Nuclear Safety Council's Instruction IS-29, of 13th October 2010, on safety criteria at spent fuel and high-level radioactive waste storage facilities (BOE, 2-11-2010)

Article 2.a) of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, confers on this Public Body the faculty to "prepare and approve Instructions, Circulars and Guides of a technical nature relating to nuclear and radioactive facilities and nuclear safety- and radiological protection-related activities".

Article 11.d) of the Regulation Governing Nuclear and Radioactive Facilities currently in force, approved by Royal Decree 1836/1999, of 3rd December, includes the facilities for the storage of nuclear materials in the nuclear facility category, the authorisation regime being developed in Chapters II to VI of Title II relating to nuclear facilities of said Regulation.

The purpose of the management of spent fuel and radioactive waste is to provide appropriate measures for protecting people, assets and the environment, both at the present time and in the future, against the risks entailed by ionising radiations, according to the technology and scientific practice existing at each moment in time, minimising the burden of said materials for future generations. All of the above is in accordance with the provisions of Article 38 of Law 25/1964, of 29th April, on Nuclear Energy and fulfils the basic radiological protection principles of dose justification, optimisation and limitation on which the Regulation on Health Protection against Ionising Radiations (Royal Decree 783/2001, of 6th July) is based.

The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, signed in Vienna on the 5th of September of 1997 and ratified by the Spanish State on the 30th of April of 1999, covers the radiation protection goals and safety requirements applicable to the management of said materials and in particular those applicable to spent fuel.

General Radioactive Waste Plans are approved by the Government with the support of the Nuclear Safety Council's preliminary report, according to Article 38 A of Law 25/1964, of 29th April, on Nuclear Energy. In accordance with the successive General Radioactive Waste Plans, the current spent fuel and high-level waste management strategy necessarily requires an intermediate stage that provides the appropriate confinement, retrieval capacity, monitoring and protection during a limited period of time, considering the principle of interdependence with subsequent or future management stages and the interfaces between the different organisations involved.

The present Instruction brings together the basic objectives of spent fuel and high-level waste management, the basic principles of radiation protection, the basic safety functions, the design criteria, the basic operational requirements and the safety assessment of this type of facilities, bearing the principles of good engineering practice and the current state of the art in mind.

Regardless of the criteria included in this Instruction, it is the responsibility of the licensee of the storage facility during its lifecycle (from the planning, siting, design, component manufacturing, authorisation processes, construction, operation and modification to the dismantling and decommissioning) to comply with general safety organisation and management, quality assurance, human factors and facility personnel training requirements and criteria, such as those included in Instruction IS-26 on basic nuclear safety requirements applicable to nuclear facilities or Instruction IS-20 establishing the safety requirements relating to spent fuel storage containers, or other administrative, regulatory or technical standards which are likewise applicable.

On the other hand, in order to harmonise the different national regulations, the Western European Nuclear Regulators Association (WENRA) has established a set of common requirements or reference levels based on international standards which must be applied in each of the national legal codes and which, therefore, have also been taken into account when preparing this Instruction.

By virtue of the above and in accordance with the legal authorisation envisaged in Article 2, Section a), of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, prior consultation of the affected sectors and after the appropriate technical reports, this Council, in its meeting of 13th October 2010, has stipulated the following:

First. *Purpose and Scope of application*

The purpose of the present Nuclear Safety Council Instruction is to set the basic safety criteria and requirements that must be fulfilled in the design, manufacturing, construction, testing, operation and safety analysis of nuclear facilities for the storage of spent fuel and high-level waste.

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.
- Law 15/1980, of 22nd April, creating the Nuclear Safety Council.
- Royal Decree 158/1995, of 3rd February, on the Physical Protection of Nuclear Materials.
- Royal Decree 1838/1999, of 3rd December, approving the Regulation Governing Nuclear and Radioactive Facilities.
- Royal Decree 783/2001, of 6th June, approving the Regulation on Health Protection against Ionising Radiations.
- Royal Decree 1546/2004, of 25th June, approving the Basic Nuclear Emergency Plan (PLABEN).
- Instrument Ratifying the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, signed in Vienna on the 5th of September of 1997 and given in Madrid on the 30th of April of 1999.

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

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

Confinement.–The prevention of the release of radioactive material by means of series of barriers.

Confinement barrier.–A structure, system or component that provides this capability in part or in full, including ventilation systems.

Design bases.–The set of information identifying the specific functions that a structure, system or component of the spent fuel and high-level waste storage facility 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 design.

