The CSN provides users of this website with an unofficial translation of the law in question. You are therefore advised that this translation is for your information only and may not be entirely up to date when you consult it. For official texts, look up the law in the Boletín Oficial del Estado, where you can find laws in any of the official languages of the State of Spain.

CSN

El CSN pone a disposición de los usuarios de esta web una traducción no oficial del texto de la norma de referencia. Se advierte, por tanto, de su carácter puramente divulgativo, y de la posibilidad de que no se encuentre debidamente actualizada en el momento de su consulta. El texto oficial es el publicado en el Boletín Oficial del Estado en cualquiera de las lenguas oficiales del Estado español.

III. OTHER PROVISIONS

NUCLEAR SAFETY COUNCIL

3571 *CSN's Regulatory Instruction IS-44, dated February 26, 2020, addresses requirements of emergency planning, preparedness and response in nuclear facilities.*

Article 2.a) of Law 15/1980, dated April 22nd, on creation of the *Consejo de Seguridad Nuclear* (Nuclear Safety Council or *CSN*), grants this public authority the power "to develop and approve Instructions, Circular Orders and Guides of a technical nature relating to radioactive and nuclear installations, as well as to activities in the areas of Nuclear Safety and Radiation Protection".

In addition to the roles assigned to the CSN in the abovementioned Law relating to control, supervision and inspection of activities carried out in nuclear facilities that have to do with Nuclear Safety and Radiation Protection during their operation and until dismantling, article 2.f) of Law 15/1980, dated April 22nd, establishes CSN actions in case of emergency.

Nuclear emergency management includes an onsite response level, which is a licensee responsibility and part of the site's Onsite Emergency Plan (Spanish acronym, *PEI*) and procedures elaborating on it, as well as an external response level, which is the responsibility of competent emergency management authorities, as established on Offsite Emergency Plans.

As a result of its in-house experience in the development of drills and the management of emergencies faced by Spanish nuclear power plants, the CSN has fostered continuous improvement processes to do with emergency preparedness, planning and management, as well as the implementation and evaluation of yearly *PEI* drills and exercises. These involve the approval and revision of CSN Safety Guides No. 1.03 "Emergency Plan in Nuclear Power Plants" and No. 1.09 "Emergency Drills and Exercises in Nuclear Power Plants", as well as the submittal to Licensees of Regulatory Safety Instructions and individualized letters containing additional criteria from Technical Directorates.

The accident occurred at the Japanese nuclear power plant of Fukushima in 2011 resulted in a number of lessons learned by nuclear power plants with regards to their approach in responding to accident conditions beyond the site's design base. Such approach entailed the implementation of additional safety measures, which is why the CSN sent licensees Complementary Technical Instructions (Spanish acronym, *ITC*) including, amongst other, emergency management requirements.

In addition to the documentation mentioned in previous paragraphs and for aspects relating to emergency management, the drafting of this CSN Technical Instruction took into consideration European Union directives, standards issued by the USA's Nuclear Regulatory Commission (NRC), recommendations issued by international agencies such as the International Atomic Energy Agency and the OECD's Nuclear Energy Agency, recommendations contained within the document "HERCA-WENRA Approach for a better cross-border coordination during the early phase of a nuclear accident" drafted by HERCA (Head of the European Radiological Protection Competent Authorities) and WENRA (Western European Nuclear Regulators Association), as well as relevant aspects of the CSN's Regulatory Safety Instructions IS-36 on "Emergency Operating Procedures and Severe Accident Management in Nuclear Power Plants" and IS-37 on "Analyses of Design Bases Accidents in Nuclear Power Plants".

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The most important means to prevent and mitigate the consequences of nuclear power plant accidents is the concept of defense in depth, that is, the establishment of a set of consecutive and independent protection levels referring to both design and construction, as well as to their performance, with the aim to ensure that no single failure of a technical, human or organizational nature leads to harmful health and/or environmental effects, and that the combination of failures that might lead to significantly harmful effects is highly unlikely.

One of the protection levels shall be comprised of an emergency management system containing effective response actions against emergency scenarios resulting from reasonably foreseeable accidents. Such system shall include three phases:

- Emergency planning: Determining in advance the objectives, structure, competent authorities, responsibilities and actions for a systematic, coordinated and effective response to the different types of emergencies identified in the site's risk assessment.
- Emergency preparedness: Ensuring the site's capacity to take the necessary actions with the aim to effectively prevent and mitigate the consequences of a nuclear emergency.
- Emergency response: Carrying out applicable actions to address a nuclear emergency, in coordination with nation-wide offsite response plans, so that the consequences for health, quality of life, the property of individuals and the environment can be minimized.

In view of all the above, this CSN Instruction is issued to collect and organize the requirements to be complied with by Spanish nuclear facility licensees in the area of emergency preparation, planning and management.

Requirements established within this Regulatory Safety Instruction have a graded approach commensurate with risks inherent to each nuclear facility.

In light of the above and in conformance with the legal authorization granted by article 2, section a) of Law 15/1980 created by the CSN on April 22, 1980, after consultation with the affected sectors and issuance of the necessary technical reports, the CSN Plenary Board at its meeting on February 26, 2020 agreed to the following:

One. *Purpose and field of application.*

This Regulatory Safety Instruction aims to establish requirements in the area of nuclear and radiological emergency planning, preparedness and management. Such requirements apply within the onsite response level established in Spain's nuclear facilities. This Instruction is also applicable to all life-cycle phases of nuclear facilities.

Two. *Definitions.*

The definitions of terms and concepts in this Regulatory Instruction correspond to the contents included in the following standards:

- Law 25/1964, dated April 25th, on Nuclear Energy.
- Law 15/1980, dated April 22nd, on creation of the *Consejo de Seguridad Nuclear* (Nuclear Safety Council or CSN).
- Spain's Royal Decree 1836/1999, dated December 3th, approving Spain's Regulation on Nuclear and Radioactive Facilities.
- Spain's Royal Decree 783/2001, dated July 6th, approving Spain's Regulation on Health Protection against Ionizing Radiations
- Spain's Royal Decree 1546/2004, dated June 25th, which authorizes the Basic Nuclear Emergency Plan.
- Spain's Royal Decree 1564/2010, dated November 19th, which approves the Basic Planning Guide for Civil Protection in case of Radiological Risk.

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

Emergency Support Center (Spanish acronym, *CAE*): Organization which can support any Spanish nuclear power plant in case of a large-scale incident, supplying additional equipment and personnel to complement onsite resources. This unique infrastructure would provide its services on a centralized basis.

Alternative Emergency Management Center (Spanish acronym, *CAGE*): Alternative emergency management center onsite which can be used alternatively to other existing centers (Technical Support Center, Operations Support Center, Medical Service, etc.).

