

**NUCLEAR REGULATORY AUTHORITY,  
GHANA**



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**DRAFT INTEGRATED MANAGEMENT SYSTEMS REGULATIONS FOR  
FACILITIES AND ACTIVITIES INVOLVING THE USE OF IONISING  
RADIATION IN GHANA**

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**2024**

# INTEGRATED MANAGEMENT SYSTEMS REGULATIONS FOR FACILITIES AND ACTIVITIES IN GHANA

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In exercise of the power conferred on the Minister responsible for the Nuclear Regulatory Authority hereinafter referred to as the Authority) acting on the advice of the Board by Sections 91 of the Nuclear Regulatory Authority Act, 2015 (Act 895) (hereinafter referred to as the Act), these Regulations are made this .... day \_\_\_\_\_ of \_\_\_\_\_

### *General Provisions*

#### **Application**

1. These regulations apply to facilities and activities that give rise to radiation risks and which include

- (a) nuclear installations comprising
  - (i) a nuclear power plant;
  - (ii) a research reactor;
  - (iii) a subcritical and critical assembly;
  - (iv) any adjoining radioisotope production facility;
  - (v) a facility for the storage of spent nuclear fuel;
  - (vi) a facility for the enrichment of uranium;
  - (vii) a nuclear fuel fabrication facility;
  - (viii) a conversion facility;
  - (ix) a facility for the reprocessing of spent nuclear fuel;
  - (x) a facility for the predisposal management of radioactive waste arising from a nuclear fuel cycle facility; and
  - (xi) a nuclear fuel cycle related research and development facility;
- (b) a facility for the mining or processing of uranium ores or thorium ores;
- (c) an irradiation installation;
- (d) a facility and/or activity for the management and of radioactive waste, including the discharge of effluents, and the remediation of a site affected by residual radioactive material from a past activity;
- (e) any other place where

- (i) a radioactive material is produced, processed, used, handled, stored or disposed of on a scale that gives rise to the need to provide protection and safety; or
- (ii) a radiation generator is installed;
- (f) any activity that involves the production, use, or import and export of sources of ionising radiation for medical, industrial, agricultural, educational and research purposes;
- (g) the transportation of radioactive material;
- (h) the decommissioning or closure of a nuclear or radioactive material producing facility;
- (i) an activity that involves the design and manufacture of equipment and other works and services to a facility or an activity that gives rise to radiation risks;
- (j) an industrial activity that involves naturally occurring radioactive material that is, or that may be, subject to the requirements for protection and safety.
- (k) an authorised person, throughout the lifetime of a facility and the duration of an activity, for all operational states and for accident conditions, and in a nuclear or radiological emergency.

## **Requirement of Management System**

2. (1) An applicant shall establish a management system that

- (a) defines how the applicant intends to conduct the activity for which the authorisation is sought, to meet the organisational goals of the applicant;
- (b) gives utmost priority to nuclear and radiation safety, security and safeguards, as applicable;
- (c) ensures total compliance with the requirements of the relevant regulations; and
- (d) provides measures for assessment, evaluation and continuous improvement.

(2) Where the application for authorisation is granted and the applicant becomes an authorised person, the authorised person shall

- (a) ensure the participation of personnel in the implementation and continuous development of the management system;

- (b) ensure that the management system describes the organisational structure, responsibilities of management, policies, strategies, processes, procedures and other supporting documents;
- (c) before any changes that have safety and security significance are made to the management system, obtain approval from the Authority;
- (d) ensure that the entire personnel, as well as the suppliers, third parties and contractors working at the facility or engaged in any activity at or with the facility are committed to and comply with the management system;
- (e) retain prime responsibility when outsourcing any process, receiving any item, product or service from the supply chain; and
- (f) ensure that the management system supports the achievement of the fundamental safety and security objective of protecting people and the environment from harmful effects of ionising radiation.

