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## I. GENERAL PROVISIONS

# MINISTRY OF TERRITORIAL POLICY AND PUBLIC SERVICE

**16041** *Royal Decree 1400/2018, of the 23rd of November, approving the Regulation on Nuclear safety in nuclear facilities.*

Council Directive 2009/71/EURATOM of the 25th of June 2009, establishing a Community framework for the nuclear safety of nuclear facilities, aimed to establish such a framework to maintain and promote the continuous improvement of nuclear energy safety and its regulation, and to ensure that Member States adopt appropriate national provisions for a high level of nuclear safety in the protection of workers and the general public against the risks resulting from ionising radiation from nuclear facilities.

In the application of this Directive, it was necessary to take into account the fundamental safety principles established by the International Atomic Energy Agency, as well as the work carried out jointly by the safety authorities of the Member States with nuclear power plants in the country under the wing of the Western European Nuclear Regulators' Association (WENRA), by which many nuclear safety reference levels have been defined for electricity-generation reactors.

Subsequently, following the accident in March 2011 at the Fukushima Daiichi nuclear power plant in Japan, the European Council of the 24th-25th of March 2011 commissioned the Commission to review the existing regulatory framework on nuclear safety and to conduct an analysis of the improvements that were necessary, the result of which was the proposal that gave rise to Council Directive 2014/87 / EURATOM of July 8th, 2014, which amends Directive 2009/71 / EURATOM of June 25th, 2009, in order to strengthen the European regulatory framework on nuclear safety.

As far as Spain is concerned, Law 25/1964, of the 29th of April, on nuclear energy, constitutes the legal framework that establishes the basic nuclear safety principles and requirements regarding these facilities. This Law has been revised several times, in order to take into account changes that have occurred in the various contexts related to its scope of application; including (but not limited to) the current institutional framework, the existence of the Autonomous Communities, the incorporation of the commitments accepted by Spain relating to the international treaties and agreements to which it has adhered, the development of safety criteria in the radioactive waste management sector, the dismantling of facilities and the updating of the sanctioning regime. The latest of these revisions was carried out through Law 12/2011, of May 27th, regarding civil liability for nuclear damage or damage caused by radioactive materials.

Within the Spanish legal framework, Law 15/1980, of April 22nd, establishing the Nuclear Safety Council, reformed by Law 33/2007, of November 7th, establishes this Organisation as the only competent authority in Spain with regards to matters of nuclear safety and radiation protection, one which has been developing and regulating the nuclear safety of nuclear facilities via various Council directives which are binding.

Likewise, Law 15/1980, of April 22nd, establishes that the right of access to information and public participation in relation to the powers of the Nuclear Safety Council with regard to nuclear safety and radiation protection shall be governed by the provisions of Law 27/2006, of July 18th, which regulates the rights of access to information, public participation and access to justice with regard to environmental matters.

The existence of this legal framework, together with the regulatory framework constituted by the Regulation on nuclear and radioactive facilities, approved by Royal Decree 1836/1999,

of December 3rd, meant that, at the time, transposition via a specific provision of Directive 2009/71 / EURATOM was not necessary as this Directive sets out general principles related to nuclear safety, such as the existence of an independent regulatory body, the prioritisation of safety, the responsibility of the licensee, transparency in matters related to the safety of the facilities and their management, matters which were already included in the Spanish legal system and which, in essence, derive from the Convention on Nuclear Safety, signed within the remit of the International Atomic Energy Agency, of which Spain is a member.

Directive 2014/87 / EURATOM is now modifying Directive 2009/71 / EURATOM in some significant aspects, establishing that at all stages of the life cycle of a facility, the objective must be the prevention of accidents and, in the event that they occur, the mitigation of their consequences, and that: a) early radioactive emissions that require emergency measures outside the site but without sufficient time to apply them must be avoided, along with b) significant radioactive emissions that need protection measures for the population that are not limited in duration or area. This safety objective has to be binding upon new facilities and be considered as a reference for the application of improvements in the case of existing ones.

Likewise, Directive 2014/87 / EURATOM has introduced other changes, both in the regulatory framework and in the regulatory authority, reinforcing aspects such as effective independence, adequate availability of human and financial resources, transparency or the prevention of conflicts of interest, among others.

Additionally, it establishes notable requirements for the holders, such as the responsibility of the non-delegable holder, the reinforcement of processes involving the demonstration of safety (licensing processes and Periodic Safety Reviews), a management system focused on nuclear safety, the reinforcement of the safety culture, the reinforcement of the structures and means necessary for the management of emergencies "in situ" and coordination for the external management, the availability of adequate financial and human resources, the qualification of the staff and any subcontracted personnel, training, reinforcement of the concept of defence in depth, or emphasis on early notification of events.

As regards the Member State, Directive 2014/87 / EURATOM maintains the obligation set out in Directive 2009/71 / EURATOM to carry out, at least once every 10 years, a self-assessment of its national framework and competent regulatory authorities, inviting an international peer review of these matters in order to constantly improve nuclear safety, and adds the obligation to conduct a peer review regarding a "specific aspect related to safety", at least once every six years, and whenever an accident causes situations that require emergency measures outside the site.

