Nuclear Safety Council Instruction number IS-19, of October 22nd 2008, on the requirements of the nuclear facilities management system

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CSN

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Nuclear Safety Council Instruction number IS-19, of October 22nd 2008, on the requirements of the management system for nuclear facilities

Article 2.a) of the Law creating the Nuclear Safety Council, Law 15/1980 of April 22nd, in the wording given by Law 33/2007of November 7th, attributes to this public entity powers to "draw up and approve technical instructions, circulars and guides regarding nuclear and radioactive facilities and activities relating to nuclear safety and radiological protection" in relation to the safe operation of the said nuclear and radioactive facilities, that is without undue risk for persons or the environment. This article has been reinforced by Law 33/2007 of November 7th, which incorporates the promotion of participation by the stakeholders and the public in the process of drawing up these instructions.

In July 2006, the International Atomic Energy Agency (IAEA) published its *Safety Requirements* document No. GS-R-3 *The Management System for Facilities and Activities*, which defines the applicable requirements to establish, implement, evaluate and continuously improve a management system for nuclear and radioactive facilities. The requirements defined imply the integration of management of the aspects of nuclear and radiological safety, health, environmental, security, quality and economic elements, to ensure the protection of people and the environment. Document GS-R-3 replaces the IAEA Code and Safety Guides 50-C/SG-Q *Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations*, of 1996.

At present the Spanish nuclear facilities have separate or not fully integrated systems for the management of nuclear safety and radiological protection, occupational risk, environmental protection, security and economic issues, and have implemented Quality Assurance Programmes that meet the requirements of IAEA code 50-C/SG-Q, as a result of which many or most of the concepts of the *Safety Requirements* document No. GS-R-3 have already been introduced; consequently, the effort to be made would fundamentally be that required to integrate the management of these items.

In addition, during 2006 the nuclear power plants have drawn up Integrated Management Manuals based on the Unesa Guideline CEN10, Rev. 0, of July 2004, which constitutes a first step in implementation of the integrated management of aspects affecting safety.

The present Nuclear Safety Council Instruction defines the requirements for the establishment, implementation, evaluation and on-going improvement of a management system at nuclear facilities, integrating nuclear safety and radiological protection, the health, environmental protection, security, quality and economic issues, based on the IAEA *Safety Requirements* document No. GS-R-3. This document, and the corresponding IAEA guidelines through which it is enacted, constitute acceptable references for the implementation and application of this Instruction.

Although document GS-R-3 replaces IAEA Code and Safety Guides 50-C/SG-Q, this document does not explicitly include all the quality requirements applicable to nuclear facilities, for which reason point 2.4 of this Instruction provides that the applicable quality requirements are those contained in standard UNE 73 401:1995, which contains and does not contradict the requirements established in Appendix B of 10CFR50 and in IAEA code 50-C/SG-Q. These standards are also acceptable references in the application of quality requirements.

Safety is the fundamental principle on which the aforementioned management system is based. The present Instruction does not seek to define all those specific requirements,

except the quality requirements established in point 2.4, which are to be considered in relation to the health, environmental protection, security and economic management and which have already been established in other regulations, but to define the requirements in order to manage their compliance in an integrated manner.

This Instruction contributes to the achievement of the two major objectives of a management system:

– Improve the safety performance of the organisations through the planning, control and supervision of activities relating to nuclear safety under normal, transient and emergency situations.
– Encourage and promote a solid safety culture through the development and strengthening of appropriate attitudes and behaviours with respect to nuclear safety among individuals and groups of persons, with a view to ensuring that they perform their tasks safely.

The contents of this Instruction are based on two key concepts: the activities of a nuclear facility may be structured and interpreted as a set of interactive processes and all the persons participating in these processes contribute to the achievement of the objectives of safety and quality.

