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## **DRAFT REGULATION**

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# **Regulation for Leadership and Management for Safety in Nuclear Facilities**

**(FANR-REG-01)**

**Version 1**

**2022**

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Federal Authority for Nuclear Regulation (FANR)

P.O. Box 112021, Abu Dhabi, United Arab Emirates

[regulation@fanr.gov.ae](mailto:regulation@fanr.gov.ae)

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## Preamble

This regulation is issued by the Federal Authority for Nuclear Regulation pursuant to the powers conferred to its Board of Management in Article 11(4) and Article 38(1) of the Federal Law by Decree No. 6 of 2009 Concerning the Peaceful Uses of Nuclear Energy (the Law).

## Definitions

### Article (1)

1. For the purposes of this regulation, the following terms shall have the meaning ascribed to them in Article 1 of the Law, unless the context requires otherwise: Accident, Authority, Closure, Commissioning, Construction, Decommissioning, Design, Emergency, Ionizing Radiation, Licence, Licensee, Nuclear Facility, Nuclear Security, Operation, Person, Radiation Protection, Radiation Sources, Radioactive Material, Radioactive Waste, Regulated Activity, Regulatory Inspection and Safety.
2. In addition, the following terms shall have the meanings set forth below.

<b>Counterfeit Items</b>	Items that are intentionally manufactured, refurbished or altered to imitate original products without authorization in order to pass themselves off as genuine.
<b>Fundamental Safety Objective</b>	The objective to protect people and the environment from the harmful effects of Ionizing Radiation, as described in the International Atomic Energy Agency (IAEA) Safety Standard 'Fundamental Safety Principles' (Safety Fundamentals (No. SF-1), 2006 edition).
<b>Fraudulent Item</b>	Items that are intentionally misrepresented with the intent to deceive. Fraudulent items include items provided with incorrect identification, falsified or inaccurate certification.
<b>Individual(s)</b>	Employees of the applicant for a Licence to conduct a Regulated Activity relating to a Nuclear Facility or of the Licensee as well as employees of the Licensee's consultants or contractors.
<b>Interested Parties</b>	A general term encompassing all public or private organisations (with the exception of the Authority), entities

or individuals with a stake or interest in a particular Regulated Activity.

**Leadership**

The use of a person's capabilities and competences to give direction to Individuals and groups of Individuals, and influence their commitment to achieving the Fundamental Safety Objective and to applying the 'fundamental safety principles' by means of shared goals, values and behaviour.

**Management System**

A set of interrelated or interacting roles and elements for establishing policies, goals, strategies, plans and objectives of the Licensee's organisation, and enabling them to be achieved in an efficient manner. It includes the Licensee's organisational structure, resources and organisational processes. The Management System supports the Licensee's achievement of the Fundamental Safety Objective.

**Management System Review**

A regular and systematic evaluation by the Senior Management of the suitability, adequacy, effectiveness and efficiency of the Licensee's Management System in executing the policies and achieving the goals, strategies, plans and objectives of the organisation.

**Product**

An all-inclusive term used in place of any of the following: assembly, component, equipment, module, sub-assembly, sub-system, system or element of an item or equipment related to a Nuclear Facility and that may influence Safety.

**Safety Culture**

The assembly of characteristics in the Licensee's organisation and the attitude of Individuals, which establishes that protection and safety issues as an overriding priority receive the attention warranted by their significance.

**Security Culture**

The characteristics in a Licensee's organisation and attitude of Individuals, which establish that Nuclear Security issues receive the attention warranted by their significance.

**Senior Management** The person who, or group of people which within the organisation, directs, controls and assesses the Licensee's organisation at the highest technical level, including the chief executive officer and chief nuclear officer.

**Supply Chain** Processes and Persons involved in the production, procurement and the distribution of Products or services.