### **Graded Approach**

3. (1) An authorised person shall ensure that the application of the requirements of the management system are graded in a manner that enables appropriate resources to be deployed on the basis of
  - (a) the significance and complexity of each product or activity;
  - (b) the hazards and the magnitude of the potential impact or risks associated with the safety, security, safeguards, radiation protection, environmental, quality and economic elements of each product or activity; and
  - (c) the possible consequences where a product fails or an activity is carried out incorrectly.
- (2) The grading of the application of the management system requirements by the authorised person shall be applied to the products and activities of each process.

### **Integration of the Management System**

4. An authorised person shall ensure that
  - (a) essential elements including safety, health, environmental, security, safeguards, quality, human-technology-and-organisational-factors, societal and economic

elements, are integrated in the management system in order not to compromise protection, safety and security;

(b) the management system is

(i) developed, applied and continuously improved; and

(ii) aligned with the safety and security goals, strategies, plans and objectives of the organisation.

(c) the protection, safety and security significance of the various functions are taken into consideration during the planning and implementation of the management system or when making any modifications to it;

(d) the applicability of significant modifications are assessed before their execution, and the effect of the modifications continuously assessed and monitored;

(e) the management system contains procedures to identify, assess and manage protection, safety risks and security threats relating to the nuclear and other radioactive material, facilities and activities and its operation;

(f) the senior management of the organisation demonstrates leadership for safety and security by, among others,

(i) encouraging and supporting the individuals within the organisation to achieve safety and security goals and perform their tasks safely and securely;

(ii) engaging the individuals within the organisation to participate in the enhancement of protection, safety and security performance;

(iii) communicating clearly the basis for the decisions that are relevant to safety and security;

(iv) establishing, advocating and adhering to an organisational approach to safety, security and safeguards that stipulates safety, security and safeguards as of utmost priority, and which require to be given the attention warranted by their significance;

(v) acknowledging that safety and security encompass interactions between people, technology and the organisation;

(vi) establishing behavioural expectations and fostering a strong safety and security culture as described in the management system;

- (vii) establishing the acceptance of personal accountability in relation to safety and security on the part of the individuals in the organisation, and ensuring that decisions taken at each level takes into account the priorities and accountabilities for safety and security;
- (viii) setting goals for safety and security that are consistent with the organisation's policy for safety and security;
- (ix) ensuring that the actions of management serve to encourage the reporting of safety-related and security-related problems, develop questioning and learning attitudes, and correct acts or conditions that are averse to safety and security; and
- (g) the organisational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organisation and with external organisations are clearly specified in the management system;
- (h) the measures necessary to implement regulatory requirements are reflected in the management system;
- (i) provisions are made in the management system to identify any changes, including organisational changes and the cumulative effects of minor changes, that could have significant implications for safety and security and to ensure that changes are appropriately analysed and addressed; and
- (j) a process is established in the management system for an independent review to be made before decisions significant for safety and security are made.

## **Responsibility of Management**

5. An authorised person shall ensure that the senior management of the authorised person
  - (a) is made accountable for the management system even where individuals are assigned responsibility for coordinating the development, application and maintenance of the management system;
  - (b) establishes a policy that addresses safety, security and safeguards;

- (c) develops individual values, institutional values and behavioural expectations for the organisation to support the implementation of the management system and acts as a role model in the promulgation of the values and expectations;
- (d) communicates to individuals the need to adopt the individual values, institutional values and behavioural expectations in order to comply with the requirements of the management system;
- (e) fosters the involvement of the employees of the authorised person in the implementation and continual improvement of the management system;
- (f) ensures that there is clarity as to how, by whom, and at which step in the process, decisions are to be made within the management system; and
- (g) ensures that the entire personnel working at all facilities and activities mentioned in Regulation 1, comply with the management system.

