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III. OTHER PROVISIONS

THE NUCLEAR SAFETY COUNCIL

10881

The Nuclear Safety Council's Instruction IS-26, of 16th June 2010, on basic nuclear safety requirements applicable to nuclear installations.

Article 2.a) of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, in the wording given by Law 33/2007, of 7th November, reforming the previous Law, confers on this public entity the faculty to "prepare and approve instructions, circulars and guides of a technical nature relating to nuclear and radioactive installations and nuclear safety- and radiological protection-related activities" related to the safe operation, i.e. without undue risks for people or the environment, of nuclear and radioactive installations. The new wording strengthens the promotion of the involvement of interested parties and the public in the process of drafting these instructions.

Royal Decree 1838/1999, of 3rd December, approving the Regulation Governing Nuclear and Radioactive Installations (RINR) fundamentally regulates the administrative and procedural aspects for the granting of licenses. For technical aspects, in the absence of Spanish regulations, the different licenses have been based on the regulation from the country of origin of the design and the technical standards that develop such regulation.

This course of action has become consolidated in nuclear installations by means of the successive operating licenses, technical requirements of the regulation from the country of origin of the technology having been set therein to maintain a similar level of nuclear safety requirements with these countries. Currently, the recent modification of the RINR (Royal Decree 35/2008) establishes in its Article 8.3 that "The Licensee must continuously strive to improve the nuclear safety and radiological protection conditions of its installation. In order to do so, it must analyse the best existing techniques and practices, in accordance with the requirements set by the Nuclear Safety Council (CSN), and implement those that are suitable in the opinion of the Council", which introduces as a regulatory basis for the installation the continuous improvement of the safety of the installation and the CSN's authority to require the best practices and techniques to this end.

On the other hand, the International Atomic Energy Agency (IAEA) has been implementing over the last few years a policy of edition of safety standards that constitute a full regulatory system model. The IAEA's highest regulatory-level documents have served as the basis for this Instruction.

Additionally, in order to harmonise the different regulations of its member states (including Spain), the Western European Nuclear Regulators Association (WENRA) has set a series of requirements at different safety reference levels which can be extrapolated as regards basic principles to all nuclear installations, even though their application is only intended in nuclear power plants.

Within this international regulatory framework, the aim of the present Instruction is to set the basic nuclear safety requirements applicable to the nuclear installations defined in the Council of the European Union's Directive 2009/71/EURATON, of 25th June 2009, establishing a Community framework for the nuclear safety of nuclear installations, for the different phases of their life cycle, from their siting and design to their decommissioning, on the basis of the documentation generated by the IAEA, and including WENRA's most general reference levels.

By virtue of all the above and in accordance with the legal authorisation envisaged in Article 2.a) of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, according to the wording given by Law 33/2007, prior consultation of the affected sectors and after the appropriate technical reports, this Council, in its meeting of the 16th of June of 2010, has stipulated the following:

First. *Object and Scope of application.*

1.1 This Instruction sets the basic nuclear safety requirements applicable to:

a) All enrichment plants, nuclear fuel fabrication plants, nuclear power plants, reprocessing facilities, research reactor facilities, spent fuel storage facilities, and

b) Radioactive waste storage facilities that are located in the same premises and are directly related to the installations listed in sub-paragraph a).

Second. Definitions.—The definitions of the terms and concepts contained in the present Instruction match those contained in the following regulations:

Law 25/1964, of 29th April, on Nuclear Energy (BOE No 107, 4th May 1964, Second Article).

Law 15/1980, of 22nd April, creating the Nuclear Safety Council (BOE No 100, 25th April 1980).

Royal Decree 1838/1999, of 3rd December, approving the Regulation Governing Nuclear and Radioactive Installations (BOE No 313, 31st December 1999).

Council of the European Union's Directive 2009/71/EURATOM, of 25th June 2009, establishing a Community framework for the nuclear safety of nuclear installations.

In addition, the following definitions apply within the context of the present Instruction:

Anticipated operational occurrence.—An operating condition that deviates from normal operation and that it is expected to occur one or more times during the life of the nuclear installation. The criteria used to design the installation prevent these occurrences from causing significant damage to elements important to safety or from giving rise to accident conditions.

Beyond design-basis accidents.—Situations not contemplated in the initial design of the installation that could give rise to more severe consequences than those of a design-basis accident.

