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The logo for the Consejo Superior de Normas (CSN) is displayed. It features a green vertical bar on the left, followed by the letters 'CSN' in a bold, sans-serif font. The 'C' is green, and the 'S' and 'N' are blue.

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III. OTHER PROVISIONS

THE NUCLEAR SAFETY COUNCIL

10075 *Nuclear Safety Council Instruction IS-25, of 9th June 2010, on criteria and requirements on the performance of probabilistic safety assessments and their applications for nuclear power plants.*

Probabilistic Safety Analyses (PSAs) constitute a risk analysis technique by means of which a quantitative estimate of the risk of accidents and a modelling of the facility consisting in the breakdown of the possible sequences of events that might lead to an accident and, within each sequence, the possible combinations of single events that might give rise to it, are obtained. By means of PSAs it is possible to know the significance for safety of the contents of those analyses, which are essentially aspects of design, procedures and operational practices of each facility.

Article 2.a) of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, confers on this Public Entity 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" related to the safe operation, i.e. without undue risks for people or the environment, of nuclear and radioactive facilities.

Article 36 of Law 25/1964, of 29th April, on Nuclear Energy stipulates that: "nuclear facilities must carry out their activity such that the safety conditions that might be required are maintained, adopting those measures needed to prevent nuclear and radiological accidents and to mitigate their consequences in case they take place."

Probabilistic Safety Analyses analyse risks to determine the frequency with which the possible sequences of events that might give rise to accidents with serious consequences in the facility object of the analysis or its surroundings might occur. The facility's aspects of design, procedures and operational practices that might cause and bring about nuclear accidents are analysed by means of PSAs.

Additionally, the work that has been carried out in the Western European Nuclear Regulators Association (WENRA) in order to harmonise the regulations of the different member states has been taken into account in this Instruction. As a result of this effort, a set of common requirements known as "reference levels", which must be reflected in national regulations, has been established. It has been considered necessary to develop an Instruction that takes these criteria into account so as to give consistency to the process of regulatory development that has been undertaken by the CSN as a result of this harmonisation process.

Thus, this Instruction is aimed at the Nuclear Power Plant (NPP) licensees, who must perform a probabilistic analysis of the risks entailed by the operation of their plants in order to verify that all potential risk scenarios thereof - including multiple failures, common-cause failures and human errors - have been properly weighed up in accordance with their expected frequency and estimated significance and that there are adequate preventive or mitigative measures to face up to those situations.

However, PSA results cannot be the only aspect to be taken into consideration during the decision making; applicable regulations must also be reviewed and the defence in depth and the appropriate safety margins must also be maintained.

Under 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 9th June 2008, has agreed the following:

First. Object and Scope of Application.- The purpose of this Instruction is to require NPP licensees to perform a Probabilistic Safety Analysis (PSA) and to set the criteria and requirements that the performance and use thereof in the design, construction and operation of NPPs must meet.

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 No107, 4 May 1964).

Law 15/1980, of 22nd April, creating the Nuclear Safety Council (BOE No100, 25 April 1980).

Royal Decree 1838/1999, of 3rd December, approving the Regulation Governing Nuclear and Radioactive Facilities (BOE No313, 31 December 1999).

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

Probabilistic Safety Analysis (PSA): it is a risk analysis technique aimed at building probabilistic-logic models for determining the frequency with which the possible sequences of events that might give rise to accident situations with serious consequences in the facility object of the analysis or its surroundings might occur. It is a systematic technique by means of which the facility's aspects of design, procedures and operational practices that might cause and determine the evolution towards accident situations are analysed.

PSA at power: a PSA that assesses the risk caused by initiating events during power operation.

PSA in other modes of operation: a PSA that assesses the risk caused by initiating events during modes of operation different from power operation.

Level-1 PSA: it consists in the analysis of the design and operation of the nuclear power plant so as to identify potential sequences of accidents that might lead to damages to the reactor core and changes in its structural geometry, their root causes and their average annual frequency.

