

# NRRC Specific Regulations

## Integrated Management System for Facilities, Activities and Practices with Radiation Sources

**NRRC-R-01-SR13**



هيئة الرقابة النووية والإشعاعية  
Nuclear and Radiological Regulatory Commission

**2023**

**Specific Regulation**

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Radiation Sources

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## Preamble

In accordance with the provisions of the Radiation Safety Regulation (NRRC-R-01), approved by the NRRC's Board of Directors in resolution No. (R/1/1/2022), dated 20 April 2022, in chapter (3) section (12), this specific regulation establishes specific criteria for the development and implementation of an integrated management system, prioritizing safety and security in facilities applying activities, and practices.

This specific regulation has been prepared on the basis of International Atomic Energy Agency (IAEA) standards, as well as the and the international best practices and the experiences of similar international regulatory bodies, and in accordance with the Kingdom's international commitments, and it has been approved by the NRRC's CEO resolution No. 1367 dated 9/7/2023.



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## **Chapter 1: Objective, Scope, and Definitions**

### **Section 1: Objective**

1. This specific regulation establishes the requirements for the development and implementation of an integrated management system (hereinafter referred to as the IMS) in line with a related and approved international quality management standard, prioritizing safety and security in all facilities applying activities, and practices with radiation sources in the Kingdom.

### **Section 2: Scope**

2. This specific regulation applies to:
  - a. All authorized facilities and activities with radiation sources in the Kingdom;
  - b. All authorized persons intending to operate facilities and apply activities and practices with radiation sources in the Kingdom, regardless of whether they are fully or partly owned or controlled by a person from another country or by a foreign corporation; and
  - c. The provision of services to external facilities that requires the presence of employees in controlled or supervised areas.
3. This specific regulation does not apply to:
  - a. Nuclear fuel cycle facilities, activities or practices;
  - b. Facilities, activities or practices with nuclear related items; and

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- c. Research reactors.
4. The requirements defined in this specific regulation are in line with and complement the requirements set in the international quality management standard prescribed under Article 1 and the relevant NRRC regulations concerning facilities and activities with radiation sources.

### **Section 3: Definitions**

#### ***Accident***

Any unintended event including operating errors, equipment failures and other mishaps. The consequences or potential consequences of which are not negligible from the point of view of protection and safety.

#### ***Abnormal events***

Events that fall outside the remit of agreed or expected activities that may also lead to undesirable outcomes.

#### ***Continuous improvement***

Recurring activity to increase the ability to fulfil requirements.

#### ***Conformity***

Fulfilment of a requirement.

#### ***Corrective action***

Action to eliminate the cause of a detected nonconformity or other undesirable situation.



***Document***

Information and its supporting medium.

***Fraudulent items***

Items that are intentionally misrepresented with intent to deceive.

***Information***

Meaningful data.

***Integrated management system***

A single coherent management system for facilities and activities in which all the component parts of an organization are integrated to enable the organization's objectives to be achieved.

***Interested party***

A person, company, etc., with a concern or interest in the activities and performance of an authorized facility and activity.

***Lesson learned***

A good work practice or innovative approach that is captured and shared to inform potential application. A lesson learned may also be an adverse work practice or experience that is captured and shared to avoid recurrence.

***Organization***

Group of people and facilities with an arrangement of responsibilities, authorities, and relationships.

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### ***Organizational structure***

Arrangement of responsibilities, authorities and relationships between people.

### ***Quality control (QC)***

Part of quality management intended to verify that structures, systems and components correspond with predetermined requirements.

## **Chapter 2: Integrated Management System (IMS) Fundamentals**

### **Section 4: Safety, Security, and IMS Harmonization**

5. The authorized person shall establish, implement, sustain and continuously improve an IMS which, among others:
  - a. Ensures compliance with the applicable regulations and regulatory provisions;
  - b. Clearly defines the organizations safety and security policy;
  - c. Establishes goals, strategies, plans and objectives for the organization that are consistent with the organization's safety and security policies;
  - d. Seeks the integration of the elements of the management system;
  - e. Demonstrates the organization's management commitment to safety and security;
  - f. Ensures that safety and security is embedded at all organizational and operational levels;



- g. Ensures that processes and procedures are developed and effectively managed to achieve the organization's goals without compromising safety and security;
  - h. Integrates safety, health, environmental, security, quality, human, organizational, societal and economic elements, so that safety and security are not compromised;
  - i. Ensures that no benefits are offered as substitutes for measures for protection and safety.
  - j. Integrates all the key elements for safety and security from any previously implemented management system; and
  - k. Anticipates abnormal events to prevent safety-threatening events as effectively as possible and provides instructions for the case that any such should occur.
6. The authorized person shall ensure that the implemented IMS:
- a. Includes appropriate arrangements to record decisions concerning the organization's management and activities;
  - b. Includes appropriate arrangements to record the planned and systematic actions necessary to build confidence regarding the compliance with all safety and security requirements;
  - c. Includes the necessary provisions for the resolution of conflicts that arise from the decision-making processes that affect safety and security;