This Regulation is expected to incorporate the aforementioned Directive 2014/87/Euratom into the Spanish regulatory framework regarding the establishment of the basic nuclear safety requirements applicable to nuclear facilities, having been developed in accordance with the principles of good regulation in accordance with the requirements of article 129 of Law 39/2015, of 1st October, of the Common Administrative Procedure of the Public Administrations.

In accordance with the principles of necessity and efficiency, the regulation of these basic nuclear safety requirements is in the general interest, having a positive impact on the protection of people and the environment against the risks arising from ionising radiation, giving due priority to nuclear safety over any other interests and promoting its continuous improvement.

Another aspect that makes it advisable to approve this Regulation is the fact that, although our regulatory framework already incorporates, to a large extent, the different requirements demanded by this Directive, it does not have a specific regulatory standard on the nuclear safety of nuclear installations, whereas

other matters in this field have been regulated by means of royal decree, such as: radiation protection, through the Regulation on health protection against ionising radiations, approved by Royal Decree 783/2001, of the 6th of July; the management of radioactive wastes, through Royal Decree 102/2014, of the 21st of February, for the responsible and safe management of spent nuclear fuel and radioactive wastes; physical protection, through Royal Decree 1308/2011, of the 26th of September, on the physical protection of nuclear facilities and materials and radioactive sources; and licensing processes, through the aforementioned Regulation on nuclear and radioactive facilities. Likewise, some aspects of the Directive have been identified which are not covered in our judicial structure and which, it is believed, need to be transposed and incorporated into these Regulations, along with others arising from specific CSN directives, thereby creating a unified text within the remit of Spanish Royal Decrees. In this way, this Regulation is integrated into an existing regulatory framework applicable to installations that, in some cases, have been in the operating phase for a long time, with no intention of generating additional impacts, except those strictly necessary to comply with Directive 2014/87/Euratom, thus acting in accordance with the necessary principles of proportionality and efficiency.

In this respect, legal certainty is reinforced by the adoption of this Regulation, since, on the one hand, it is coherent with the existing standards in this area and, on the other, it favours the certainty and clarity of the legal system by incorporating Directive 2014/87/Euratom into Spanish law in relation to the basic nuclear safety requirements.

The following are the articles of basic development of national legislation on nuclear safety of this Regulation which, therefore, do not derive from Directive 2009/71/Euratom or Directive 2014/87/Euratom, cited above: 9 (limits and dose optimisation), 10 (physical protection), 12.2 and 3 (safety study), 15 (monitoring of site conditions), 17 (main safety functions), 20 (internal events), 21 (design requirements of safety-relevant structures, systems and components), 22 (safety classification), 23 (environmental and seismic qualification of structures, systems and components), 24 (construction and assembly), 25 (entry into service), 26 (maintenance, inspection and testing), 27 (internal administrative control), 30 (control of the release of radioactive material), 31 (modifications to the installation), 33 (ageing management), 34 (spent nuclear fuel and radioactive waste), 35 (requirements prior to cessation of operation) and 36 (provisions for dismantling during design, construction and operation).

It should be pointed out that this Regulation establishes obligations on the licensees or, in their absence, on the applicants for authorisations of nuclear facilities included within its scope of application, without including those obligations established by the Directive for the State in relation to the regulatory framework or the competent regulatory Authority, which are already considered to have been transposed into the current Spanish regulatory framework.

The starting point for the preparation of this project has been, in addition to Directive 2014/87, Instruction IS-26, of the 16th of June 2010 issued by the Nuclear Safety Council, on basic safety requirements applicable to nuclear facilities (Official Spanish State Bulletin of the 8th of July 2010), which currently is one of the regulatory standards transposed by Directive 2009/71 EURATOM.

During the preparation of this Spanish Royal Decree, consultations were held with business and social economic stakeholders and the Autonomous Communities, with it having been submitted, in its project phase, to the public participation process in line with the provisions of Law 27/2006, of the 18th of July, which regulates rights concerning access to information, public participation and access to justice regarding the environment, having been likewise advised by the Environmental Assessment Council.

The present Royal Decree has been drawn up by virtue of article 94 of Law 25/1964, of April 29th, regarding nuclear energy, which authorises the Government "to establish the necessary Regulations for its application and development", having been favourably informed by the Nuclear Safety Council.

Furthermore, in accordance with the provisions of Article 33 of the Treaty establishing the European Atomic Energy Community (EURATOM), this Spanish Royal Decree was communicated to the Commission of the European Union during its processing as a project.

This Regulation is included in the Annual Normative Plan for 2018, which was approved by the Council of Ministers on December 7th, 2017.

By virtue of the above, in response to a proposal by the Minister of Environment, in agreement with the Council of State and after deliberation of the Council of Ministers at its meeting on the date of the 23rd of November 2018,

I ORDER:

Sole article. *Approval of the Regulation on nuclear safety in nuclear facilities.*

Approval is granted regarding the Regulation on Nuclear Safety in Nuclear Installations, the text of which is included below.

Single transitory Provision. *Adaptation of licensees.*

Licensees will adapt to the provisions of articles 12.2, 21.1, 22.1, 27.1 and 36.2 of these Regulations within 3 years of its entry into force.

Single derogatory Provision. *Annulment of Standards.*

All regulations of similar or lower status which contradict or oppose those provided this Spanish Royal Decree are hereby repealed.

