

This is an unofficial translation of the text.

The translation is prepared based on Govt. Decree No. 118/2011 (VII. 11.) being effective as of 10.04.2018

Annex 2 of Government Decree No. 118/2011 (VII. 11.)

Nuclear Safety Code

Volume 2

Management systems of nuclear facilities

2.1. INTRODUCTION

2.1.1. Objective of regulation

2.1.1.0100. The objective of this regulation is to define the requirements for designing, implementing, operating, assessing and continually improving a management system in the nuclear facility that integrates safety, health, environmental, security, quality, societal and economic elements to ensure that safety is appropriately considered in all activities of the licensee.

2.1.1.0200. The main objective of the requirements for the management system is to ensure, by considering implications of all actions not within separate management systems but with regard to safety as a whole, that safety is not compromised.

2.2. MANAGEMENT SYSTEM

2.2.1. General requirements

2.2.1.0100. The licensee shall establish, operate, assess, and continuously develop a management system. The system shall be in accord with the goals of the licensee and shall contribute to their achievement. The primary goal of the management system shall be to achieve and enhance safety by:

- a) coherent collection of all relevant requirements for the operation of the licensee,
- b) describing the planned and systematic actions necessary to ensure that these requirements are fulfilled, furthermore
- c) ensuring that health, environmental, security, quality, societal and economic requirements, expectations are considered in accordance with the safety requirements, to help preclude their potential negative impact on safety.

2.2.1.0200. Safety shall be paramount within the management system, overriding all other demands.

2.2.1.0300. The management system shall identify and integrate the following requirements:

- a) legislative and regulatory requirements;
- b) all requirements that are proclaimed by the interested parties and formally agreed on by the licensee; as well as
- c) national and international requirements and standards applied by the licensee.

2.2.1.0400. The licensee shall demonstrate the operation of its management system and effective fulfilment of the requirements.

2.2.1.0500. The management system shall be so designed and operated that it is suitable for addressing non-conformances and it ensures prevention of overburden of the operating staff. The system shall ensure that non-conformities do not jeopardize safety of the nuclear facility.

2.2.2. Safety culture

2.2.2.0100. The managements of the licensee organisation and the supplier organisations shall consistently and definitely expect and support the attitude required for a strong safety culture at all levels, and shall ensure that the employees recognise and understand the key considerations of safety culture. Among other things, they shall implement this in such a way that they do not support excessive self-confidence and encourage an open reporting culture and a questioning attitude, which prevent activities and conditions unfavourable from a safety point of view. All individuals in the organization, starting from the senior management, shall contribute to fostering and sustaining a strong safety culture.

2.2.2.0110. In order to appropriately exercise the competences and fulfil the tasks in compliance with the safety requirements, commitment to nuclear safety shall be considered as an indispensable aspect during the assignment of the management and selection of employees.

2.2.2.0120. Safety culture level of the organizations taking part in the operation of the nuclear facility shall be continuously enhanced throughout the lifetime of the nuclear facility.

2.2.2.0200. Senior managers and all other managers shall advocate and support the following:

- a) A common understanding of safety and of safety culture, including awareness of radiation risks and hazards relating to work and to the working environment, an understanding of the significance of radiation risks and hazards for safety, and a collective commitment to safety by teams and individuals;

b) acceptance by individuals of personal accountability for their attitudes and conduct with regard to safety;

c) an organizational culture that supports and encourages trust, collaboration, consultation and communication;

d) the reporting of problems relating to technical, human and organizational factors and reporting of any deficiencies in structures, systems and components to avoid degradation of safety, including the timely acknowledgement of, and reporting back of, actions taken;

e) measures to encourage a questioning and learning attitude at all levels in the organization and to discourage complacency with regard to safety;

f) proposing safety related concerns and problems without prejudicial consequences and their adequate management;

g) the means by which the organization seeks to systematically enhance safety and to foster and sustain a strong safety culture;

h) safety oriented decision making in all activities;

i) mutual consideration of the aspects of safety culture and security culture.

2.2.2.0210. Suitability and effectiveness of the means fostering and sustaining safety culture shall be regularly verified in self-assessments and reviews of the management system.