**Suspect Items** Items where there is indication or suspicion that they may not be genuine.

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## **Objective and Scope**

### **Article (2)**

1. This regulation establishes the requirements for the establishment, sustainability and continuous improvement of Leadership and Management for Safety and an effective Management System within a Nuclear Facility, which support and sustain a strong Safety Culture and Security Culture to ensure that the Fundamental Safety Objective is achieved.
2. This regulation applies to the siting, Design, Construction, Commissioning, Operation, Closure, Decommissioning of a Nuclear Facility, as well as any subsequent period of institutional control. This regulation also applies to all the operational states of a Nuclear Facility, to Accident conditions and to a nuclear or radiological Emergency at a Nuclear Facility.
3. This regulation applies, as appropriate, to the applicant for a Licence to conduct a Regulated Activity relating to a Nuclear Facility who shall demonstrate, and/or to the Licensee who shall ensure the implementation, of the requirements established by this regulation.

## **PART 1**

### **Responsibility for Safety and Leadership for Safety**

#### **Responsibility for Safety**

### **Article (3)**

1. The Licensee shall ensure that the Fundamental Safety Objective is achieved.
2. The Senior Management shall ensure the following:
  - a) Safe siting, Design, Construction, Commissioning, Operation and Decommissioning or Closure of a Nuclear Facility;
  - b) The Products used and the activities conducted in a Nuclear Facility meet the standards of Safety, quality and management;
  - c) Safe management and control of all Radioactive Material and Radiation Sources that are produced, processed, used, handled, transported, stored or disposed of.
  - d) Managers and Individuals at all levels in the organisation develop and maintain an understanding of radiation risks and potential consequences, and of management of radiation risks relevant to their responsibilities;
  - e) Provision is made for adequate resources and funding to ensure Safety, including the long-term management and disposal of Radioactive Waste, as well as the

Decommissioning (or Closure) of a Nuclear Facility with due consideration given to the protection of the future generations.

- f) Adequate resources are provided and arrangements are made, implemented and regularly reviewed, where appropriate, for preparedness and response to a nuclear or radiological Emergency.

### **Responsibilities of the Licensee's Board of Directors**

#### **Article (4)**

- a) The board of directors shall demonstrate strong and effective Leadership for Safety and shall be responsible for promoting and supporting a strong Safety Culture and Security Culture in the organisation.
- b) In its decision-making, the board of directors shall ensure that Safety and the Management System supporting achievement of the Fundamental Safety Objective are not compromised by other priorities.
- c) The board of directors shall provide adequate competences and sufficient resources to the organization of the Licensee to carry out the activities thereof safely.
- d) The board of directors shall monitor, through the Senior Management, the overall Safety performance of the organisation and shall take the necessary actions to ensure the highest level of Safety.

### **Management's Leadership for Safety**

#### **Article (5)**

1. The Senior Management shall demonstrate Leadership for Safety by:
- a) Establishing, advocating and adhering to an organisational approach to Safety that stipulates that, as an overriding priority, issues relating to Safety receive the attention warranted by their highest significance;
- b) Acknowledging that Safety encompasses interaction between people, technology and the Licensee's organisation;
- c) Establishing behavioural expectations that support a strong Safety Culture and Security Culture;
- d) Establishing the acceptance of personal accountability in relation to Safety on the part of all Individuals in the Licensee's organisation and establishing that decisions taken at all levels take account of priorities and accountabilities for Safety.



2. Taking into account their duties, managers at all levels in the organisation shall ensure that their Leadership includes the following:
  - a) Setting goals for Safety that are consistent with the policy for Safety of the Licensee's organization, actively seeking information on Safety performance within their area of responsibility and demonstrating commitment to improving Safety performance;
  - b) Developing individual and organisational values and expectations for Safety throughout the organisation by means of their decisions, statements and actions;
  - c) Ensuring that their actions serve to encourage the reporting of Safety related problems, develop questioning and learning attitudes and correct acts or conditions that are adverse to Safety.
3. The managers at all levels in the organisation shall:
  - a) Encourage and support all Individuals to achieve Safety goals and perform their tasks safely;
  - b) Engage all Individuals to enhance Safety performance;
  - c) Clearly communicate the basis for a decision relevant to Safety.