First final provision. *Legislative authority.*

This Spanish Royal Decree is a basic standard and is issued under the provisions of Article 149.1.25 of the Constitution, which attributes the remit of public safety as well as the mining and energy regime to the State.

Second final Provision. *Empowerment to issue regulations.*

The Ministry of Environment, the Interior Minister and the Nuclear Safety Council are authorised, within the scope of their respective competences, to develop and apply the provisions of this Spanish Royal Decree.

Third final Provision. *Incorporation of European Union Law.*

Through this Spanish Royal Decree, Directive 2014/87 / EURATOM of the Council of July 8th, 2014, amending Directive 2009/71 / EURATOM, of July 25th 2009, which establishes a Community framework for safety in nuclear facilities which refers to the establishment of the basic nuclear safety requirements applicable to nuclear facilities.

Fourth final Provision. *Entry into force.*

The present Royal Decree shall enter into force on the day following its publication in the "Official State Gazette".

Given in Madrid, The 25th of November 2018.

FELIPE R.

The Minister for Territorial Policy and the Civil Service,  
MERITXELL BATET LAMAÑA

**REGULATION ON NUCLEAR SAFETY IN NUCLEAR FACILITIES**

## INTRODUCTORY TITLE

**General provisions***Article 1. Objective.*

The purpose of these Regulations is to establish the basic requirements for nuclear safety applicable to nuclear facilities during their entire life cycle, in order to:

- a) ensure a high level of nuclear safety to protect workers and the general public against the risks resulting from ionising radiation from nuclear facilities;
- b) maintain nuclear safety and promote its improvement.

*Article 2. Scope of application.*

The provisions of these regulations are applicable to the following facilities:

- a) Any nuclear power plant or reactor, nuclear fuel enrichment facility, nuclear fuel assembly manufacturing facility, reprocessing facility for spent nuclear fuel, storage facility for spent nuclear fuel or high activity radioactive waste, installation of temporary storage for spent nuclear fuel or highly radioactive waste.
- b) Storage facilities for radioactive waste that are on the same site and are directly related to the facilities listed under a).

*Article 3. Definitions.*

For the purposes of these Regulations, the following definitions are applicable:

**Accident:** Any deviation from normal operation whose actual or potential consequences are significant from the point of view of protection against radiation or nuclear safety.

**Design basis events:** Accident conditions in anticipation of which a nuclear facility is designed, according to established design criteria and in consideration of which damage to fuel, where appropriate, and the release of radioactive materials are kept within the authorised limits.

**Severe accident:** Severe condition where significant degradation of the fuel occurs, with loss of confinement functionality as a consequence of failure of control over critical conditions or refrigeration.

**Facility design basis:** Set of conditions and events that are expressly taken into account in the design of a nuclear facility, including updates, in accordance with established criteria, so that the facility can support them without exceeding the limits authorised for the planned operation of structures, systems and safety components.

**Design basis of structures, systems and components:** Set of information that identifies the specific functions performed by a structure, system or component of the facility, as well as the values (or range of values) of the parameters related to that function, which have been chosen as boundary conditions for the design. These values can be: conditions derived from commonly accepted practices to achieve the functional objectives, or requirements derived from analysis (based on calculations or experiments) of the effects of the postulated accident for which the structure, system or component must fulfil its function.

**Licensing bases:** Set of mandatory requirements, including the licensee's commitments, applicable to the facility.



Life cycle of the nuclear facility: this includes all stages of planning, siting, design, construction, exploitation and dismantling.

Serious conditions or conditions beyond the design basis: More serious conditions than those related to design basis accidents; such conditions can be caused by multiple failures, such as the complete loss of all fail-safes in a safety system, or by an extremely unlikely event.

Key safety structures, systems and components: The following are Structures, Systems and components (SSC) that are important to safety:

1. Safety SSC or related to safety: those features that must continue to fulfil their function, before any postulated initiating event, to guarantee the main safety functions of the facility as specified in Article 17 of these nuclear safety regulations.

2. SSCs relevant to safety:

a) Those taken into account in the analysis of internal or external events, or of serious conditions, in order to guarantee the main safety functions or the safety objectives established in Article 6 of these regulations.

b) Those that are designed to avoid any breach of the dose limits established for workers or members of the public during the normal operation of the plant.

c) Those that have been shown to have a significant impact on facility risk levels.

d) Those whose failure could impede the operation of the systems defined as being important for safety in 1, in those situations where the said SSC could be required.

Incident: Any deviation from normal operation whose actual or potential consequences are significant from the point of view of protection against radiation or nuclear safety.

Nuclear facilities: Those installations to which this Regulation applies, as set out in Article 2.

Nuclear safety: this refers to the achievement of proper operating conditions for a nuclear facility, the prevention of accidents and the mitigation of their consequences, which result in the protection of workers and the general public and the environment from the risks produced by ionising radiation from nuclear facilities.

Management system: This refers to a set of interrelated or interactive elements to help establish policies and objectives and to allow those objectives to be reached efficiently and effectively.

Operational situation: Term that includes any operational situation at the facility, from different normal operating conditions to accident situations.