Pursuant to the above, and in keeping with the legal entitlement contemplated in article 2.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, this Nuclear Safety Council has agreed as follows during its meeting held on October 22nd 2008:

One. Objective

1.1. The objective of the present Instruction is to identify the applicable requirements for establishing, implementing, assessing and continually improving a nuclear facilities management system integrating safety (1), the health, environmental, security (2), quality and economic elements, to ensure that safety is properly taken into account in all activities of an organization.

1.2. The objective of the requirements of the management system is to ensure, by considering the implications of all actions not within separate management systems but with regard to safety as a whole, that safety is not compromised.

Two. Field of application and scope

2.1. The present Instruction is applicable to the establishment, implementation, evaluation and continually improvement of the nuclear facilities management system.

2.2. It is applicable throughout the lifetime of nuclear facilities including siting, design, construction, commissioning, operation And decommissioning

2.3. Compliance with the requirements applicable to nuclear facilities shall be managed in an integrated manner to ensure the safety. The definition of specific requirements shall be beyond the scope of this Instruction, with the exception of the quality requirements established in point 2.4, which shall be met in relation to the health, environmental, security and economic management, as established in other regulations.

(1) This term refers to nuclear safety and radiological protection.
(2) Security-related activities may be of a confidential nature.

2.4. The quality requirements shall be managed in an integrated manner with the other elements of the management system, shall fulfil the requirements of standard UNE 73 401 of June 1995 “Quality assurance at nuclear facilities” and shall attain the highest

internationally recognised standards of quality in the nuclear field.

2.5. The requirements of the management system, as defined in the present Instruction, cover issues that are either directly related to safety or are part of the management structure, without which safety cannot be ensured and maintained. Consequently, questions such as management commitment, communications and other aspects are included from the perspective of seeking to enhance safety as well as performance.

Three. Definitions

The definitions of the terms and concepts used in the present Instruction correspond to those established in this section and those contained in the legal documents indicated below:

– Nuclear Energy Act, Law 25/1964, of April 29th, modified by Law 33/2007, of November 7th.

– Law creating the Nuclear Safety Council, Law 15/1980, of April 22nd, modified by Law 33/2007, of November 7th.

– Royal Decree 1836/1999, of December 3rd, approving the Regulation on Nuclear and Radioactive Facilities, modified by Royal Decree 35/2008 of January 18th.

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

To which are added the following specific definitions:

Corrective action: action to correct the causes of a non-conformity, preventing its repetition.

Correction action: action to correct a non-conformity.

Improvement action: action to improve the efficiency or effectiveness of a process or activity that meets the applicable requirements.

Preventive action: action to prevent the occurrence of a potential non-conformity.

Top management: person or group of persons directing, controlling and evaluating an organisation from its highest levels.

Self-assessment: systematic and continuous process applied by the top management and the management personnel at other levels of the organisation to assess the efficiency of performance in all their areas of responsibility.

Safety culture: The assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.

Integrated management system documents: the term document may include policies, procedures, instructions, specifications and drawings (or representations on other media), training materials and any other documents that describe processes, specify requirements or establish product specifications.

Independent assessment: evaluations such as auditing or surveillance activities performed to determine the degree of compliance with requirements relating to the management system, assess the efficiency of the management system and determine opportunities for improvement. These evaluations may be carried out by the organisation itself or on its behalf, for internal purposes, by the stakeholders, for example clients and regulators (or other persons on their behalf) or external independent organisations.

Stakeholder groups: persons or groups having an interest in the operation of an organisation. Examples of stakeholder groups may be clients, owners, employees, suppliers, partners, trade unions, professional

organisations, regulatory authorities, the media, the public, other countries, etc.

Non-conformity: non-compliance with a mandatory external requirement (law, standard, etc.) or voluntary internal requirement (policy, procedure, etc.).

Regulatory authority: authority or set of authorities having legal powers to undertake the regulatory process, including the granting of authorisations, and in this way regulate nuclear and radiological safety and the safety of radioactive wastes and transport. This description includes the national authority in charge of regulating safety in the transport of radioactive materials and the regulatory authority responsible for radiological protection and safety.

