Nuclear Safety Council Instruction number IS-21, of January 28th 2009, on the requirements applicable to modifications at nuclear power plants

Published in the Official State Gazette (BOE) number 43 of February 19th 2009

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Article 2.a) of the Law creating the Nuclear Safety Council attributes to this Public Entity powers to "draw up and approve technical instructions, circulars and guides relating to nuclear and radioactive facilities and activities relating to nuclear safety and radiological protection" as regards the safe operation of nuclear and radioactive facilities, in other words without undue risks for persons or the environment.

The system and procedures applicable to authorisations for nuclear facilities are regulated in title II of Royal Decree 1836/1999, of December 3rd, modified by Royal Decree 35/2008, of January 18th; chapter V (articles 25 to 28) establishes the basic principles regarding the requirements and the information to be submitted by the licensees to the Ministry of Industry, Tourism and Trade and to the Nuclear Safety Council on the different modifications carried out at the facility. Specifically, this chapter addresses aspects relating to modifications to the design or operating conditions affecting the nuclear safety or radiological protection of an installation and the performance of tests. Article 25 provides that the licensee of the facility should analyse such modifications in order to verify that the criteria, standards and conditions serving as a basis for the authorisation of the said facility continue to be met and, depending on whether or not such criteria are met, should adhere to certain processes to obtain the appropriate administrative authorisation or inform the authorities of the actions performed.

Likewise, the Operating Permits of the nuclear power plants and the Complementary Technical Instructions of the Nuclear Safety Council through which they are developed impose certain additional requirements to be met by design modifications.

The Nuclear Safety Council also approved Safety Guide GS-1.11, on *Design modifications at Nuclear Power Plants*, the objective of which was to recommend an acceptable method for compliance with the requirements established in article 25 of the Regulation on Nuclear and Radioactive Facilities and in the operating permits of the operating nuclear power plants in relation to modifications in the design and operating conditions of the facilities, and to the performance of tests at these installations. This guide also identifies the information on such modifications to be submitted to the Nuclear Safety Council and to the Directorate General for Energy Policy and Mines.

In addition, the Western European Nuclear Regulators Association,(from hereon WENRA) has established a series of reference levels on different safety issues with a view to harmonising the different regulations, among them reference levels on design modifications.

Pursuant to the above, the present Instruction develops the different requirements on modifications to facilities described in the Regulation on Nuclear and Radioactive Facilities, replaces the Complementary Technical Instructions of the Operating Permits regulating design modifications and incorporates the WENRA reference levels on design modifications not yet included in the Spanish standards.

Pursuant to the above, and in keeping with the legal entitlement contemplated in article 2. section a) of Law 15/1980 of April 22nd, creating the Nuclear Safety Council, in the wording given by Law 33/2007 of November 7th, and following the appropriate technical reports and consultations with the affected sectors, this Nuclear Safety Council has agreed as follows during its meeting held on January 28th 2009:

One. Objective and scope of application

1. The objective of the present Instruction is to develop the different requirements applicable to modifications at nuclear power plants and to identify those requiring any of the types of authorisation described in the Regulation on Nuclear and Radioactive Facilities.

Likewise, this instruction incorporates the international reference levels regarding safety assessment, the implementation and the documentation of any modification to be performed.

2. In general, consideration is given within the scope of application of this Instruction to modifications in design, operating conditions and the performance of tests potentially affecting nuclear safety and radiological protection, specifically the following:

1) Modifications to the structures, systems and components of the plant.

2) The performance of tests not described in the Safety Analysis Report or Technical Specifications.

3) Modifications to the assessment methods, procedures, manuals or other documents.

4) Temporary modifications.

5) Anomalous conditions, be they degraded or non-conformities.

3. The present Instruction shall be applicable to the licensees of pressurised water reactor (PWR) and boiling water reactor (BWR) nuclear power plants, unless the specific applicable type is indicated.

Two. Definitions

The definitions of the terms and concepts used in the present Instruction shall be as set out in the following standards:

– Nuclear Energy Act, Law 25/1964, of April 29th.

– Law 15/1980, of April 22nd, creating the Nuclear Safety Council.