Defence in depth.—The hierarchical deployment, at different levels, of diverse structures, systems and components and procedures to prevent the escalation of anticipated operational occurrences or accidents and to maintain the effectiveness of the physical barriers that fulfil safety functions placed in between a radiation source or radioactive materials and workers, members of the public or the environment.

Design bases.—The set of information identifying the specific functions that a structure, system or component of the installation carries out as well as the values (or range of values) of the parameters related to that function that have been chosen as boundary conditions for the design. These values can be: conditions derived from practices commonly accepted for achieving the functional goals, or requirements derived from analyses (based on calculations or experiments) of the effects of the postulated accident for which the structure, system or component must fulfil its function.

Design-basis accidents.—The set of accident conditions against which a nuclear installation is designed. In these conditions, the criteria used for the design help to keep the deterioration of nuclear materials and the release of radioactive materials within authorised limits. Occasionally, they are known as "postulated accidents".

Diversity.—It is said of those redundant systems (see redundancy) that have different operational characteristics, which enables lowering the possibility of a failure caused by a factor that might affect both systems in the same way (common-cause failure).

Double-contingency principle.—A principle applied in the design of installation processes such that the design of a process must include enough safety factors so that a criticality accident is not possible unless two unlikely and independent changes in the conditions of the process were to occur simultaneously.

External events.—Events originating outside the installation, either natural or due to industrial or human activities, susceptible of having effects on the nuclear power plant's risk, such as earthquakes, extreme weather conditions, explosions or airplane crashes.

Failure in safe position.—A characteristic of a system or component whereby the failure either does not entail a risk of accident or automatically leads the component to a safe situation for the installation.

Human and organisational factors.—The set of processes and parameters, internal and external, of the groups and organisation of a nuclear installation, which affect nuclear safety by means of their influence on the individuals themselves and on the interactions between individuals and between them and the installation.

Independence.—A property of SSCs that meet any of the following characteristics: a) their ability to perform the required function is not impaired by the operation or failure of other equipment; or b) their ability to perform their function is not impaired by the appearance of effects derived from the postulated initiating event for which their operation is required.

Intrinsic safety.—Safety based on physical processes which, owing to their own nature, prevent the unwanted situation or stop its progression.

Element important to safety.—It comprises:

1. Those structures, systems and components whose malfunction or failure could lead to an undue exposure to radiation of site personnel or members of the public;
2. Those structures, systems and components that prevent anticipated operational occurrences from leading to accident conditions;
3. Those elements that are aimed at mitigating the consequences of accidents caused by a malfunction or failure of structures, systems and components.

It is subdivided into “safety elements” and “elements relevant to safety”.

Safety element (or safety-related element).—An element whose operation is given credit in the analyses of design-basis accidents for:

1. Leading the installation to a safe condition and keeping it in said condition in the long term,
2. Keeping the radiological consequences of anticipated operational occurrences and of design-basis accidents within their specified limits.

Element relevant to safety.—An element that does not belong to a safety element but:

1. Whose operation is given credit to mitigate anticipated operational occurrences or accidents, or is used in emergency operating procedures.
2. Whose failure might prevent safety elements from carrying out their safety function.
3. Whose failure might cause the actuation of a safety element.

Licensee of the installation.—Any individual or legal entity who is the licensee of an activity and, in accordance with the provisions of the legislation currently in force, is responsible for a nuclear installation and is subject to a declaration or authorisation procedure for the performance of its activities.

Life cycle of the nuclear installation.—It comprises the stages of planning, site selection, design, component manufacturing, construction, commissioning and testing, operation, final shutdown after operation, and decommissioning.

Management system.—A set of interrelated or interactive elements (system) for establishing policies and objectives and for enabling the achievement of those objectives in an efficient and effective manner. The system integrates all elements of an organisation into one coherent management system to enable all of the organisation’s objectives to be achieved. These elements include the structure, the resources and the processes. Personnel, equipment and organisational culture, as well as the documented policies and processes, are part of the management system. The organisation’s processes have to address the totality of the requirements relating to the organisation established in, for example, the IAEA’s Safety Standards and other international codes and standards.

Passive safety.—Safety based on components whose functionality does not depend on an external factor, such as a conditioning, a mechanical movement or the supply of energy, i.e. their actuation is ensured by physical principles not dependent on off-site power.

Postulated initiating event.—An event identified during design as being capable of leading the installation to anticipated operational occurrences or accident conditions.