Operations Support Center (Spanish acronym, *CAO*): Onsite infrastructure and resources used to support operations in case of emergency.

Technical Support Center (Spanish acronym, *CAT*): Main emergency management center onsite.

Offsite Emergency Center (Spanish acronym, *CEE*): Center outside but near the premises, comprising managerial, technical and administrative personnel who coordinate emergency response actions and carry out roles relating to logistical support, technical consultancy, radiological control and surveillance, as well as activities to report to and collaborate with competent authorities.

Offsite Support Center (Spanish acronym, *CSE*): Center outside the premises, comprising managerial, technical and administrative personnel who facilitate support actions for the licensee's corporate organization, and carry out roles relating to logistical support, technical consultancy, radiological control and surveillance, as well as activities to report and collaborate with competent authorities.

Extensive Damage: Regarding nuclear power plant safety, this concept refers to accidents going beyond design bases and implying long-term loss of electrical power and/or the ultimate heat sink, or the loss of large station areas.

Exercise: Set of scheduled activities which cover specific and partial *PEI* aspects and are aimed at periodically training and qualifying onsite licensee personnel within the Emergency Response Organization (Spanish acronym, *ORE*) in the actions to be rolled out in case of emergency. It is also intended to test and improve procedures used to articulate such scheduled activities and material resources allocated to the *PEI*.

Severe Accident Management Guidelines (SAMG) (Spanish acronym GGAS): Guidelines or procedures containing operational strategies to mitigate the consequences of a severe accident.

Extensive Damage Mitigation Guidelines (EDMG) (Spanish acronym GMDE): Guidelines or procedures containing alternative operational strategies to prevent or mitigate the consequences of an extensive damage accident.

Severe Damage Management Guidelines (SDMG) (Spanish acronym GEDE): Guidelines or procedures (aligned to SAMG and EDMG) associated to overall emergency management.

Emergency Response Organization (Spanish acronym, ORE): Operational structure organized in various hierarchical levels to which suitable operational procedures, human resources and technical means are allocated with the aim to facilitate adequate licensee response in case of emergency.

Emergency worker: Any individual with a role during an emergency and who could be exposed to radiation while responding to the emergency. Emergency worker can refer to workers hired directly or indirectly by the licensee, as well as to employees from offsite organizations.

Onsite Emergency Plan (Spanish acronym, *PEI*): Official Operating Document which describes foreseeable facility accidents, the licensee's organization for accident response, notification to competent agencies, protection measures for workers, equipment and means for specific use in case of emergency, as well as the training and exercise program that ensures organizational effectiveness.

It shall additionally establish actions foreseen by the licensee with the aim of providing assistance in offsite interventions, upon request from the Nuclear Safety Council, in line with offsite emergency plans established by competent agencies.

Radiological Surveillance Program during Emergencies (Spanish acronym, *PVRE*) Set

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of studies, sampling procedures, analyses and measures intended to determine the presence of radionuclides coming from the site, within the different ecosystem compartments to assess, in case of emergency, the evolution of radioactive elements, estimate potential radiological risks for people and establish precautionary and corrective measures, if applicable.

Protected Point: Place onsite used as a liaison, meeting, communication and hold point in between emergency response activities carried out onsite by emergency workers. It is equipped with communication means and material needed to facilitate such activities.

Emergency On-call Team: *ORE* personnel available within a specific period to increase on-duty shift crew staffing and who are required to respond adequately during the first phases of an emergency.

SAT: Systematic process aimed at establishing: learning objectives based on the results of specific job analyses; the design and implementation of training and development programs based on said learning objectives; the tools and human resources needed to satisfactorily meet said objectives; a system for the evaluation of the degree of individual achievement of the learning objectives; and finally, methods for the evaluation and review of the training and development program based on actual job performance. Job position analysis may involve a set of methodologies, from those less complex such as a thorough competence assessment, to other more complex like a full-scope task analysis.

PEI Drill: Set of scheduled activities aimed at facing a hypothetical emergency scenario that leads to *PEI* activation and allows the assessment of *PEI* effectiveness, licensee's response organization capabilities to manage emergency situations, preparation level reached, performance efficiency of participating organizations and use of available means.

PEI Initiating Event: Set of circumstances, incidents or accidents that may occur onsite or offsite during operation and that entail a risk for facility safety and trigger *PEI* activation.

Licensee-Surveilled Area (Spanish acronym, *ZBCE*): Area where the facility is located and adjacent lots in which the licensee may freely determine the course of action based on proprietary reasons or in agreement with the owners. The size of this area is established in the site's licensing basis and is directly related to accident analysis results included within the Final Safety Analysis.

Three. *Emergency Management Planning*

3.1 Accidents and Emergency Categories. The design of an emergency management system for nuclear facilities shall ensure that at least the following accident types can be managed:

1. Accidents analyzed within the site's Final Safety Analysis (FSA), as established in article 20 a) 3rd and article 30.1 a) 3rd of Spain's Regulation on Nuclear and Radioactive Facilities (Spanish acronym: *RINR*).
2. Beyond-design-basis accidents which were required to be analyzed by the *CSN* during any facility licensing phase.

3. In the case of nuclear power plants, scenarios to be analyzed as required by the CSN's Complementary Technical Instructions relating to post-Fukushima stress tests, more specifically:

a) Extensive damage accidents.
b) Scenarios with loss of large areas.

Depending on the level of safety degradation and potential radiological consequences offsite, analyzed facility accidents and scenarios are assigned to a particular emergency category. Emergencies are always declared by the *PEI* Director in accordance with a set of initiating events pre-established and consistent with accident analyses, and based on the following criteria:

1. Emergency Category 1 - Prealert: Operational scenarios or events of a limited nature in scope and severity that suggest potential degradation of the site's safety level. These events or scenarios on their own are not an imminent threat to facility safety or to

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the protection of site personnel or the public in general.

2. Emergency Category 2 - Emergency Alert: Operational scenarios or events that lead or could lead to a significant reduction of facility safety levels and which, therefore, could affect the protection of site personnel or the public in general.

That means it is not expected to have a release of radioactive material causing offsite exposure levels and requiring the implementation of urgent measures to protect the public in general. Exposure levels are expected to be lower than 5 mSv in 48 hours (effective dose) or 50 mSv in 48 hours (equivalent thyroid dose).

3. Emergency Category 3 - Site Emergency: Operational scenarios or events that lead or could lead to a very significant increase of exposure levels for site personnel and that require protective actions.

This category also includes the release of radioactive material, which could go beyond the *ZBCE* but would not result in dose levels exceeding the criteria requiring the implementation of urgent offsite protection measures. That means exposure levels between 5 and 10 mSv in 48 hours (effective dose) or 50 to 100 mSv in 48 hours (equivalent thyroid dose) could occur offsite.