Level-2 PSA: from the results of level 1 it analyses the behaviour of the containment building, evaluates the release of radionuclides released from failed fuel and quantifies off-site releases.

Sensitivity Analysis: it is the process whereby the impact of the change in the probability of an event or a modelling hypothesis on the results of the PSA is assessed.

Uncertainty Analysis: it is the process whereby the sources of uncertainty in the analyses are identified and characterised, their impact on the results of the PSA is assessed and a quantitative measure of this impact is developed insofar as it is possible.

Importance Measures: indices that indicate the significance of an event or a group of events. The most used importance measures are the following three:

Risk Reduction Worth (RRW). It indicates how much would the results of the PSA decrease assuming the basic event does not happen (the probability of failure equals zero).

Fussell-Vesely (FV). The fractional contribution to the results of the PSA of a specific basic event for all accident sequences containing this basic event.

Risk Achievement Worth (RAW). It indicates how much would the results of the PSA increase assuming the basic event takes place (the probability of failure equals one).

Initiating Event: it is an event that disturbs the normal operation of the nuclear power plant leading to a deviation of certain parameters (pressure, temperature, reactivity, etc.) from which an accident sequence can evolve. Initiating events can be either internal or external.

Internal Event: an event originating inside the facility susceptible of having effects on plant safety due to failures of structures, systems or components or to human errors.

External Event (within the framework of PSAs): an event originating inside the facility susceptible of having effects on plant safety, such as onsite fires and flooding.

Other external events: events originating outside the facility, either of natural origin or due to industrial or human activities, susceptible of having effects on the risk of the NPP, such as earthquakes, extreme weather conditions, explosions or airplane crashes.

Third. Scope and Contents of PSAs.

3.1 NPP licensees must perform PSAs under the terms described in the present Instruction. PSAs will have a scope of Level 1 and Level 2, including internal and external events, both at power operation and other modes of operation. In other words, they have to be PSAs in which all possible internal and external events in all modes of operation of the nuclear reactor are analysed, also taking into account other sources of radioactivity that might give rise to source terms similar to the reactor core, in particular the spent fuel pool. PSAs must be extended to the analysis of possible radioactive releases to the outside of the plant in case of an accident.

3.2 Additionally, other external events contributing to a risk for the nuclear power plant, such as those due to severe weather conditions, to installations or the transport of dangerous materials or to earthquakes, must also be analysed.

These analyses may be performed by means of PSA techniques or other appropriate methodologies.

3.3 Licensees must base PSAs on realistic models of the response of the plant and take human actions into account.

3.4 Licensees must analyse in PSAs all relevant dependences between systems and human actions, functional dependences and local dependences as well as common-cause failures.

3.5 Licensees will include in Level-1 PSAs sensitivity, importance and uncertainties analyses, that significantly impact to the risk and in Level-2 PSAs also sensitivity analyses and, where appropriate, analyses of uncertainties associated with the most significant severe-accident phenomena from the point of view of risk.

3.6 Human reliability analyses must be performed by taking into consideration the factors that might affect human behaviour in all states of the plant.

Fourth. Quality and Updating of PSAs.

4.1 The PSAs of each nuclear power plant must be updated by the licensee in a continuous manner or after every refuelling outage such that they reflect the reality of the plant at all times.

4.2 PSAs must be performed, maintained and documented in accordance with the requirements of the quality assurance system implemented by the licensee for safety-related documents.

4.3 PSAs must be performed and updated in accordance with proven methodologies that reflect the state of the knowledge and taking the available international experience into consideration.

4.4 As an essential part of PSA updating processes, NPP licensees will keep appropriate databases to continuously collect, both individually and collectively, the statistical experience needed for a better quantification of the frequency and probability parameters of the events included in the models of the PSAs.

Fifth. Use and Applications of PSAs.