Management personnel at all levels: group of persons directing, controlling and evaluating the activities of an organisation from any of its levels.

Processes: set of mutually related or interacting activities that transform inputs into results. Examples of processes at a nuclear facility are design, maintenance, operation, documentary control, inspections and testing, the control of measuring and testing equipment, the control of corrective actions, waste management, interfaces with the regulatory authority, etc.

Products: these are the results of processes. Examples of products at nuclear facilities are structures, systems, components, documents, procedures, records, services, etc.

Resources: persons, infrastructures, the working environment, information and know-how, suppliers and material and financial assets.

Management system review: regular and systematic evaluation performed by senior management of an organisation of the suitability, adequacy,, efficiency and effectiveness of its management system in executing of the policies and achieving the goals and objectives of the organization.

Safety (nuclear safety and radiological protection): achievement of the correct operating conditions and prevention of accidents or mitigation of their consequences, the result being the protection of the workers, the public and the environment against undue dangers caused by radiation.

Management system: set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective way . The management system integrates all the elements of an organisation into aone coherent management system in order to allow all the objectives of the organisation to be achieved.
These elements include the structure, resources and processes. The personnel, equipment, institutional culture and documented policies and processes are part of the management system. The organisation's processes have to address all the requirements on the organisation as established in, for example, the IAEA safety standards and other international codes and standards.

Four. Management system

4.1. General requirements

4.1.1. A management system shall be established and continuously assessed and improved. The system shall be aligned with the objectives of the organisation and shall contribute to their achievement. The management system shall be aimed mainly at achieving and improving safety:

–Bringing together in a coherent manner all the requirements for managingt of the organisation.

– Identifying the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied.

– Ensuring that requirements relating to the health, environmental , security, quality and economic management are not considered separately from safety requirements, with a view to helping to prevent their having negative effects for safety.

4.1.2. Safety shall be paramount within the management sustem, overriding all other demands.

4.1.3. In addition to its own requirements, the management system shall identify and integrate all the other requirements applicable to the facility, including legal and regulatory requirements, the requirements formally agreed to with stakeholder groups or the requirements of codes and standards adopted for use by the organisation.

4.1.4. The organisation shall at all times be able to demonstrate the effective fulfilment of its management system requirements.

4.2. Safety culture

4.2.1. The management system shall promote and support a solid safety culture by means of the following:

– Ensuring a common understanding of the key aspects of the safety culture within the organisation.

– Providing the means by which the organisation supports individuals and teams in carrying out their tasks safely and successfully,, taking into account the interaction between individuals, technology and the organisation.

– Reinforcing a learning and questioning attitude ar all at all levels of the organisation.

– Provision of resources facilitating the efforts of the organisation to develop and continuously improve its safety culture.

4.3. Grading of application of the requirements of the management system

4.3.1. The requirements of the management system shall be graded to ensure that adequate resources are assigned on the basis of the following considerations:

– The importance for safety and the complexity of each element of the facility or activity.

– The risks and magnitude of the possible impacts associated with safety, the health, environmental, security, quality and economic elements of each product or activity.

– The possible consequences of failure of a product or the incorrect performance of an activity.

4.3.2. The requirements of the management system shall be applied in a graded manner to the products and activities of each process.

4.4. Management system documentation

4.4.1. The management system shall be described in a specific document and developed by way of the documents, procedures and instructions required for its adequate application.

4.4.2. The management system documentation shall include the following:

– The declaration of the policies of the organisation.

– A description of the management system.

– A description of the structure of the organisation.

– A description of the functional responsibilities, general responsibilities, levels of authority and interactions of those in charge of the management, performance and evaluation of the work.

– A description of the processes and complementary information explaining how the work will be prepared, revised,

performed, recorded, evaluated and improved.

4.4.3. The management system documentation shall be drawn up in such a way as to be understandable for those required to use it, legible and easily identified and shall be available at the place of use.