Redundancy.—The provision of alternative (identical or diverse) structures, systems and components, so that any one can perform the required function regardless of the state of operation or failure of any other.

Safety culture.—The set of characteristics and attitudes in organisations and individuals which makes, as an overriding priority, nuclear safety and radiological protection issues receive the attention warranted by their importance.

Safety function.—A function intended to prevent accidents or to mitigate their consequences, the result of which is the protection of workers, the public and the environment against undue risks caused by radiation.

Security.—The conditioning and maintenance of facilities and activities in secure conditions by means of measures aimed at preventing, detecting and responding to unauthorised accesses or unauthorised actions affecting nuclear materials or other radioactive materials or their associated facilities.

Single-failure criterion.—It refers to the requirement that a system retains its capacity to fulfil its safety function despite the failure of any one of its components (single failure).

Site area.—A plot of land, delimited and owned by the licensee, where an authorised installation is located, the inside of which being subjected to a series of controls, limits and regulations.

Structures, systems and components (SSCs).—A general term encompassing all of the elements of an installation. Structures are the passive elements: Buildings, vessels, shielding, etc. A system comprises several components or structures, assembled in such a way as to perform a specific (active) function. A component is discrete element of a system. Examples of components: Wires, transistors, integrated circuits, motors, relays, solenoids, pipes, fittings, pumps, tanks and valves.

Third. *Objective and General requirements*

General safety objective of nuclear installations:

3.1 The licensee of the nuclear installation must have as general safety objective to protect people and the environment from the harmful effects of ionising radiations. In compliance with said objective, the licensee of the installation must adopt measures to:

a) Limit, minimise and control the exposure to radiation of people and the release of radioactive materials into the environment.

b) Limit the probability of events that might lead to the loss of control over any radiation source.

c) Mitigate the consequences of suchevents in case they take place.

d) Minimise the generation of radioactive waste.

3.2 The general safety objective shall be applied to all nuclear installations and activities during their entire life cycle, including the preparation and management of the transports of radioactive material and the management of radioactive waste.

Organisation and Management of Safety:

3.3 The licensee of a nuclear installation must have, during its entire life cycle, the appropriate human, technical and financial resources to preserve the safety conditions of the installation. These capabilities must be documentarily analysed and substantiated.

3.4 The licensee of the installation will set up an organisational structure suitable for maintaining safety as well as for guaranteeing a proper response in emergency situations. To this end, the responsibilities, authority and lines of communication of all installation personnel with tasks important to safety must be clearly established. The organisation and the functions and responsibilities of the different units must be described in the Operation Handbook and the On-Site Emergency Plan, as established in the Regulation Governing Nuclear and Radioactive Installations.

3.5 The licensee of the nuclear installation must set up, implement and continuously evaluate and improve a management system that integrates nuclear and radiological safety, occupational risk prevention, environmental protection, physical protection, quality, and financial aspects so as to guarantee that safety is properly taken into account in all the activities of the organisation.

3.6 The licensee must set guidelines to maintain a proper safety culture within the organisation, which must be included in a document that states, at the highest level, the organisation’s commitment to the safety of the installation. These guidelines must be notified to all the people of the organisation with tasks important to safety, in such a way that they are

understood and applied, and extended to all contractors and service suppliers, who must incorporate them to all activities that might affect the safety of the installation.

3.7 The licensee shall set up one or more safety committees with the aim of advising during the decision-making processes on nuclear safety and radiological protection issues.

Quality Assurance:

3.8 The licensee of the installation shall set up and implement a quality system with the purpose of safeguarding the safety of the installation, which guarantees that the quality requirements during the life cycle and those relating to the preparation and management of the transports of radioactive material and the management of radioactive waste are defined and applied in accordance with the required standards and degree of stringency.

3.9 The quality system will classify the requirements according to the importance to safety of the elements, activities and processes throughout the different stages of the life cycle of the installation.

3.10 The quality system will allow to assess the observance of the applicable safety requirements as well as to identify potential improvements in safety.

Records and reports:

3.11 The licensee of the installation shall identify the types of documents and records that are important to the installation's safety or radiological protection during the different design, construction and commissioning, operation, decommissioning, and closure phases .

3.12 A document and record control process shall be set up.

3.13 The periods of temporary or permanent retention of the documents and records shall be established according to their importance to the safety of the installation.