Design basis events: For each postulated initiating event, this refers to a set of hypotheses, and initial and boundary conditions that allow the enveloping nature of all the developments expected for this initiating event to be ensured.

External hazards: Events originating outside the facility that is not a postulated initiating event, whether natural or caused unintentionally by humans, with a potential impact on the nuclear safety of the facility.

Postulated initiating event: An event defined by design, capable of giving rise to anticipated operational events or design-basis accidents.

Internal event: fires, explosions, dynamic effects of broken pipes, generation of projectiles, floods or anything else that is not a postulated initiating event and that originates within the facility itself, is unintentional and can have a potential impact on the nuclear safety of the facility.

Planned operational event: Any deviation from normal operation that is expected to occur one or more times during the life of the nuclear facility and which by design should not evolve into an accident.

Authorisation holder or owner: Any natural or legal person who is wholly responsible for a facility included in the scope of these Regulations, as specified in the corresponding authorisation.

These definitions shall be applied in the absence of those which, within the specific scope of their regulation and within the framework of European Union law, are expressly established by the Nuclear Safety Council in the instructions issued.

*Article 4. Competent authority.*

This refers to the Ministry of the Environment, the Interior Minister and the Nuclear Safety Council, who, within the scope of their functions, ensure compliance with the provisions of these Regulations.

*Article 5. Licensee's responsibilities.*

This refers to primary and non-delegable responsibility for nuclear safety, which rests with the holder of the authorisation.

This responsibility includes control of the activities of contractors and subcontractors that may affect the nuclear safety of the nuclear facility or facilities.

It shall be the non-delegable responsibility of the holder of the authorisation or, failing that, of the party who requests, under the provisions of the Regulation on Nuclear and Radioactive Facilities, approved by Spanish Royal Decree 1836/1999, of December 3rd, in compliance with the terms of these Regulations.

## TITLE I

### General requirements

*Article 6. Safety objective for nuclear facilities.*

The purpose, design, construction, commissioning, operation and dismantling of nuclear facilities must aim to:

- a) Prevent accidents and, in the event that they occur, the mitigation of their consequences.
- b) Avoid, either by physical impossibility or by being extremely unlikely with a high level of confidence:

1. early radioactive releases that require emergency measures outside the site without sufficient time for their application;
2. major radioactive emissions that require protection measures for the population that must not be limited in duration or area.

*Article 7. Organisation and management system.*

The holder must:

1. Provide, throughout the entire life cycle of the facility, the necessary technical, economic and human resources with adequate qualifications and competencies, as well as an appropriate organisational structure to maintain nuclear safety and ensure adequate response capacity in emergency situations.
2. Have a nuclear safety policy that promotes continuous improvement through:
  - a) The identification of any new information and analysis of anything relevant within a timeframe appropriate to its significance for nuclear safety.
  - b) The systematic review of nuclear safety taking into account in-house and external operational experience, advances in nuclear safety and in science and technology.



c) The implementation of identified nuclear safety improvements that are reasonably feasible, within the appropriate timeframes.

3. Establish, implement, evaluate and continuously improve an integrated management system, including nuclear safety, occupational risk prevention, environmental protection, physical protection, quality and economic aspects, to ensure that nuclear safety is duly taken into account with regard to all activities of the organisation. This management system must give due priority to nuclear safety above any other consideration, guaranteeing its maintenance and promoting its continuous improvement.

4. Make sure that the integrated management system incorporates all the necessary measures to promote and improve an organisational nuclear safety culture that, among other things, enhances the ability to scrutinise safety principles and practices and to report on safety issues at all levels of the organisation.

5. Take into account the influence of human and organisational factors on nuclear safety throughout the entire life cycle of the facility.

6. Guarantee that the quality requirements are defined and applied in an appropriate manner to achieve the safety objective established in Article 6 of this Regulation, and that these requirements are integrated into its management system throughout the life cycle of the facility.

7. Ensure that contractors (and subcontractors under their responsibility) whose activity may affect the safety objective established in article 6 of these Regulations have the adequate human, technical and economic resources for the efficient and safe performance of assigned tasks.

#### Article 8. *Training.*

The holder must:

1. Establish a global staff training policy structured according to importance and recognising the relevance of nuclear safety.

2. Guarantee that any staff performing functions that may affect the nuclear safety of the facility have adequate qualifications.

3. Implement and update both initial and ongoing training programmes for the facility staff, taking into account a systematic training structure.

#### Article 9. *Dose limits and optimisation.*

The siting, design, construction, commissioning, operation and dismantling of nuclear facilities must aim to ensure that:

1. Any doses received by exposed workers and by the public, in any operational situation, are justified and as low as reasonably possible and are below the values established in the specific norms and applicable requirements.

2. The radiological consequences reasonably foreseeable in future generations do not exceed those allowed for the present generation.

#### Article 10. *Physical protection.*

Throughout the entire life cycle of a nuclear facility, the owner must adopt the necessary measures to maintain an adequate level of physical protection at the facility.

In relation to the obligations in this area, the provisions of Royal Decree 1308/2011, of the 26th of September, on the physical protection of nuclear facilities and materials and radioactive sources, Law 8/2011, of the 20th of April, establishing measures for the protection of critical infrastructures, and Royal Decree 704/2011, of the 20th of May, approving the Regulation on the protection of critical infrastructures, will apply.

