NRRC Technical Regulations

Leadership and Management for Safety

NRRC-R-04 2022



هيئة الرقابة النووية والإشعاعية (Nuclear and Radiological Regulatory Commission

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Regulation Leadership and Management for Safety

2022 NRRC-R-04

Preamble

In accordance with the provisions of the Law of Nuclear and Radiological Control issued by Royal Decree No. (M/82) dated 25/7/1439 AH, and NRRC's Statue issued by the Minsters' Cabinet Resolution No. (334) dated 25 /6/1439 AH, the NRRC prepared regulations that ensure control over radiological activities and practices as well as nuclear and radiological facilities.

This regulation has been prepared on the basis of International Atomic Energy Agency (IAEA) standards, international best practices and the experiences of similar international regulatory bodies, and in accordance with the Kingdom's international commitments. This Regulation has been presented in "the Public Consultation Platform" for the public review, comments, feedback.

This regulation has been approved by the NRRC's Board of Directors in resolution No. (R/1/1/2022), dated 20/04/2022.



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Chapter 1: Objective, Scope, and Definitions

Section 1: Objective

1. The objective of this regulation is to provide requirement for establishing, sustaining and continuously improving leadership and management for safety, and an effective management system at the organization and its personnel.

Section 2: Scope

- 2. This regulation applies to all nuclear facilities and activities throughout their entire lifetime, for all operational states and for accident conditions, and in a nuclear or radiological emergency.
- 3. The requirements of this regulation apply to any person applying for a site, construction, operating, or decommissioning license for a nuclear facility and to an organization holding such a license.
- 4. The requirements apply, to the appropriate extent, to the plant supplier, suppliers contributing to nuclear fuel fabrication, safety-significant design and expert organizations, testing and inspection organizations, component and material manufacturers, and other suppliers of safety-significant products and their subcontractors.
- 5. This regulation does not address nuclear security issues related to a nuclear facility.



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Section 3: Definitions

Competence

The ability to apply knowledge and skills to achieve intended results.

Graded approach

For a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied are commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control.

Independent assessment

Assessments such as audits or surveillance carried out to determine the extent to which the requirements for the management system are fulfilled, are conducted to evaluate the effectiveness of the management system and to identify opportunities for improvement.

Lifetime

The period during which an authorized facility is used for its intended purpose, until decommissioning or closure.

Management system

A set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives. The management system integrates all elements of an organization into one coherent system to enable all of the organization's objectives to be achieved. These elements include the organizational structure, resources, and processes.

Management system manual

The manual should specify the management system of the license applicant and how the system integrates safety, health, security, safeguards, quality, economic and environmental issues. The manual should include at least thefollowing:

- i. An overall description of the management system.
- ii. The policy statements of the organization.
- iii. A description of the structure of the organization.
- iv. A description of the functional responsibilities, accountabilities, levels of authority, and interactions of those managing, performing, and assessing the work.
- v. A description of the processes and supporting information explaining how the work is to be prepared, reviewed, carried out, recorded, assessed, and improved.
- vi. A description of interactions with external organizations and interested parties.
- vii. A description of how the management system complies with regulatory requirements.

Process

A course of action or a proceeding, especially a series of progressive stages in the manufacture of a product or some other operation. It is a set of interrelated or interacting activities that transforms inputs into outputs.

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Product

The results or output of a process.

Responsible manager

The responsible manager ensures that the provisions, license conditions, and regulations issued by the NRRC concerning the safe use of nuclear energy, the arrangements for security and emergencies, and the nuclear safeguards are complied with.

Safety culture

The assembly of characteristics and attitudes in organizations and individuals establishing that, as an overriding priority, protection and safety issues receive the attention warranted by their safety significance.

Self-assessment

Self-assessment is a structured, objective, and visible process whereby individuals, groups, and management within an organization evaluate their own operational safety against predetermined performance expectations. A self-assessment program or a self-assessment loop is only complete when identified corrective actions have been implemented and their adequacy confirmed.

Supplier

Any person or organization to whom a registrant or licensee delegates duties, totally or partially, in relation to the design, manufacture, production or construction of a source. Supplier refers to an organization or person manufacturing or providing a product.

Vendor

A vendor is a design, contracting, or manufacturing organization supplying a service, component, or facility.