4. Emergency Category 4 - General Emergency: Operational scenarios or events onsite that cause a real or potential risk of radiation exposure for the public or the release of radioactive material to the atmosphere, thus requiring the implementation of urgent protection measures offsite.

That means exposure levels higher than 10 mSv in 48 hours (effective dose) or higher than 100 mSv in 48 hours (equivalent thyroid dose) could occur offsite.

3.2 Initiating events. For every accident category and situation identified to comply with section 3.1, it is necessary to determine the initiating events which, once their occurrence is confirmed, require *PEI* activation and the rolling out of specific *PEI* protocols for each type of accident.

The definition of events shall be clear, concise and not susceptible to interpretations, thus permitting unmistakable communication of the nature and scope of a particular emergency.

For each accident category, the initiating events identified shall be classified in different groups depending on their nature, type of risk produced, affected facility systems and associated radiation level.

In operational nuclear power plants, making this classification entails defining at least the following initiating events:

1. Related to the nuclear steam supply system.
2. Related to other nuclear power plant systems.
3. Related to fire.
4. Related to plant security.
5. Related to events which are external in nature or have nothing to do with the abovementioned.
6. Related to Radiation Protection.

In the case of nuclear power plants in permanent shutdown and nuclear power plants being decommissioned, the type and number of initiating events will depend on risks associated to the site, its permit and its decommissioning phase.

Events will be classified in mutually exclusive groups with the aim to categorize actual emergency severity and thus cover the entire spectrum of potential events.

For the remaining nuclear facilities, the description of each initiating event shall ensure at all times that the most conservative aspects and most limiting conditions associated to the applicable event are taken into account.

3.3 Actions. For each emergency category, associated actions shall be established. These are as follows:

– Operational actions aimed at restoring facility safety levels.
– Notifying actions aimed at informing about facility conditions.

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– Emergency follow-up and evaluation actions.
– Response actions aimed at minimizing accident consequences.
– Protective actions.
– Activation actions for means, resources or infrastructures.
– Support actions for affected personnel.

The description of actions associated to each emergency category shall be clearly and concisely documented, and shall make reference to:

– The event or group of events requiring their implementation.
– The person/party responsible for their implementation.
– The means, resources and infrastructures needed.
– The expected outcome.
– Other actions which, in order to maximize effectiveness, could be required in parallel, either previously or afterward.

All strategies supporting the actions for each emergency category shall be designed in accordance with the Radiation Protection optimization principle.

In multi-unit nuclear power plants and when not all units are affected by the emergency, the licensee shall develop specific operational actions in the non-affected unit(s).

Actions for each emergency category shall take into account licensee responsibilities relating to protection and guardianship of all personnel onsite.

Actions for each emergency category shall consider all possible facility operational modes and, if needed, specific actions shall be developed for some operational modes, when needed.

3.3.1 Reference exposure levels in case of emergency. The licensee shall implement protection actions for onsite personnel who are not emergency workers , with the objective that, during an emergency, they do not receive a dose due to the emergency-related exposure scenario and under no circumstances higher than exposure levels established for the public on the Regulation on health protection against hazards associated to ionizing radiation exposure (Spanish acronym: *RPSRI*).

The licensee shall establish, as part of the development of actions required by section 3.3., a dosimetry control system for emergency workers, as well as mechanisms suitable for use during an emergency to adopt reference exposure levels for emergency worker in accordance with the following criteria:

– Whenever possible, adopted reference levels shall be below dose limits established for exposed workers in the above-mentioned Regulation.
– Reference levels lower than or equal to 100 mSv shall be established, depending on circumstances, for cases when the requirements of the previous paragraph cannot be met,
– Reference levels between 100 mSv and 500 mSv of effective external radiation dose shall be established, depending on circumstances, with the aim of facing exceptional scenarios in which it is paramount to save lives, prevent serious health effects or avoid the development of catastrophic conditions.

The licensee shall ensure that all emergency workers who are onsite and are liable to undertake actions whereby an effective dose of 100 mSv may be exceeded are clearly and comprehensively informed in advance of the associated health risks and the available protection measures and undertake these actions voluntarily. The licensee shall provide offsite organizations supporting emergency response with the dose information of workers participating in emergency response activities, to ensure such workers undergo medical surveillance in accordance with existing requirements and commensurate with received dose levels.

3.3.2 Specific criteria for actions resulting from Security-related initiating events. Clear and precise measures shall be established to ensure that, when security-related initiating events are identified, the *PEI* director is promptly advised by the head of security so that:

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– The initiating event is correctly identified and classified.
– Event severity, evolution and effects on Nuclear Safety and Radiation Protection onsite are correctly assessed.
– Coordination of actions foreseen within the Security Plan's Contingency Program and the *PEI* is made easier.
– Actions foreseen in case of security events to prevent or minimize threats and their onsite impact, including required operational facility actions of a preventive nature, are implemented.

3.4 Emergency Response Organization. Endowment. The licensee shall establish an Emergency Response Organization (Spanish acronym, *ORE*) adequately sized, qualified and equipped to tackle the accidents and situations described on section 3.1 and to carry out the actions defined according to section 3.3.

More specifically, the *ORE* shall comply with the following four criteria:

1. Sustainability, to ensure an ongoing capability to implement foreseen mitigation actions.
2. Flexibility, to ensure personnel turnovers, rest periods and arrival of support teams external to the ORE.
3. Completeness, to ensure the capacity to undertake tasks required by each emergency category actions, regardless of their priority associated to the accident type and evolution.
4. Robustness, to ensure control of emergency workers and their protection against all risks, including radiation.

Within the *ORE*, it is necessary to establish:

– An on-duty shift crew permanently onsite, and
– For operating nuclear power plants, an emergency on-call team easily activated and available onsite within an hour following activation.
– In the case of other facilities to which this Safety Instruction applies, an emergency on-call team easily activated and compliant with onsite availability criteria. In case their presence onsite exceeds one hour, justification is required.

Composition of the on-duty shift crew and emergency on-call team during the initial emergency phase, as well as subsequent activation of other emergency workers if required due to emergency severity and characteristics, shall ensure *ORE*'s capability to carry out the following:

– Emergency management and control activities.
– Plant operations and mitigation strategies needed to reach and maintain safe shutdown in the case of nuclear power plants, and safe conditions in the remaining facilities.
– Fire protection actions.
– Radiation Protection and Chemistry emergency tasks.
– Emergency category declaration activities.
– In-house and external communications.
– Notifying to competent authorities and agencies.
– Headcount, rescue and decontamination activities.
– Activities to request and manage offsite support.
– Dose estimates onsite and offsite.
– Radiological surveillance and characterization onsite and in the vicinity.
– Evacuation of non-essential personnel.
– Record keeping tasks for *ORE* activities.
– Other tasks within the scope of actions associated to each emergency category.

