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## **Regulation**

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# **Regulation for Management Systems for Nuclear Facilities (FANR-REG-01)**

## **Version 0**

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Federal Authority for Nuclear Regulation (FANR), 2010  
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## Definitions

### Article (1)

For purposes of this regulation, the following terms shall have the meanings set forth below.

**Institutional Control** Control of a Radioactive Waste site by an Authority or institution designated under the laws of the State. This control may be active (monitoring, surveillance, remedial work) or passive (land use control) and may be a factor in the design of a Nuclear Facility (e.g., near surface repository).

Most commonly used to describe controls over a repository after closure or a facility undergoing. Also refers to the controls placed on a site that has been released from regulatory control under the condition of observing specified restrictions on its future use to ensure that these restrictions are complied with.

**Management System Review** A regular and systematic evaluation by Senior Management of an organisation of the suitability, adequacy, effectiveness and efficiency of its Management System in executing the policies and achieving the goals and objectives of the organisation.

**Physical Protection Plan** A plan that describes the duties and responsibilities of members of the security organisation. The Plan shall address: organisation and staffing; Physical Protection including the designation of Protected Areas and Vital Areas; guard training and qualification; information security; Cyber Security; and responses to security contingencies including consideration of concurrent Nuclear Safety related Emergencies and security threats.

**Probabilistic Risk Assessment (PRA)** A comprehensive, structured approach to identifying failure scenarios constituting a conceptual and mathematical tool for deriving numerical estimates of risk.

Level 1 comprises the assessment of failures leading to the determination of the frequency of core damage.

Level 2 constitutes the assessment of containment response and leads to the determination of frequency of containment failure resulting in release to the environment of a given percentage of the reactor core's inventory of radionuclides.

**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.

**Security Culture** Characteristics and attitude in organisations and of individuals which establish that security issues receive the attention warranted by their

significance.

**Senior Management** Senior Management means the person who, or group of people which, directs, controls and assesses an organisation at the highest level.

## **Scope**

### **Article (2)**

The Authority, pursuant to Articles [5], [43] and [44], of the Law, authorises the promulgation of this regulation. This regulation defines generic Management System requirements applicable throughout all phases (these include; Siting, Design, fabrication, Construction, Commissioning, Operation and Decommissioning) of the lifetime of a Nuclear Facility including any subsequent period of Institutional Control.

## **The Management System**

### **Article (3)**

1. The Licensee shall establish, implement, assess and continually improve a Management System that is aligned with the goals of the organisation and contributes to its achievement.
2. The main objectives of the Management System shall be to achieve and enhance Safety by:
  - a. Bringing together in a coherent manner all the requirements for managing the organisation;
  - b. Describing the planned and systematic actions necessary to provide adequate assurance that all these requirements are satisfied; and
  - c. Ensuring that health, environmental, security, quality and economic requirements are not considered separately from Safety requirements, to help preclude their possible negative impact on Safety.
3. Safety shall be paramount within the Management System overriding all other demands.
4. The Management System shall identify and shall integrate all statutory and regulatory requirements that apply to the Regulated Activities and Facilities of the Licensee.
5. Upon the Authority's request, whether as a part of a Licence application, within the framework of a Regulatory Inspection or a request for documentation and records or any

other Authority request, the Licensee shall demonstrate to the Authority an effective Management System and the fulfilment of its requirements.

## **Safety Culture and Security Culture**

### **Article (4)**

The Licensee shall use the Management System to promote and support a strong Safety Culture and Security Culture by:

1. Ensuring a common understanding of the key aspects of Safety Culture and Security Culture within the organisation;
2. 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;
3. Reinforcing a learning and questioning attitude at all levels of the organisation;
4. Providing the means by which the organisation continually seeks to develop and improve its Safety Culture and Security Culture; and
5. Ensuring that security measures balance any conflicting objectives of Safety, Operations, and security. Safety and security shall be considered together, such that one does not compromise the other. Potential conflicting requirements should be carefully analysed to ensure that they do not jeopardise Nuclear Safety.