Defence in depth:

3.14 The licensee of a nuclear installation must include during the design, construction, operation, decommissioning, and waste transport and management multiple barriers to prevent and mitigate off-site releases of radioactive material above authorised limits. The defence in depth is ensured by maintaining the following protection levels:

a) Minimising deviations from normal operation and failures in systems. Thus, the installation must be properly and stringently designed, built, maintained and operated in accordance with sufficiently proven quality levels and engineering practices so as to prevent operational occurrences and accidents.

b) Detecting, controlling and interrupting deviations with regard to normal operation conditions. In order to do so, the nuclear installation must have the proper safety systems and normal operation and failure procedures to prevent anticipated operational occurrences from deteriorating and turning into accident situations.

c) Having the necessary safety systems and procedures to lead the installation, after a design-basis accident situation, firstly, to a controlled situation, and, subsequently, to a safe state, maintaining at least one radioactive material confinement barrier.

d) Reducing to the minimum the probability of occurrence of beyond design-basis accidents and the uncontrolled release of radioactive materials as well as having operating procedures or guides for managing these accident situations.

e) Attenuating the radiological consequences of possible releases of radioactive materials that might occur as a result of an accident.

Safety Analysis. Safety Analysis Report:

3.15 The licensee must analyse the installation from the point of view of nuclear safety and radiological protection such that the capacity of the barriers and elements important to safety to prevent accidents and mitigate their consequences is verified. This safety analysis must be documented in a Safety Analysis Report in accordance with that established in the Regulation Governing Nuclear and Radioactive Installations.

3.16 The codes, standards and design bases applicable to every structure, system and component important to the safety of the installation must be clearly defined, analysed and documented in the “Safety Analysis Report” or in documents referenced therein.

3.17 The Safety Analysis Report must be periodically updated such that it reflects the modifications made in the installation, in the site conditions and in the applicable codes, standards and design bases.

Risk Analysis:

3.18 The licensee of the installation shall conduct an analysis of the risks entailed by the operation thereof in order to verify that all potential risk scenarios of the installation, including multiple failures, common-cause failures and human errors, have been properly weighed up in accordance with their expected frequency and estimated seriousness and that there are adequate preventive or mitigative measures in place to face up to such situations.

Periodic Safety Review:

3.19 Every ten years at the most, the licensee of the nuclear installation must conduct and document a Periodic Safety Review (PSR), the goal of which will be to make an overall assessment of the behaviour of the installation during the considered period by means of a systematic analysis of all nuclear safety and radiological protection aspects.

3.20 The PSR must confirm that the installation still complies with its design bases or establish the necessary corrective measures if they are not observed in some case.

3.21 Nuclear installations must carry out, within the framework of the PSR, the appropriate modifications to converge, wherever it is feasible, with the best nuclear safety and radiological protection practices and standards internationally in effect at the time.

Human factors:

3.22 The licensee of the installation must take the aspects related to human factors into account during the life cycle thereof such that the safety of the operation is improved in both normal conditions and operational occurrences and accident situations.

3.23 The licensee of the installation must pay special attention to and have specific programmes for reducing, detecting and correcting human errors.

Dose limits and restrictions:

3.24 The doses received by workers and the public during the performance of the activities that are carried out in the installation, including normal operation activities and those associated with anticipated operational occurrences, must observe that established in the Regulation on Health Protection against Ionising Radiations (Royal Decree 783/2001, of 6th July).

3.25 The release of radioactive effluents into the environment must comply with the established limits, aiming, in addition, that it be as low as possible by taking socioeconomic factors and the best available techniques into consideration.

3.26 The design of a nuclear installation, as well as the planning of the activities to be carried out in it, must guarantee that the doses received by exposed workers and the public as a result of design-basis accidents are below the values that are set in the specific standards and the requirements applicable to them.

3.27 In addition, the design of nuclear installations must ensure that the radiological consequences that are reasonably foreseeable in future generations are not greater than those allowed for the current generation.

Emergencies:

3.28 The licensee of each nuclear installation shall have an On-Site Emergency Plan detailing the envisaged measures and the assignment of responsibilities to face up to the accident conditions foreseeable therein, mitigate their consequences, protect installation personnel and immediately notify the competent authorities of their occurrence.

3.29 Regarding those facilities included in the Basic Nuclear Emergency Plan (BNEP), their licensees will establish the necessary channels and procedures for collaborating with the proper

authorities in the implementation of Off-Site Emergency Plans and in the response envisaged therein to protect the population in case of an accident in the terms contemplated in the BNEP (Royal Decree 1546/2004, of 25th June) or any other applicable regulations.