## TITLE II

**Safety requirements**

## CHAPTER I

**Safety assessment***Article 11. In-depth defence.*

To achieve the safety objective established in Article 6 of this Regulation, the licensee must apply the principle of in-depth defence, incorporating multiple levels of protection in such a way that the radiological consequences for workers and any releases of radioactive material outside the facility are such that the associated doses remain within established limits in the cases of normal operation, anticipated operational events and design-basis accidents. In any case, external releases should be minimised as much as possible, including internal and external events and serious conditions. To this end, the design and operation of the facility must guarantee maintenance of the following levels of defence:

- a) Minimise the possibility of deviations from normal operation, systems failures and human errors.
- b) Detect, control and stop any deviations from normal operating conditions.
- c) Make the necessary safety systems and procedures available to restore the facility to a safe condition after a design-basis accident situation.
- d) Reduce the probability of occurrence of serious conditions and any uncontrolled release of radioactive materials as far as possible and have operating procedures or guidelines for the management of such accidental situations.
- e) Mitigate the radiological consequences of any possible releases of radioactive materials and radiological consequences for workers that may occur as a result of an accident.

*Article 12. Safety assessment.*

1. The licensee must carry out an assessment of the facility (location, design and operation) to confirm that an adequate level of nuclear safety has been achieved and that the facility complies with the safety objective established in article 6 of this Regulation.

- a) The scope and degree of detail of the assessment must be proportional to the nature and potential magnitude of the risk corresponding to the facility and the site.
- b) The licensee must analyse the facility in such a way as to confirm the effectiveness of the structures, systems and components important for the safety, viability and effectiveness of the human actions required and the capacity of the barriers to prevent accidents and mitigate their consequences.

2. This safety assessment must be documented in a Safety Study, and that Study (or a document referenced therein) must explicitly identify the codes, standards and design bases that apply to all structures, systems and components that appear from the analysis to be important to safety and that need to be clearly identified and defined.

The Safety Study must be kept up-to-date, so that it reflects the analyses and modifications made to the facility, the site conditions and the applicable codes, standards and design bases.

3. The licensee shall use as a complement to the safety assessment a systematic approach to the analysis of the risks of the facility, in order to verify that all of

the possible scenarios that may result in risks, including all the initiating events or process deviations, internal events and external failures, multiple failures, common-cause failures and human errors have been adequately considered in the design and operation of the facility, according to their expected frequency and estimated severity, also checking that there are adequate preventive or mitigating measures that can be taken to deal with said situations.

These risk analyses must be updated appropriately so that they truthfully reflect the situation of the facility and its location.

Article 13. *Periodic safety review.*

1. The licensee, under the supervision of the Nuclear Safety Council, must systematically and periodically re-evaluate the nuclear safety of the facility at least once every ten years. The purpose of this periodic safety review is to confirm the nuclear safety of the facility and obtain an overall assessment of its performance during the period in question, via systematic analysis of all aspects of nuclear safety and radiation protection.

The periodic safety review must:

- a) Confirm that the facility continues to comply with its design bases, or establish the necessary corrective measures if in any way they are not met.
- b) Confirm the availability and validity of measures for the prevention of accidents and the mitigation of their consequences, and the application of the principle of defence in depth.
- c) Ensure that nuclear safety remains at a high level during the following period.

2. Based on the periodic safety review, the licensee must introduce nuclear safety improvements within the facility that are reasonably feasible in terms appropriate to their safety importance, taking as a reference the safety objective established for facilities in article 6 of these Regulations.

To do so, the best practices and the evolution of international standards for nuclear safety and radiation protection must be taken into consideration. It must also take into account those aspects related to ageing, operational experience and the results of the most recent research and advances in science and technology that are compatible with the existing design.

## CHAPTER II

### Location

Article 14. *Initial site assessment.*

The party requesting preliminary or siting authorisation must:

1. Evaluate the potential site of a nuclear facility to determine the effects that it may have, from the point of view of nuclear safety, on the surrounding population and environment, as well as the possible constraints that the site may impose on the design of the facility, including aspects related to transport routes and emergency management.

2. To take into account in the assessment of the potential impacts of the facility on the site, and without prejudice to the provisions of Law 21/2013, of the 9th of December, on environmental assessment, which is obligatory for nuclear facilities under this Regulation:

- a) The various interactions between the facility and the population and the environment, including factors such as population density and distribution, meteorology, surface and groundwater hydrology, geology, seismology, land and water uses, and

other ecological and environmental factors, as well as those attributable to planned human activities.

b) The availability of services located off-site, which can help maintain the nuclear safety of the facility and the protection of the population, such as, among others, electricity supply, fire, access, communications and emergency services.

3. When assessing the potential impacts of the facility site, consider, from a nuclear safety perspective, the risks associated with external events that could affect the nuclear safety of the facility and that should be considered in the design of the same.

#### Article 15. *Monitoring of site conditions.*

The licensee must operate programmes throughout the life cycle of the facility to survey and monitor:

1. The characteristics of the site and external events that may affect the nuclear safety of the same, evaluating the potential impact of the changes observed on the facility. The human actions to be taken into account as potential inducers of external events are all those considered in the initial design of the facility, as well as authorised actions taking into account the provisions of Article 3 bis of the Regulation on Nuclear and Radioactive facilities, approved by Spanish Royal Decree 1836/1999, of December 3.