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- d. Defines the structures, processes, responsibilities and internal and external communication channels of the organization;
  - e. Includes provisions and requirements for independent review of the decision-making processes that affect safety and security;
  - f. Includes appropriate arrangements for the identification and analysis of any change that may have significant safety or security consequences, including changes in the organization or cumulative effects of minor changes.
7. The authorized person, irrespective of the organization's size or the scale of its activities, shall address in the implemented IMS, at least, the requirements which are set in the corresponding international quality management standards, such as ISO 9001.

### **Section 5: Graded Approach**

8. The authorized person shall ensure that the development, scope, content, and implementation of the IMS are commensurate with the incurred safety and security risks associated to the operation of the facility and the applied activities and practices.
9. Considering the organization's needs and based on the magnitude of the risks associated to the facility and the applied activities, the authorized person shall appropriately define general and specific grading levels for addressing regulatory requirements, safety, security, and operational performance.



10. When defining the grading levels under Article 9, the authorized person shall consider the following factors:
  - a. The safety and security characteristics of the facility and the radiation sources used;
  - b. The maturity and complexity of the applied activities and practices and the associated safety and security risks;
  - c. The significance of hazards related to safety, health, environment, security, and economical aspects;
  - d. The magnitude and likelihood of normal and potential occupational and public exposures;
  - e. The necessary measures to mitigate the consequences of foreseeable incidents and accidents;
  - f. The available human resources and the competence of the staff; and
  - g. The related regulatory requirements.
  
11. Considering the grading levels under Article 9, the authorized person shall ensure that the implemented IMS management system includes appropriate arrangements addressing the regulatory requirements for the scope and content of the:
  - a. Safety assessment;
  - b. Radiation protection program;
  - c. Radioactive waste management activities;

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- d. Radioactive sources security plan;
  - e. Emergency preparedness and response; and
  - f. Transport security plan of radioactive sources.
12. The authorized person has the responsibility to prove that the objectives, scope, and content of the implemented IMS are in line with a graded approach.

### **Chapter 3: Specific requirements for the IMS**

#### **Section 6: Processes and procedures**

13. The authorized person shall ensure that the IMS processes are in line with the organization's objectives, plans and strategies related to safety and security.
14. The authorized person shall ensure that the IMS processes are developed and managed in such a way that:
- a. The compliance with the related requirements does not compromise safety and security;
  - b. The responsibilities for safety, security and quality are clearly specified, and assigned to competent individuals;
  - c. Their sequence and interrelationships are specified;
  - d. The supporting documentation is preserved;
  - e. The related documentation is consistent with the organization's documents; and



- f. The results of the assessment of the implementation performance, and of the efficiency and effectiveness of the processes and procedures are recorded.
15. The authorized person shall ensure that updates or modifications of the IMS processes, and new processes are designed, verified, validated where relevant, approved and applied in a way that does not compromise safety and security.
16. The authorized person shall ensure that the implemented IMS specifies appropriate evaluation, inspection, testing, verification, and validation procedures, as well as the related acceptance criteria and responsibilities for aspects concerning safety and security.
17. The authorized person shall ensure that any process that may have safety and security consequences is implemented under controlled conditions.
18. The authorized person shall ensure that approved and updated IMS procedures, instructions and plans concerning safety and security are applied, which have been validated before their first use and are periodically reviewed by authorized personnel.
19. The authorized person shall ensure that:
  - a. Production, monitoring, measuring, and testing equipment is appropriately maintained to enable the verification of compliance with the applicable requirements of operational aspects with a safety and/or security impact; and

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- b. Procedures for checking, calibrating, and maintaining monitoring, measuring, and testing equipment are defined in the IMS to ensure the reliability of the related measurements.

### **Section 7: IMS documentation**

- 20. The authorized person shall ensure the availability of the necessary documentation for the IMS, including:
  - a. The description of the IMS (i.e., overview of policies, objectives, etc.);
  - b. Generic IMS procedures; and
  - c. Detailed operational procedures.
- 21. The authorized person shall document the IMS in a readable and understandable language to the personnel.
- 22. The authorized person shall ensure that the IMS documentation clearly addresses all the organizational and operational aspects that are relevant to safety and security.
- 23. The authorized person shall ensure that documentation is:
  - a. Hierarchically organized;
  - b. Controlled;
  - c. Identifiable;
  - d. Traceable;



- e. Reviewed and approved according to regulatory and technical updates; and
  - f. Communicated to the personnel and interested parties.
24. The authorized person shall establish a review and approval documentation cycle, considering different roles and responsibilities, to verify the proper implementation of changes on applicable laws, regulations, and technical requirements concerning safety and security.
25. The authorized person shall ensure:
- a. The protection of sensitive information concerning safety and security; and
  - b. The availability of the most recent version of the ims documentation to the NRRC.