Physical protection:

3.30 During the entire life cycle of a nuclear installation, the licensee shall adopt the necessary measures of prevention, detection, assessment, delay, reaction and coordination with the Spanish Armed and Security Forces to maintain an appropriate level of physical protection of the installation. The installation's physical protection systems and services shall be designed and kept operational in accordance with the criteria set in the applicable regulations.

Fourth. *Site.*

General criteria:

4.1 All potential sites for a nuclear installation must be properly evaluated so as to determine the effects the latter might have on the surrounding population and environment as well as the possible constraints the site might place on the design. Thus, the different interactions between the installation and the environment , including factors such as population density and distribution, meteorology, surface water and groundwater hydrology, geology, seismology, land and water uses and other ecological and environmental factors, as well as those attributable to human activities, must be taken into account during the selection of the site.

4.2 The availability of off-site services which might help to maintain the safety of the installation and the protection of the population, such as, amongst others, power supply, fire fighting, access, communication and emergency services, must also be taken into consideration.

4.3 The risks associated with external events, natural or due to human action must be determined during the site evaluation process, in order to be considered in the design of the nuclear installation. The frequency and severity of such events, as well as the foreseeable evolution of the associated risks, shall be taken into account for a period of time that encompasses the anticipated life of the installation, from its construction to the decommissioning phase. The combination of natural events and environmental conditions that might contribute to worsen the derived risks shall also be taken into consideration.

4.4 During the evaluation, the nuclear installation's possible thermal or chemical impacts on the site must be considered, as well as the potential interaction between those emissions and liquid or gaseous radioactive effluents.

4.5 The preferred methods to ensure that site-associated risks are kept acceptably low are the nuclear installation's proper design and the adoption of site protection measures. If necessary, the licensee's own administrative procedures could also be applied as guarantee.

Monitoring of the conditions of the site:

4.6 The licensee must evaluate the changes in site-related aspects during the life of the installation in order to ensure that the safety conditions stay unchanged.

4.7 The characteristics of the site that might affect the safety of the nuclear installation, the risks associated with extreme events (natural or attributable to human activities) and the conditions of the surrounding area that might be affected by the possible impact of the nuclear installation (normal operation, occurrences and accidents) must be the object of surveillance and monitoring during the entire life cycle of the installation, from the moment its construction begins to the closurestatement.

Fifth. *Design.*

Barriers to prevent the dispersion of radioactive material:

5.1 The design of the installation must have a series of barriers (inherent elements, structures, systems, components and procedures) that confine the radioactive material inside specified places with the aim of complying with the concept of defence in depth.

5.2 The design of the barriers must prevent, insofar as possible, the failure of a certain barrier as a result of the failure of another one.

Safety functions:

5.3 The licensee of the nuclear installation must specifically define the safety functions that structures, systems and components must carry out to prevent the appearance or progression of occurrences and accidents, mitigate their consequences and take the installation to and keep it in a safe situation.

5.4 The licensee of the nuclear installation must analyse whether at least the following essential safety functions are applicable to it:

Reactivity control.
Residual heat removal.
Radioactive material confinement and shielding.

Accident Analysis:

5.5 The licensee shall determine the postulated initiating events that might cause an emission of radiation or of amounts of radioactive materials that might compromise the established dose limits by considering plausible failures of the installation's structures, systems and components and human factors that could take place in any operational state of the installation. Amongst these initiating events, an encompassing set of sequences of occurrences and accidents shall be determined, and the safety functions, the associated structures, systems and components and the safety requirements of an administrative nature used to apply the defence-in-depth concept shall be defined for each one of them.

5.6 The set of analysed events will take both internal and external events and their plausible combinations into account according to engineering judgments or probabilistic methods.

5.7 The analysis of accidents shall be conducted with safety margins such that the maintenance of the safety functions is guaranteedwith due considerations to the uncertainties inherent to the processes involved.

5.8 In the case that during the operation of the nuclear installation other events or combinations of events not considered by the original design are identified as plausible, the overall behaviour of the installation must be reviewed in order to minimise, insofar as possible, the risk of an off-site release of radioactive material and the exposure of the public and the environment to radiations.