2.2.2.0300. The licensee shall ensure that suppliers and subcontractors also meet the requirements stated in Sections 2.2.2.0100.–2.2.2.0210.

2.2.3. Differentiation of the application of management system requirements

2.2.3.0100. The criteria used to prioritise the development and application of the management system shall be documented in the management system. The following shall be taken into account:

a) the safety significance and complexity of the organization, operation of the facility or conduct of the activity;

(b) the hazards and the magnitude of the potential impacts, risks associated with the safety, health, environmental, security, quality and economic elements of each facility or activity;

(c) the possible consequences for safety if a failure or an unanticipated event occurs or if an activity is inadequately planned or improperly carried out.

2.2.3.0200. The differentiation approach shall be applied to the products and activities of each process.

2.2.4. Documentation of the management system

2.2.4.0100. The documentation of the management system shall include as a minimum:

a) policy statements associated with the activities of the licensee, highlighting the fundamental safety objective, and the safety policy declaring the paramount of protection of the public and the environment;

b) a description of the management system and how the relevant legal and regulatory requirements are fulfilled;

c) a description of the structure of the organization;

d) determination of functional responsibilities, accountabilities, levels of authority, and interactions for the employees managing, performing, and assessing work;

e) description of processes and supporting information that explain how work shall be prepared, reviewed, carried out, documented, assessed, and improved; furthermore

f) a description of the interactions with external organizations and with interested parties including the authorities and partner organizations.

2.2.4.0200. The documentation of the management system shall reflect:

a) the organization of the licensee and the activities performed by it, and

b) complexity and interactions of the processes.

2.2.4.0300. The documentation of the management system shall be developed to be unambiguously applicable to those who use it. Documents shall be easy to read, easily identifiable, and the valid versions shall be available at the point of use.

2.2.4.0400. The documentation of the management system shall be made electronically accessible for the nuclear safety authority.

2.3. MANAGEMENT RESPONSIBILITY

2.3.1. Management commitment

2.3.1.0100. The management at all level shall demonstrate its commitment to the establishment, implementation, assessment, and continuous improvement of the management system and shall provide adequate resources to carry out these activities.

2.3.1.0200. The senior management shall determine individual and institutional values as well as behavioural expectations for the organization to support the implementation of the management system, and shall provide good example of the implementation of these values and expectations in practice.

2.3.1.0300. The management at all levels shall communicate to employees the need to adopt the individual and institutional values and behavioural expectations as well as to comply with requirements of the management system.

2.3.1.0400. Management at all level shall promote involvement of the whole organization in the implementation, continuous improvement and development of the management system.

2.3.1.0500. The senior management shall ensure that it is clear when, how, and by whom decisions are to be made within the management system.

2.3.1.0600. The owner's measures shall not limit the licensee in its safety related decision making.

2.3.1.0700. The requirements for professional applicability and paramount of nuclear safety shall prevail in the decisions related to the staffing of the senior management.

2.3.1.0800. The owner shall ensure the financial resources to sustain and improve the level of safety.

2.3.1.0900. The owner's decisions shall not limit the licensee in undertaking its responsibilities.

2.3.2. Interaction with interested parties

2.3.2.0100. The expectations of the interested parties, in order to enhance their satisfaction, shall be considered by the senior management during the activities and interactions of the processes of the management system while ensuring that safety is not compromised.

2.3.2.0200. Senior management shall identify interested parties for their organization and shall define an appropriate strategy for cooperating with them. Senior management shall ensure:

a) appropriate means of communicating routinely and effectively with and informing interested parties with regard to radiation risks associated with the operation of facilities and the conduct of activities;

b) appropriate means of timely and effective communication with interested parties in circumstances that have changed or that were unanticipated;

c) appropriate means of dissemination to interested parties of necessary information relevant to safety;

d) appropriate means of considering in decision making processes the concerns and expectations of interested parties in relation to safety.

2.3.3. Organizational policies

2.3.3.0100. The senior management shall develop the policies of the organization. The policies shall be in accord with the activities of the nuclear facility and the licensee.