### Section 8: Quality Assurance

26. The authorized person shall ensure that the implemented IMS includes:
- a. Appropriate Quality Assurance (QA) and Quality Control (QC) arrangements for the processes, procedures, systems and devices related to safety and security; and
  - b. Appropriate arrangements to ensure the regular calibration of the measuring equipment used for safety and security purposes and the traceability of the associated measurements.

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## **Section 9: Management of Resources**

27. The authorized person shall ensure that the organization has in-house, or maintains access to, the full range of competences and the resources necessary to conduct its activities and to discharge its responsibilities for ensuring safety and security at each stage in the lifetime of the facility or activity, and during an emergency response.
28. The authorized person shall ensure that the IMS includes plans and arrangements to guarantee that the safety and security provisions are supported by:
- a. Systems in place to identify resource requirements;
  - b. Mechanism to control organization's resources;
  - c. Measures to ensure that safety and security are considered in allocation of resources;
  - d. Systems capable to track and monitor resources; and
  - e. Systems capable to review resources allocation if circumstances change to ensure continued safety and security of operations.

## **Section 10: Interested Parties**

29. The authorized person shall ensure that the implemented IMS includes appropriate arrangements for interacting with and managing the interested parties with respect to:

- a. The communication of radiological risks associated with the operation of the facilities and the application of activities, and practices with radiation sources;
- b. The communication of unforeseen circumstances;
- c. The exchange of necessary information about safety and security; and
- d. The identification of interested parties' interests and expectations in safety and security-related decision-making processes.

### **Section 11: Training and Education**

30. The authorized person shall ensure that the implemented IMS includes appropriate plans and arrangements that demonstrate:
  - a. The systems or processes used to identify and determine the competency requirements for operations with a safety and/or security impact;
  - b. How the safety and security training needs of the organization's staff are identified and covered to meet the related competency requirements;
  - c. That an adequate plan, program, or method exists to ensure that training requirements are met, such as succession-planning or refresher training;
  - d. That there is a systematic process for developing, approving, and reviewing training to ensure it is effective and covers the identified needs;

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- e. That the systems or processes used ensure the content and delivery of the training involves stakeholder consultation, considers adult learning styles and other relevant factors so that the training is effective;
  - f. How training records for all staff will be controlled, monitored, and kept up to date; and
  - g. The training programs are informed by the organization's performance assessment and reviewed on a regular basis.

## **Section 12: Communication**

- 31. The authorized person shall ensure that the implemented IMS includes appropriate arrangements for the effective communication of information related to safety and security throughout the organization.
- 32. The authorized person shall ensure that the arrangements referred in Article 31 address:
  - a. Identification of communication needs;
  - b. The communication processes and infrastructure which are maintained or put in place to address the communication needs;
  - c. The modes of communication that the staff, including contractors, are expected to use;
  - d. The methods that the staff, including contractors, use to communicate information with a safety and/or security impact efficiently and effectively;



- e. The procedure applied for the communication of safety and/or security risks associated with the operation of facilities and the application of activities;
- f. The procedure applied for the communication of unforeseen circumstances regarding safety, health, environment, security, and quality aspects;
- g. The dissemination of relevant and necessary information for safety and security;
- h. The method to identify the interested parties' interests and expectations in safety and security-related decision-making processes are identified;
- i. The procedure applied to communicate topics concerning the prevention of human and organizational failures that may impact safety and security;
- j. The procedure applied to report on and learning from accidents and other incidents following the Regulation on Radiation Safety (NRRC-R-01).

## **Chapter 4 : Suppliers and Subcontractors**

### **Section 13: Supply chain management**

33. The authorized person shall include appropriate arrangements in the implemented IMS to ensure that the full responsibility for safety and security of the facilities and activities under authorization remains to it and it is delegated, in whole or in part, to its suppliers and/or subcontractors.