4.4.4. The management system documentation shall reflect the following:

– The characteristics of the organisation and its activities.

– The complexities of the processes and their interactions.

Five. Management responsibility

5.1. Management commitment
5.1.1. Management at all levels shall demonstrate their commitment to the establishment, implementation, assessment and continual improvement of the management system and shall assign the resources required to carry out these activities.

5.1.2. The top management shall develop individual and institutional values and behavioural expectations for the organisation to support the implementation of the management system and shall act as role models in the promulgation of these values and expectations.

5.1.3. Mmanagement at all levels shall communicate to individuals the need to adopt these individual and institutional values and behavioural espectation as well to comply with the requirements of the management system.

5.1.4. Management at all levels shall promote the participation of all the employees in the implementation and on-going improvement of the management system.

5.1.5. The top management shall ensure that there is a clear definition of when, how and by whom decisions will be taken within the management system.

5.2. Satisfaction of stakeholder groups
5.2.1. The top management shall take into account the expectations of the stakeholder groups in the activities and interactions in the processes of the management system, in order to enhance satisfaction of the said stakeholder groups and at the same time guarantee that safety is not compromised.

5.3. Organisational policies
5.3.1. The top management shall establish the policies of the organisation, which shall be appropriate for the organisation's activities and facilities.

5.4. Planning
5.4.1. The top management shall establish goals, strategies, plans and objectives (at times known as business plans, strategic plans, operating plans, etc.) in keeping with the policies of the organisation.

5.4.2. The top management shall establish the goals, strategies, plans and objectives of the organisation in an integrated manner, such that their collective impact on safety be adequately understood and managed.

5.4.3. The top management shall ensure that measurable objectives are established at different levels of the organisation and by means of appropriate processes for implementation of the goals, strategies and plans.

5.4.4. The top management shall ensure that implementation of the plans is periodically revised on the basis of these objectives and that the measures necessary to correct deviations from the plans are adopted when necessary.

5.5. Responsibilities and authority relating to the management system
5.5.1. The top management of the organisation is ultimately responsible for the management system and shall ensure its

establishment, implementation, evaluation and on-going improvement.

5.5.2. A person or organisational unit reporting directly to the top management shall be accountable and have authority for the following:

– Coordination of the establishment and application of the management system and of its evaluation and continual improvement.

– Reporting on the operation of the management system, including its influence on safety and the safety culture and on needs for improvement.

– Solving of possible conflicts between requirements and within the processes of the management system.

5.5.3. The organisation owning the facility shall retain overall responsibility for the management system in those cases in which an external organisation participates fully or partially in development of the system.

Six. Management of resources

6.1. Assignment of resources

6.1.1. The top management shall determine and provide the resources required for performance of the activities of the organisation and to establish, apply, evaluate and continuously improve the management system.

6.1.2. The information and know-how of the organisation shall be managed as a resource.

6.2.Human resources

6.2.1. The top management shall determine the degree of competence required for individual at all levels and shall provide training and adopt adequate measures to achieve and maintain the required level of competence. The effectiveness of of the actions adopted shall be evaluated.

6.2.2. The top management shall ensure that the employees have the competence required for the performance of the tasks assigned to them and that they understand the impact of their activities on safety. The personnel shall have received appropriate training and preparation and shall have acquired the skills, knowledge and experience required to ensure their competence. Training shall be used to ensure that the personnel are aware of the interest and importance of their activities and how they contribute to safety and to achievement of the objectives of the organisation.

6.3. Infrastructure and working environment

6.3.1. The top management shall determine, provide, maintain and re-evaluate the infrastructure and the working environment required for the activities to be performed safely and a manner such that compliance with the requirements is facilitated.

Seven. Performance of processes

7.1. Establishment of processes

7.1.1. The processes (3) of the management system (4) required to achieve the objectives, provide the resources for compliance with the requirements, generate the products of the organisation and safely operate the facility shall be identified. The development and implementation of the processes shall be planned, evaluated and continuously improved.