2.3.4. Design

2.3.4.0100. The senior management

a) shall develop the strategies, plans, and objectives that are in accord with the policies of licensee;

b) shall develop standardized, harmonized policies of the organization, as well as strategies, plans, and objectives in a manner that ensures that their collective impact on safety is clear and manageable;

c) shall ensure that measurable safety objectives related to practical implementation of policies, strategies, and plans are established through appropriate processes at various levels in the organization.

d) shall ensure that the achievement of the safety objectives is regularly assessed during the implementation of the strategies, plans; furthermore

e) shall ensure that, if necessary, measures are taken to address deviations from the plans.

2.3.5. Responsibility and authority related to the management system

2.3.5.0100. Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety.

2.3.5.0200. Senior management shall retain accountability for the management system even where individuals are assigned responsibility for coordinating the development, application and maintenance of the management system.

2.4. RESOURCE MANAGEMENT

2.4.1. Provision of resources

2.4.1.0100. The senior management shall define and provide the necessary resources and competences for the activities of licensee and for the establishment, implementation, assessment, and continuous improvement of the management

system; furthermore shall decide on the use of these resources at each stage in the lifetime of the facility, in each operating state and during each activity.

2.4.1.0200. Information and knowledge accumulated in the organization shall also be managed as a resource.

2.4.2. Human resources

2.4.2.0100. The senior management shall determine the professional requirements for employees at all levels and shall provide training or take other actions to achieve and maintain the required level of knowledge and competence; furthermore, it shall evaluate the effectiveness of the measures taken. The achieved competency and expertise shall be continuously maintained.

2.4.2.0150. Senior management shall determine which competences and resources the organization has to retain or has to develop internally, and which competences and resources may be obtained externally, for ensuring safety.

2.4.2.0200. The management shall ensure that the assigned work is performed by competent employees. Proper training and education about the management system requirement shall ensure that they are aware of the importance and safety impact of their activities.

2.4.3. Infrastructure and work environment

2.4.3.0100. The senior management shall determine, ensure, maintain, and regularly re-evaluate the infrastructure and work environment required for safe work and for the fulfilment of requirements.

2.4.2.0300. Competences within the organization include leadership at all levels, the development and maintenance of a strong safety culture, as well as the expertise required for safe planning, construction, installation, commissioning, operation and termination.

2.4.2.0400. Senior management shall ensure that employees at all levels:

a) are competent to perform their assigned tasks and to work safely and effectively, and

b) aware of and understand the standards that they are expected to apply in completing their tasks.

2.5. PRACTICAL IMPLEMENTATION OF PROCESSES

2.5.1. Process development and regulation

2.5.1.0100. The processes shall be identified that are required to achieve the objectives, to provide the means to fulfil all requirements, and to produce the

products of licensee. The development, implementation, assessment, and conditions required for the operation and continuous improvement of these processes shall be planned. The sequence and interactions of processes shall also be planned. Particular attention shall be given to interactions between processes within the organization, and to interactions with external suppliers processes, and to that these processes do not impact safety negatively.

2.5.1.0200. The methods necessary for efficient process development and control shall be determined and implemented.

2.5.1.0300. The development of each process shall ensure that the following are achieved:

a) the regulatory, legislative, safety, health, environmental, security, quality, societal and economic requirements, expectations related to the process are specified and addressed;

b) hazards and risks are identified together with the necessary corrective or preventive actions;

c) interactions with interconnected processes are defined;

d) input data of processes are identified;

e) the process flow is described;

f) the output of processes are identified;

g) conditions, methods and criteria necessary for validating the process results are determined in the regulation of the process; furthermore

h) criteria for process measurement are established.

2.5.1.0400. The relations and activities of different employees or groups participating in the process shall be planned, controlled, and managed, in order to ensure effective communication and clear assignment of responsibilities.