## **PART 2**

### **Management for Safety**

#### **General Requirements**

##### **Article (6)**

1. The Senior Management shall be responsible for establishing, applying, sustaining and demonstrating commitment to the implementation and continuous improvement of the Management System of the Licensee's organisation to ensure Safety.
2. The Senior Management shall remain accountable for the Management System even where Individuals are assigned responsibility for the development, application and maintenance of the Management System.
3. The Senior Management shall establish a Safety policy and shall ensure:
  - a) Consistency of goals, strategies, plans and objectives of the Licensee's organisation with the Safety policy and their development in such a manner that does not compromise Safety at the expense of other priorities;
  - b) Supporting the implementation of the Management System;
  - c) Acting as a role model in the implementation of the values and expectations included in the Safety policy;

- d) Communicating to Individuals the obligation to adopt these values and behavioural expectations in order to comply with the requirements of the Management System;
  - e) Mandating the involvement of Individuals in the implementation and continual improvement of the Management System of the organisation;
  - f) Establishing measurable Safety goals that are in line with the strategies, plans and objectives at various levels in the organisation, and clearly identifying as to when, how and by whom decisions are to be made within the Management System;
  - g) Establishing a periodic review of goals, strategies, objectives and plans of the organisation against the Safety objectives, and enabling actions to be taken to address any deviation.
4. Expectations of Interested Parties shall be considered by the Senior Management in the activities and interactions of the Management System processes, with the aim of enhancing the Interested Parties' satisfaction whilst ensuring that Safety and Nuclear Security are not compromised.
  5. The Senior Management shall designate a qualified Individual to report directly to the Senior Management. The designated Individual shall have the authority to and responsibility for the following:
    - a) Coordinating the development and implementation of the Management System;
    - b) Reporting on the performance of the Management System, including the Management System influence on Safety, Nuclear Security, Safety Culture and Security Culture and any need for improvement;
    - c) Resolving conflicts relating to the requirements and processes of the Management System.
  6. The applicant for a Licence to conduct a Regulated Activity related to a Nuclear Facility and a Licensee may delegate the work of establishing and implementing the Management System to others, such as own contractors, agents or consultants, but shall retain the primary responsibility for the Management System.

## **Management System**

### **Article (7)**

1. The applicant for a Licence to conduct a Regulated Activity relating to a Nuclear Facility shall establish, and the Licensee shall maintain, implement, assess and continually improve a Management System that is in line with the policies, goals, strategies, objectives and plans of the organisation, and contributes to their achievement.

2. As part of a Licence application and within the framework of a Regulatory Inspection or any other request from the Authority, the Licence applicant shall demonstrate and the Licensee shall ensure the implementation of an effective Management System and fulfilment of the applicable requirements.
3. The main objectives of the Management System shall be to enhance Safety and support a strong Safety Culture by:
  - a) Bringing together in a coherent manner all the requirements to safely manage activities of the Licensee's organisation;
  - b) Describing the planned and systematic actions necessary to provide adequate assurance that all the requirements to safely manage the activities of the Licensee's organisation are met;
  - c) Ensuring that health, environmental, security, quality, human and organisational factors, and economic and financial requirements and considerations are not considered separately from Safety requirements so as to preclude their possible negative impact on Safety;
  - d) Ensuring that Safety is paramount within the Management System, overriding all other considerations.
4. The Management System shall identify and shall integrate all legislative and regulatory requirements that apply to the Regulated Activities and Nuclear Facilities of the Licensee.
5. Arrangements shall be made in the Management System for establishing an independent review committee to evaluate decisions significant to Safety and formulate recommendations to the Senior Management and the board of directors of the organisation, as required.
6. The following shall be specified in the Management System with regards to the review committee:
  - a) Requirements for the independent nature of the review committee;
  - b) The necessary competencies to conduct the review;
  - c) Engagement with the Senior Management and the board of directors, as required, for the recommendation of decisions significant to Safety. .
7. The Management System shall include arrangements to support a clear, systematic, timely and transparent decision-making process at all levels of the Licensee's organisation. Such a decision-making process shall rely, inter alia, on technical and qualitative inputs.
8. Arrangements shall be made in the Management System to identify and resolve any conflicts arising in the decision-making process, including identification and resolution of

potential conflicts between Nuclear Security measures and Safety measures, in a manner that shall not compromise Safety.