Design basis accidents.–The set of accident conditions against which the spent fuel and high-level waste storage facility is designed. In these conditions, the criteria used for design help to keep the deterioration of nuclear fuel and the release of radioactive materials within authorised limits. Occasionally, they are known as “postulated accidents”.

Design life.–Regarding a structure, system or component (SSC), it refers to the operating time, anticipated in the design, during which that SSC is expected to fulfil its function in the terms established in its specifications.

Item important to safety.–It comprises:

1. Those structures, systems and components (SSCs) whose malfunction or failure could lead to undue radiation exposures of site personnel or members of the public.
2. Those SSCsthat prevent anticipated operational occurrences from leading to accident conditions.
3. Those features that are provided to mitigate the consequences of accidents caused by a malfunction or failure of structures, systems or components.

High-level waste.–Waste containing noticeable concentrations of long-lived alpha emitters and of beta-gamma emitters and generate heat in significant amounts. The spent fuel unloaded from nuclear reactors – once it has been decided that it is not going to be reprocessed – and the vitrified waste produced during the reprocessing thereof are included in this category.

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

Special waste.–Nuclear fuel accessories, neutron sources, used intranuclear instrumentation or replaced components from the reactor vessel system and reactor internals – generally of a metallic nature – having a high radiation rate due to neutron activation and that other waste which is not susceptible, given its radiological characteristics, of being managed at the final low- and medium-level waste surface storage facility existing in Spain that are deemed to be special radioactive waste for the purposes of this Instruction.

Spent fuel.–Nuclear fuel irradiated and permanently removed from the core of a reactor.

Subcriticality.–A state or condition applicable to nuclear fuel where the neutron multiplication constant is smaller than one.

Spent fuel and high-level waste storage facility.–A facility designed – in a manner independent from or connected to another, already existing nuclear facility – to receive, handle, condition, store and retrieve spent fuel and high-level radioactive waste without it entailing an undue risk for the health of workers, the public and the environment. It may also hold special waste that is managed at the facility itself. Storage ponds of nuclear power plants are excluded from this definition because they are a typical system necessary for the operation thereof.

Useful (or service) life.–Referring to a structure, system or component, it is the period of time from its commissioning to its withdrawal from service. The useful life can be longer than the design life, provided that the actual operating conditions have been less severe that those anticipated in the design. The remaining life margin a structure, system or component has left can be calculated by comparing the design conditions to the actual operating conditions.

Third. ***General objectives and requirements of the design of the facility***

3.1 General objectives:

3.1.1 The general safety objective of the licensee of the spent fuel and high-level waste storage facility must be to protect people and the environment from the harmful effects of ionising radiations. To this end, the licensee must design, build and operate the facility so that the spent fuel and high-level waste are received, handled, conditioned, stored and removed without entailing risks for the health of workers, the public and the environment.

3.1.2 In order to meet this goal, measures must be adopted 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 said events in case they occur.

d) Minimise the generation of radioactive waste.

3.1.3 The licensee of the facility must prove in the Safety Study that these objectives are fulfilled both in normal operation and abnormal conditions and in case of accident.

3.2 Safety functions:

3.2.1 Spent fuel and high-level waste storage facilities must be fitted with (physical, operational or administrative) devices so as to fulfil the following safety functions during the lifecycle of the facility in both normal operation and abnormal or accident conditions:

a) Subcriticality control. The design of the storage facility must guarantee subcriticality conditions at all times during all postulated storage operations, taking the double contingency criterion into consideration and including the appropriate margins for the uncertainties of the data and methods used in the calculations.

b) Confinement. The confinement of the radioactive material contained in the stored spent fuel and waste must be guaranteed throughout the life of the facility, taking the concepts of defence in depth and protection by multiple barriers into account.

c) Residual heat removal. The residual heat of spent fuel and radioactive waste must be removed, according to passive safety criteria.

d) Protection against radiation by means of the use of suitable shielding materials and thicknesses.

e) Retrievability. The design of the facility must allow the retrieval of spent fuel and waste at any time for inspection, reconditioning, shipment or transfer to another management facility or mode.

3.3 General requirements:

3.3.1 Defence in depth. The safety of the storage facility must be guaranteed during the lifecycle of the facility by setting multiple protection levels to prevent or minimise the radiological consequences of possible accidents, and must be applied to all safety-, organisation- and design-related activities.