2. The environmental conditions that may be affected by the possible impact of the nuclear facility, evaluating the potential effects of the changes observed. Likewise, the owner must evaluate the potential impact of modifications to the facility on the site, to ensure that the safety objective established in article 6 of these Regulations is maintained.

### CHAPTER III

#### Design

#### Article 16. *Application of the principle of in-depth defence.*

1. The design of the facility must contemplate the presence of intrinsic safety mechanisms, multiple physical barriers and procedures for all operational situations throughout its life cycle, in order to prevent any uncontrolled emission of radioactive material or mitigate its consequences, as well as combined safety elements to contribute to the effectiveness of said physical barriers.

2. The design should, as far as possible, aim to prevent:

- a) Threats to the integrity of the barriers;
- b) the failure of a barrier in the event of an event that could threaten it;
- c) the failure of one barrier as a consequence of the failure of another.

#### Article 17. *Fundamental safety functions.*

1. The design of the nuclear facility, both during normal operation and before the occurrence of any postulated initiating event or external or internal events that have been foreseen in the design, or serious conditions that have been analysed but have not led to a severe accident, must ensure compliance with the main safety functions:

- a) Control of reactivity, which in the case of fuel manufacture and the storage of fresh or spent nuclear fuel, must ensure sub-criticality.
- b) Cooling of the reactor, spent fuel and high-activity waste.
- c) Confinement and shielding of radioactive material, which ensures compliance with the established dose limits.

2 Furthermore, in facilities where spent fuel or radioactive waste is stored, its recoverability must be assured in the event of any postulated initiating event or external or internal events foreseen in the design.

Article 18. *Accident analysis.*

1. Design basis events: The owner must identify the postulated initiating events that need to be adequately considered in the design in order to comply with the main safety functions.

The base design events of the structures, systems and safety components are derived from its analysis.

2. Serious conditions: The licensee must analyse the serious conditions that must be adequately considered in the design to comply with the main safety functions or the safety objective established in article 6 of these Regulations.

Article 19. *External hazards.*

The holder must:

1. Verify that the facility is designed to cope with the external hazards postulated on the site, so as to guarantee compliance with the fundamental safety functions.

2. Analyse the design of the facility to guarantee compliance with the safety objective established in article 6 of these Regulations relating to extreme external events of natural or unintended human origin.

Article 20. *Internal hazards.*

The holder must:

1. Confirm that the facility is designed to deal with postulated internal hazards, so as to ensure compliance with the main safety functions, and adopt the principle of defence in depth against such internal hazards, implementing measures to avoid them before they occur; to detect and control them or stop them as soon as possible if they occur; and to avoid spreading to other areas that may affect nuclear safety.

2. Analyse the design of the facility to guarantee compliance with the safety objective established in article 6 of these Regulations relating to internal hazards that go beyond the design base of the facility.

Article 21. *Design requirements for key safety structures, systems and components.*

1. The owner must identify the functions that the structures, systems and components need to perform to ensure compliance with the main safety functions or the safety objective established in article 6 of these Regulations for facilities.

2. The design of structures, systems and components important for safety must guarantee compliance with their functions with a high level of reliability. To this end, the following alternatives will be selected, taking into account the following order of priority:

- a) Intrinsically safe processes.
- b) Passive design elements.
- c) Active design elements.
- d) Administrative checks.

3. With regard to the design of key safety structures, systems and components:

a) Criteria and design standards must be applied in line with the necessary reliability according to their importance for safety.

- b) The needs of maintenance, testing and ageing management must be taken into account.
- c) Only tried and tested technologies may be used.

*Article 22. Safety classification.*

1. The structures, systems and components of a nuclear facility must be identified and classified according to their importance for safety. The method used for this classification should be based on analysis of postulated initiating events, internal and external hazards and serious conditions, complemented when appropriate by risk analysis and engineering judgement.

2. The structures, systems and components that are important for safety must be designed, manufactured, tested, installed, operated and maintained in accordance with their safety classification.

*Article 23. Seismic and Environmental Qualification of Structures, Systems and Components.*

The structures, systems and components that are important for the safety of the facility must be designed so as to ensure that they fulfil their functions, throughout the entire life cycle of the facility, in the operational situations in which they must perform their function, taking into consideration the environmental and seismic conditions considered in the safety assessment.

#### CHAPTER IV

##### **Construction, assembly and commissioning**

*Article 24. Construction and assembly.*

The owner must guarantee that the construction, manufacturing and assembly processes of the structures, systems and components of the facility are carried out according to their safety and seismic classification and environmental qualification.

The said construction, manufacturing and assembly processes must:

- a) Ensure that the design bases of the facility comply with the established safety margins.
- b) Ensure reliability, according to its importance for safety. Article 25.

*Commissioning.*

The owner, prior to the entry into service of structures, systems and components, must confirm that they have been installed and tested in order to verify compliance with the design bases of the facility.

#### CHAPTER V

##### **Operation**

*Article 26. Maintenance, inspection and testing.*

The licensee must prepare, document and implement maintenance, testing, surveillance and inspection programmes for the structures, systems and components that are important for safety, to ensure that their availability, reliability and operability are maintained in accordance with their design bases.