Safety classification:

5.9 The structures, systems and components of a nuclear installation must be identified and classified according to their importance to safety. The method for carrying out this classification must be based, first of all, on the hypotheses and results of the accident analysis, identifying the structures, systems and components guaranteeing the safety functions, and complemented, when appropriate, with the hypothesis and results of the risk analyses and engineering judgments.

5.10 The Structures, systems and components must be designed, manufactured, installed and operated according to their safety classification, in such a way that the quality standards, inspections and tests are suitable for verifying that their safety function is properly fulfilled, and that their reliability and classification are maintained during normal operation, anticipated operational occurrences and design-basis accidents during the entire life of the installation.

5.11 Structures, systems and components must be designed such that the failure of one of them does not entail the failure of others of a higher classification for safety.

Design requirements for maintaining safety functions:

5.12 The licensee of the installation must guarantee safety functions with a high degree of confidence. The following hierarchy of design measures will be used insofar as possible:

1. Selection of intrinsically safe processes.

2. Passive-design elements.
3. Active-design elements.
4. Administrative controls.

5.13 The following design criteria shall be included in the design of structures, systems and components, according to the required reliability and the risk of the installation:

a) Inherent safety.
b) Passive safety.
c) Failure in safe position.
d) Single failure.
e) Double contingency.
f) Independence.
g) Redundancy.
h) Diversity.

5.14 Structures, systems and components important to safety shall be designed such that their maintenance, inspection and testing is made easier to guarantee their functional capacity during the life of the installation.

5.15 Safety structures, systems and components shall be capable of carrying out their safety functions even when faced with the loss of support systems classified as being not safety-related or, otherwise, shall be designed so that they go into a safe state in the event of failure.

5.16 The design of structures, systems and components important to safety must be based on technologies proven and validated in operating conditions similar to those of operation.

5.17 Safety structures, systems and components shall be designed with safety margins, uncertainties being included, with the purpose of giving reasonable assurances that there will be no significant consequences even when operational limits are exceeded.

5.18 Safety systems and components must be designed such that they automatically actuate in case of anticipated operational occurrences and rapidly evolving accidents, and keep the installation in a safe state without the manual intervention of operating personnel being required for a period of time long enough for the necessary subsequent actions to be considered and implemented.

Environmental and seismic qualification:

5.19 The structures, systems and components of the installation must be designed such that it is guaranteed that they fulfil their safety functions in any anticipated environmental and seismic condition throughout the entire life of the installation as well as in conditions of anticipated operational occurrences and design-basis accidents.

Protection against external and internal events:

5.20 Nuclear installations must be designed so that safety functions are maintained in the event of any external event that is anticipated throughout the life of the installation.

5.21 Potential paths for the generation of on-site flooding and other internal events shall be identified and taken into consideration in the design of nuclear installations, including the necessary means for safety functions not to be affected by them, and for limiting their consequences.

Fire protection:

5.22 Safety functions must be maintained in the case that fires take place inside the installation.

5.23 The following protection levels must be included:

a) Fire generation prevention measures.
b) Fire detection, alarm and extinguishing systems. The design must include measures against the adverse effects of the activation and possible improper actuations of the fire extinguishing system.

c) Measures to ensure the confinement of the fire in areas delimited by fire barriers.

5.24 The structures, systems and components that are necessary, in a redundant or diverse manner, to fulfil each safety function must be arranged such that they are separated by fire barriers. If due to the characteristics of the design this approach is not possible, a combination of active and passive methods that fulfil such function shall be used.

Instrumentation and control:

5.25 Nuclear installations with systems or components important to safety must have monitoring and control equipment for the different safety functions as well as a control room to supervise the proper operation of the installation.

5.26 Means for monitoring all essential processes and equipment during an accident and thereafter must be set up.

5.27 In case the risk of the installation requires it, means for remote shutdown from outside the control room shall be installed.

5.28 For instrumentation and control systems important to safety based on digital technology, appropriate standards and precautions for development, equipment testing and maintenance shall be established, which will be applied during the entire life of the system, particularly in the stage of development of the software application.

Sixth. *Construction and Commissioning.*

Construction and assembly:

6.1 The structures, systems and components of a nuclear installation must be built, manufactured and assembled:

1. Such that their technology is proven or qualified by operating experience, tests or analyses, such that they meet their design requirements with safety margins,
2. With the aim of obtaining the required reliability,
3. In accordance with a quality assurance programme according to their safety classification.