3.4.1 Emergency Director The licensee shall appoint the organization's individual in charge of leading and managing a site emergency: The Onsite Emergency Plan (*PEI)*

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Director. Some key *PEI* Director roles are as follows:

– Declaring the emergency category and emergency termination.
– Notifying the authorities, and
– Managing all actions and operations required to deal with the emergency.

Personnel qualified to cover the role of *PEI* Director and the order of precedence are clearly defined, as well as the protocol to transfer emergency management responsibility in case of replacement.

3.4.2 Other *ORE* positions. An organization chart containing all *ORE* positions shall be put together, providing information on the number of persons, hierarchical structure, and roles and responsibilities of each job position. Compliance with *ORE*'s sustainability, flexibility, completeness and robustness requirements shall be ensured, with the aim to carry out all tasks associated to each emergency category action.

Similarly, for every *ORE* position, it is necessary to draft a list of members within the licensee's organization who could serve in that position, establishing an order of preference when needed.

3.4.3 On-duty shift crew and emergency on-call team. With the aim to adequately size the on-duty shift crew and emergency on-call team in terms of the number of members and their qualification, the *ORE* shall be analyzed taking into account the aspects listed below. Operating nuclear power plants shall follow the analysis methodology allowing them to determine the resource needs of their emergency response organization.

The following aspects shall be considered during the analysis:

– The most conservative postulated accident, within the accidents analyzed in section 3.1. In other words, the most severe accident covering others for the purposes of this analysis.
– Analyzed accident(s) shall be assessed under two complementary boundary conditions, that is:

• Offsite events limiting the possibility of the emergency on-call team to access the site for 24 hours.
• Events causing the loss of large areas and part of the on-duty shift crew, if applicable according to the requirements of section 3.1.

– Human and material resources needed for the actions required to deal with the accident.
– Maximum time granted to emergency on-call team members to arrive onsite after on-call activation.
– Tasks that could be carried out by other *ORE* personnel not affected by a time limit in terms of their arrival onsite after activation.
– Time postulated for each operational action required to mitigate accident consequences, as well as other action alternatives when needed, all of it together with the implementation of actions associated to each emergency category.
– Tasks assigned to each *ORE* job position, their priority, implementation time needed and capabilities of *ORE* members to perform such tasks under accident conditions.
– Tasks associated to alternative mitigation actions in case foreseen actions cannot be carried out.
– Foreseeable response times of applicable offsite support under specific accident conditions.
– Needs associated to long-term emergencies lasting a number of days, weeks or months.

This analysis shall yield the following:

– Minimum on-duty shift crew staffing permanently onsite.
– Minimum staffing of the on-call emergency team.
– Maximum time granted to emergency on-call team members to arrive onsite after team activation.

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– Number of external supports, their capabilities and expected time for onsite arrival by each of these supports.
– Other aspects potentially needed to ensure compliance with analysis results.

Military Emergency Response Unit (Spanish acronym, *UME*) capabilities, available as a result of agreements between *UME* and nuclear power plant licensees, shall not be considered when carrying out this analysis.

The analysis required herein shall be reviewed and updated in accordance with state-of-the-art emergency management standards, at least every time the licensee carries out a periodic safety review, every time the *ORE* is modified and whenever required by the CSN.

3.5 Facilities, means and equipment foreseen for emergency management. All facilities, means and equipment necessary to comply with tasks associated to each emergency category action, shall be identified. Similarly, their characteristics shall ensure adequate compliance with assigned functions (measurement range, pump output pressure, rated voltage, etc.).

Specifically, the means, equipment and instrumentation needed to recognize initiating events shall be identified. In case of non-functionality of any means, equipment or instrumentation, compensatory measures and their implementation timeline shall be determined.

Facilities, means and equipment needed for emergency management shall be subject to a maintenance and test program compliant with section 4.5 of this Instruction, with the aim to ensure their reliability and availability.

3.5.1 Emergency management centers. Sites with nuclear facilities shall be equipped, at least, with the following emergency management centers:

– Control room or equivalent: It will serve as an emergency management center until the Technical Support Center is constituted.
– Technical Support Center (Spanish acronym, *CAT*).

Operating nuclear power plants shall also have an Alternative Emergency Management Center (Spanish acronym, *CAGE*).

The remaining nuclear facilities shall determine the need to have an alternative emergency management center depending on their risk assessment and the functionality and reliability of the above-mentioned *CAT*.

Emergency management centers need to comply with specifications relating to:

– Habitability.
– Ergonomics.
– Robustness in case of onsite and external events.

The functions and activation and usage procedures of each emergency management center shall be defined and need to include:

– Criteria for activation and evacuation, if needed.
– Overlaps with other emergency management centers in order to ensure one center is activated and available at all times.

Additionally, it is also necessary to specify the following for each emergency management center:

– Available documentation required to fulfill the assigned function.
– Means of communication available.
– Individual personal protective equipment available for *ORE* personnel that might need it, specifying the number of self-contained breathing apparatus and masks, as well as other personal protective equipment items.
– Available IT tools.
– Portable radiation measurement equipment available and procedures on their usage.
– Portable lighting equipment available.
– Activation procedures and usage criteria in each center, depending on accident

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severity and emergency duration.
– Access routes to each center and internal site pathways, which shall identify potentially contaminated routes and contamination-free routes.
– Equipment and logistics ensuring non-radiological habitability under the most severe usage conditions of each center for a specific period of time following center activation.

3.5.1.1 Equipment specifications for emergency management centers. Emergency management centers shall be equipped with communication means enabling:

– In-house communications onsite between *ORE* personnel and every center.
– Voice and data communications between each center and, on the one hand, the Operational Coordination Center of the offsite emergency directorate (Spanish acronym, *CECOP*) and, on the other hand, the CSN's Emergency Room (Spanish acronym, *Salem*).

These communication means shall have a redundancy level sufficient to ensure their reliability in case of multiple equipment, network or support failures.

Emergency management centers shall be equipped with tools to forecast offsite radiological consequences based on known accident data and its likely evolution.

Portable measurement equipment available at emergency management centers shall be capable of measuring under foreseeable ranges during emergencies. Such equipment shall be properly maintained to ensure its functionality at all times.

Portable lighting equipment with a minimum autonomy of 8 hours.

3.5.1.2 Alternative Emergency Management Center (*CAGE*) specifications. This emergency management center is an alternative to normal centers (CAT, CAO, Medical Service, etc.) in case the latter were unavailable during an Extensive Damage Emergency or any other circumstance resulting in the evacuation of such normal centers. It shall also be used under any other scenario if so decided by the *PEI* Director based on pre-established criteria.