7.1.2. The sequence and interactions of the processes shall be determined.

(3) The processes to be determined shall include, in addition to the operating processes, the support, strategic and organisational improvement processes.

(4) It may be acceptable for certain activities having a functional orientation to coexist with process-oriented activities.

7.1.3. The methods required to ensure the effectiveness in the performance and control of the processes shall be determined and applied.

7.1.4. In establishing each process the following shall be ensured:

– All the requirements of the process are specified and addressed, among them the regulatory, statutory, legal, safety-related, health,, environmental n, security, quality and economic requirements.

– The hazards and risks are determined, together with the necessary mitigation measures.

– The interactions with interrelated processes are determined.

– The process inputs are determined.

– The flow of the process is described.

– The products of the process are determined.

– The measurement criteria applicable to the process are established.

7.1.5. The activities of the different individuals or groups participating in a single process, along with the interrelations between them, shall be planned, controlled and managed such that there be assurance of efficient communications and the assignment of clearly defined responsibilities.

7.2. Management of processes
7.2.1. For each process a person shall be designated with authority and responsibilities for the following:

– Establishment and documentation of the process and maintenance of the necessary support documentation.

– Assurance of efficient interaction between interrelated processes
– Assurance that the documentation relating to the process is coherent with the existing documents.

– Assurance that the records required to demonstrate achievement of the results of the process are specified in the pertinent documentation.

– Tracking of performance of the process and corresponding reporting.

– Promotion of process improvement.

– Assurance that the process, including all subsequent modifications, fulfils the goals, strategies, plans and objectives of the organisation.

7.2.2. For each process the inspection, testing, verification and validation activities, acceptance criteria and responsibilities for performance shall be specified. Also specified for each process shall be what activities should be carried out by persons or groups of persons different from those responsible for their initial performance and when.

7.2.3. Each process shall be evaluated in order to ensure that its efficiency is maintained.

7.2.4. In each process the activities shall be carried out under controlled conditions, using appropriate procedures, instructions, drawings or other resources, which shall be revised periodically in order to ensure their suitability and efficiency. The results shall be compared with the expected values.

7.2.5. The processes subcontracted to external organisations shall be identified and controlled. In these cases the licensee shall continue to be responsible for these processes.

7.3. Generic management system processes
7.3.1. The following generic management system processes shall be included among the processes to be implemented:
Documentary control
7.3.2. The management system documents shall be controlled. All persons participating in the preparation, revision, examination or approval of documents shall have been expressly appointed, shall be competent in the performance of these tasks and shall have access to appropriate information on which to base their contributions or decisions. There

shall be assurance that the users of the documents have knowledge of and use appropriate and correct documents.

7.3.3. Modifications made to documents shall be revised and recorded and shall be subject to the same degree of approval.

Control of products
7.3.4. Product specifications and requirements, including subsequent product modifications, shall be in accordance with the established standards and incorporate all the applicable requirements. Products having interfaces or mutually interacting shall be determined and controlled.

7.3.5. Inspection, testing, verification and validation activities shall be completed prior to the acceptance, implementation, use or operation of the products. The tools, instruments and equipment used for these activities shall be appropriate as regards range, type accuracy and precision.

7.3.6. Compliance by the products with the specified requirements shall be confirmed and the tests and preventive maintenance activities required to ensure their satisfactory operation shall be scheduled and performed.

7.3.7. There shall be assurance that the products are supplied in such a way as to allow their compliance with the applicable requirements to be verified.

7.3.8. Controls shall be applied to ensure that the products have been subjected to the necessary inspection, testing, verification and validation activities.

7.3.9. Each product shall be identified in order to ensure that it is used appropriately. When traceability is a requirement, the identification assigned to each product shall be controlled and recorded, this to be unique and unambiguous throughout the complete life cycle of the product.

7.3.10. Products shall be handled, transported, stored, maintained and used as specified, in order to prevent them from sustaining damage, being lost, becoming deteriorated or being used incorrectly or inadvertently.