2.5.2. Process management

2.5.2.0100. A competent employee shall be designated for each process who will be responsible for the following:

a) developing and documenting the process, maintaining and managing the necessary support documentation;

b) ensuring conformity and effective interaction among interrelated processes;

c) ensuring that the process documentation is consistent with any related documents;

d) ensuring that the records required to demonstrate that process results have been achieved are specified in the process documentation;

e) monitoring the performance of the process and the preparation of the performance report;

f) promoting improvements within the process; furthermore

g) ensuring that the process, its subsequent modifications included, is in accordance with the policies, strategy, plans, and objectives of the licensee.

2.5.2.0200. For each process the inspection, testing, verification, and validation activities, their acceptance criteria and responsibilities for implementing these activities shall be determined. It shall be specified which activities and when are to be performed by designated independent employees or groups.

2.5.2.0300. Processes shall be evaluated to ensure efficiency.

2.5.2.0400. All safety related activities determined in each process shall be executed by using valid documentation, especially approved procedures, instructions, drawings, or other appropriate means. To ensure the adequacy and effectiveness of the specified documents and means, they shall be validated before the first use and periodically reviewed. Results shall be compared with the expected values.

2.5.2.0500. Contractual processes executed out by external organizations shall be regulated within the management system. The licensee shall retain overall responsibility for processes executed by suppliers.

2.5.3. General management system processes

2.5.3.0100. At least the following general processes shall be developed and implemented in the management system.

Document management

2.5.3.0200. The preparation and use of the documents shall be controlled. Competent employees shall be assigned to prepare, revise, review, and approve documents, and they shall be granted access to all the information on which input data or decisions are based. It shall be ensured that document users use and are aware of the appropriate and valid documents.

2.5.3.0300. Modifications of documents shall be reviewed, documented, and subjected to the same approval process as original documents.

2.5.3.0350. The organization shall exactly know the services and products provided for it.

Control of products

2.5.3.0400. The organization shall be capable of developing the specifications for products or services, subsequent modifications included, by its own in accordance with the respective regulation and standard. Product descriptions shall incorporate the applicable requirements. Products that interconnect or interact with each other shall be identified and controlled within the organization.

2.5.3.0500. Activities for inspection, testing, approval, and validation shall be completed before the acceptance, implementation, or operational use of products. The tools and equipment used for these activities shall be of the appropriate type, range and accuracy.

2.5.3.0600. The licensee shall confirm that products meet the safety requirements, and shall ensure that products properly function in service.

2.5.3.0700. Products shall be produced in a way that it can be verified that they meet the requirements.

2.5.3.0800. It shall be ensured that the products do not avoid required verification processes.

2.5.3.0900. Products shall be identified to ensure proper product use. When traceability of the products is required or necessary, individual product identification shall be controlled and recorded by licensee.

2.5.3.1000. Products shall be handled, transported, stored, maintained, and operated as specified in order to avoid their damage, loss, dilapidation, or improper use.

Control of records

2.5.3.1100. Necessary records shall be specified in the management system and their management shall be controlled. All records shall be readable, complete, identifiable, and easily traceable.

2.5.3.1200. Retention time of records, associated test materials and samples shall be determined to be in accordance with legislations and knowledge management obligations of the licensee. Transferring devices used for the records shall ensure that the records are readable within the defined retention period.

Procurement

2.5.3.1300. Suppliers shall be selected based on specified criteria and their performance shall be evaluated.

2.5.3.1310. The management system shall provide rules for limiting the levels of supplier chains, selection of suppliers, and for examination, assessment and supervision of the suppliers.

2.5.3.1400. Requirements for procurement shall be developed and specified in the procurement documents. The licensee shall have proof that the products meet these requirements before the product is used.

2.5.3.1500. Requirements for reporting and resolution of non-compliances shall be specified in the procurement documents.

Communication

2.5.3.1600. Important information related to the safety, health, security, quality, societal and economic objectives shall be introduced to the persons in the organization of the licensee and, if necessary, to other interested parties.

2.5.3.1700. Internal communication concerning the implementation and effectiveness of the management system shall be applied among various levels and functions of the organization of the licensee. External communication concerning the implementation of the activities of the organization shall be used with interested parties.

Managing organizational and operational changes

2.5.3.1800. Organizational and operational changes shall be evaluated and classified based on their importance to nuclear safety and each change shall be justified and verified.