Center design shall be essentially functional and robust, equipped with ionizing radiation protection and shielding, qualified to resist severe earthquakes, and with a minimum capacity to host simultaneously 70 individuals in 1-unit sites and 120 individuals in 2-unit sites. It shall be located further than 91.44 meters (100 yards) from buildings sensitive to potential impact of an aircraft, at a non-floodable elevation.

It shall be equipped with secured power supply, reinforced communications in comparison to the Technical Support Center, including satellite communications, filtered ventilation system, as well as other auxiliary services guaranteeing center habitability for at least 72 hours after activation.

Furthermore, the Alternative Emergency Management Center (*CAGE*) shall be equipped with:

– An emergency management area.
– A lab for active sample measurement.
– Equipment and personnel decontamination areas.
– An area to store different types of small materials (radiometric, protection, lighting and supplies).

3.5.2 Other emergency centers and areas. In the case of nuclear power plants in operation, it is necessary to define and identify the following emergency centers and areas:

– Operations support centers (Spanish acronym, *CAO*).
– Muster points for personnel subject to evacuation.
– Offsite emergency center (Spanish acronym, *CEE*).
– Offsite support center (Spanish acronym, *CSE*).
– Air evacuation platforms for arrival by air of offsite support.
– Safe areas where severe accident mitigation equipment are stored.
– Protected points.

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– Medical facilities.

For the remaining types of nuclear facilities, it is necessary to determine if the abovementioned emergency centers and areas are necessary and, if so, which would be their scope according to the site's risk analyses and characteristics.

For each of these centers, the following shall be described:

– Location.
– Equipment to be available.
– Roles in case of emergency.
– Activation modes.
– Personnel using them.
– Coordination mechanisms with other emergency centers.

3.5.3 Offsite support center (Spanish acronym, *CAE*). With the aim to ensure the diversity, independence and efficient complementarity to available emergency response measures, licensees of operating nuclear power plants shall establish and adequately maintain a centralized offsite facility resourced with specific equipment (duly tested and maintained) and professionals qualified and trained to install and operate such equipment, as well as to support the site's operational mitigation strategies within the first 24 hours following activation by the *PEI* Director. This facility shall be equipped with sufficient means to ensure availability of *CAE*-assigned personnel and equipment in each nuclear power plant.

It is necessary to establish the following:

– Criteria applied to request *CAE* means.
– Action procedures, including transport.
– Training programs and exercises.
– Required actions in case deficiencies are identified.

3.5.4 Other means. The licensee shall establish and adequately maintain portable equipment needed to carry out extensive damage mitigation strategies.

Similarly, the licensee shall establish and maintain transport equipment and means needed to carry out the radiological surveillance program for emergencies offsite.

Equipment and means needed to mitigate initiating events relating to fire and security shall comply with requirements in their specific plans.

The licensee shall have the equipment and means needed to ensure that under expected availability and environmental conditions of resources and infrastructures foreseen for extensive assessed damage scenarios, radioactive releases can be estimated in case of accident, including those involving extensive damage.

The licensee shall have onsite or offsite transport means, either of their own or hired, to carry out expected actions for protection and support of affected personnel, defining their actuation time, endowment and capabilities.

3.6 Onsite Emergency Plan. As required by Spain's Regulation on Nuclear and Radioactive Facilities (Spanish acronym: *RINR*), article 20.d), a facility licensee shall have an official operating document called Onsite Emergency Plan (Spanish acronym, *PEI*).

The *PEI* shall comply with *RINR* requirements and will be the document, along with the procedures through which it is endorsed, used to justify compliance with all requirements in this Regulatory Instruction.

The *PEI* could be supplemented by a set of procedures that need to be numbered in one of their annexes, refer to specific aspects mentioned on the *PEI* and are considered as the documentation through which it is endorsed.

The *PEI* shall contain the following information:

– General principles and bases, both administrative and technical, used to develop it.
– Detailed description of objectives, applicability and scope.
– The site's geographical location, more specifically, its geographical coordinates and elevation above sea level.

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- Expected facility licensee collaboration with competent and concerned administration bodies and agencies in charge of implementing and maintaining the efficacy of offsite emergency plans, as well as of carrying out protection measures and other emergency actions in accordance with the Basic Nuclear Emergency Plan (Spanish acronym, *Plaben*) and the Basic Planning Guide for Civil Protection in case of Radiological Risk (Spanish acronym, *DBRR*), as applicable.
- Mechanisms to coordinate and support offsite nuclear emergency plans.
- The list of procedures elaborating on it.
- Basic criteria and requirements established in this CSN Instruction.

3.6.1 Onsite Emergency Plan amendments. *PEI* modifications altering or modifying Nuclear Safety and Radiation Protection aspects need to be approved by the competent Ministry, based on a favorable report from the CSN. The approval request shall include a document justifying the changes proposed.

It is understood that Nuclear Safety and Radiation Protection aspects are modified when the nature of *PEI* modifications include the following:

a) Changes resulting from the application of new regulations or guidelines or instructions relating to emergency management.
b) Changes in the wording of initiating events.
c) Modifications in classification criteria for emergency categories and their declaration.
d) Modifications of the criteria and content of notifications to the authorities.
e) Changes in the licensee's response organizations and interaction between organizational units.
f) Changes in emergency equipment and in the installation and endowment of human and/or material resources associated to the response organization.
g) Changes in emergency response actions and measures.
h) Changes in Offsite Emergency Support roles.
i) Changes in plan maintenance mechanisms, including those affecting the *PEI* coordinator or the Training Plan and personnel training.

PEI modifications involving changes to the Emergency Response Organization shall include a document on change management that addresses the following content:

- Analysis and justification of organizational changes.
- Identification of affected documentation and program for their update,
- Training required for individuals affected by such changes and plans to undergo such training.
- Analysis of the impact of changes on the organization's technical capability, and
- Description of the change implementation process and program.

3.6.1.1 Minor Onsite Emergency Plan modifications. Other *PEI* modifications not entailing any of the aspects listed in section 3.6.1 could be considered as minor *PEI* changes.

Facility licensees can make minor changes to their *PEI* without the need for Ministry approval in case their operating license allows them to do so.

When a licensee approves a new *PEI* revision integrating only minor changes, the revised *PEI* version shall be submitted to the CSN within the timeline specified in article six of this SI, attaching a report justifying that the changes made are actually minor in accordance with the abovementioned criteria.

In all cases, minor *PEI* changes shall not entail a reduction of applicable revision requirements.