3.3.2 Protection by multiple barriers. In order to guarantee the confinement of radioactive materials in all operating conditions during fuel element and waste handling and storage operations, the design of the facility shall at least establish two confinement barriers for normal operating conditions, guaranteeing that at least one confinement barrier remains in place during any accident condition.

The first barrier must provide confinement as close as possible to the radiation source. The second barrier must provide confinement when the first barrier accidentally stops performing its function.

3.3.3 The design shall comprise means suitable for preventing the uncontrolled release of radioactive material.

Fuel element rod cladding, fuel element storage baskets, fuel containers, and high-level waste containers and packages must be protected against degradation or such that degradation during storage does not give rise to operational safety issues.

3.3.4 Passive safety. The safety of the facility must be based on an inherently safe design that preferably includes characteristics based on passive systems for the performance of safety functions.

3.3.5 Lifting and handling systems must be equipped with redundant means with the capacity and qualification required to perform their safety function and fulfil the single failure criterion or prove that the consequences are acceptable in case a load is dropped.

3.3.6 Passive and active systems, particularly spent fuel and high-level waste handling and conditioning systems, shall be designed to facilitate and minimise maintenance needs.

3.3.7 Retrievability. It must be justified and proven that the changes in the properties of conditioned spent fuel and high-level waste units during storage do not affect the capacity for retrieval and handling.

3.4 Design bases:

3.4.1 The design of the storage facility must take into account the following aspects:

a) The expected life of the facility. The design of spent fuel and high-level waste storage facilities must take the expected design life into consideration in order to prevent and correct potential long-term degradation phenomena caused by the corrosion, erosion and ageing of the structures, systems and components important to the safety of the storage.

b) The expected inventory and a reserve capacity – or justification that it is available in some other way – to allow shuffle manoeuvres so as to facilitate the maintenance, inspection, retrieval or reconditioning of those spent fuel and high-level waste containers or packages that show indications or signs of degradation.

3.4.2 The design bases of the facility must be defined and documented in the official operating documents.

3.4.3 The design of the facility must consider and analyse design-basis events deemed to be representative of the Categories that are indicated in Annex I of this Instruction.

In order to consider an event to be a design-basis event in the different Categories defined in Annex I, cut-off (threshold) values of the annual frequency (probability) of the occurrence thereof may be used, as indicated in said Annex.

3.4.4 The design of storage facilities shall contemplate non-radiological risks that might indirectly give rise to initiating events, as indicated in Annex II.

3.4.5 Material design, manufacturing and construction standards shall consider the design life of the storage.

3.4.6 Structures, systems and components classed as being important to safety shall be designed to adapt to the effects of and be compatible with the characteristics of the land and the environment and to be capable of withstanding the effects of environmental and external human-induced phenomena without harming their capacity to perform safety functions or the conditions associated with normal operation, maintenance and the testing required. For extended storage periods, the uncertainties of climate change shall be taken into consideration.

3.4.7 Structures, systems and components classed as being important to safety must be designed to withstand the most unfavourable and severe of the natural phenomena registered in the surroundings of the proposed site, leaving enough safety margins and taking into account the limitations of the data and the period of time when said data were obtained. Likewise, the design must be capable of withstanding the effects of a credible combination of the conditions of normal, abnormal or accident operation with the effects of natural phenomena.

3.4.8 The design of structures, systems and components important to safety must be based on technologies proven and validated under similar operating conditions and according to codes, standards and materials that take the design life into consideration.

3.4.9 The facility shall be equipped with the appropriate measures for monitoring the limits specified in the Safety Study that make it possible to guarantee the performance of safety functions.

3.4.10 Structures, systems and components designed to mitigate or prevent abnormal conditions and design-basis accidents may be different from but must complement in any case those designed for normal operation.

3.4.11 The ageing of structures, systems and components and the physical and chemical characteristics of spent fuel and radioactive waste must be considered, maintenance, testing and inspection provisions being established when necessary. The inspection and maintenance programme shall contemplate the environmental conditions of the facility and the ageing of SSCs. The results obtained from this programme must be used to review the suitability of the design in the lifecycle of the facility.

3.4.12 The storage facility must also be designed to prevent the massive collapse of the structures of the building or heavy objects from dropping, as a result of a structural failure of the building, on top of spent fuel and high-level waste or on top of structures, systems and components important to safety.

3.4.13 The overall design of the facility, the layout of the different areas, access controls, onsite routes, emergency exits and, in general, the arrangement of structures, systems and components shall take the optimisation principle (ALARA) into account.