9. Arrangements shall be made in the Management System to identify and appropriately analyse the actual and potential impact of any changes on Safety, including organisational changes and changes in corporate governance structure or the arrangements thereof, and the cumulative effects of minor changes.

### **Graded Approach**

#### **Article (8)**

1. The Management System shall be developed and implemented using a graded approach based on criteria that shall be documented in the Management System taking the following into consideration:
  - a) The Safety significance and complexity of:
    - I. the Licensee's organisation,
    - II. the Operation of a Nuclear Facility, or
    - III. conducting a Regulated Activity.
  - b) The hazards and the magnitude of the potential risks associated with the Safety, Nuclear Security, safeguards, Radiation Protection, environmental, quality and economic elements of a Nuclear Facility;
  - 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. The graded approach shall also be followed for the implementation of the requirements of the Management System on the Products and activities of each process within the organisation.

### **Documentation**

#### **Article (9)**

1. The Management System shall be documented. The documentation of the Management System shall be complete, controlled, usable, readable, easily identifiable and readily available.
2. The documentation of the Management System shall include, as a minimum, description of the following:
  - a) Policies of the Licensee on values and behavioural expectations;

- b) The Fundamental Safety Objective;
  - c) the Licensee's organisation, including the governance and structure thereof;
  - d) Responsibilities and accountabilities within both the Management System and Licensee's organisation;
  - e) Levels of authority, including all interactions of those managing, performing and assessing work and all processes;
  - f) Compliance of the Management System with the legislative and regulatory requirements that apply to the Licensee's organisation; and
  - g) Interactions with external organisations and Interested Parties.
3. All Individuals responsible for preparing, reviewing, revising and approving documents of the Management System shall be competent to perform the tasks and shall be given access to appropriate information on which to base their work, input or decisions.

## **Resources Management**

### **Article (10)**

1. The Senior Management shall determine the competences and resources necessary to safely carry out the activities of the organisation. This shall address the need for a sufficient number of qualified and experienced Individuals to perform the activities of the Licensee.
2. The Senior Management shall ensure that :
  - a) Competence requirements are specified for Individuals at all levels;
  - b) Training is provided or other actions taken to achieve and sustain the required proficiency level of competence of Individuals;
  - c) Regular evaluations of the effectiveness of the actions taken to ensure that the required proficiency level of Individuals is achieved and maintained are conducted.
3. The Senior Management shall make arrangements to ensure that the Licensee's organisation has in-house, or accessibility to, the full range of competences and the resources necessary to conduct its activities and discharge its responsibilities to ensure Safety during the siting, Design, Construction, Commissioning, Operation, Closure, Decommissioning of a Nuclear Facility as well as during any subsequent period of institutional control or during a nuclear or radiological Emergency.
4. The board of directors and the Senior Management, as applicable, shall determine the competences and resources the Licensee's organisation has to retain or develop internally, and which competences and resources may be obtained externally to ensure Safety.

5. Arrangements shall be established and maintained to retain and avoid a high turnover of staff in the organisation.
6. The board of directors and the Senior Management, as applicable, shall ensure that competences to be sustained in-house include competences for Leadership at all management levels, competences to support and sustain a strong Safety Culture and Security Culture, and expertise to understand technical, human and organisational aspects relating to a Nuclear Facility in order to ensure Safety.
7. The board of directors and the Senior Management, as applicable, shall establish that Individuals at all levels, including managers, are competent and experienced to perform the assigned tasks, work safely and effectively and understand the standards that they are expected to apply in the completion of their tasks.
8. All Individuals in the Licensee's organisation shall be trained in the relevant requirements of the Management System. Training shall be conducted to ensure that Individuals are knowledgeable of the relevance and importance of how their activities contribute to ensuring Safety in the achievement of the Licensee's organisation goals, strategy, plans and objectives.

### **Knowledge Management**

#### **Article (11)**

1. The information and knowledge of the organisation shall be managed as a resource through:
  - a) Identification of important information, knowledge and experiences within the Licensee's organisation; and
  - b) Appropriate management, retention and transfer of the identified important information, knowledge and experiences within the organisation.