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34. The authorize person shall include appropriate arrangements in the implemented IMS to ensure that suppliers of radiation sources and subcontractors involved in radiological practices, meet all applicable specific regulations in the Kingdom and products and services are delivered in a quality assured manner.
35. The authorized person shall ensure that the implemented IMS includes appropriate arrangements for the minimization of risks associated to of Counterfeit, Fraudulent and Suspect Items (CFSIs) along the supply chain and to treat them.
36. The authorized person shall ensure that the implemented IMS includes appropriate arrangements to control purchasing activities as applicable for each defined grading range:
- a. Specifications and purchase orders;
  - b. Use of qualified suppliers and subcontractors;
  - c. Agreement on appropriate quality control and acceptance criteria;
  - d. Provisions for settlement of non-conformities and corrective actions and their reporting;
  - e. Quality, safety, and security records to be provided.
37. The authorized person shall ensure that the IMS includes appropriate procedure and criteria for the selection of suppliers and subcontractors.



## **Chapter 5 : Non-Conformities and Corrective and Preventive Actions**

### **Section 14: Non-Conformities**

38. The authorized person shall ensure that the implemented IMS includes appropriate arrangements for the identification of non-conformities with an impact to safety and security and the application of suitable corrective and preventive actions.
39. The authorized person shall encourage the organization's personnel to identify non-conformities and be involved in dealing with them, giving priority to safety and security considerations when defining the necessary corrective and preventive actions.
40. The authorized person shall allocate responsibilities for the monitoring and following up of non-conformities until the adequate completion of the related corrective actions.
41. The authorized person shall include appropriate arrangements in the implemented IMS for the identification of responsibilities and steps to properly identify, segregate, and report non-compliant products and/or activities based on their significance for safety and security and for the allocation of resources for the correction, prevention, and closure of non-conformities.
42. The authorized person shall include appropriate arrangements in the implemented IMS to ensure that Individuals responsible for analyzing non-conformities and determining the associated causes have an adequate understanding of the area in which they are working and

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should have access to pertinent background information concerning the non-conformities.

43. The authorized person shall ensure that the implemented IMS includes a procedure and defines specific thresholds or criteria for investigating deviations from expected outcomes.
44. The authorized person shall ensure that the implemented IMS defines the retention periods for records of non-conformities based on their significance.

#### **Section 15: Prevention of Non-Conformities**

45. The authorize person shall take proactive steps to ensure that a potential non-conformity does not occur.
46. The authorized person shall promote an open atmosphere in the organization to facilitate the identification and handling of any deficiency, non-conformity, and preventive needs.
47. The authorized person shall encourage its personnel to report observed defects or malfunctions during the operation of the facilities and the application of activities, and to propose improvements.
48. The authorized person shall include appropriate arrangements in the implemented IMS to systematic monitor and evaluate the effectiveness of the preventive actions.





## **Chapter 6: Assessments and Improvements**

### **Section 16: Audits**

49. The authorized person shall be responsible to regularly conduct assessments at all levels of the organization to identify, correct and prevent problems related to safety, security, and performance.
50. The authorized person shall:
  - a. Include appropriate arrangements in the implemented IMS to ensure that internal and external audits are carried out on a regular basis to verify compliance with all aspects of the management system and to confirm its continuing effectiveness.
  - b. Select and assign auditors based on their qualifications and experience.
  - c. Establish in the implemented IMS and requirements for the qualifications of prospective auditors and the use of technical specialists to conduct audits.
51. The authorized person shall include appropriate arrangements in the IMS for carrying out and scheduling independent assessment (internal audits, external audits, surveillance and reviews, checks, inspections, and tests) of the processes and activities.

### **Section 17: IMS Review**

52. The authorized person shall be responsible to improve the implement-

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ed IMS and the operational processes and procedures as part of its organizational culture for safety and security.

53. The authorized person shall make appropriate arrangements for the regular review of the implemented IMS to identify opportunities for the improvement of the IMS and the organization's performance in general.
54. The authorized person shall ensure that relevant operating experience, radiological safety and security standards, and new knowledge gained from good practices and incidents in the industry, are analysed and considered to improve the organization's operations and the implemented IMS.
55. The authorized person shall identify and analyse any changes that may have significant safety and security consequences through the implemented IMS, including organizational changes or cumulative effects of minor changes.
56. The authorized person shall ensure that the implemented IMS includes appropriate arrangements to assess the applicability of significant changes and their effects in safety and security, prior to their application.

### **Section 18: Lesson Learned**

57. The authorized person shall encourage its personnel to share the gained operational experience and knowledge within the organization.
58. The authorized person shall coordinate with the NRRC regarding the lessons learned from significant events and share the relevant experience.



59. The authorized person shall ensure that the operational knowledge and experience gained is used to improve processes and supports decision-making for the prevention of accidents and incidents.
60. The authorized person shall ensure that the implemented IMS defines a structured approach for capturing, organizing, evaluating, and applying lessons learned from accidents, incidents, operational experience, and best practices, and disseminating them to the personnel.

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