3.4.14 The overall design of the facility must provide for the space needed to carry out the characteristic operations of the facility, the movement of equipment, the repair thereof and the tests or trials of components.

3.4.15 The design of the facility must minimise the generation of radioactive waste in the processes and the risks associated with its handling.

3.4.16 The design of the facility must ensure that the waste, spent fuel containers and waste packages are compatible with the handling, storage and transport systems and those related to the disposal or other management strategies such as the need for the subsequent treatment or conditioning of the spent fuel and high-level waste.

3.4.17 Spent fuel and waste containers, baskets, packaging or packages shall be uniquely identified with a system that lasts for the entire storage period.

3.5 Ancillary systems:

3.5.1 The design of the storage facility shall include the necessary ancillary systems so as to guarantee the safe operation both in normal operation and in case of accident.

3.5.2 The facility shall be equipped, when necessary, with a gas treatment and ventilation system to guarantee the containment of environmental contamination both in normal operation and in case of accident. All environmental confinement systems of the facility shall be provided with monitoring capabilities in order to allow the licensee to take the corrective actions needed to maintain safety conditions.

3.5.3 The design of the facility must provide the necessary measures to reduce the risk of and limit the damage due to fires by means of protection levels based on the prevention of the generation of fires and the detection, alarm sounding, fighting and confinement of fires by designing fireproof barriers such that safety functions are fulfilled in all cases.

3.5.4 The design of the facility shall guarantee an appropriate and reliable lighting for operation, inspection and/or security in all facility areas. Likewise, there will be emergency lighting and signposted access and escape routes throughout the facility, operable in case of any postulated event. Onsite and offsite communications systems shall be set up to meet the needs of the facility in both normal operation and an emergency.

3.5.5 The structures, systems and components required for the handling of spent fuel containers or high-level waste packages shall be designed to:

a) Guarantee a safe operation in all anticipated conditions in order to ensure that handling failures do not have unacceptable radiological consequences.

b) Prevent fuel elements or high-level waste packages or their respective containers from being damaged and, if necessary, set restrictions on operations such as weight lifting by and/or the speed of movement of handling equipment and have alternative routes that may be applied to minimise the consequences of crashes or collisions, or automatic switches or physical restrictions to prevent incompatible risks or operations.

c) Safely handle and retrieve defective or damaged containers or packages during the lifecycle of the facility or intervene under the conditions of a postulated accident.

d) Have measures to make the maintenance and repair thereof easier, and, if necessary, for example, have a shielded enclosure, in order to achieve that the operational dose to be received by workers is as low as reasonably achievable.

e) Prevent an accidental release or the dropping of loads in case of a failure or loss of power (fail safe criterion).

f) Handle equipment manually until a safe position is reached in case of a failure or loss of power.

3.5.6 Those equipment and systems necessary for maintenance, periodic testing and inspection programmes shall be identified in order to ensure they work properly.

3.6. Radiation protection:

3.6.1 The design of the facility and the operation under normal conditions must provide an acceptable radiation protection level, ensuring that the doses received by exposed workers or the public remain below the limits set in the Regulation on Health Protection against Ionising Radiations and, if appropriate, below the fraction of said limits that might have been set (dose restriction).

3.6.2 The design of the storage facility must define, establish and delimit a controlled area. It shall be understood by controlled area the area surrounding the storage facility where the licensee thereof exercises its authority over its use and inside of which the operations are carried out.

3.6.3 The minimum distance between the spent fuel or high-level waste that is stored in the facility and the edge of the controlled area must be at least 100 m. The controlled area may be crossed by a road, river or railway provided effective traffic control measures are established and guaranteed in order to protect the public.

3.6.4 During normal operation and anticipated operational occurrences, the annual effective dose to any member of the public that is located beyond the controlled area shall not exceed 250 μSv (microSievert) by exposures due to:

a) Effluent and solid waste discharges into the environment, except radon and its descendants.

b) External irradiation due to the operations inside the storage facility.

c) Any external or internal irradiation due to any contribution from a nearby, nuclear fuel cycle nuclear or radioactive facility.

3.6.5 In order to guarantee that population exposure remains at the lowest value that is reasonably achievable, operational restrictions to the doses due to radioactive effluents and the external irradiation levels generated inside the facility shall be set taking economic and social factors into account.