– Royal Decree 1836/1999, of December 3rd, approving the Regulation on Nuclear and Radioactive Facilities.

– Royal Decree 783/2001, of July 6th, approving the Regulation on the Protection of Health against Ionising Radiations.

– Instruction IS/02, Revision 1, of July 2004 on the documentation of refuelling activities at light water nuclear power plants.

– Standard UNE-73-106-94 “Control of temporary changes at operating nuclear power plants”.

– Standard UNE-73-401-95 “Quality assurance at nuclear facilities”.

– Standard UNE 73-103-92 “Control of design changes at operating nuclear power plants”.

In addition to the above, certain terms are used that, within the context of this Instruction, are understood as follows:

Licensee of a nuclear facility: this coincides with the term “operator” as used in the Nuclear Energy Act. Consequently, the licensee of a nuclear facility is the natural or legal person holding the authorisation necessary for the start-up of the facility.

Foreseen operating event: is an operating condition that deviates from normal operation and is expected to occur one or more times during the lifetime of the nuclear facility. The criteria used in designing the facility mean that these events do not cause significant damage to items of importance for safety or give rise to accident conditions.

Design basis accident: is the set of accident conditions that a nuclear facility is designed, to withstand in which the deterioration of nuclear materials and the release of radioactive materials remain within the

authorised limits. These are sometimes known as “postulated conditions”.
Beyond design basis accidents: are situations not considered in the initial design of the facility and that would give rise to more serious consequences than those of a design basis accident.

Design basis: is the corpus of information that identifies the specific functions performed by a structure, system or component of the facility, along with the values (or range of values) of the parameters relating to this function that have been selected as bounding conditions for the design. These values may be conditions deriving from practices commonly accepted to achieve the functional objectives or requirements deriving from analyses (based on calculations or experiments) of the effects of the postulated accident for which the said structure, system or component is required to fulfil its function.

Licensing basis: is understood to be set of obligatory nuclear safety and radiological protection requirements, regulatory commitments and exemptions deriving from both the initial standards and those subsequently incorporated.

Structures, systems and components: is the general term that includes all the elements of a facility. The structures are the passive elements: buildings, vessels, shielding, etc. A system consists of several components or structures assembled in such a way as to perform a specific function. A component is a specific item within a system, for example cables, transistors, integrated circuits, motors, relays, solenoids, pipes, accessories, pumps, tanks and valves.
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Postulated initiating event: is an event identified at the design phase as being capable of taking the facility to foreseen operating event or accident conditions.

A safety significant element includes the following:

1. Those structures, systems and components whose malfunctioning or failure might give rise to an undue exposure to radiation for the site personnel or the members of the public.

2. Those structures, systems and components that prevent foreseen operating events from giving rise to accident conditions.

3. Those elements that are designed to mitigate the consequences of the malfunctioning or failure of structures, systems or components.

These are divided into “safety-related elements” and “safety significant elements”.

Safety element (or safety-related element): is an element to whose operation credit is given in design basis accident analysis to:
1. Take the facility to safe shutdown conditions and keep it in these conditions in the long term.

2. Limit the radiological consequences of foreseen operating events and design basis accidents within the specified limits.

Safety significant element: is an element not forming part of a safety-related element but:

1. To whose operation credit is given for the mitigation of foreseen operating events or accidents or used in emergency operating procedures.

2. Whose failure may prevent safety-related elements from fulfilling their safety function.

3. Whose failure may cause the actuation of a safety-related element.

Modification of the facility: the modification of the facility is understood to be any change in the facility or the procedures affecting the design functions, the methods for these functions to be carried out or controlled or the evaluations performed to demonstrate that the foreseen functions are fulfilled. Likewise, a modification is understood to be both the alteration or elimination of existing elements

or procedures and the implementation of new elements or procedures.
The modifications referred to in the Instruction include both physical changes to the structures, systems and components and changes in the operating conditions, these being understood as changes in the practices of the facility, in the procedures, in the analyses performed to demonstrate compliance with the design basis and in the methods of evaluation used in these analyses.

Temporary modification: any direct or indirect alteration of the functional characteristics of the plant systems, equipment or components introduced temporarily in any operating mode to:

1. Address temporary operating needs not foreseen by previously approved procedures.

2. Provide a temporary solution to malfunctions detected pending the adoption of a permanent solution, either repair or the introduction of a definitive design change as established in the UNE 73-103/92 standard.

