level of detail shall be commensurate with the potential magnitude and nature of the hazard relevant for the nuclear installation and its site;
- (c) licence holders are to regularly assess, verify, and continuously improve, as far as reasonably practicable, the nuclear safety of their nuclear installations in a systematic and verifiable manner. That shall include verification that measures are in place for the prevention of accidents and mitigation of the consequences of accidents, including the verification of the application of defence-in-depth provisions;
- (d) licence holders establish and implement management systems which give due priority to nuclear safety;
- (e) licence holders provide for appropriate on-site emergency procedures and arrangements, including severe accident management guidelines or equivalent arrangements, for responding effectively to accidents in order to prevent or mitigate their consequences. Those shall in particular:

- (i) be consistent with other operational procedures and periodically exercised to verify their practicability;
 - (ii) address accidents and severe accidents that could occur in all operational modes and those that simultaneously involve or affect several units;
 - (iii) provide arrangements to receive external assistance;
 - (iv) be periodically reviewed and regularly updated, taking account of experience from exercises and lessons learned from accidents;
- (f) licence holders provide for and maintain financial and human resources with appropriate qualifications and competences, necessary to fulfil their obligations with respect to the nuclear safety of a nuclear installation. Licence holders shall also ensure that contractors and subcontractors under their responsibility and whose activities might affect the nuclear safety of a nuclear installation have the necessary human resources with appropriate qualifications and competences to fulfil their obligations.

Article 7

Expertise and skills in nuclear safety

Member States shall ensure that the national framework requires all parties to make arrangements for the education and training for their staff having responsibilities related to the nuclear safety of nuclear installations so as to obtain, maintain and to further develop expertise and skills in nuclear safety and on-site emergency preparedness.

Article 8

Transparency

1. Member States shall ensure that necessary information in relation to the nuclear safety of nuclear installations and its regulation is made available to workers and the general public, with specific consideration to local authorities, population and stakeholders in the vicinity of a nuclear installation. That obligation includes ensuring that the competent regulatory authority and the licence holders, within their fields of responsibility, provide in the framework of their communication policy:

- (a) information on normal operating conditions of nuclear installations to workers and the general public; and

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- (b) prompt information in case of incidents and accidents to workers and the general public and to the competent regulatory authorities of other Member States in the vicinity of a nuclear installation.
2. Information shall be made available to the public in accordance with relevant legislation and international instruments, provided that this does not jeopardise other overriding interests, such as security, which are recognised in relevant legislation or international instruments.
3. Member States shall, without prejudice to Article 5(2), ensure that the competent regulatory authority engages, as appropriate, in cooperation activities on the nuclear safety of nuclear installations with competent regulatory authorities of other Member States in the vicinity of a nuclear installation, inter alia, via the exchange and/or sharing of information.
4. Member States shall ensure that the general public is given the appropriate opportunities to participate effectively in the decision-making process relating to the licensing of nuclear installations, in accordance with relevant legislation and international instruments.

SECTION 2

Specific obligations

Article 8a

Nuclear safety objective for nuclear installations

1. Member States shall ensure that the national nuclear safety framework requires that nuclear installations are designed, sited, constructed, commissioned, operated and decommissioned with the objective of preventing accidents and, should an accident occur, mitigating its consequences and avoiding:
- (a) early radioactive releases that would require off-site emergency measures but with insufficient time to implement them;
 - (b) large radioactive releases that would require protective measures that could not be limited in area or time.
2. Member States shall ensure that the national framework requires that the objective set out in paragraph 1:
- (a) applies to nuclear installations for which a construction licence is granted for the first time after 14 August 2014;

- (b) is used as a reference for the timely implementation of reasonably practicable safety improvements to existing nuclear installations, including in the framework of the periodic safety reviews as defined in Article 8c(b).

Article 8b

Implementation of the nuclear safety objective for nuclear installations

1. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that where defence-in-depth applies, it shall be applied to ensure that:

- (a) the impact of extreme external natural and unintended man-made hazards is minimised;
- (b) abnormal operation and failures are prevented;
- (c) abnormal operation is controlled and failures are detected; (d) accidents within the design basis are controlled;
- (e) severe conditions are controlled, including prevention of accidents progression and mitigation of the consequences of severe accidents;
- (f) organisational structures according to Article 8d(1) are in place.

2. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that the competent regulatory authority and the licence holder take measures to promote and enhance an effective nuclear safety culture. Those measures include in particular:

- (a) management systems which give due priority to nuclear safety and promote, at all levels of staff and management, the ability to question the effective delivery of relevant safety principles and practices, and to report in a timely manner on safety issues, in accordance with Article 6(d);
- (b) arrangements by the licence holder to register, evaluate and document internal and external safety significant operating experience;
- (c) the obligation of the licence holder to report events with a potential impact on nuclear safety to the competent regulatory authority; and,

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- (d) arrangements for education and training, in accordance with Article 7.

Article 8c

Initial assessment and periodic safety reviews

Member States shall ensure that the national framework requires that:

- (a) any grant of a licence to construct a nuclear installation or operate a nuclear installation, is based upon an appropriate site and installation-specific assessment, comprising a nuclear safety demonstration with respect to the national nuclear safety requirements based on the objective set in Article 8a;
- (b) the licence holder under the regulatory control of the competent regulatory authority, re-assesses systematically and regularly, at least every 10 years, the safety of the nuclear installation as laid down in Article 6(c). That safety reassessment aims at ensuring compliance with the current design basis and identifies further safety improvements by taking into account ageing issues, operational experience, most recent research results and developments in international standards, using as a reference the objective set in Article 8a.

Article 8d

On-site emergency preparedness and response

1. Without prejudice to the provisions of the Directive 2013/59/Euratom, Member States shall ensure that the national framework requires that an organisational structure for on-site emergency preparedness and response is established with a clear allocation of responsibilities and coordination between the licence holder, and competent authorities and organisations, taking into account all phases of an emergency.

2. Member States shall ensure that there is consistency and continuity between the on-site emergency preparedness and response arrangements required by the national framework and other emergency preparedness and response arrangements required under Directive 2013/59/Euratom.

CHAPTER 2a

PEER REVIEWS AND REPORTING

Article 8e

Peer reviews

1. Member States shall, at least once every 10 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 such peer reviews shall be reported to the Member States and the Commission, when available.
2. Member States shall ensure that, on a coordinated basis:
 - (a) a national assessment is performed, based on a specific topic related to nuclear safety of the relevant nuclear installations on their territory;
 - (b) all other Member States, and the Commission as observer, are invited to peer review the national assessment referred to in point (a);
 - (c) appropriate follow-up measures are taken of relevant findings resulting from the peer review process;
 - (d) relevant reports are published on the above mentioned process and its main outcome when results are available.
3. Member States shall ensure that arrangements are in place to allow for the first topical peer review to start in 2017, and for subsequent topical peer reviews to take place at least every six years thereafter.
4. In case of an accident leading to situations that would require off- site emergency measures or protective measures for the general public, the Member State concerned shall ensure that an international peer review is invited without undue delay.

Article 9

Reporting

1. Member States shall submit a report to the Commission on the implementation of this Directive for the first time by 22 July 2014, and then by 22 July 2020.
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 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 22 July 2011. 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.

1a. The obligations of transposition and implementation of Articles 6, 8a, 8b, 8c and 8d shall not apply to Member States without nuclear installations, unless they decide to develop any activity related to nuclear installations subject to a licence under their jurisdiction.

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.

*Article 11***Entry into force**

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

*Article 12***Addressees**

This Directive is addressed to the Member States.

Done at Luxembourg, 25 June 2009.

For the Council
The President
L. MIKO.