3.6.6 The dose any individual situated on top of or beyond the closest edge of the controlled area might receive during a design-basis accident may not exceed:

a) An effective dose of 50 mSv (milliSievert).

b) An equivalent dose to the skin of 500 mSv

c) An equivalent dose to the crystalline lens of 150 mSv.

3.6.7 The storage facility must be designed such that, when it is to be dismantled, the decontamination and disassembly of structures, systems and components is facilitated, endeavouring to minimise the quantity and activity of the generated waste and to achieve that occupational exposures remain as low as reasonably achievable.

3.7 Physical protection.–Spent fuel and high-level waste storage facilities must comply with all national laws relating to the physical protection of nuclear materials and implement the security systems, services and procedures which nuclear facilities have to comply with in accordance with the provisions of the applicable legislation.

3.8 Quality assurance:

3.8.1 Throughout the lifecycle of the storage facility, the licensee must develop, implement and keep a documented quality assurance system defining the applicable quality and safety objectives according to the standards and degree of rigour required.

3.8.2 The Quality Assurance Programme must be applied in all phases of the lifecycle of the facility to all activities related to:

a) The maintenance of the subcriticality of the stored spent fuel.

b) The protection against radiation.

c) The removal of spent fuel heat.

d) The shielding of spent fuel and radioactive waste packages.

e) The control of corrosion on containers or packages.

f) Operating procedures relating to spent fuel and radioactive waste containers.

g) The maintenance, testing, examination and inspection of structures, systems and components important to safety.

h) Spent fuel and radioactive waste container management systems.

i) The keeping of records relating to the characteristics of spent fuel and radioactive waste during storage.

j) Safeguard and security systems.

3.8.3 The design shall consider a record management system and the conservation of all the relevant documentation and information on the phases of the lifecycle of the facility as well as on the characteristics of the stored fuel elements and waste that makes the future dismantling thereof easier.

Fourth. ***Basic performance criteria and requirements***

4.1 The routine activities and operations for the reception of spent fuel and radioactive waste containers, their preparation, handling and conditioning for storage proper, the inspection of every storage unit or package, as well as their retrieval and preparation in order to send them to another facility, shall be carried out according to operational limits and conditions, which shall at least include:

a) The design characteristics and parameters relating to spent fuel that back up the nuclear criticality studies, including at least: the inventory, the source term, the degree of enrichment, the concentration of neutron poison, the burnup, the restriction of movement and configurations.

b) The conditions that guarantee subcriticality in all possible spent fuel handling and storage configurations (including operational occurrences and accident conditions).

c) The environmental conditions inside the storage (temperature, humidity, contaminants); the limits that guarantee the life of the facility and the prevention of the degradation of radioactivity confinement barriers (e.g. the cladding of spent fuel elements, the storage basket, the storage container or the waste immobilisation matrix); the limits of the unavailability of systems important to safety; the maximum allowed temperatures for concrete structures, containers, etc.

d) The thermal limits for preventing the effects of waste or spent fuel heat generation on each individual waste or spent fuel container as well as on the storage as a whole.

e) The gas concentration limits for preventing the risks of ignition, fire, explosion and deformation of waste and spent fuel containers or packages and the associated radiation protection aspects.

f) The operating conditions of the spent fuel and high-level waste container handling systems.

g) The storage reserve capacity must be available at any moment of the operation of the facility.

h) The management of processes – including audits, inspections and tests – is properly implemented so that spent fuel and high-level waste fulfil the acceptance criteria.

4.2 The licensee of the facility must develop – in accordance with current legislation – an onsite emergency or self-protection plan and, if appropriate, the channels and procedures to collaborate with the competent authorities in the implementation and activation, if necessary, of the corresponding offsite civil protection emergency plan in the terms envisaged therein.

4.3 The licensee of the facility must implement and develop an operating experience programme that makes it possible to collect, differentiate, analyse and document the operating experience and events of the facility in a systematic manner. Said programme shall analyse the experience of similar facilities at the national and international levels. The licensee shall make sure that the results and conclusions obtained from operating experience and good practices are implemented so as to prevent the repetition of and suppress phenomena adverse to safety.

4.4 The licensee must implement during the anticipated storage period a programme for managing the life of structures, systems and components defined as being important to safety and define the preventive or corrective maintenance, periodic testing and inspection intervals necessary to maintain the safety of the storage by means of the required reliability and qualification.

4.5 The monitoring, periodic testing and inspection of the stored material and the facility must be carried out according to a programme based on written procedures, which shall be available before the operation of the facility starts.