Degraded condition: is a situation in which a structure, system or component has undergone a loss of quality or its functional capacity has been reduced.

Non-conforming condition: is a condition affecting a structure, system or component and involving non-compliance with the requirements set out in the Licensing Basis due to factors relating to inadequacies in design, testing, assembly or modifications.

Anomalous condition: a general term used to encompass degraded conditions and non-conforming conditions.

Significant operating interference: a significant operating interference is understood to exist when the installation or testing of the modification may cause a foreseen operating event in the plant or damage to safety-related elements or imply a reduction in the personnel for safe operation of the plant.

Three. Authorisations for nuclear power plant modifications

As established in article 25 of the Regulation on Nuclear and Radioactive Facilities, a plant modification requires authorisation when the conditions, standards and criteria on which the operating permit is based are modified.

If none of the circumstances described in the present section and requiring authorisation occur, the licensee may proceed with the modification, notifying the Nuclear Safety Council and the Directorate General for Energy Policy and Mines, in accordance with the provisions of section six of this Instruction. If the circumstances described in section four of this Instruction were to occur, the licensee shall proceed as described therein.

3.1. Authorisations

3.1.1. Authorisation for modification
Modifications affecting nuclear safety and radiological protection must be analysed to check that the conditions, standards and criteria included in the authorisations, official operating documents and specific Nuclear Safety Council instructions continue to be fulfilled.

A modification in the design or the operating conditions of the facility (including modifications to the basic design, installation and operation documentation of the plant) or the performance of tests at the facility is considered to modify the criteria, standards and conditions on which its authorisation is based when any of the following circumstances arise as a result of it:

1. Increase in the frequency of occurrence of any accident previously analysed in the Safety Analysis Report.

2. Increase in the probability of malfunctioning of any safety significant structure, system or component previously analysed in the Safety Analysis Report.

3. Increase in the consequences of any accident previously analysed in the Safety Analysis Report.

4. Increase in the consequences of malfunctioning of any safety significant structure, system or component previously analysed in the Safety Analysis Report.

5. Possibility of occurrence of any accident different from those previously analysed in the Safety Analysis Report.

6. Possibility of occurrence of any malfunctioning of safety significant structures, systems or components with results different from those previously analysed in the Safety Analysis Report.

7. The design basis limits of the fission product barriers described in the Safety Analysis Report are exceeded or altered.

8. The evaluation methods described in the Safety Analysis Report and used to establish the design basis or perform safety analyses are modified.

Authorisation must be sought for the modification if any of the aforementioned circumstances arise. This authorisation must be effective before entry into service of the modification or performance of the test.

This type of authorisation shall also be sought for complex modifications or modifications that are significant from the point of view of nuclear safety or radiological protection, even though the aforementioned circumstances do not arise, when this is required by the Directorate General for Energy Policy and Mines or the Nuclear Safety Council or considered necessary by the operator.

3.1.2. Authorisation for performance and installation

In accordance with the provisions of article 25.2 of the Regulation on Nuclear and Radioactive Facilities and independently from the authorisation described above, when the Directorate General for Energy Policy and Mines or the Nuclear Safety Council considers the modification to be major in its scope or to involve significant construction or installation works, the Directorate General for Energy Policy and Mines shall require the licensee to request an authorisation for the performance and installation of the modification. In no case may these activities be carried out before this authorisation is granted.

Four. Favourable reports

Modifications that may imply a significant interference in operation during their phase of implementation or involving works estimated to imply collective doses higher than one Sievert per person (1 Sv.p) must be favourably reported on by the Nuclear Safety Council prior to their performance.

Five. Process for the treatment of modifications at nuclear power plants

The licensee of the facility shall be responsible for the analysis of modifications and shall ensure that all his suppliers adhere to adequate procedures for the identification of modifications or activities requiring the process of analysis dealt with in this Instruction.