In order to maintain knowledge, the Senior Management shall determine, provide, maintain and re-evaluate the necessary infrastructure and working environment.

### **Process Implementation**

#### **Article (12)**

- 1) The processes of the Management System that are needed to achieve the Licensee's organisation goals, strategies and plans and the Fundamental Safety Objective shall provide means to meet all applicable requirements. The activities of the organisation during the siting, Design, Construction, Commissioning, Operation, Closure,

Decommissioning of a Nuclear Facility, as well as any subsequent period of institutional control, shall be planned, implemented, assessed and continually improved.

- 2) The sequence and interactions of the Management System processes shall be explicitly determined.
- 3) The methods necessary to ensure the effectiveness of both the implementation and the control of the processes in the Management System shall be determined and implemented.
- 4) The development of each process in the Management System shall ensure achievement of the following:
  - a) Process requirements, such as applicable legislative, regulatory, Safety, Radiation Protection, environmental, Nuclear Security, safeguards, quality and economic requirements, are specified and addressed;
  - b) Hazards and risks are identified together with any necessary mitigating actions;
  - c) Interactions with interfacing processes are identified;
  - d) Process inputs are identified;
  - e) Process flow is described;
  - f) Process outputs are identified; and
  - g) Process measurement criteria are established.
- 5) The activities of and interfaces between different Individuals or teams involved in a single process in the Management System shall be planned, controlled and managed in a manner that ensures effective communication and clear assignment of responsibilities.

## **Process Management**

### **Article (13)**

1. Processes and activities shall be developed and effectively managed to achieve the organisation's goals, strategies, plans and the Fundamental Safety Objective.
2. A qualified Individual for each process who has the relevant authority and responsibility shall be designated to do the following:
  - a) Develop and document the process, and maintain the necessary supporting documentation;
  - b) Ensure effective interaction between interfacing processes;



- c) Ensure that process documentation is consistent with any existing documents of the organisation;
  - d) Ensure that the records required to demonstrate that the process results have been achieved are specified in the process documentation;
  - e) Monitor and report on the performance of the process;
  - f) Promote improvements in the process;
  - g) Ensure that the process, including any subsequent changes to it, is in line with the goals, strategies and plans of the organisation and the Fundamental Safety Objective.
3. For each process, all activities for inspection, testing, verification and validation, as well as their acceptance criteria and the responsibilities for carrying out such activities, shall be specified. Each process shall specify if and when these activities are to be performed by designated Individuals or teams other than those who have originally performed the work. The process shall specify when and at what stages independent inspection, testing, verification and validation are required to be conducted.
4. Each process shall be periodically evaluated to ensure that it remains effective.
5. The work performed in each process or activity that may have implications on Safety shall be carried out in accordance with the latest approved procedures, instructions and drawings. Such procedures, instructions and drawings shall be validated by an assigned process owner before their initial use and shall be periodically reviewed to ensure their adequacy and effectiveness. Results of the periodic reviews shall be compared with expected values.
6. The control of processes that are implemented by the third party to which services or tasks are outsourced are identified within the Management System. The Licensee's organisation shall retain primary responsibility for the processes that are implemented by such third parties.
7. The sequencing of a process and the interaction between processes are specified so that Safety is not compromised. Effective interaction between interfacing processes within the organisation shall be ensured. Effective interactions between processes implemented within the organisation and processes implemented by an external service provider shall also be maintained.
8. New processes or modifications to existing processes are designed, verified, approved and applied so that Safety is not compromised.



## **Control of Documents and Records**

### **Article (14)**

1. All documents in the Management System shall be controlled, including policies, processes, procedures, instructions, specifications and drawings (or representations in other media), training material and any other documents that describe processes, specify requirements or establish Product specifications. Document users shall be fully aware of correct and appropriate documents and use them.
2. Changes to documents shall be reviewed and recorded, and shall be subject to the same level of approval as the initial documents.
3. Policies, processes, procedures and instructions shall be established to adequately classify and protect the information included in the document control system to comply with all the relevant applicable requirements for data security.
4. Records shall be specified and controlled in the Management System, and shall be readable, complete, identifiable and easily retrievable.
5. Records shall be maintained for evidence that activities which may influence quality and Safety were performed in line with the established procedures and specifications.
6. The retention time of all documents, records, and associated test materials and specimens shall be in line with legislative and regulatory requirements and according to the Authority-approved knowledge management procedures of the Licensee.
7. The media used for records of the Licensee shall ensure that the records are readable for the duration of the retention times specified for each record.