4.6 The results of the stored material and facility inspection, monitoring and maintenance programmes must be recorded. Said programmes must be reviewed at appropriate intervals so as to incorporate the lessons learnt from experience, particularly from incidents in supporting activities such as the preparation of maintenance and testing.

4.7 The licensee must perform a safety review (Periodic Safety Review) at appropriate intervals – in accordance with current regulations – and shall include the deviations from the limits and acceptance criteria during storage and the changes that occur in the interdependencies in the different stages of the spent fuel and high-level waste management.

4.8 The normal operation of the storage facility and the response to incidents and design-basis accidents shall be carried out according to written procedures that must take the limits and conditions of the facility into consideration.

4.9 Said operating procedures shall develop the following topics:

a) Inventory control: The licensee must implement a system suitable for updating the information on the inventory of spent fuel and waste stored in the facility.

b) The reception, handling, storage, retrieval and shipment of spent fuel and high-level waste containers. The contingency measures of these activities shall be included, including the failure to comply with waste acceptance criteria, degradation, loss of integrity, and retrieval of waste by means of normal methods.

c) Measures to guarantee the subcriticality.

d) Monitoring of radiation (of the facility, effluents and the environment).

e) Basic operating systems and their support systems, e.g.: package and container handling systems, the ventilation and residual heat removal system, and the radiation protection system.

f) Periodic monitoring and inspection of the facility and equipment.

g) Response to anticipated operational occurrences and accident conditions.

h) Emergency planning.

i) Safeguard measures.

j) J) Physical protection.

k) Record custody and document control.

l) Fire monitoring.

Fifth. ***Assessment of the safety of the facility***

5.1 In accordance with the current Regulation Governing Nuclear and Radioactive Facilities, the documentation for the corresponding authorisations set forth in Chapters II to VI of its Title II must contain the Safety Study of the storage facility that enables to verify the capacity of the safety devices and barriers to prevent accidents and mitigate their consequences, which shall serve as a constant reference basis for the safe operation of the facility and include:

a) The general description of the facility and the methods adopted to achieve the basic safety goals.

b) The characterisation of the site and the assessment of site-related safety aspects.

c) The detailed description of the facility and its components, equipment and systems, its design-basis accidents and operation modes, including accident conditions.

d) The list of regulations, codes and standards used and the analysis of the compliance therewith.

e) The description of the aspects of the Organisation of the facility in the management of safety, the control of operations, the consideration of the interdependencies in radioactive waste management, General Radioactive Waste Plans and radiation protection.

f) The description of handling and storage operations and activities.

g) The acceptance criteria for spent fuel and radioactive waste containers.

h) The structural evaluation of the facility.

i) The thermal and heat removal evaluation.

j) The evaluation of the shielding and materials used.

k) The evaluation of the criticality and the subcriticality margins.

l) The evaluation of the confinement of radioactivity.

m) The assessment of radiation protection.

n) The assessment of the safety of the facility against postulated initiating events and its comparison with safety criteria and dose limits.

o) The description of the technical bases of operational limits and technical specifications.

p) The description of emergency operation procedures and accident action guides, inspection and test needs, personnel training and qualification, the operating experience programme and the management of ageing.

q) Proof of the compliance with long-term storage limits and conditions and the definition of a programme for the monitoring thereof and the compliance therewith.

r) The definition of a programme for monitoring the environmental conditions of the facility.

s) The assessment of the risks entailed by the operation of the facility in order to verify that all potential risk scenarios of the facility, including multiple failures, common-cause failures and human errors, have been weighed up according to their expected frequency and estimated seriousness and that there are adequate preventive or mitigatory measures in place to face up to said situations.

t) The pre-operational testing programme.

u) The evaluation of the Quality Assurance Programme.

v) The evaluation of the Decommissioning Programme.

w) The Radioactive Waste Management Plan. Characterization of the waste to be stored.

x) The environmental and radiological impact assessment in normal conditions and in case of accident.

y) The Fire Protection Programme, including objectives, functions, the description of design bases and the Fire Risk Analysis.

The list included in Annex II of this Instruction may be used as an aid to identify such onsite or offsite risks, such as natural or man-induced phenomena.

5.2 When a risk not previously contemplated is identified by means of the safety assessment, changes in the design must be made or operating procedures must be established to control it or additional measures must be implemented, such as e.g. additional training for personnel.