### **Goals, Strategies, Plans and Objectives**

6. (1) An authorised person shall ensure that the senior management of the authorised person
- (a) establishes measurable goals, strategies, plans and objectives that are consistent with the policy of the organisation in respect to safety, security and safeguards;
  - (b) develops goals, strategies, plans and objectives for the organisation, in a manner that does not compromise safety and security by reason of other priorities;
  - (c) establishes measurable safety and security goals that are in line with the strategies, plans and objectives, at various levels in the organisation;
  - (d) with the approval of the Authority, establish a process
    - (i) for the review of the goals, strategies and plans against the safety and security objective at intervals of at least 12 months; and
    - (ii) that enables action to be taken where necessary to address deviations;
  - (f) establish measures that enable the strategies and ways of working to be unambiguous and consistent, and to be communicated to personnel;

- (g) provides clear plans of action and procedures as well as adequate resources to achieve the goals;
  - (h) institute measures that enable the set goals to be measurable and their achievement to be tracked; and
- (2) The authorised person shall ensure that the management system provides procedures for the planning and follow-up of activities.

### **Interaction with Interested Parties**

7. An authorised person shall ensure that the senior management of the authorised person
- (a) identifies interested parties for the organisation and define an appropriate strategy for interaction with them;
  - (b) establishes processes and plans derived from the strategy, for interaction with interested parties to include appropriate means of:
    - (i) communicating routinely and effectively with interested parties regarding radiation risks associated with the operation of facilities and the conduct of activities;
    - (ii) timely and effective communication with interested parties in circumstances that have changed or that were unanticipated;
    - (iii) dissemination to interested parties of necessary information relevant to safety; and
    - (iv) ensuring that safety related concerns and expectations of interested parties are considered in decision making.

### *Other Responsibilities*

## **Authorised Person's Responsibility**

### **8. (1) An authorised person shall ensure that**

- (a) the applicable regulatory requirements are adhered to during the procurement of products that bothers on the nuclear and radiation safety and security of a facility and/or activity referred to in Regulation 1;
  - (b) an organisation that contributes to the installation delivery or installation modifications understands and complies with the delivery-related requirements; and
  - (c) suppliers of items, products and services important to safety adhere to safety and security requirements and meet the expectations of the organisation in respect of safe and secure conduct in their delivery.
- (2) The authorised person shall assess and ensure the suitability of the procedures of any third-party engaged before the procedures are implemented with regard to any nuclear or other radioactive material, facility or activity referred to in Regulation 1.
- (3) The authorised person shall ensure that a quality assurance programme is developed, implemented, and maintained for all activities, work tasks, procurements, etc. at the various stages of the life-cycle of any nuclear or other radioactive material, facility or activity referred to in Regulation 1.

## **Responsible Manager of Facilities and Activities**

### **9. An authorised person shall**

- (a) appoint a manager with responsibility to ensure that the provisions, authorisation conditions and regulations are strictly complied with;
- (b) ensure that the responsible manager has adequate authority to attend to the duties assigned to the manager;
- (c) ensure that performance of work and the flow of information are
  - (i) organised to make the responsible manager aware of all the essential factors affecting the safety and security of the facility; and
  - (ii) handled as required by their safety and security significance; and

- (d) the responsible manager and any person assisting the manager or acting for the manager have up-to-date knowledge of the operation of the facility and the factors that affect safety and security.

### **Planning and Follow-up of Activities**

- 10. An authorised person shall ensure that the management of the nuclear and other radioactive material, facility or activity, establish strategies and ways of working as well as set goals that support the implementation of the policy on safety, security, safeguards, quality and any other legal or regulatory requirement.

### **Provision of Resources**

- 11. An authorised person shall ensure that

- (a) enough resources are made available to enable the facility or activity to function efficiently under every circumstance, including under operational occurrence and simultaneous accidents at one or several facilities;
- (b) senior management makes adequate provision for the organisation to have in-house, or maintain access to, the full range of competences and the resources necessary
  - (i) to conduct the activities of the organisation
  - (ii) to discharge the responsibilities of the organisation so as to ensure safety and security at each stage in the lifetime of the facility or activity, and during an emergency response;
  - (iii) to establish, implement, assess and continually improve the management system;
- (c) senior management determines the competences and resources the organisation has to retain or has to develop internally, and those competences and resources that may have to be obtained externally, to ensure safety and security;
- (d) the structure of the organisation, the tasks, the number of necessary personnel, qualification requirements, and recruitments planned with associated trainings, are organised early enough to be fully operational at the commissioning stage, and are maintained throughout the facility's lifetime;