*Article 27. Internal administrative checks.*

The holder must:

- 1. Establish administrative checks on the structures, systems and components according to their importance for safety.



2. Establish administrative checks to ensure that activities that may affect those structures, systems and components that are important for safety are adequately analysed and controlled under all operating conditions, in line with the facility safety assessment.

Article 28. *Procedures and guides.*

The holder must:

1. Ensure that a coherent set of procedures and guidelines exists for any operational situation at the facility, including normal, abnormal and emergency conditions, specifying the actions to be taken to maintain the facility in safe conditions, to re-establish the main safety functions or mitigate the loss thereof, and maintain the safety objective established in article 6 of this Regulation.
2. Verify and validate the operating procedures and guidelines before their entry into force.
3. Maintain updated procedures and guidelines to reflect the situation of the facility and the organisation, as well as the experience and knowledge acquired.
4. Ensure that the personnel involved are adequately trained in the management and application of procedures and guidelines.
5. Ensure that, in locations with more than one unit, the procedures and guidelines for normal, abnormal and emergency conditions take into account safe operation and accident management for each of the units of the site simultaneously.

Article 29. *Emergencies.*

The holder must:

1. Ensure an interior emergency plan, in line with the provisions of the Regulation on Nuclear and Radioactive Facilities, approved by Spanish Royal Decree 1836/1999, of December 3.
2. Ensure the availability of adequate resources at the site for the management of emergency conditions, as well as the mechanisms to receive external assistance.
3. Establish the channels and procedures necessary to collaborate with the competent authorities in charge of external emergency plans, the provision of information to the local community and the planned response in case of external emergencies, under the terms provided in Law 17/2015, of July 7th, of the National Civil Protection System; in Spanish Royal Decree 1546/2004, of June 25th, which approves the Basic Nuclear Emergency Plan (PLABEN) or Spanish Royal Decree 1564/2010, of November 19, which approves the basic guidelines for civil protection planning against radiological risk, or the provisions of any other applicable regulations.

Article 30. *Control of the emission of radioactive material.*

Control of radioactive material emissions must be effected in accordance with the provisions of the Regulation on the Protection of Health against Ionising Radiation, approved by Spanish Royal Decree 783/2001 of July 6th.

Article 31. *Modifications to the facility.*

The owner must ensure that no modification of the facility, individually or in conjunction with others, whether permanent or temporary, impairs the ability to operate the facility safely, ensuring compliance with the fundamental safety functions and the objective of facility safety.

Article 32. *Operational experience.*

The holder must:

1. Establish and enact a systematic programme for collection, screening, analysis, documentation and internal communication of proprietary and external operating experience in order to identify, select and diligently implement important lessons learned regarding safety, as well as notify the competent authority of any events with a potential impact on the safety of the facility.

2. Establish agreements with organisations responsible for the design, manufacture, construction, maintenance and supply of structures, systems, components and services important for safety, so that they can keep the operational experience up to date and promptly communicate any detection of faults and deviations that may affect safety conditions and provide support for their analysis and resolution.

Article 33. *Ageing management.*

The owner must carry out an ageing management programme for those structures, systems and components that are important for safety according to the specific applicable regulations, in order to ensure the maintenance of their functions under the conditions foreseen in their design bases, during the operation phase of the facility.

Article 34. *Spent nuclear fuel and radioactive waste.*

The owner is responsible for managing the waste generated and stored in the facility in accordance with the provisions of Spanish Royal Decree 102/2014, of February 21, on the Safe Management of Spent Fuel and Radioactive Waste.

Article 35. *Prerequisites for the cessation of operations.*

The owner, prior to the cessation of operations, must perform a safety and risk assessment of the facility as appropriate for the shut-down, including the corresponding accident analysis. These accident analyses must deduce the limits and operating conditions of the structures, systems and components that are important for safety, and the actions and monitoring requirements applicable to future shut-downs.

## CHAPTER VI

### Dismantling

Article 36. *Forecasts during design, construction and operation.*

1. The owner, during the design, construction and exploitation phases, must anticipate all needs and take the activities required for the safe dismantling of the facility into account.

2. The licensee must establish and maintain a decommissioning plan for the facility in accordance with the provisions required by the Regulation on Nuclear and Radioactive Facilities, approved by Spanish Royal Decree 1836/1999, of December 3rd.

First additional Provision. *Application of the safety objective to nuclear facilities that obtained construction authorisation before August 14, 2014.*

Section B of Article 6 should be interpreted as a reference for the timely implementation of reasonably feasible nuclear safety improvements at nuclear facilities that obtained construction authorisation before August 14, 2014.

Second additional Provision. *Nuclear Safety Council Guides.*

The safety guidelines (GS) issued by the Spanish Nuclear Safety Council are not mandatory, but are methods accepted by that body to verify compliance with the regulatory requirements regarding nuclear safety and radiation protection, and therefore adherence to them exempts the holder from the requirement to demonstrate the adequacy of said methods.