2.5.3.1900. Implementation of such changes shall be planned, controlled, communicated, followed up, and documented in order to ensure that nuclear safety is not compromised.

2.6. MEASUREMENT, EVALUATION AND DEVELOPMENT

2.6.1. Monitoring and measuring

2.6.1.0100. Independent reviews and self-assessments of the management system shall be regularly conducted to evaluate its effectiveness and to identify opportunities for its improvement. Lessons and any resulting significant changes shall be analysed for their implications for safety.

2.6.2. Self-evaluation

2.6.2.0100. Self-evaluation shall be performed at all management levels in order to evaluate the performance of the management system effectively and to improve safety culture.

2.6.3. Independent assessment

2.6.3.0100. The senior management shall regularly require independent assessments:

a) to evaluate the effectiveness of processes in achieving requirements, policies, strategies, plans, and objectives;

b) to determine the adequacy of work performance and leadership;

c) to evaluate the safety culture of the licensee;

d) to monitor product quality;

e) to determine options for improvement.

2.6.3.0200. An organizational unit or work position shall be established that is responsible for performing independent assessments and analyses. This organizational unit or employee shall have adequate authority to perform its responsibilities.

2.6.3.0300. Employees performing independent assessments shall not assess their own work.

2.6.3.0400. Senior management shall evaluate the results of independent evaluations, take any necessary actions, and document and communicate their decisions as well as reasons for the decisions.

2.6.4. Management system review

2.6.4.0100. Management system review shall be regularly performed as scheduled in order to ensure continuous suitability and effectiveness, considering the new requirements and organizational and environmental changes, and to verify that the management system is capable of accomplishing the objectives set by and for the licensee.

2.6.4.0200. Inspection shall cover but not be limited to the following:

a) results from different assessments,

b) results delivered and objectives achieved by the licensee and its processes,

c) non-compliances, corrective and preventive measures,

d) experience, lessons learned from other organizations, as well as

e) opportunities for innovation.

2.6.4.0300. Vulnerabilities and obstructive factors shall be identified, evaluated, and corrected in a timely manner.

2.6.4.0400. Reviews shall identify whether modification of or improvement in policies, strategies, plans, objectives, goals, and processes are necessary.

2.6.5. Non-compliances, corrective and preventive measures

2.6.5.0100. Causes of non-compliances shall be identified; corrective and preventive measures shall be taken to prevent their recurrence.

2.6.5.0200. Products and processes that do not meet specified requirements shall be identified, separated, controlled, registered, and reported to management within the organization of the licensee. The impact of non-compliances shall be evaluated; the evaluation might result in the following decisions:

- a) acceptance,
- b) correction in a specified time period, or
- c) rejection and discard or eradication in order to prevent their unintended use.

2.6.5.0210. For counterfeit and fraudulent products as special non-conformities targeted preventive, control and corrective processes shall be developed and operated in the management system.

2.6.5.0300. Concessions granted to allow acceptance of a non-conforming product or process shall be subject to internal licensing process and authorization if necessary. When non-conforming products and processes are corrected, they shall be submitted to repeated inspection to demonstrate that they meet the requirements or expected results.

2.6.5.0400. Corrective actions for eliminating non-compliance shall be determined and implemented. Preventive measures to avoid their recurrence and to eliminate the causes of potential non-compliances shall be determined and executed.

2.6.5.0500. All corrective and preventive measures shall be monitored, and their effectiveness shall be evaluated and reported to the appropriate management level within the organization of the licensee.

2.6.5.0600. Potential non-compliances that may decrease the performance of the licensee shall be identified by feedback from other external or internal organizations, by technical developments and research, through the sharing of knowledge and experience, and by techniques that determine best practical methods.

2.6.6. Improvement

2.6.6.0100. The opportunities for improvement of the management system shall be identified and measures to improve and correct processes shall be selected, planned, implemented, and documented.

2.6.6.0200. Plans for improvement shall contain assurance for adequate resources. Measures for improvement shall be monitored until their completion, and the effectiveness of the improvement shall be controlled.