3.6.2 Management and control of Onsite Emergency Plan configuration and procedures elaborating on it. The licensee shall establish mechanisms and criteria to periodically analyze, update and improve the *PEI* and the procedures elaborating on it, as well as to officially approve a new *PEI* revision.

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The licensee shall have a procedure establishing required timelines for the entry into force of a new *PEI* revision relating to:

– Distribution of controlled copies to the licensee's emergency centers, both onsite and offsite.
– Training for *ORE* personnel on changes included in the new *PEI* revision.

PEI revisions shall come into effect, at the latest:

– The day after their approval by the licensee, in case only minor changes were made.
– In the remaining cases, the day after modification approval resolution by the competent Ministry is firm for all purposes.

Documents elaborating on the *PEI* shall always be updated and come into effect the same day the corresponding *PEI* version comes into effect onsite. Revisions of documentation elaborating on *PEI* and not associated to *PEI* revision shall come into effect the day after their approval by the licensee.

The licensee shall have distribution records for controlled *PEI* copies and procedures elaborating on it, as well as for additional emergency support documentation assigned to emergency management centers.

Four. *Preparation and maintenance of emergency management.*

4.1 Qualification and training of *ORE* personnel. The licensee shall carry out a systematic analysis of needs associated to all *ORE* job positions using the SAT methodology. Analysis results will support the development of induction and refresher training programs for *ORE* personnel.

The licensee shall determine induction training needs for each *ORE* job position, as well as the process to update training contents yearly with the aim to include in-house operating experience, information on relevant accidents and CSN requirements.

The licensee shall establish an emergency preparedness training program containing the minimum practical and theoretical training required per person and year, as well as the contents to be delivered in order to cover all training requisites for each *ORE* job position. Similarly, the following shall also be established:

– Criteria to evaluate program compliance.
– Compensatory measures in case of program non-compliance. Such cases shall be duly justified.

It is necessary to ensure that all *ORE* job positions are sufficiently staffed with properly trained and qualified professionals, taking into account necessary shift work and turnovers for all types of emergencies, including those that may last weeks and, in the case of nuclear power plants, those that may affect more than one unit.

4.2 Exercise-based training plan. The licensee shall establish an exercise-based training plan which shall:

– Identify all tasks and activities for actions within each emergency category, including strategic actions associated to the Extensive Damage Management Guidelines (Spanish acronym, *GEDE*) and Extensive Damage Mitigation Guidelines (Spanish acronym, *GMDE*), when applicable.
– Ensure that all tasks and activities are periodically trained by all *ORE* personnel responsible for the implementation of such tasks and activities.
– Establish a period of less than five years to cover all training contents linked to every possible scenario and accident.
– Establish an exercise evaluation procedure that favors the gathering of lessons learned.
– Establish compensatory actions in case of program non-compliance. Such cases shall be duly justified.

An annual exercise program shall be developed based on the exercise-based training

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plan that is to be submitted to the CSN in the last quarter of the year prior to their implementation.

The scope of the exercise-based training plan shall at least address the following:

– Operation of equipment and systems (for communications, accident evaluation, dose estimate, fire protection, healthcare, radiological surveillance, portable devices, plant systems).
– Use of personal protective equipment.
– Basic knowledge on emergency protection measures.
– Command and control actions.
– Coordination of emergency groups.
– Knowledge of the facility and of emergency equipment, means and premises.
– Handling of procedures, instructions and guidelines.

The exercise-based training plan shall contain at least the following aspects:

– Evaluation and identification of initiating events.
– Categorization and declaration of emergencies.
– Communications and notifications.
– First Aid, rescue and decontamination.
– Radiological evaluation and surveillance (onsite and offsite).
– Procedures for taking samples during accidents.
– Fire protection.
– Location of personnel, area evacuation, headcount and access control.
– Coordination amongst emergency centers, support centers and agree support service providers.
– Application of Severe Accident Management Guidelines or Manuals (in facilities where these are available).
– Implementation of strategies contained within the *GEDE* and *GMDE* (in facilities where these are available).
– Activities and tasks assigned to offsite support groups.

The frequency of exercises containing the abovementioned aspects is annual. However, in the case of exercises to test offsite support groups, their capabilities, the compatibility of their equipment with plant means and the mechanisms to ensure coordination with their organizations, the frequency shall be no less that once every five years.

Lessons learned through the exercise evaluation procedure shall be integrated within the *PEI*, the procedures elaborating on it or other emergency management documents, as applicable and within a period not exceeding two years since they were identified.

Documentation records for each exercise shall be kept.

The facility licensee shall draft and send to the CSN during the first quarter of the year a report on implementation of the training and qualification program for licensee *ORE* personnel. The report shall include information on initial and refresher training for emergency preparedness, as well as on training program deviations.

This report shall contain at least the following information regarding the induction training program for *ORE* candidates:

– Scheduled classroom sessions.
– Completion dates.
– Name and position to be covered by classroom session attendees.
– List of personnel included within the induction training program who did not attend training.
– Result of individual evaluations for each participant.
– Lessons learned and improvement proposals identified.

With regards to classroom training and refresher training for *ORE* personnel, the report shall contain the following information:

– List of classroom sessions completed, date, name and position of participants.

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- Result of individual evaluations for each classroom session participant.
- List of exercises carried out.
- Completion dates.
- Name and position of personnel expected to attend each exercise.
- Support organizations participating in each exercise.
- List of personnel included within the exercise program who did not participate in such exercises.
- Result of individual evaluations for each exercise participant.
- Lessons learned, timelines and actions for implementation, actions pending and people in charge.
- Other recommendations, if applicable.

The licensee shall ensure that lessons learned and recommendations included in the report are implemented within a timeline commensurate with their emergency management system relevance.

The licensee shall ensure that at least once per semester, the progress of actions and recommendations derived from the report is monitored and recorded.

4.3 *PEI* drills. The licensee shall prepare a multi-annual drill program:

a) In the case of operating nuclear power plants, an annual emergency drill shall be carried out.
b) In all other facilities, drill frequency shall be that established by their *PEI*.

The licensee shall draft a plan for each drill, outlining objectives and ensuring that all *ORE* positions are activated as part of the response.

The licensee shall ensure that the operation of the facility is not disturbed while carrying out the drill.

The CSN may request the licensee to carry out an emergency drill at any time with the aim to check its emergency response capabilities. To do that, the CSN would issue the necessary specific instructions.

The CSN shall establish the minimum scope of the drill scenario every year.

In accordance with the minimum scope and for every five-year cycle, scenario content shall include at least the following situations in case they apply to the site:

- Hostile action onsite.
- Rapidly evolving accident, starting as or quickly changing to a category 3 or category 4 emergency.
- Multiple units affected simultaneously.
- Extensive damage accident.
- Loss of emergency centers.