Third additional Provision. *Peer review.*

1. The Ministry of Environment and the Spanish Nuclear Safety Council will carry out periodic self-assessments of the national legislative, regulatory and organisational framework at least once every ten years, as well as of the competent regulatory authorities, and will invite an international review by relevant parties, with the aim of constantly improving nuclear safety. The results of this international review will be communicated to the Member States and to the European Commission, when available.

2. The Nuclear Safety Council will ensure that, in coordination with the rest of the Member States:

- a) A national assessment is carried out regarding a specific issue related to the nuclear safety of nuclear facilities;
- b) all other Member States and the European Commission are invited as observers to a peer review of the national assessment referred to in point a);
- c) appropriate follow-up measures are adopted regarding the respective results of the peer review process;
- d) reports are published regarding this process and its main outcome, once the results are available.

This peer review on a specific topic will take place at least once every six years.

3. In the event of an accident that causes situations requiring emergency measures beyond the site or protection measures for the general public, the Ministry of Environment and the Spanish Nuclear Safety Council will ensure that an international peer review is effected without undue delay.

Fourth additional Provision. *Reports to the European Commission.*

The Ministry of Environment will present a report to the European Commission before July 22nd, 2020 regarding the application of Directive 2009/71 / EURATOM, of June 25th, 2009, which establishes a Community framework for the nuclear safety of nuclear facilities, as amended by Council Directive 2014/87 / EURATOM of July 8th, 2014.

Fifth additional Provision. *Transparency.*

1. In relation to information on nuclear safety of nuclear installations and its regulation to be made available to workers and the general public, to interest groups living in the vicinity of a nuclear installation, as well as to the competent regulatory authorities of other Member States in the vicinity of a nuclear installation, under normal operating conditions and in the event of incidents or accidents, the provisions shall be complied with:

- a) Law 15/1980, of the 22nd of April, creating the Nuclear Safety Council, and the Statute of the Nuclear Safety Council, approved by Royal Decree 1440/2010, particularly in relation to the function of said Council of informing the citizens on matters within its competence and, in particular, on all the facts

relevant to the operation of nuclear facilities, especially in relation to their safe operation, to the radiological impact on people and the environment, to the events occurring at them and to the corrective measures implemented to prevent recurrence of the events. Also, in relation to the obligation of the Nuclear Safety Council to provide information to the Government and the Congress of Deputies and the Senate, as well as to the governments and autonomous parliaments concerned, on any circumstance or event affecting the safety of nuclear facilities or the radiological quality of the environment anywhere within the national territory.

b) Law 27/2006, of the 18th of July, which regulates the rights of access to information, public participation and access to justice in environmental matters, especially in relation to the dissemination and making available to the public of information on environmental matters and the participation of interested parties and the public in the processes of regulatory development in this area.

c) The Regulation on nuclear and radioactive facilities, approved by Royal Decree 1836/1999, of the 3rd of December, in relation to the provisions for the processing of public information relating to the request for prior authorisation of a nuclear facility, which provides a legal channel for public participation in the decision-making process relating to nuclear facilities, as well as in relation to the local information committees established during the construction, operation and dismantling of nuclear power plants in order to report on the performance of the activities regulated in the corresponding authorisations and to deal jointly with other issues of interest.

d) The Basic Nuclear Emergency Plan (PLABEN), approved by Royal Decree 1546/2004, of the 25th of June, mainly as regards the procedures for guaranteeing information coverage, in the event of an emergency, to the population effectively affected, to the public Administrations involved and to the rest of the population, and as regards notifications to the different international organisations competent in this area and to the authorities of bordering countries and other States.

e) Resolution of the 20th of October 1999, of the Undersecretariat, which provides for the publication of the Agreement of the Council of Ministers of the 1st of October 1999, relating to public information on applicable health protection measures and on the behaviour to be followed in the event of a radiological emergency, as regards the measures and procedures for informing the public with a view to reinforcing public health protection in the event of a radiological emergency.

f) Council Decision 87/600/Euratom of the 14th of December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency, as regards notification and provision of information to the European Commission and other Member States in the event of a radiological emergency.

g) Instruction IS-10, revision 1, of July 30th 2014, of the Nuclear Safety Council, establishing the criteria for the reporting of events to the Council by nuclear power plants, in relation to the criteria established for requiring the licensees of operating nuclear power plants to report events that might be related to nuclear safety or radiation protection.

h) Instruction IS-19, of the 22nd of October 2008, of the Nuclear Safety Council, on the requirements of the nuclear facilities management system, in relation to the obligation of the licensees to inform the people of the organisation and, when necessary, other interest groups of the information relevant to the safety objectives.

2. Such information shall be made available to the public provided that it does not compromise other essential interests, such as security, in accordance with the limits established for such purposes by Law 15/1980 and Law 27/2006.

3. The Nuclear Safety Council shall participate, as appropriate, in cooperation activities on nuclear safety of nuclear installations with the competent regulatory authorities of other Member States in the vicinity of a Member State

nuclear facility, in accordance with the provisions of Law 15/1980 and of the Statute of the Nuclear Safety Council.

4. Finally, as regards the opportunities to be provided to the general public for it to participate effectively in the decision-making process relating to the granting of authorisations to nuclear installations, the provisions to this effect are to be found in Law 21/2013, of the 9th of December, on environmental assessment, and in the Regulations on nuclear and radioactive installations.