## **Graded Approach**

### **Article (5)**

1. The application of Management System requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:
  - a. The significance and complexity of each product or activity;
  - b. The hazards and the magnitude of the potential impact (risks) associated with the Safety, security, safeguards, Radiation Protection, environmental, quality and economic elements of each product or activity; and
  - c. The possible consequences if a product fails or an activity is carried out incorrectly.
2. Grading of the application of Management System requirements shall be applied to the products and activities of each process.

## **Documentation**

### **Article (6)**

1. The documentation of the Management System shall include a description of the Management System, the organisational structure, the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work. Additionally a description of the processes and supporting information that explain how work is prepared, reviewed, carried out, recorded, assessed and improved shall be documented.
2. The documentation of the Management System shall be developed to be understandable to those who use it. Documents shall be readable, readily identifiable and available at the point of use.

## **Management Responsibility**

### **Article (7)**

1. The Senior Management of the Licensee shall be responsible and shall demonstrate its commitment for the Management System and shall ensure that it is established, implemented, assessed and continually improved.
2. The Licensee shall ensure management at all levels:
  - a. Develops individual values, institutional values and behavioural expectations for the organisation to support implementation of the Management System and shall act as role models in the promulgation of these values and expectations;
  - b. Communicates to individuals the need to adopt these individual values, institutional values and behavioural expectations in order to comply with the requirements of the Management System; and
  - c. Fosters the involvement of all employees of the Licensee in the implementation and continual improvement of the Management System.
  - d. Ensures that it is clear at what time , how and by whom decisions are to be made within the Management System;
3. The expectations of interested parties shall be considered by the Licensee's Senior Management in the activities and interactions in the process of the Management System with the aim of enhancing their satisfaction while at the same time ensuring that Safety and security are not compromised.
4. The Licensee shall ensure that Senior Management:
  - a. Establishes and monitors the implementation of goals, strategies, plans and objectives consistent with the policies of the organisation and in an integrated manner so that their collective impact on Safety is understood and managed:

- b. Establishes measurable objectives for implementing these goals, strategies and plans through appropriate processes at various levels in the organisation, and
  - c. Performs a regular assessment of the organisation's compliance with the Management System's objectives, and actions are taken to address any deviations from the plan where necessary.
5. The Licensee shall ensure that Senior Management designates a qualified individual reporting directly to Senior Management with the authority and responsibility to:
- a. Co-ordinate the development and implementation of the Management System;
  - b. Report on the performance of the Management System, including its influence on Safety, Security, Safety Culture and Security Culture and any need for improvement; and
  - c. Resolve conflicts relating to the requirements and processes of the Management System.
6. The Licensee may delegate to others, such as contractors, agents or consultants the work of establishing and implementing the Management System but shall retain primary responsibility for the Management System.

## **Resource Management**

### **Article (8)**

1. The Licensee shall ensure the availability of adequate resources to carry out the activities of the organisation and to establish, plan, implement, assess and continually improve the Management System.
2. The Licensee shall ensure that Senior Management determines the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. The Licensee shall regularly evaluate the effectiveness of the actions taken ensuring suitable proficiency is achieved and maintained.
3. Senior Management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for Safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities affect Safety

## **Knowledge Management**

### **Article (9)**

1. The Licensee shall ensure that the information and knowledge of the organisation is managed as a resource.
2. The Licensee shall ensure that Senior Management determines, provides, maintains and re-evaluates the infrastructure and the working environment necessary for work to be carried out in a safe manner and for all applicable requirements to be met.

## **Process Implementation**

### **Article (10)**

1. The Licensee shall ensure that the processes of the Management System that are needed to achieve its goals, provide the means to meet all applicable requirements, and deliver the products of the organisation for each phase in the lifetime of a nuclear facility are planned, implemented, assessed and continually improved.
2. The sequence and interactions of the processes shall be determined.
3. The methods necessary to ensure the effectiveness of both the implementation and the control of the processes shall be determined and implemented.
4. The development of each process shall ensure that the following are achieved:
  - a. Process requirements, such as applicable regulatory, statutory, legal, Safety, Radiation Protection, environmental, security, quality and economic requirements, are specified and addressed;
  - b. Hazards and risks are identified, together with any necessary mitigatory actions;
  - c. Interactions with interfacing processes are identified;
  - d. Process inputs are identified;
  - e. The process flow is described;
  - f. Process outputs (products) are identified; and
  - g. Process measurement criteria are established.
5. The activities of and interfaces between different individuals or groups involved in a single process shall be planned, controlled and managed in a manner that ensures effective communication and the clear assignment of responsibilities.