The process to be adhered to for the analysis of modifications shall be as follows:

Preliminary analysis: any modification to the facility shall be subjected to a preliminary analysis to determine whether it directly or indirectly affects aspects relating to plant safety and, therefore, requires the subsequent performance of a safety assessment. In addition, the preliminary analysis shall determine whether the modification:

– Implies any change to any of the official operating documents, in which case it shall be subject to the administrative procedure foreseen for review, or

– Implies a significant interference in operation or a collective dose higher than

1 Sv.p, in which case a favourable report by the Nuclear Safety Council shall be requested.

Safety assessment: this is a detailed assessment that will be carried out for those modifications so requiring, in accordance with the results of the preliminary analysis, due to safety-related aspects being affected.

The assessment shall consist of providing a justified response to the eight points included in section 3.1.1 of this Instruction, in order to determine whether the modification requires authorisation.

Safety analysis: safety analyses shall be performed on those modifications that, in accordance with the safety assessment, require authorisation. This analysis shall demonstrate that following the modification the facility will continue to meet the applicable safety criteria, standards and requirements. This analysis shall accompany the corresponding request.

The licensing basis to be applied to the design modification shall be that in force as of the performance of the preliminary analysis, and shall include the contents of the latest mandatory annual report issued.

Six. Documentation to be submitted

The documentation relating to modifications to facilities that is to be submitted to the Ministry of Industry, Tourism and Trade and/or the Nuclear Safety Council, as appropriate and in accordance with the terms contemplated in the articles of the present text, is as follows:

– Documentation on modifications requiring authorisation.

– Documentation on modifications for favourable reporting.

– Documentation on modifications generating changes in the Operating Technical Specifications.

– Periodic information.

6.1. Documentation on modifications requiring authorisation

6.1.1. Modifications requiring authorisation

The request to be submitted to the Ministry of Industry, Tourism and Trade shall be accompanied by the following documentation:

a) Technical description of the modification, identifying the underlying causes.

b) Safety analysis performed, which shall include the applicable standards.

c) Identification of documents that would be affected by the modification, including the text proposed for the safety analysis report and the operating technical specifications, when applicable.

d) Identification of tests prior to entry into service, where applicable.

e) Specific quality plan, when drawn up as a result of the scope or complexity of the modification.

6.1.2. Modifications requiring performance and installation authorisation

The documentation to be submitted with the request for authorisation for performance and installation to the Ministry of Industry, Tourism and Trade is as follows:

a) Description of the modification, identifying its underlying causes.

b) Standards to be applied in the design, construction, installation and testing of the modification.

c) Basic design of the modification.

d) Foreseen organisation and quality assurance programme for project performance.

e) Identification of the scope and content of the analyses required to demonstrate the

compatibility of the modification with the rest of the facility and to guarantee maintenance of its levels of safety.

f) Destination of the equipment to be replaced, where appropriate.

g) Acquisition plan and budget in the case of major modifications.

The documentation to be submitted with the request for authorisation, prior to entry into service, shall be that identified in section 6.1.1; in order not to repeat information, part of the documentation submitted with the request for performance and installation may be referenced.

6.2. Documentation on modifications for favourable reporting

The request to be submitted to the Nuclear Safety Council shall be accompanied by the documentation indicated in point 6.1.1 of this Instruction. The safety analysis shall focus on the measures foreseen to minimise the risks deriving from implementation of the modification.

6.3. Documentation on modifications generating changes in the operating technical specifications

In the case of requests for changes to the Operating Technical Specifications generated by modifications that have not required authorisation or favourable reporting, the licensee shall submit the following documentation to the Nuclear Safety Council:

a) Technical description of the modification, identifying the underlying causes.

b) Basic design and standards applied in the modification, along with the preliminary analysis and safety analysis performed.

c) Tests prior to entry into service, whenever applicable.

6.4. Periodic information

During the first three months of the calendar year a report shall be submitted to the Ministry of Industry, Tourism and Trade and to the Nuclear Safety Council on the permanent modifications (including modifications to the basic design, installation and operation documentation of the plant) foreseen, implemented or in the course of being implemented at the plant.

The periodic reports on modifications shall include the following information:

1. Identification of the modification.

2. Copy of the preliminary analysis performed.

3. In those cases in which the preliminary analysis determines the need for a safety assessment, a copy shall be included. Where the safety assessment is supported by other specific studies, it shall be sufficient for a reference to these studies to be included.