- (e) individuals at each level, including managers and other workers
  - (i) are competent to perform their assigned tasks and to work safely, securely and effectively;
  - (ii) understand the standards that they are expected to apply in completing their tasks; and
  - (iii) understand the safety and security implications of their work;
- (f) the management system has instituted measures that enable the organisation to comply with the applicable legal and regulatory requirements of the working environment;
- (g) the competences to be sustained in-house by the organisation include
  - (i) competences for leadership at all management levels;
  - (ii) competences for fostering and sustaining a strong safety and security culture; and
  - (iii) expertise to understand technical, human and organisational aspects relating to the facility or the activity in order to ensure safety and security;
- (h) competence requirements for individuals at all levels are specified and that training is conducted, or other actions are taken, to achieve and to sustain the required levels of competence;
- (i) an evaluation, approved by the Authority, shall be conducted regularly to determine the effectiveness of the training and of the actions taken.
- (j) The information and knowledge of the organisation is managed as a resource.

### *Development and Management of the Processes of the Management System*

## **Development and Implementation of Management System**

**12. (1)** An authorised person shall ensure that

- (a) each process is developed and managed in a manner that enables requirements to be met without compromising safety and security;
- (b) each process is documented, and the necessary supporting documentation is maintained;

- (c) the process documentation is consistent with the existing documentation of the organisation;
  - (d) the records that demonstrate that the results of the respective processes have been achieved are specified in the process documentation;
  - (e) new processes or modifications to existing processes are designed, verified, approved and applied in a manner that does not compromise safety and security;
  - (f) the processes, including any subsequent modifications to them, are aligned with the goals, strategies, plans and objectives of the organisation;
  - (g) in the development, implementation and evaluation of processes, the responsibilities, procedures, and sequence of activities are planned, controlled and managed to ensure effective communication and clear assignment of responsibility for those involved in the process;
  - (h) the management system processes are specified, and suitable for the relevant stage in the lifetime of the facilities and activities;
  - (i) the management system processes take into account radiation and nuclear safety as well as the co-ordination of security and emergency preparedness arrangements; and
  - (j) in the definition and establishment of the processes, the requirements specific to each stage in the lifetime of the facility or activity are complied with.
- (2) The authorised person shall provide written instructions for process-related procedures and the manner of carrying out the activities.
- (3) The authorised person shall ensure that
- (a) the possibility of human error in work performances is taken into account when defining the processes and the activities contained in them;
  - (b) the processes are planned to identify and disclose potential errors as early in the process as possible;
  - (c) work performances are planned and carried out under controlled conditions using only the approved instructions and procedures as well as the appropriate equipment;

- (d) each individual is responsible for the quality of the work of that individual and that the personnel are given adequate training and instructions before they start work;
- (e) the management system establishes procedures for the control of outsourced processes and activities;
- (f) process implementation and effectiveness are continuously followed and periodically assessed as approved by the Authority;
- (g) the processes and supporting documentation are continuously improved; and
- (h) throughout the lifetime of the facility or activity, the management system includes the processes for document management, product control, control of records, procurement, communication, organisational change management, and project management to support safety, security and quality management.

## **Process Management**

**13. (1)** An authorised person shall designate a qualified individual for each process who shall have the authority and responsibility to

- (a) develop, document the process and maintain the necessary supporting documentation;
- (b) ensure effective interaction between interfacing processes;
- (c) ensure that process documentation is consistent with existing documents;
- (d) ensure that 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 the process, is aligned with the goals, strategies, plans and objectives of the organisation; and
- (h) ensuring that each process is at intervals of, at least 12 months, approved by the Authority, evaluated to ensure that the process remains effective and efficient;

**(2)** The authorised person shall specify

- (a) the activities which require inspection, testing, and verification and validation; the acceptance criteria in respect of the activities and the responsibilities for carrying out the activities; and
  - (b) the time and stage at which independent inspection, testing, and verification and validation are to be conducted.
- (3) The authorised person shall ensure that
- (a) the work performed in each process is carried out under controlled conditions, by using approved procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness;
  - (b) the results of the review are compared with expected values; and
  - (c) the control of outsourced processes and activities to external organisations are identified within the management system.
- (4) The authorised person shall submit to the Authority the list of processes categorised according to their safety and security significance.