Commissioning:

6.2 Prior to the commissioning of a nuclear installation, it must be guaranteed that the structures, systems and components thereof have been manufactured, built and tested according to design and safety requirements.

6.3 Likewise, the licensee of a nuclear installation is required to implement a pre-nuclear test programme (before proceeding to load nuclear substances) and a nuclear test programme, which shall include the tests, verifications and checks to be conducted on the different structures, systems and components the installation consist of, in accordance with that established in the Regulation Governing Nuclear and Radioactive Installations.

Seventh. *Operation.*

Operating personnel:

7.1 In order to maintain nuclear safety in all operational and emergency situations, the licensee of the nuclear installation must have enough personnel, with the proper qualifications and competences, assigned to the installation in all necessary disciplines throughout the entire operating life thereof.

7.2 Training activities shall be specific for the different jobs, included in a programme, which shall be kept updated, and given by duly qualified personnel. All teaching material needed to ensure the appropriate competence of all personnel shall be made available. Documentary records of the observance of the training schedule shall be kept.

7.3 The licensee of the installation must make sure that all personnel not belonging to its organisation who perform tasks important to the safety of the installation are in possession of the proper qualification for the efficient and safe performance of the assigned tasks.

Maintenance, inspection and testing:

7.4 The licensee of the installation must prepare, document and implement programmes for maintaining, testing, monitoring and inspecting structures, systems and components important to safety in order to ensure that they maintain their availability, reliability and operability according to their design bases during the life of the installation and to identify, where appropriate, whether corrective measures are necessary.

Technical specifications:

7.5 The licensee of the installation must come up with technical specifications, which shall consist in a set of operational limits and conditions, as well as the actions to be taken in case of non-compliances, in addition to monitoring and other requirements, both technical and managerial, that guarantee the safe operation of the installation in all operational modes, in accordance with the design bases and the analyses contained in the Safety Analysis Report and that established in the Regulation Governing Nuclear and Radioactive Installations.

Operating procedures:

7.6 The licensee of the installation must have a set of operating procedures for normal, abnormal and emergency conditions that specify the actions to be taken to keep the installation in safe conditions or to re-establish or compensate for the safety functions in case of the loss thereof. Likewise, it must have operating procedures or guides for mitigating the consequences of beyond design-basis accident situations.

7.7 The licensee must verify and validate operating procedures before they come into effect and keep them updated to reflect the situation of the installation and the organisation. It will take responsibility for all involved personnel being properly trained in the use and application thereof.

Control of the emission of radioactive material:

7.8 The licensee of the installation must monitor, control and limit the emission of radioactive material therefrom and its concentration in the environment, in order to ensure that the doses resulting from such emissions are below authorised limits and, when appropriate, the established dose restrictions.

7.9 The management by conventional methods of waste material with radioactivity content (declassification) shall require prior proof – and authorisation, when appropriate – of the radiological impact associated with such management being acceptable in accordance with the radiological criteria established in the corresponding regulations.

Modifications in nuclear installations:

7.10 The licensee of the nuclear installation must analyse and control the modifications thereof, both temporary and permanent, to ensure that none of them reduces the capacity or reliability of the installation to perform all safety functions and the capacity to operate it in a safe manner. All modifications must be analysed, verified and validated by the licensee prior to their implementation in order to check that the applicable criteria, standards and conditions are still met.

7.11 Modifications shall require authorisation when comply with the conditions established in the corresponding regulations.

7.12 Design modifications must be implemented without them interfering in the safety of the installation. The configuration of the installation must be updated together with the implementation of the modification, as well as the training of affected operating personnel.

7.13 The process for analysing and authorising modifications of manuals, procedures and evaluation methods related to safety functions shall follow the same process than that established for physical modifications of structures, systems and components.

Operating experience and advances in nuclear safety:

7.14 The licensee of the installation must set up and carry out a programme for systematically collecting, selecting, analysing, implementing corrective actions and documenting its own operating experience and that from other similar facilities.

7.15 The licensee of the installation must establish the appropriate contractual precautions with the organisations in charge of designing, building, maintaining and supplying structures, systems and components, as well as of supplying other processes important to safety, so that the latter immediately inform it of the detection of failures and deviations in the supplied structures, systems and components and processes, and support the former in re-establishing safety conditions.

7.16 The licensee of the installation must adopt the actions to improve safety on the basis of existing operating experience, research results of and scientific and technological advances compatible with the existing design, unless the licensee's analysis shows that they are not warranted.