4. Status as of the date of drawing up of the report (foreseen, implemented or in the course of implementation).

Instruction IS-02, Revision 1, of July 2004, on the documentation of refuelling activities at light water nuclear power plants, which regulates the documentation on refuelling activities, includes the information on modifications of the facility that is to be submitted to the Nuclear Safety Council in relation to refuelling activities.

Seven. Implementation of permanent modifications

The processes for the implementation, testing and placing in service of safety significant modifications at the facility must be clearly defined and the responsibilities clearly identified in the licensee's corresponding procedures.

This section describes the aspects to be taken into account for the performance of these activities.

7.1. Implementation of modifications

The following requirements should be fulfilled for the implementation of these modifications:

– The work involved in installing, supervising and controlling modifications shall be performed by qualified personnel with the experience and training necessary for such tasks, in accordance with the procedures of the facility.

– During the design and installation phase measures shall be put into place to control simultaneous modifications affecting the same items of equipment or systems and avoid their coming into conflict.

– The scope, safety implications and consequences of the modifications proposed shall be revised by personnel not directly involved in their design or implementation.

– A maximum time period of two years shall be established for the implementation of modifications, after which the validity of the corresponding safety assessment shall be revised, taking into consideration the current situation of the plant, as compared to the situation existing when the safety assessment or analysis was performed and adapting to the updated licensing basis.

– During the development phase analyses shall be performed to minimise the radiological impact (ALARA studies) during the installation and operation of the modification.

– Analyses shall be performed to minimise the generation of radioactive wastes and the management of such wastes shall be defined.

– The conditions in which the facility or the affected equipment and systems should be in order for the modification to be performed shall be determined and the special temporary procedures required to address possible contingencies during its installation shall be drawn up.

– Measures shall be established for the control and analysis of the possible negative aspects of alterations or deviations with respect to the foreseen design occurring during the installation phase.

– The preparatory activities for the works, such as the temporary removal of supports, shielding, lagging, the installation of scaffolding, temporary alterations to the fire-fighting system and systems for the mitigation of flooding, etc. shall be planned and analysed to minimise their impact. The alterations shall be restricted to the time strictly necessary and the necessary compensatory measures shall be taken.

– During installation, the measures required to minimise the dispersion of radioactive contamination shall be contemplated.

– Human factors methods and criteria shall be adequately incorporated in all the phases of the process and modification activities.

7.2. Testing and placing in service

The performance of tests and placing in service constitutes the final stage of the process of modification. This should be accomplished under the control of the operator, in accordance with the procedures governing the process of performing modifications.

A testing programme shall be established (checks, measurements, evaluations) to verify that the plant is able to operate safely after the modification. The objective of this programme is to demonstrate that the modification fulfils the design specifications.

In general, the testing programme shall consider the specific tests of the modification and operability tests. The specific modification tests must include the following:

– Testing of equipment prior to installation.

– Tests demonstrating the correct operation of the changes implemented.

– Functional testing of the affected system.

The operability tests shall correspond to the surveillance requirements of the Operating Technical Specifications, which must be fulfilled in order declare the components and systems affected by the modification operable.

The procedures of the facility must clearly identify the departments responsible for establishing and defining the necessary tests of each of the types indicated above.

The tests specific to the modification, including the acceptance criteria, shall be established and defined in the detailed design of the modification.

The acceptance tests shall explicitly include the specific acceptance criteria based on the functional criteria established in the design of the modification.

The placing in service of the modification shall be conditioned on the successful completion of the testing programme.

Prior to placing a modification in service it is important to guarantee the following:

– The necessary documentation is available, in accordance with the provisions of the section of this Instruction on “Updating of documentation”.

– The final configuration of the modified system has been verified, in comparison with the design configuration (As-built configuration).

– It has been determined whether the modification may affect the simulator or its computer codes, and updating of the simulator has been planned where necessary.

– The personnel have been trained on the changes.

– The design, authorisation, quality assurance, installation and testing documentation has been revised to verify its completeness and accuracy. The completion of the modification shall include a verification that the provisional connections, procedures, assemblies, etc. used during implementation have been removed or cancelled.