## **Control of Products and Services**

### **Article (15)**

1. The supplied Products and services that may influence Safety shall be assessed to ensure that they meet the established specifications as well as the requirements established by the Authority, including the requirements relating to quality. Products and services that interface or interact with each other shall be identified and controlled.
2. Activities for inspection, testing, verification and validation of the Products and services in the Licensee's organisation shall be completed before acceptance of the Products and services, their implementation, installation or operational use. The tools and equipment used for the inspection, testing, verification and validation of the Products and services shall be of a proper range, type, accuracy and precision.

3. Products shall meet the specified requirements, including the requirements of quality, and shall perform adequately in service.
4. Products shall be provided in such a form that compliance with their design, quality and service requirements can be verified.
5. Controls shall be applied to ensure that Products and services do not bypass the required verification activities, as set out in paragraph 2 of this Article.
6. Products shall be identifiable to ensure proper use, and where traceability of a Product is a requirement, the Licensee shall control and record the unique identification of the Product.
7. Each Product shall be handled, transported, stored, maintained and operated in compliance with the specifications to prevent damage, loss, deterioration or inadvertent use.

## **Purchasing**

### **Article (16)**

1. For purchasing Products and services that may influence Safety, the Management System shall include procedures and arrangements for the procurement activities, including procedures and arrangements for the qualification, selection, evaluation of suppliers and their performance, and an internal oversight of the Supply Chain.
2. Suppliers of Products and services shall be selected based on specific relevant criteria, and their performance shall be evaluated.
3. Requirements for services and Products shall be developed and specified in the procurement documents.
4. The Licensee shall maintain the necessary competence to set out the scope and standard of a required Product or service and subsequently assess whether the Product or service supplied meets the applicable Safety requirements.
5. Requirements for the reporting, evaluation, resolution, recording and reporting of non-conformances of Products or services, including of Counterfeit, Fraudulent and Suspect Items shall be specified in the procurement documents.
6. The Licensee shall retain responsibility for Safety for all Products and services received, including purchasing processes carried out by other organisations.
7. The Licensee shall have controls, processes and programs in place for the oversight of contractors and suppliers to detect and prevent Counterfeit, Fraudulent and Suspect Items (CFSI).

## Communication

### Article (17)

1. At the internal level, the Senior Management shall communicate to the Individuals and ensure their understanding and implementation of the following:
  - a) The requirements related to Safety and Nuclear Security;
  - b) The Licensee's policies, goals, strategies, plans, objectives and processes on Safety, security and quality.
2. The board of directors and the Senior Management shall identify the Interested Parties for the organisation, and shall approve a strategy to be developed and implemented for interaction with the Interested Parties and the public.
3. The processes and plans resulting from the strategy shall include the following:
  - a) Appropriate means of communicating routinely and effectively with the Interested Parties and the public on the radiation risks associated with the Operation of a Nuclear Facility and on conducting the related activities;
  - b) Appropriate means of timely and effective communication with the Interested Parties and the public in circumstances that have changed or were unanticipated;
  - c) Appropriate means of disseminating necessary information relevant to Safety to the Interested Parties and the public;
  - d) Appropriate means of taking into consideration in the decision-making processes the Safety-related concerns and expectations of the Interested Parties;
  - e) The organisation's Safety, Nuclear Security, quality policies, related goals, strategies, objectives and plans to all Interested Parties to ensure that they are familiar with the expectations and requirements and understand them.