Chapter 2: Leadership and Management for Safety

Section 4: Responsibility for Safety

- 6. The licensee, starting with the senior management, shall ensure that the fundamental safety objective of protecting people and the environment from the harmful effects of ionizing radiation is achieved.
- 7. The licensee shall retain the prime responsibility for safety throughout the lifetime of facilities and activities, and this responsibility cannot be delegated.
- 8. The licensee shall be responsible for establishing, implementing, sustaining, and continuously improving a management system that gives due priority to safety.
- 9. The licensee shall ensure that adequate arrangements are made for preparedness for and response to a nuclear or radiological emergency.
- 10. The senior management shall establish goals, strategies, plans, and objectives for the organization that are consistent with the organization's safety policy and review them periodically.
- 11. The senior management of the licensee shall ensure that managers and personnel at all levels in the organization develop and maintain an understanding of radiation risks and potential consequences and how to manage radiation risks relevant to their responsibilities.

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Section 5: Leadership for Safety

- 12. Managers at all levels in the organization shall demonstrate leadership for safety and commitment to safety. The management shall establish, advocate, and adhere to an organizational approach to safety stipulating that safety is an overriding priority.
- 13. The management of the organization shall by leadership behavior foster a strong culture of safety.
- 14. The management of the organization shall acknowledge and manage safety as an outcome of the system encompassing interactions between people, technology, and the organization.
- 15. The management of the organizations participating in siting, designing, constructing, commissioning, operating, and decommissioning a nuclear facility shall in their decisions and actions reflect their commitment to improving safety performance and to correcting acts or conditions that are adverse to safety.

Section 6: Provision of Resources

16. The senior management shall determine, provide, and lead the competences and resources necessary to carry out the activities of the organization safely. The licensee shall have access to the professional expertise and technical knowledge required for all activities at each stage in the lifetime of the facility to discharge the responsibilities for ensuring safety.

- 17. The senior management shall ensure that competence requirements for individuals at all levels are specified and shall ensure that training is conducted, or other actions are taken, to achieve and sustain the required levels of competence. The effectiveness of the training and of the actions taken to ensure the adequate competence shall be evaluated systematically.
- The licensee shall ensure that the responsible manager, who is subject to approval by the NRRC, posses the relevant competency to ensure that:
 - a. The facility being constructed is designed so that the nuclear and radiation safety requirements applicable to the operation of the facility can be met;
 - The facility is constructed in compliance with the conditions stated in the construction license and the plans approved at the construction license stage and during construction;
 - c. The actions related to the construction of the facility do not pose potential risks to the nuclear and radiation safety of the on-site plant units currently in operation;
 - d. The security arrangements and emergency arrangements of the facility and the requirements pertaining to nuclear safeguards are duly taken into account during design and construction of the facility;
 - e. The personnel participating in the licensee's project has the necessary competence and qualifications required for their duties;

- f. The nuclear facility is safe to operate;
- g. The necessary security arrangements and emergency arangements and nuclear safeguards are implemented;
- h. The personnel of the nuclear facility have the necessary competence and qualifications;
- i. Decommissioning is planned and implemented in compliance with the approved plans in such a way that the requirements pertaining to nuclear and radiation safety, security arrangements, and emergency arrangements as well as nuclear safeguards are duly met; and
- j. For a site with more than one nuclear facility, the decommissioning activities of the facility do not pose potential risks to the safety of other nuclear facilities still in operation.

Section 7: Management for Safety

- 19. Safety shall be achieved and maintained by means of an effective management system. The licensee shall ensure that the management system integrates all elements of management so that requirements for safety are established and applied coherently with other requirements and so that safety is not compromised by other requirements or demands.
- 20. The management system shall have a clearly defined safety policy that gives safety an overriding priority, requires continuous improvement of safety, and incorporates principles for achieving adequate quality.

- 21. The licensee shall ensure that all organizations participating in the siting, design, construction, commissioning, operation, and decommissioning of a nuclear facility use a management system for ensuring the management of safety.
- 22. The senior management shall ensure that appropriate interaction with interested parties takes place. The senior management shall also identify potential stakeholders for their organization and create an acceptable strategy, methods, and means of communication with them.
- 23. The management system shall cover all organizational activities that have an impact on the nuclear facility's safety. For each activity, requirements significant to safety shall be identified, and measures shall be established to ensure conformity with requirements. Regulatory requirements shall be reflected in the management system.
- 24. The organization's processes and activities shall be carefully planned, implemented, and controlled in accordance with properly validated, approved, and current procedures, which shall be reviewed on a regular basis.
- 25. The management system shall include independent safety reviews for decision making and verifications of organizational activities, that shall be carried out for defined activities as necessary. Arrangements shall be made for the resolution of conflicts arising in decision making processes.
- 26. The organizational structures, processes, responsibilities, accountabilities, authorities, and interfaces within the organization and with

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external organizations shall be clearly specified and documented in the management system.