7.3. Updating of documentation

The updating of the project documentation following the implementation of modifications at the facility shall be carried out systematically and sufficient priority shall be given to the process to ensure both the correct operation and maintenance of the equipment involved and the analysis and assessment of the subsequent changes that might be introduced. This process shall be included in a procedure identifying the criteria and documents to be updated prior to placing the modification in service and the time periods for the updating of the rest of the documentation.

The following criteria shall be applied:

– As from the placing in service of the modification, the updated operating and surveillance procedures should be available, along with the changes made to the drawings and other documents for immediate use by the operating personnel.

– The changes to the documentation affected shall be edited as soon as possible, with priority given to the documents of greatest significance for safety.

– A time limit shall be established between the physical implementation of a modification and the documentary closure of the dossier, in order to facilitate updating of the affected documentation in the shortest time possible.

– The updating of the safety analysis report and other official operating documents shall be accomplished in accordance with the provisions of the operating permits.

Eight. Implementation of temporary modifications

The following requirements shall be met for the installation and management of these modifications:

– All temporary modifications shall be clearly identified at the point of application and at any relevant control post.

– The temporary modifications, along with the corresponding preliminary analysis and safety assessment where applicable, shall be included in a single file which shall be available in the control room during such time as they are open.

– The operating personnel shall be duly informed of all temporary modifications and of their consequences for operation of the plant.

– Temporary modifications shall be managed in accordance with plant specific procedures.

– The number of simultaneous temporary modifications shall be kept as low as possible. The period of validity of temporary modifications shall be limited.

– The licensee shall periodically revise the existing temporary modifications in order to determine whether they continue to be necessary.

– The maximum period of implementation of a temporary modification shall be set out in the modification itself and a specific milestone for its completion shall be established. In any case, if the cycle in which it has been installed is exceeded, its continuity shall be confirmed.

Nine. Anomalous conditions

In the event of situations determined to be anomalous being discovered at the plant, with the conditions and requirements established in the authorisation not fully met, due to the existence of a degraded condition or a non-conformity, these shall be assessed and resolved within a reasonable period of time and depending on their safety significance, with corrective measures subsequently taken to return the plant to the required conditions.

If it is not possible to restore normal conditions immediately, the affected structures, systems and components shall be identified. Depending on the type of structure, system or component, a determination of operability or an assessment of functionality shall be performed.

The determination of operability may lead to the need to apply what is established in the Operating Technical Specifications, fulfilling the notification requirements established therein, or following an evaluation, to the identification of compensatory and corrective measures.

In the case of systems, structures and components not subject to the technical specifications but included in the licensing basis, the assessment of functionality may lead to the need to establish compensatory and corrective measures.

In both cases, these compensatory and corrective measures shall be considered to constitute a modification to the facility, as a result of which the process defined in this Instruction should be adhered to.

If the decision is taken to restore the facility to a situation in keeping with the requirements of the authorisation, the process defined in the present Instruction for nuclear power plant modifications shall not be applicable.

The analyses performed and actions taken in either of these cases shall be included in a document approved by the director of the nuclear power plant.

Ten. Infringements and penalties

The present Nuclear Safety Council Instruction shall be binding, in keeping with the requirements of article 2.a) of the Law creating the Nuclear Safety Council, Law 15/1980, of April 22nd, for which reason

non-compliance therewith shall be penalised as set out in Chapter XIV (articles 85 to 93) of the Nuclear Energy Act, Law 25/1964, of April 29th.

Eleven. Single transitory provision. Period of adaptation

The licensees of the nuclear power plants shall have six months, as from the date of publication in the Official State Gazette, in which to adapt their practices and procedures to the provisions of the present Instruction.

Twelve. Single final provision

The present Instruction shall enter into force on the day following the date of its publication in the Official State Gazette.

Thirteen. Single derogatory provision

All legal standards of equal or lower standing and opposing the present Instruction are hereby annulled, including the Complementary Technical Instructions incorporated in the Operating Permits of the Nuclear Power Plants and referring to modifications to the facility.

Madrid, January 28th 2009
The President of the Nuclear Safety Council,
Carmen Martínez Ten