## Organisational Changes

### Article (18)

1. The organisational changes, including those relating to the Licensee's governance structure and governance arrangements, shall be:
  - a) Evaluated and classified according to their importance to Safety and security, and each change shall be justified. Objectives for organisational changes shall be defined;
  - b) Planned, controlled, monitored, tracked and recorded to ensure that Safety is not compromised;

- c) Communicated to the Authority in accordance with the regulatory requirements and Licence conditions, or as may be requested by the Authority.
2. Notwithstanding the above, changes in the organization related to key Safety positions directly reporting to the Senior Management shall be communicated to the Authority at least one (1) month in advance for review and comments, if any.

### **PART 3**

#### **Safety Culture and Security Culture**

##### **Article (19)**

1. The Management System shall be used to promote and sustain a strong Safety Culture and Security Culture within the Licensee's organisation.
2. All Individuals in the organisation shall contribute to fostering and sustaining a strong Safety Culture and Security Culture.
3. The Senior Management and other managers shall promote and sustain the following:
  - a) A common understanding of key aspects of Safety, Safety Culture and Security Culture within the organisation by carrying out the following:
    - I. Creating awareness and understanding of the Ionizing Radiation risks and Safety hazards, including those related to work and the work environment.
    - II. Ensuring collective commitment to Safety by Individuals and teams within the organisation.
  - b) Acceptance of personal accountability by Individuals for adherence to Safety Culture and Security Culture;
  - c) Providing the means by which the organisation supports Individuals and teams to carry out their tasks safely and successfully whilst taking into account the interaction between the human, technical and organisational factors;
  - c) Reinforcing a learning and questioning attitude across all levels of the organisation and discouraging complacency about Safety;
  - d) Establishing an organisational culture that supports and encourages trust, collaboration, consultation and communication;
  - e) Establishing mechanisms supporting the Individual's rights, responsibilities and the accountability to raise Safety and security concerns and prevent retaliation or discrimination when such concerns are raised;

- f) Providing the means by which the organisation continually seeks to develop and improve its Safety Culture and Security Culture;
- g) Ensuring that Nuclear Security measures do not compromise Safety objectives. Potential conflicting requirements of Nuclear Security and Safety should be carefully analysed to ensure that Safety is not jeopardised;
- h) Establishing mechanisms for:
  - I. reporting problems relating to the human, technical and organisational factors within the organisation,
  - II. reporting within the organisation of any deficiencies in structures, systems and components to avoid degradation of Safety;
  - III. timely acknowledgement and reporting within the organisation of corrective actions taken to address the reported issues.

## **PART 4**

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

#### **General requirements**

##### **Article (20)**

1. Effectiveness of the Management System shall be monitored and measured by the Senior Management and management across all other levels in the organisation to confirm the ability of the licensee's organisation to achieve the intended results and identify opportunities for improvement of the Management System, including minimizing the occurrence of problems relating to Safety. Assessments of Leadership for Safety and of Safety and Security Culture in the Licensee's organisation shall also be conducted.
2. Processes shall be established for the feedback and analysis of operating experience, including initiating events, Accident precursors, near misses, Accidents and Nuclear Security events so that lessons may be learnt, shared and acted upon.
3. Periodic assessments as specified under Articles 20 and 21 of this regulation shall be conducted at planned intervals to support the continuous improvement of the Management System and Leadership for Safety and ensure their continuing suitability and effectiveness.
4. Performance based measures and criteria shall be defined and implemented to monitor and ensure that Safety and Nuclear Security, safeguards and Radiation

Protection requirements are met during the siting, Design, Construction, Commissioning, Operation and Decommissioning or Closure of a Nuclear Facility.

5. The results of the assessments and findings on the effectiveness and suitability of the Management System and of the Leadership for Safety shall be analysed and acted upon, including to foster and sustain a strong Safety Culture and a learning attitude within the Licensee's organisation and to improve Leadership for Safety. They shall be communicated to all levels in the Licensee's organisation, including the board of directors.

### **Self-Assessment**

#### **Article (21)**

1. The Senior Management and management at all levels in the Licensee's organisation shall carry out periodic self-assessments to evaluate and improve the effectiveness of the Management System.
2. Self-assessment of Leadership for Safety Culture and Security Culture shall also be conducted and include assessment at all organisational levels and for all functions in the organisation. The Senior Management shall also ensure that such self-assessment is done with the involvement of Safety Culture and Security Culture of recognised experts within the Licensee's organisation.
3. The findings and/or any significant changes resulting from the periodic self-assessments referred to in paragraph (1) of this article shall be analysed for their implications on Safety.