Scenario contents shall not be distributed to or known by personnel in the licensee's emergency organization who are to participate in the drill.

Two months prior to the date of the drill, it is as necessary to submit to the CSN, as confidential information and to the attention of the individual/unit in charge, a detailed Drill Plan proposal which shall take into account the following:

- Minimum scope established by the CSN.
- Specific scenarios considered.
- Zero hour marking the start of simulation.
- Initial operating conditions onsite.
- The foreseen timeline of initiating events, and
- Estimated times when these will take place.

Drill duration, which shall not be known by site personnel, needs to ensure achievement of objectives foreseen in the yearly drill plan.

With the exception of duly justified cases, only operations personnel not in the shift crew at the time of the drill will be allowed to participate and carry out specific roles as part of the drill.

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All personnel onsite have to participate in the drill, with the exception of a few limited cases which shall be duly justified before the drill.

The drill scenario will have a window approach, meaning the start of the drill may coincide with stable facility operation and appearance of a first initiating event, or alternatively, with a specific emergency response moment declared prior to the start of the drill. Similarly, the end of the drill may coincide with the recovery of facility safety and control functions, or be determined in a particular emergency response moment, even if this did not occur.

The licensee shall appoint a main *PEI* drill controller who, with the support of a team sized according to the proposed scenario and licensee's *ORE* size, shall ensure objective compliance, assess *ORE* actuation during *PEI* drill, and evaluate the suitability of equipment and procedures used during emergency management.

In its detailed drill planning, the licensee shall establish expected response actions for each scheduled event. The licensee shall have command orders available to address hypothetical deviations from drill objectives, if needed.

Prior to the start of the drill, the licensee shall promptly confirm that conditions onsite or in the surroundings do not impede drill rollout. If conditions changed during the drill, the licensee could interrupt it if rendered necessary.

The licensee shall establish a drill program ensuring that all *ORE* personnel have taken part in a drill at least once every five years.

It is required to keep documentation records for each drill carried out. As a minimum requirement, such records shall contain:

– The scenario.
– Command and control orders.
– Controller(s) reports.

Furthermore, for each drill the licensee shall draft a report containing the following information:

– Main drill aspects.
– Name and position of participating personnel.
– Compliance with set objectives.
– Command and control actions.
– Support organizations participating in the drill.
– List of personnel included within the drill program who did not participate in such drills.
– Lessons learned, timelines and actions for implementation, actions pending and people in charge.
– Other recommendations, if applicable.

This report shall be submitted to the CSN within two months after drill completion.

4.4 Emergency preparedness organization. The licensee shall ensure that its organization has a group with sufficient human and technical resources to comply with the requirements of this Instruction at all times.

The sizing of such group shall be commensurate with the size of both the facility and *ORE*.

Such group shall be led by the *PEI* Coordinator, who will have direct hierarchical access to the facility director with the aim to ensure the licensee's emergency management system operability and to satisfactorily address any arising incidence.

4.5 Maintenance of emergency facilities, equipment and means. The licensee shall ensure that all installations, equipment and means needed to carry out the actions associated to each emergency category undergo a type of maintenance ensuring their availability at all times. To do that, they shall draft the necessary procedures containing at least the following information:

– Inventory of emergency equipment and means.

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– Description, location and features of each equipment or facility.
– Description of required tests.

The licensee shall establish a maintenance and test program to ensure the operability of emergency facilities, the functionality of equipment and the availability of material needed during emergency management activities. Such program shall at least contain the following:

– The types of tests (verification, calibration, functionality, etc.).
– Test acceptability criteria.
– Test frequency.
– Compensatory measures in case acceptability criteria are not met.

This program shall also include a test scheme to check in-house communication coverage onsite.

Five. *Emergency response.*

5.1 Notifying to competent organizations. The licensee shall notify the occurrence of any initiating event mentioned on section 3.2 of this Instruction to the following parties:

– CSN's *Salem*, and
– The Operational Coordination Center of the offsite emergency directorate.

Notification timelines are as follows:

– Within 30 minutes after identification of the initiating event via a voice transmission channel.
– Within 60 minutes after identification of the initiating event via a data transmission channel.

Voice and data transmission channels to be used when notifying an initiating event shall be established by the CSN, which will inform the licensee.

The reporting form shall at least contain the following information:

– Affected facility.
– Organizations which were informed.
– Type of event.
– Emergency category.
– Time of occurrence
– Facility status.
– Barrier integrity, if applicable.
– Weather conditions.
– Source term estimate.
– Global estimate of offsite radiological impact.
– Request for external support.
– Foreseen evacuation of non-essential personnel.
– Existence of wounded or contaminated individuals, and
– Any other information that is relevant or was expressly required by the CSN's *ORE* or Offsite Plan Management.

The results of offsite radiological impact calculation codes, when they exist, shall be attached as annexes to the notification form.

In nuclear power plants sites with two units, the notifying form shall contain all the information needed to have detailed knowledge of the status of each unit and the emergency category onsite, declaring the most conservative category for each unit at all times, as well as carrying out the necessary specific actions in each unit.

The licensee shall submit a new notifying form every time any of the reported parameters changes in a way in which onsite emergency management or offsite emergency management could be impacted.

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In situations where foreseen automatic parameter transmission channels from the site to the CSN's *Salem* are lost or not being received, or if required by the CSN, previously established parameters shall be exchanged between the CSN and the licensee by non-automatic alternative means in intervals of no more than 30 minutes or with the frequency established by the CSN's *ORE*.

The decision to evacuate non-essential personnel from the site shall be communicated to the CSN's *Salem* for information purposes, and to the Operational Coordination Center of the offsite emergency directorate for authorization purposes.

When activation of the filtered containment venting system of operating nuclear power plants is being considered, the *PEI* Director shall inform the CSN's *Salem* and the Operational Coordination Center of the offsite nuclear emergency directorate as soon as possible to ensure adequate coordination with authorities in charge of offsite emergency management. Such coordination shall be developed onto a *PEI* procedure.

Emergency termination shall also be reported by phone, confirming it with a data transmission channel as soon as possible.

5.2 *ORE* activation. The licensee shall develop an *ORE* activation procedure, which shall at least refer to the following aspects:

– Activation means and mechanisms.
– Timelines for personnel arrival onsite.
– Levels of activation.
– Tests for periodic checks.
– Acceptability criteria for such tests.
– Compensatory and corrective measures in case acceptability criteria are not met.

Activation, either real or simulated, shall be documented.

An annual report shall be drafted and submitted to the CSN in the first quarter of each year, containing information on activation tests carried out throughout the previous year, as well as a section referring to deficiencies identified and lessons learned.