7.17 The licensee must notify its own operational events and analyse outside operating experience significant for the safety of the installation, in accordance with the criteria set in the Regulation Governing Nuclear and Radioactive Installations and the regulations that develop it.

7.18 The nuclear installation must have a set of performance indicators enabling to monitor its operation in a continuous manner with the purpose of verifying that the safety of the installation stays within appropriate margins.

Life management:

7.19 The nuclear installation must have a Life Management Programme that identifies the mechanisms of degradation and ageing of structures, systems and components important to safety, specifying their possible consequences and determining their expected operating life and the activities required to maintain their operability and reliability.

Radioactive waste:

7.20 The licensee of the installation must control the inventory of generated radioactive waste, minimising their production insofar as possible and recycling them provided it is technically and economically feasible. Only that waste not susceptible of the application of that processes shall be conditioned for its final storage, taking into consideration the technical and economic conditions current at the time being.

7.21 The licensee of the nuclear installation shall ensure that the means for collecting and segregating radioactive waste are adapted to each category thereof, their nature and toxicity and the subsequent management paths being taken into account. Methods suitable for preventing the mixing of different categories of waste and of incompatible materials shall be established.

7.22 The licensee of the nuclear installation shall ensure that, when decisions are made during the different radioactive waste management stages, the interactions and relations with other stages are previously identified and acknowledged such that a well-balanced compromise between safety and overall effectiveness is reached.

Eighth. *Final shutdown after operation and Decommissioning.*

Requirements during design and operation:

8.1 The licensee of a nuclear installation must envisage and keep, even from the planning and design stage, a plan for carrying out its decommissioning and closure in safe conditions.

8.2 The plan for decommissioning a nuclear installation must consider both the strategy and funding contemplated for its execution, and technical forecasts in order to perform the decontamination, disassembly and demolition tasks that have to be carried out at the end of its operation, as well as the envisaged final management for the radioactive waste that is generated and, where appropriate, the spent fuel that remains in the installation.

8.3 All relevant information from the installation's design, construction and operation stages that might make the subsequent installation decommissioning activities easier must be recorded and kept.

Nuclear safety requirements during the final-shutdown-after-operation and decommissioning phases:

8.4 Prior to the start of the final-shutdown-after-operation and decommissioning phases, the licensee must review the installation's Safety Analysis Report so as to include an "Accident Analysis" consistent with the initiating events postulated during these phases, identifying the safety and defence-in-depth measures needed to maintain safety functions in each phase. The operational limits and conditions of structures, systems and components and the applicable monitoring and maintenance actions and requirements shall be deduced from this accident analysis.

8.5 During the phases of final shutdown after operation and of decommissioning of the installations within the scope of this Instruction, that indicated in the following paragraphs of Section 7: 7.1, 7.2, 7.3, 7.6, 7.7, 7.8, 7.9, 7.10, 7.11, 7.12, 7.13, 7.14, 7.17, 7.20, 7.21, 7.22 shall apply in relation to the operation of structures, systems and components important to safety during these phases.

Ninth. Exemptions.—The licensees of the nuclear installations object of the present Instruction may request to be temporarily exempted from observing any of its requirements by properly justifying the reasons for their request and establishing an alternative manner in which the established requirements will be observed.

Tenth. *Infractions and sanctions*.—The present Nuclear Safety Council Instruction is binding in accordance with that established in Article 2.a) of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, such that the failure to comply with it shall be punished in accordance with the provisions of Chapter XIV of Law 25/1964, of 29th April, on Nuclear Energy.

Sole Additional Provision. *Technical standards and instructions.*

The technical standards that develop this Instruction shall be included in other Instructions or Safety Guides issued by the Nuclear Safety Council.

In order to be able to specify or determine the concepts and objectives expressed in this Instruction, the technical standards and detail practices internationally accepted or those from the country of origin of the technology of the nuclear installation may also be used.

Sole Transitory Provision.

Nuclear installation licensees shall have a period of one year from the moment this Instruction comes into force to adapt to that established therein.

Sole Final Provision. *Entry into force.*

The present Instruction shall come into force on the day following that of its publication in the "Official State Gazette".

Which I announce to inform you for all pertinent purposes.

In Madrid, on the 16th of June of 2010.—Carmen Martínez Ten, the President of the Nuclear Safety Council.