5.1 There are essentially two types of applications of PSAs. In first place, those applications related to the prioritisation of programmatic aspects, for which the aspects contained in PSAs will be sorted by importance measures. In second place, those related to modifications in aspects of design, specifications or procedures, including severe accident-management measures, in order to prove that the risk of the nuclear power plant is maintained within acceptable levels, which will be based on risk sensitivity analyses with regard to the aspect for which the application is proposed.

5.2 The methodologies for the two types of applications and for specific applications within each type will be proven methodologies that reflect the state of the knowledge and take the available international experience into consideration.

5.3 PSAs must be used as an aid to safety management, and the role of PSAs in the decision-making process will be defined.

5.4 PSA results must be used by licensees to develop and validate training programmes, including simulator training for control room operators.

5.5 It must be ensured that those components that significantly contribute to risk according to PSA results are included in test and verification programmes.

5.6 It must be ensured that those components that significantly contribute to risk according to PSA results are included in the Technical Specifications and described in the Safety Study.

5.7 As a result of its PSA having been conducted with the full scope mentioned in Section 3, the licensee of the nuclear power plant will have the aspects that most contribute to the risk of its facility clearly identified and will have made the modifications to the design, procedures or those aspects that prove to be practicable in order to reduce risk wherever it is still reasonable.

Sixth. Conditions on the use of PSAs.

6.1 Whenever PSAs are used, the limitations thereof will be taken into account and recognized. These limitations will be verified for each application of the PSA in order to verify its acceptability.

6.2 In any case, the arguments derived from PSAs on the basis of the impact on the estimated risk will not be the only argument for making a decision on the acceptance or not of an application. The performance of an analysis of the application must take into account the arguments of safety analyses on the basis of the criteria and rules for which the nuclear power plants were designed. The aspects of defence in depth, safety margins and application regulations will be analysed for each application of the PSA.

6.3 From the point of view of risk, i.e. of the part that the PSA contribute to the decision-making process referred to in Section 5, an application proposed by the licensee of the corresponding facility will be acceptable if it results in a reduction of the risk estimated by means of PSAs. The application may also be acceptable if the application results in a small increase in risk that might be deemed negligible due to being below an acceptance threshold.

6.4 PSA applications that result in a significant increase in risk will not be acceptable.

6.5 In those cases where PSAs do not consider with sufficient detail all the impacts on risk of the applied-for application, the licensee must complete the analyses with the appropriate qualitative arguments. The CSN will decide case by case whether those qualitative arguments are appropriate or not.

6.6 After the CSN approval of an application of an NPP's PSA, its effect will have to be overseen by the licensee by monitoring the application in order to verify that the hypotheses with which it was approved are still being fulfilled. Likewise, after the approval of an application, the PSA's models and data must be updated to reflect the new situation of as well as the changes in the nuclear power plant in accordance with the PSA-maintenance processes referred to in Section 4.1. Thus, the cumulative effects of PSA applications will always be recorded by means of those processes.

6.7 As part of its process for evaluating the authorisations submitted by a power plant for which the licensee has only included deterministic arguments, the CSN may require the licensee to analyse by means of the PSA the impact on risk of the proposed the applications.

Seventh. *Exemptions.* - Licensees of nuclear facilities whose operating license was granted before the entry into force of this Instruction may request being exempted of observing a requirement of this Instruction by duly justifying the reasons for their request, adding a safety analysis and establishing the alternative way in which the set criteria will be observed. In order for it to be effective, this exemption must be approved by the Nuclear Safety Council.

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.

Single Transitory Provision. *Adjustment Period.*

NPP licensees will have a period of six months from the publication of this Instruction in the Official State Gazette to send the CSN a detailed schedule of the execution of level-2 tasks in other operation modes, external events in other operations modes and level 2 of external events with the aim of reaching the full scope and including the rest of requirements.

Sole Repealing Provision.

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

Sole Final Provision.

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

In Madrid, on the 9th of June of 2010.- Carmen Martínez Ten, the President of the Nuclear Safety Council.