5.3 *ORE* actions in case of emergency. The licensee shall implement the actions relating to each initiating event, as required in section 3.3, with a special focus on personnel dosimetry controls onsite and the deployment of all operational and protection capabilities available at the facility.

5.4 Communications. It is required to have at least two independent, redundant communication networks between the licensee's emergency management centers and the CSN's *Salem*. Such networks shall be reliable and enable voice and data transmission with the aim to provide the information required under the most severe accident scenarios and offsite events with potential consequences outside the facility.

In the case of nuclear power plants with fuel onsite, licensees shall also have an alternative, highly reliable communication system using satellite technology. Such system shall be available for communications with both offsite emergency management centers (*CECOP* in the case of the Offsite Nuclear Emergency Plan and *Salem* in the case of the CSN) and *ORE* personnel.

In addition to voice communication, submittal of emergency data shall use channels and mechanisms authorized by the CSN at any given moment.

5.5 Participation of external *PEI* supports. Actions associated to each emergency category to be carried out in accordance with the requirements of section 3.3 in this Instruction, shall determine external supports needed to meet the objectives of those actions.

In the case of every external support needed for each action, it is necessary to establish the following:

– Foreseen scope of support.
– Activation mode.
– Emergency conditions that may require their activation.
– Periodic test and exercise program ensuring their capabilities.

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External supports may refer, amongst other, to support in the following areas:

– Fire protection.
– Security.
– Healthcare.
– Logistics.

5.5.1 Participation of the Military Emergency Response Unit as an external *PEI* support. With the aim to consolidate the nuclear emergency response self-sufficiency of licensees' *OREs*, actions for each emergency category developed in accordance with the requirements of section 3.3 of this SI shall be capable of being implemented and achieving their objectives without the need to use *UME* resources, which without exception are considered as additional resources to those actually needed.

Nevertheless , the licensee could also opt to have a procedure to notify the UME, to request the activation and reception of *UME*'s external support, if that was provided in existing agreements between *UME* and the nuclear industry. The abovementioned notification procedure shall honor at all times the instructions given for such scenarios by the Ministry of Home Affairs' General Directorate of Civil Protection and Emergencies.

This procedure shall at least refer to the following:

– Foreseen *UME* support.
– Methods to request the activation of *UME* support and inform *UME* about this request.
– Emergency conditions that may require their activation.
– Periodic test and exercise program ensuring *UME* capabilities onsite.

Requesting *UME* resources shall be justified and always submitted in case of emergency situations involving extremely serious accident scenarios, in line with the abovementioned agreements.

5.6 Emergency termination. It is necessary to define the criteria for terminating an emergency within the onsite response level.

Such criteria shall at least consider the following:

– Aspects relating to site and facility conditions.
– Aspects relating to coordination with competent authorities.

It is necessary to establish the actions to carry out upon emergency termination.

In case a real emergency is declared and within 30 days after the emergency is rendered terminated, the licensee shall submit to the CSN a specific emergency report containing at least the following information:

– Similar previous emergencies onsite.
– Identification of initiating events, as well as emergency classification and declaration.
– Emergency description.
– Initial and final facility status.
– Emergency timeline.
– Activation of the licensee's ORE. Name and position of participating personnel.
– Activation of emergency centers.
– Support organizations activated and and/or playing an active role.
– Command and control actions.
– Evaluation, monitoring, corrective, protective and support actions to help affected personnel during the emergency. Evaluation of the level of compliance.
– Reporting to official agencies. Coordination.
– Declaration of emergency termination and facility recovery actions.
– Data gathering and analysis.
– Emergency assessment from the perspective of Radiation Protection of participants, the public and the environment.
– Pending *PEI*-related corrective and improvement actions prior to the emergency, as well as the individuals/units responsible for such actions.
– Lessons learned, deficiencies and corrective measures triggered by the

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emergency; timelines and actions for implementation based on emergency management significance; identification of individuals/units in charge.
– Other recommendations, if applicable.

This report shall be included as operating experience for the rest of facilities.

Six. *Records and documentation.*

All records generated during the response to a real emergency shall be considered records subject to quality assurance with a permanent hold period.

Each new revision of *PEI* and the procedures elaborating on it shall be submitted to the CSN's *Salem* and to the Operational Coordination Center of the offsite emergency directorate within 10 days since its entry into force.

All emergency response documentation associated to emergency management centers shall be considered as "controlled copy".

The licensee shall keep record of evaluations made of *PEI* and the procedures elaborating on it, as well as of annual audits made to these procedures.

The CSN shall establish and update for each facility specific instructions reflecting the type of documents to be submitted by means of controlled copies to the CSN's *Salem* with the aim to adequately monitor emergencies in terms of Nuclear Safety and Radiation Protection.

Seven. *Quality Assurance Program.*

The emergency management system is subject to the licensee's quality assurance program.

The emergency management system shall be audited every year.

Procedures shall be established for all activities relating to quality assurance program implementation.

The licensee shall keep record of annual quality assurance audits of the emergency management system, which need to include at least the following:

– Audited activities.
– Non conformities.
– Observations and improvement opportunities.
– Improvement actions, corrections.
– Corrective actions.

Furthermore, all documentation issued during emergency management system processes shall be subject to the licensee's quality assurance program, including documentation associated to the Corrective Action Program (CAP).

Every half year, the licensee shall monitor the status of Quality Assurance program actions relating to emergency management.

Eight. *Exemptions and equivalent measures.*

The CSN may grant temporary exemption from any requirement in this Instruction, provided the licensee justifies both the difficulty of meeting such requirements as established and therefore its inability to ensure compliance, as well as the proposed compensatory measures for such exemption.

Upon licensee request, the CSN could favorably assess equivalent measures to comply with this Instruction requirements, provided the licensee adequately substantiates such compliance by justifying proposed equivalent measures.

Nine. *Infringements and Penalties.*

This CSN Instruction has a binding nature, in accordance with the provisions of article 2.a) of Law 15/1980, dated April 22nd, on creation of the *Consejo de Seguridad Nuclear*, meaning failure to comply with it shall be sanctioned in accordance with Chapter XIV

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(articles 85 through 93) of Nuclear Energy Law 25/1964, dated April 29th.

Single transitional provision. *Adaptation period.*

Nuclear facility licensees shall have a period of six months from the entry into force of this Instruction to submit to the relevant ministry a *PEI* change proposal fully compliant with this Instruction.

Sole derogating provision. *Repeal provision.*

Any provision of equal or lower rank that opposes this Instruction, is hereby repealed.

Sole final provision. *Entry into force.*

This Instruction shall go into effect the day after its publication in Spain's Official Gazette.

Madrid, February 26th, 2020 – The Chairman of the Nuclear Safety Council, Josep Maria Serena i Sender.