5.3 The Safety Study of the facility shall be updated at least every two years and shall be sent to the Nuclear Safety Council and reflect the modifications in the regulations or requirements: when it is not necessary to update it because no modifications have been made, this shall likewise be notified in writing. The Safety Study shall be the basis for the evaluation of changes in the facility or in the operating procedures.

5.4 Regardless of the periodic reviews of the safety of the facility, the safety of the facility must be reviewed when:

a) A significant deviation from the environmental conditions of the site is detected.

b) A significant change in the acceptance criteria for waste and spent fuel containers is proposed.

c) The properties of the waste or spent fuel have unexpectedly changed beyond the limits and conditions of the facility and no corrective actions are expected to be taken.

5.5 In case the licensee of the facility anticipates an extension of the life of the facility, it must carry out an assessment that guarantees that the safety requirements applicable to the SSCs thereof are maintained.

Sixth. *Modifications to the design*

6.1 The licensee must set up a process by means of which the proposals for changes or modifications, both permanent and temporary, to the design, the equipment, the characteristics of the materials, the control or the management are subject to an appropriate review to determine how safety could be affected. Such process, preliminary to any type of modification, must analyse and review the possible consequences and repercussions of the anticipated modification on the reliability and capacity of the storage facility itself and with regard to another associated or adjacent facility so as to verify that the applicable criteria, standards and conditions are still fulfilled.

The licensee of the facility is responsible for conducting the analyses of the modifications and must make sure that all its vendors follow the appropriate procedures so as to identify the modifications or activities that require undergoing the analysis process developed by this Instruction.

The process to be followed for the analysis of design modifications is the following:

- Preliminary analysis: any modification of the facility shall be subjected to a preliminary analysis in order to determine whether it affects, directly or indirectly, aspects related to the safety of the facility; consequently, the subsequent performance of a safety assessment is required. Additionally, by means of the preliminary analysis it shall be determined whether the modification:

  a) Entails changes to any of the official operating documents, in which case it must be subjected to the administrative procedure envisaged for revising them, or

  b) Entails a significant interference in the operation or a collective dose greater than 1 Sv-person, in which case a favourable appraisal by the Nuclear Safety Council shall be requested.

- Safety Assessment: it is a detailed assessment that shall only be conducted for modifications that so require it according to the results of the preliminary analysis, due to safety-related aspects being affected.

  The assessment shall consist in answering the eight points mentioned in the following Section 6.2 of this Instruction in order to establish whether the modification requires an authorisation.

- Safety Analysis: A safety analysis shall be conducted in those modifications whose safety assessment concludes that an authorisation is required. This analysis must prove that the facility still fulfils the applicable criteria, standards and requirements after the modification has been carried out.

6.2 Design modifications requiring a preliminary authorisation are all those modifications that:

a) Increase the frequency of occurrence of an accident previously analysed in the Safety Study.

b) Increase the probability of occurrence of a malfunction of structures, systems or components important to safety previously analysed in the Safety Study.

c) Increase the consequences of an accident previously analysed in the Safety Study.

d) Increase the consequences of a malfunction of structures, systems or components important to safety previously analysed in the Safety Study.

e) Create the chance for an accident of a different type from those previously analysed in the Safety Study to take place.

f) Create the chance for a malfunction of structures, systems or components important to safety to take place with different results from those previously analysed in the Safety Study.

g) Exceed or alter the design-basis limits of confinement barriers.

h) Modify the assessment methods described in the Safety Study, which have been used to establish the design bases and perform the safety analyses.

6.3 In the case that the changes are made in the facility or in the operating procedures, a process for reviewing the safety assessment shall be implemented so as to ensure that the potential risks do not increase as a result of these changes. Files on all accidents and incidents, even those of minor relevance, shall be kept. Said files must be periodically reviewed, together with the safety assessments and control procedures. Such activity may be used to verify the reliability of the safety assessment and the effectiveness of the procedures.

The changes which this Instruction refers to include both physical changes in structures, systems and components and changes in the operating conditions, the latter being understood as changes in the practices of the facility, the procedures, the analyses conducted to prove that the design bases are fulfilled and the assessment methods used in said analyses.

Seventh. *Exemptions*

The licensees of the activities regulated by this Instruction may request to be temporarily exempted from observing any of its requirements by properly justifying the reasons for their request, including a safety analysis, and establishing an alternative manner in which the established criteria will be observed.

Eighth. *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 (Articles 85 to 93) of Law 25/1964, of 29th April, on Nuclear Energy.