- 27. Significant organizational functions with respect to safety shall be designated. Training programs and licensing processes shall be established for the purpose of developing and maintaining the professional qualifications of the persons working in such functions, and an adequate command of the functions in question must be verified by the licensee.
- 28. Processes, procedures, and activities shall be developed and effectively managed to achieve the organization's goals without compromising safety. Effective interaction between the interfacing processes shall be ensured. Records to demonstrate that the results of the respective process have been achieved shall be specified in the process documentation.
- 29. The management system shall include effective systematic procedures for identifying, analyzing, and addressing significant safety-related nonconformances. Corrective actions necessary for eliminating the causes of non-conformances, and for preventing the occurrence of, or mitigating the consequences of, similar safety-related events shall be determined, and corrective actions shall be taken in a timely manner. The corrective actions taken shall also be evaluated using appropriate methods to determine their effectiveness.
- 30. The management system shall include processes and procedures for the feedback and analysis of operating experience, including risks, initiating events, accident precursors, near misses, accidents, and

unauthorized acts, so that lessons are learned, shared, and acted upon. Lessons learned and any resulting significant changes shall be analyzed for their implications for safety and changes in operation.

- 31. The management system shall ensure that any changes that could have implications for safety, including organizational changes, are appropriately analyzed and managed. For controlling design changes, a process of configuration management shall be established.
- 32. Safety-significant changes to the management system shall be submitted to the NRRC for approval before their implementation. Minor changes shall be submitted for information before their implementation.
- 33. The management system shall be developed and applied using a graded approach. The criteria for grading shall be documented in the management system.
- 34. The management system shall include the evaluation of advances in science and technology, safety research, and international safety standards as well as the evaluation of lessons from identifying good practices.
- 35. The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified, and readily available at the point of use.
- 36. Documents and records shall be controlled. Revisions to documents shall be controlled as specified in the management system. Moreover, any revision to documents shall be controlled, reviewed, and recorded,

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and the revised documents shall be subject to the same level of approval as the initial documents. All records shall be readable, complete, identifiable, and easily retrievable.

- 37. The licensee shall put in place arrangements with vendors, contractors, and suppliers for specifying, monitoring, and managing the supply of items, products, and services that may influence safety.
- 38. The licensee shall retain responsibility for safety when contracting out any processes and when receiving any item, product, or service in the supply chain.
- 39. The licensee shall make arrangements to ensure that suppliers of items, products, or services important to safety adhere to the safety and quality requirements established for them. Systematic procedures shall be in place to assess suppliers and their products.

Section 8: Culture of Safety

- 40. The licensee shall ensure that a strong safety culture is developed and maintained in all organizations participating in siting, designing, constructing, commissioning, operating, and decommissioning a nuclear facility.
- 41. Safety shall take priority in all decisions and operations at all levels in the organization, and complacency with regard to safety shall be discouraged.
- 42. The management system and leadership for safety shall have a systemic approach that fosters and sustains a strong safety culture. All

individuals in the organization shall contribute to fostering a strong safety culture.

Section 9: Assessment and Improvement

- 43. The senior management shall ensure that the effectiveness of the management system is continuously and regularly monitored and measured, assessed, and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety.
- 44. Self-assessments and independent assessments of the management system shall be regularly conducted to evaluate its effectiveness and to identify opportunities for its improvement.
- 45. The senior management shall conduct an overall review of the management system at planned intervals to confirm its applicability and effectiveness.
- 46. The senior management shall regularly commission self-assessments of leadership for safety and of the safety culture in their own organization. Senior management shall ensure that such self-assessment makes use of recognized experts in the assessment of leadership and of the safety culture.
- 47. The senior management shall ensure that an independent assessment of leadership for safety and safety culture is conducted regularly for the enhancement of the organizational culture of safety.
- 48. The results of self-assessments and independent assessments of leadership for safety and safety culture shall be communicated at all levels in

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the organization. The results of such assessments shall be acted upon to foster and sustain a strong safety culture.

- 49. The senior management shall ensure the continual improvement of the management system based on the results of monitoring and measuring as well as of the assessments to enhance the safety of the facility and the performance of the organization. Necessary improvements shall be implemented without undue delay.
- 50. The management system manual shall be submitted to the NRRC for approval at each licensing phase, except during the siting phase, according to Regulation on Licensing and Regulatory Oversight of Nuclear Facilities (NRRC-R-03).





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