### **Independent Assessments**

#### **Article (22)**

1. An internal organisational unit shall be established and empowered with the necessary authority to conduct periodic independent assessments on behalf of the Senior Management and the board of directors, as appropriate.
2. The periodic independent assessments shall be conducted to do the following:
  - a) Evaluate and improve effectiveness of the Management System in ensuring Safety, Nuclear 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 of the Licensee's organisation.
  - c) Determine adequacy and effectiveness of work performance and Leadership for Safety Culture and Security Culture.
  - d) Monitor Product and services' quality and conformity.

- e) Identify opportunities for improvement.
  - f) Determine the adequacy and implementation of the organisation's processes and programmes for the detection, prevention and elimination of CFSI, including for the oversight of contractors and suppliers.
3. The Individuals assigned to perform such independent assessments shall be given sufficient authority to discharge their responsibilities and shall have direct access to Senior Management; such Individuals shall not assess:
- a) Their own work;
  - b) Areas under responsibility of their own line management.
4. The independent assessments shall include the use of performance based measures and criteria established pursuant to Article 20(4) of this regulation.

### **Management System Review**

#### **Article (23)**

1. The Management System Review shall be conducted by the Senior Management at planned intervals to ensure the continuing suitability, effectiveness and efficiency of the Management System as well as its ability to enable the objectives, goals, strategies and plans of the Licensee's organisation to be accomplished taking into account the new requirements and changes in the Licensee's organisation.
2. The Management System Review shall cover, but shall not be limited to, the following:
  - a) Output from all forms of assessment;
  - b) Results delivered and goals, strategies, plans and objectives achieved by the organisation;
  - c) Processes;
  - d) Non-conformances identified and corrective and preventive actions taken.
  - e) Lessons learnt from experience gained and from events that have occurred both within and outside the Licensee's organisation as well as lessons learnt from identifying the causes of events;
  - f) Opportunities for improvement;
  - g) Technical advances and results of research and development.
3. Weaknesses and obstacles in the Management System shall be identified, evaluated and remedied in a timely manner.



4. The Management System Review shall identify whether there is a need to make changes to, or improvements in, policies, goals, strategies, plans, objectives and processes of the Licensee's organisation including its staffing.

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

### **Article (24)**

1. The Management System shall include mechanisms to identify, evaluate and correct non-conforming processes, Products, or services, as appropriate.
2. The causes and impact of non-conformance, and the causes of Safety related events that could give rise to radiation risks shall be identified and evaluated. Corrective actions shall be taken in a timely manner to manage and mitigate any potential or actual consequences and prevent their recurrence.
3. The non-conformances, as well as the corrective and preventive actions shall be promptly documented and recorded.
4. Products and processes that do not conform to the specified requirements shall be identified, segregated, controlled, recorded and reported to an appropriate level of management within the organisation. The impact of non-conformances shall be evaluated and non-conforming Products, services or processes shall be either accepted, re-drafted or corrected within a specified period of time, or rejected and discarded or destroyed to prevent their inadvertent use.
5. The Senior Management shall promote 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.
6. The assessment of non-conformances shall be conducted by Individuals whose duties are not directly or indirectly associated with the non-conformance. Such Individuals shall have sufficient expertise and technical knowledge to perform the assessment.
7. Concessions granted to allow acceptance of a non-conforming Product, service or process shall be subject to validation by the Licensee. Re-drafted or corrected Non-conforming Products, services or processes shall be subject to internal inspection to demonstrate their conformity with requirements or expected results.
8. The status and effectiveness of all corrective and preventive actions shall be monitored, evaluated and reported to management at an appropriate level in the organisation.



9. Every Individual shall be given the opportunity to identify non-conformances in processes, Products and services and propose improvements. Individuals shall be informed about the resolution of identified non-conformances.

### **Entry into Force**

#### **Article (25)**

This regulation shall be published in the Official Gazette and shall enter into force six (6) months following the date of its publication in the Official Gazette.

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