Control of records
7.3.11. Records shall be specified, developed and controlled in the documentation of the process. All the records shall be complete, legible, perfectly identified and easily recovered.

7.3.12. The period of retention, resources used to draw up, test and maintain the records in accordance with the applicable requirements and commitments of the organisation regarding management of its know-how shall be established. There shall be assurance that the records are kept legible and that they may be recovered throughout the period of conservation specified.

Procurement
7.3.13. The suppliers of products shall be selected in accordance with the specified criteria and their performance shall be evaluated.

7.3.14. The applicable requirements shall be specified in the purchasing documents. Before a product is used, a check shall be made to ensure that it meets the specified requirements.

7.3.15. The purchasing documents shall specify the requirements for the notification and resolution of non-conformities. Also specified shall be the supplier's obligation to inform the licensee and the Nuclear Safety Council of defects or non-compliances affecting the products supplied and performing safety-related functions at the nuclear facility.

Communication
7.3.16. Information of relevance for the objectives of safety, the healths, environmental protection, quality and economic issues shall be communicated to the personnel of the organisation and, when necessary, to other stakeholder groups.

7.3.17. Internal communications shall be established at the different levels and functions of the organisation on the application and efficiency of the management system.

Management of organisational changes
7.3.18. Organisational changes shall be assessed and classified depending on their safety significance and shall be justified prior to their implementation.

7.3.19. The implementation of organisational changes shall be planned, controlled, communicated, supervised and recorded in order to guarantee that safety is not compromised.

Eight. Measurement, evaluation and improvement
8.1. Surveillance and measurement
8.1.1. The efficiency of the management system shall be supervised and measured in order to confirm the capacity of the processes to achieve the intended results and determine opportunities for improvement.

8.2.Self-assessment
8.2.1. Top management and the management personnel at all the other levels of the organisation shall perform self-assessments to analyse the performance of the work and improvements to the safety culture.

8.2.2. A programme of continuous, periodic and specific self-assessment exercises shall be drawn up in relation to activities and processes related to the safety of the facility.
8.2.3. The self-assessments shall be performed by those responsible for the activities and processes analysed, at all levels of the organisation: management, supervisors, individuals and groups.

8.2.4. The self-assessments shall be performed in accordance with a previously determined methodology, compliance with the expectations applicable to the activity or process evaluated shall be verified and non-conformities and proposals for improvement shall be identified.

8.2.5. The efficiency of the self-assessment programme shall be periodically revised.

8.3. Independent assessment
8.3.1. Independent assessments shall be carried out systematically on behalf of the top management in order to:

– Evaluate the efficiency with which the processes comply with and achieve the goals, strategies, plans and objectives. Determine the suitability of performance and management of the works. Analyse the safety culture of the organisation. Supervise the quality of the products. Identify opportunities for improvement.

8.3.2. An organisational unit shall be established for the performance of independent internal assessments. This unit shall have sufficient authority and freedom to act to fulfil its responsibilities.

8.3.3. The persons in charge of the independent internal assessments shall have due training and experience and shall not evaluate their own work. Among other things, the independent internal assessment activities shall include the following: internal audits, external audits, supervisions and documentary reviews. Independent supervision shall be increased when circumstances making this advisable are identified, such as adverse trends regarding non-conformities, the identification of emerging problems, an increase in the number of safety-related jobs, etc.
8.3.4. Independent external assessments shall be systematically performed (overall assessments involving all the safety significant aspects of the organisation and the facility and specific assessments dealing with specific aspects), pursuing the same improvement objectives as the internal assessments and allowing the organisation contrast its operation with the best national and international practices.

8.3.5. The independent external assessments shall be included in the facility assessment plan and established in a regulating procedure, which shall also include their minimum frequency.

8.3.6. The top management shall evaluate the results of the independent assessments, adopt the measures required and document and communicate its decisions and their underlying reasons.