### *Management System and Process Documentation*

#### **Documentation of the Management System**

14. (1) An authorised person shall document the management system in a manner that is controlled, usable, readable, clearly identified and readily available at any point of use.
- (2) The authorised person shall ensure that the documentation of the management system includes as a minimum
- (a) a policy statement of the organisation on values and behavioural expectations;
  - (b) the fundamental safety objective;
  - (c) the nuclear security objective;
  - (d) the nuclear safeguards objectives, where applicable;
  - (e) a description of the organisation and its structure;
  - (f) a description of the responsibilities and accountabilities;
  - (g) the levels of authority, including the interactions of those managing, performing and assessing work and the processes;

- (h) a description of how the management system complies with regulatory requirements that apply to the organisation or activity; and
- (i) a description of the interactions with external organisations and with interested parties.

## **Document Management**

### **15. An authorised person shall**

- (a) establish systematic procedures for document management;
  - (b) define the procedures and requirements for
    - (i) the documentation of activities and events; and
    - (ii) storing and archiving the resulting documents; and
  - (c) in the case of documents that pertain to final disposal, ensure that additional attention is paid to maintaining the readability of the documents and their availability to different organisations even after the decommissioning or closure of facilities and activities referred to in Regulation 1.
- (1) The authorised person shall ensure
- (a) the secure retention of and accessibility of information relating to waste storage and disposal facilities and activities;
  - (b) that the document management procedures describe among other things, the identification, preparation, drawing up, review, approval, implementation, revision, distribution, archiving, and disposal of documents;
  - (c) that the documents that are to be kept have their storage periods defined, with a clear specification as to whether they are to be stored temporarily, permanently or for the long-term;
  - (d) that the materials and recording methods that are used, where necessary, meet the requirements for long-time storage and availability; and
  - (e) that the document management system takes into account the applicable information security requirements.
- (2) The authorised person shall,

- (a) in drawing up, reviewing, and approving a document, apply the independence principle;
  - (b) ensure that each party involved in drafting, reviewing and approving a document is only involved in one of these activities;
  - (c) ensure that the drawing up, revision, review, and approval of a document are based on a defined authorisation procedure;
  - (d) specify the documents required to be updated, the frequency of updates and the procedures for updating them, taking into account the safety of the document and the security significance and regulatory requirements;
  - (e) ensure that individuals responsible for preparing, reviewing, revising and approving documents are formally assigned, competent to perform the tasks , and given access to appropriate information on which to base their input or decisions;
  - (f) ensure that revisions or changes to documents are controlled, reviewed and recorded and that revised documents are subject to the same level of approval as the initial documents; and
  - (g) ensure that the materials and recording methods used by the authorised person satisfy the requirements for defined retention periods and that the document control system complies with all relevant data security requirements.
- (3) The authorised person shall on the basis of a graded approach, establish policies and programmes to protect information pertaining to the security of the nuclear and other radioactive material, facility and activity from public disclosure.

## **Product Control**

**16. (1)** An authorised person shall ensure that

- (a) specifications and requirements for products, including any subsequent changes, conform to the applicable regulations and standards;
- (b) products that interface or interact with each other are identified and controlled;
- (c) the conformity of a product is assured by the necessary inspection, testing, verification, validation, and qualification before the approval, realization, or

- commissioning of the product, and that the methods and tools used are suitable for their purpose;
- (d) the products are identifiable, verifiable, meet the specified requirements, and perform satisfactorily in service;
  - (e) where traceability is a requirement, the control procedure to identify the products is arranged and documented; and
  - (f) the products are handled, transported, stored, maintained, and used according to the accompanying instructions issued by the responsible unit or manager in order to avoid their damage, loss, deterioration, or inadvertent misuse.
- (2) The authorised person shall implement controls to ensure that products do not bypass the required product verification activities.