Sole Transitory Provision

Licensees of nuclear power plants having a spent fuel and high-level waste storage facility shall have one year from the publication of the present Instruction in the Official State Gazette (BOE) to adapt the Safety Study to that set forth therein.

Sole Repealing Provision

Any rule of equal or lower level that opposes the present Instruction is repealed.

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" (BOE).

In Madrid, on the 13th of October of 2010.- Carmen Martínez Ten, the President of the Nuclear Safety Council.

ANNEX I

Classification of design-basis events

Although the set of design-basis events of the spent fuel and high-level waste storage facility and the classification of each of the events according to its frequency of occurrence can only be established by taking the details of the design and the environmental conditions of the site where the facility is located into account, there are certain events that can be generically considered to be representative and classed into four categories according to their frequency (probability) of occurrence:

Category I: The set of events which are expected to regularly or frequently occur in the course of all activities expected for normal operation:

- Container transport, inspection, loading and unloading.
- Transfer between areas to the spent fuel storage area.
- Spent fuel conditioning.
- Spent fuel storage or retrieval.
- Maintenance or normal weather conditions.

Category II: The set of events that are not expected to occur regularly or are expected to occur with moderate frequency – once a year – such as e.g.:

- A loss of power of short duration.
- A mistake by an operator followed by an appropriate corrective action.
- A minor failure of the spent fuel transfer and handling machine.
- The failure of a single active component to perform its programmed function on demand.
- The spurious operation of certain active components.
- A minor leak through the connections of pipes in the decontamination liquid waste treatment system.

Category III: The set of infrequent events which are reasonably expected to occur at least once in the life of the facility such as e.g.:

- A loss of power for a long period of time.
- A major mechanical failure involving the spent fuel transfer machine, without there being a loss of shielding but requiring the removal of fuel.
- A fuel element falling inside the hot cell.

Category IV: The set of credible or plausible events having a low probability of occurrence that are postulated in order to establish a conservative envelope around the design bases of structures, systems and components important to safety:

- Originating in environmental phenomena or extreme weather phenomena: earthquakes, structure subsidence, extreme winds, hurricanes and tornadoes, flooding, extreme temperatures, snow, etc.
- Or having an external human origin such as e.g.: a gas explosion or a release of toxic gases and/or corrosive substances, an extreme fire or a crash due to the accidental fall of a plane (military fighter-type).

Categories I, II, III and IV correspond to the definitions of normal operation, abnormal condition, accident and design-basis accident respectively.

For the definition of design-basis events belonging to Category IV of this Annex I (design-basis accidents), a yearly frequency threshold may be used that takes into consideration a foreseeable, greater amount of years of operation of the facility in relation to the length of operation of other nuclear facilities, such as electricity-generating nuclear power plants, and the uncertainty of the probabilistic analyses for estimating the annual frequencies of this type of events.

An estimated frequency for an one-in-a-million-years event is used as the acceptable threshold value for the performance or not of a detailed analysis of the effects of this type of events and of the possible measures to mitigate them in nuclear power plants. The value to be used for the facilities that are the object of the present Instruction has to be properly defined and justified within the design bases.

ANNEX II

List of potential initiating events

Onsite events

Loss of power or fluids: electricity, air, pressurised air, vacuum, water, steam, coolant, chemical agents, or ventilation.

Improper use of electricity or chemical agents.

Mechanical failures of equipment, including the dropping of loads, ruptures, leaks, disconnections, and spurious activations of active components.

Control instrumentation failures and human errors.

Onsite fires and explosions (generation of gases, dangerous processes).

Onsite flooding, inflow of water, rupture of tanks or deposits.

Offsite events

Natural phenomena:

- Extreme weather conditions (rain, snow, ice, hail, wind, lightning strikes, high or low temperatures, humidity, etc.).
- Flooding due to a dam failing or a river overflowing its banks.
- Earthquakes.
- Subsidence of structures.
- Hurricanes and tornadoes.
- Natural fires.
- Effects of flora and fauna (clogging of air inlets and outlets, damages to civil engineering structures, etc.).

Induced human phenomena:

- Fire, explosion, release of dangerous or corrosive substances from industrial or military facilities or from transport infrastructures.
- Crash of a falling plane (accident).
- Impact of missiles due to the structural or mechanical failure of the facilities located in the vicinity.
- Loss of offsite power and loss of electrical force.
- Civil unrest (failure of infrastructures, strikes, interruption of supplies, etc.).