8.4. Management system review

8.4.1. The management system shall be reviewed at scheduled intervals, in order to ensure its continuous suitability and efficiency and its capability to facilitate the achievement of the objectives mapped out by the organisation.

8.4.2. The review shall cover, without limitation, the following items:

– Results of all the assessments.

– Results obtained and objectives covered by the organisation and its processes.

– Non-conformities and corrective, preventive or improvement actions.

– Lessons learned from other organisations.

– Opportunities for improvement.

8.4.3. Weaknesses and obstacles shall be identified, assessed and promptly solved.

8.4.4. The review shall determine the need to introduce changes or improvements in the policies, goals, strategies, plans, objectives and processes.

8.5. Non-conformities and corrective and preventive measures

8.5.1. The causes of non-conformities shall be determined and the corrective actions required to prevent them from being repeated shall be adopted.

8.5.2. Products and processes that do not meet the specified requirements shall be identified, separated, controlled and registered, and the management personnel responsible for the organisation shall be notified. The impact of non-conformities shall be assessed and the non-conforming products or processes shall be:

– Accepted.

– Repeated or corrected within the specified time period.

– Rejected and discarded or destroyed to avoid them from being used fortuitously.

8.5.3. Exceptions made to accept a non-conforming product or process must be authorised. The products or processes repeated or corrected shall be subject to inspection to demonstrate their conformity with the requirements or expected results.

8.5.4. The corrective actions and corrections required to eliminate non-conformities shall be determined and applied. The preventive actions required to eliminate the causes of potential non-conformities shall likewise be determined and adopted.

8.5.5. The situation and effectiveness of all corrective and preventive actions shall be tracked and the management personnel responsible for the organisation shall be notified.

8.5.6. Potential non-conformities that might adversely affect the performance of the organisation shall be identified. This shall be accomplished by using the feedback received from other internal and external organisations, by means of advanced techniques and investigations, the exchange of know-how and experience and the use of techniques allowing best practices to be determined.

8.6. Improvements

8.6.1. Opportunities to improve the management system shall be identified and

the measures to be applied to improve the processes shall be selected, planned and registered.

8.6.2. The implementation of improvement actions shall be overseen and their effectiveness shall be verified. The improvement plans shall include arrangements for the supply of adequate resources.

8.7. Corrective actions programmes (CAP)
8.7.1. A corrective actions programme shall be set up for the integral management of the identification, assessment and resolution of non-conformities and proposals for improvement identified as a result of external assessments, independent internal assessments, self-assessments and the suggestions and findings of the personnel and during the performance of routine plant operation and maintenance activities, and of regulatory requirements and commitments.

8.7.2. Non-conformities shall be categorised depending on their importance for plant safety and reliability.

8.7.3. The actions shall be prioritised and resolved in time periods in keeping with the level of importance assigned to the non-conformity.

8.7.4. Non-conformities of significance for plant safety and reliability shall be analysed to determine the corrective actions required to prevent them from being repeated.

8.7.5. Measures shall be established to verify the effectiveness of the actions.
8.7.6. Mechanisms shall be established to identify and assess the adverse trends of non-conformities.

8.7.7. The corrective actions programme shall be managed by means of a single computer system common to the entire organisation.

8.7.8. The effectiveness of the corrective actions programme shall be periodically reviewed.

Nine. Exemptions
The licensees of nuclear facilities covered by the present Instruction may request temporary exemption from any of its requirements, providing adequate justification of the reasons for the request and establishing the alternative routes to be used to comply with the established criteria.

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, in the wording given by Law 33/2007, of November 7th, reforming Law 15/1980, of April 22nd.

Eleven. Single final provision
The requirements established in the present Instruction shall be fully implemented at the nuclear facilities prior to the first day of January of the year two thousand and ten.

Twelve. Single derogatory provision
All legal standards of equal or lower standing and opposing the present Instruction are hereby annulled.

Madrid, October 22nd 2008
The President of the Nuclear Safety Council,
Carmen Martínez Ten