## **Process Management**

### **Article (11)**

1. The Licensee shall designate a qualified individual for each process who has the authority and responsibility for:
  - a. Developing and documenting the process and maintaining the necessary supporting documentation;
  - b. Ensuring that there is effective interaction between interfacing processes;
  - c. Ensuring that process documentation is consistent with any existing documents;
  - d. Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation;
  - e. Monitoring and reporting on the performance of the process;
  - f. Promoting improvements in the process; and
  - g. Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the organisation.
2. The Licensee shall ensure:
  - a. For each process, any activities for inspection, testing, verification and validation, their acceptance criteria and the responsibilities for carrying out these activities are specified. For each process, it is specified if and when these activities are to be performed by designated individuals or groups other than those who originally performed the work.
  - b. Each process is periodically evaluated to ensure that it remains effective.
  - c. The work performed in each process is carried out under controlled conditions, by using approved current procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness. Results shall be compared with expected values.
  - d. The control of processes contracted to outsourced processes and activities and external organisations are identified within the Management System. The Licensees organisation shall retain primary responsibility when contracting any processes.

## **Control of Documents**

### **Article (12)**

For the control of documents, the Licensee shall ensure that:

1. All documents (including policies; procedures; instructions; specifications and drawings (or representations in other media); training materials; and any other texts that describe processes, specify requirements or establish product specifications shall be controlled. All individuals involved in preparing, revising, reviewing or approving documents shall be specifically assigned this work, shall be competent to carry it out and shall be given access to appropriate information on which to base their input or decisions. The Licensee shall ensure that document users are aware of and use appropriate and correct documents.
2. Changes to documents shall be reviewed and recorded and shall be subject to the same level of approval as the documents themselves.
3. The materials and recording methods used shall meet the requirements for defined retention periods and the document control system shall comply with all relevant data security requirements.
4. The Licensee shall establish policies and programmes to protect information pertaining to the security of a Nuclear Facility from public disclosure, including information related to the Physical Protection Plan, the PRA and the PRA summary report.

## **Control of Products**

### **Article (13)**

For the control of products, the Licensee shall ensure that:

1. Specifications and requirements for products, including any subsequent changes, are in accordance with established standards and shall incorporate applicable requirements. Products that interface or interact with each other shall be identified and controlled.
2. Activities for inspection, testing, verification and validation are completed before the acceptance, implementation or operational use of products. The tools and equipment used for these activities shall be of the proper range, type, accuracy and precision.
3. Products meet the specified requirements and perform satisfactorily in service.
4. Products are provided in such a form that they can be verified that they satisfy their design and service requirements.
5. Controls are used to ensure that products do not bypass the required verification activities.

6. Products are identified to ensure their proper use. Where traceability is a requirement, the organisation shall control and record the unique identification of the product.
7. Each product shall be handled, transported, stored, maintained and operated according to the specifications laid down for it, to prevent their damage, loss, deterioration or inadvertent use.

## **Control of Records**

### **Article (14)**

For the control of records, the Licensee shall ensure that:

1. Records are specified in the process documentation and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable.
2. Records are maintained that furnish evidence that activities affecting quality were performed consistent with established procedures and specifications.
3. Retention times of records and associated test materials and specimens are established to be consistent with the knowledge management obligations of the organisation and as required by the Authority. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record.

## **Purchasing**

### **Article (15)**

For purchasing, the Licensee shall ensure that:

1. Suppliers of products are selected on the basis of specified criteria and their performance is evaluated.
2. Purchasing requirements are developed and specified in procurement documents. Evidence that products meet these requirements shall be available to the organisation before the product is used.
3. Requirements for the reporting and resolution of non-conformances are specified in procurement documents.

## **Communication**

### **Article (16)**

The Licensees management shall communicate to:

1. Its personnel the importance of Safety and security related requirements and shall demonstrate their commitment to Safety and security and to the implementation and continual improvement of the Management System. The Licensee's Safety and quality policies shall be communicated to the personnel and management shall ensure that they are understood and complied with; and
2. All suppliers and subcontractors to ensure that they are familiar with the Licensee's Safety and security and quality policies, the related goals and the Management System in general, and that they understand its expectations and requirements.

## **Organisational Changes**

### **Article (17)**

The Licensee shall ensure that organisational changes shall be:

1. Evaluated and classified according to their importance to Safety and security and each change shall be justified. Objectives for organisational changes shall be defined; and
2. Planned, controlled, communicated, monitored, tracked and recorded in their implementation to ensure that Safety is not compromised.

## **Measurement, Assessment and Continuous Improvement**

### **Article (18)**

1. The effectiveness of the Management System shall be monitored and measured by the Licensee to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement.
2. Periodic assessments shall be conducted at planned intervals to support continual improvement of the Management System and ensure its continuing suitability and effectiveness.
3. To support these assessments, the Licensee shall define and implement performance based measures and criteria to monitor and ensure Safety and security requirements are met during the Siting, Design, Fabrication, Construction, Commissioning, Operation and Decommissioning of the facility.

## **Self-Assessment**

### **Article (19)**

The Licensee shall ensure Senior Management and management at all other levels in the organisation carry out periodic and regular self-assessments to evaluate and improve the effectiveness of the Management System in ensuring Safety, security, safeguards, Radiation Protection and a strong Safety Culture and Security Culture.

## **Independent Assessments**

### **Article (20)**

1. The Licensee shall have periodic independent assessments conducted on behalf of the Senior Management to:
  - a. Evaluate and improve the effectiveness of the Management System in ensuring Safety, security, safeguards, Radiation Protection and a strong Safety Culture and Security Culture.
  - b. Evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives;
  - c. Determine the adequacy of work performance and leadership;
  - d. Evaluate the organisation's Safety Culture and Security Culture;
  - e. Monitor product quality; and
  - f. Identify opportunities for improvement.
2. The Licensee shall establish an organisational unit with the responsibility for conducting independent assessments. This unit shall have sufficient authority to discharge its responsibilities.
3. Individuals participating in independent assessments shall not assess their own work.
4. Independent assessments shall include the use of established performance based measures and criteria.

## **Management System Reviews**

### **Article (21)**

1. A Management System Review shall be conducted by the Licensee at planned intervals to ensure the continuing suitability and effectiveness of the Management System and its ability to enable the objectives set for the organisation to be accomplished.
2. The review shall cover but shall not be limited to:
  - a. Outputs from all forms of assessment;
  - b. Results delivered and objectives achieved by the organisation and its
  - c. Processes;
  - d. Non-conformances and corrective and preventive actions;
  - e. Lessons learned from other organisations; and
  - f. Opportunities for improvement.
3. Weaknesses and obstacles shall be identified, evaluated and remedied in a timely manner.
4. The review shall identify whether there is a need to make changes to or improvements in policies, goals, strategies, plans, objectives and processes organisation and staffing.

## **Non-Conformances, Corrective and Preventive Actions**

### **Article (22)**

1. The Licensee shall ensure that:
  - a. The Management System contains procedures to identify, evaluate and, as appropriate, correct non-conforming processes and products. The significance of potential non-conformances is evaluated, root causes identified, corrective and preventive action is defined, and the implementation status of corrective and preventive actions monitored and documented, as appropriate. The effectiveness of corrective actions are monitored and evaluated.
  - b. Management promotes an open atmosphere that improves the identification and handling of non-conformances and identifies opportunities for improvement. Procedures defining the process for processing non-conformances, and improvement proposals shall be implemented. The assessment of non-conformances is conducted by individuals who are independent and to the extent possible, whose duties are not directly associated with the non-conformance. These personnel have sufficient expertise and technical knowledge to perform the assessment.

- c. Concessions granted to allow acceptance of a non-conforming product or process shall be subject to authorisation. When non-conforming products or processes are reworked or corrected, they are subject to inspection to demonstrate their conformity with requirements or expected results.
  - d. The status and effectiveness of all corrective and preventive actions are monitored and reported to management at an appropriate level in the organisation.
2. Every employee of the Licensee, as well as the Licensee's consultants or contractors, is given the opportunity to identify non-conformances in processes, products, and the Management System, and to propose improvements. Employees are informed about the disposition of identified non-conformances.