## **Control of Records**

### **17. An authorised person shall ensure that**

- (a) records are defined, specified, identifiable, readable, easily traceable and controlled in the process documentation;
- (b) the retention times of records, associated test pieces, and testing materials are defined and established to be consistent with statutory requirements and the knowledge management obligations of the organisation and as required by the Authority;
- (c) the recording media, the manner of recording, and the storage conditions enable the contents to be accessible for the duration of the retention period specified for each record; and
- (d) in specifying the retention period, the nuclear and other radioactive material, facilities and activities, their lifetime and the long duration of nuclear waste management are taken into consideration. Records meeting the following criteria should be stored for the lifetime of their associated facilities or activities:
  - (i) those that would be of significant value in demonstrating capability for safe operation;
  - (ii) those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item;

- (iii) those that would be of significant value in determining the cause of an accident or malfunction of an item; and
  - (iv) those that provide required baseline data for in-service inspections.
- (e) the following records are considered for long term storage:
  - (i) approved specifications of products;
  - (ii) records of the condition of products;
  - (iii) records demonstrating that individuals are competent to perform their work;
  - (iv) records demonstrating compliance with statutory and regulatory requirements;
  - (v) configuration management records; and
  - (vi) records of the investigation of an accident, malfunction or nonconformance.
- (f) they establish storage and location requirements for the maintenance, preservation and protection of records and associated test materials and specimens from the time of their receipt until their disposal.
- (g) the following aspects of its record storage process are detailed:
  - (i) a description of the document or record storage facility;
  - (ii) a description of the filing system to be used;
  - (iii) a method for verifying that the records received are in agreement with associated transmittal documents and that the records are in good condition;
  - (iv) a method for verifying that the records agree with their records index;
  - (v) rules governing access to and control of the files;
  - (vi) a method for maintaining control of and accountability for records removed from the storage facility;
  - (vii) a method for filing corrected or supplemental information and disposing of records that have been superseded; and
  - (viii) periodic checking to ensure that records are not damaged, deteriorating or missing.

## **Purchasing**

### **18. (1) An authorised person shall ensure that**

- (a) systematic procedures are established for purchasing or procuring the facility or activity and the systems, structures, components, supplies, and services of the facility or activity to ensure the purchased products conform to the required specifications and standards and are valid;
- (b) the procedures are by means of a graded approach maintained throughout the lifetime of the facility or activity;
- (c) systematic procedures are established for defining the requirements for the purchased products;
- (d) adequate quality requirements are established for products, and compliance with the quality requirements and achievement of the required quality level are maintained;
- (e) there are adequately qualified personnel to specify the quality requirements and to control the products and suppliers; and
- (f) systematic procedures are established for resolving and reporting nonconformities or deviations from the purchasing requirements.

### **(2) The authorised person shall**

- (a) define the requirements for the selection of suppliers and the selection procedures;
- (b) ensure that the requirements, for the selection of suppliers and the selection of procedures, include the requirements pertaining to the supplier's management system and its quality management;
- (c) ensure that appropriate procedures established for supplier assessment and selection and that records are kept of the assessments;
- (d) before ordering a product, ensure that the ability of the supplier to deliver the product and the related documentation in compliance with the requirements are evaluated;
- (e) where necessary, before the commencement of manufacturing, ensure that a follow-up audit is used to determine the capability of the supplier to deliver the product in a manner that complies with the requirements;

- (f) after the assessment of the ability of suppliers to supply the required products in accordance with the required standards, keep a list of the approved suppliers;
- (g) ensure that the approval of suppliers of products that are important to safety and security is for a fixed duration only and that the periods of validity are defined in the purchasing procedures;
- (h) ensure that every supplier of safety-significant and security-significant items, products and services implements a management system that is appropriately certified or independently evaluated by a third party and complies with relevant requirements;
- (i) before commissioning, ensure that the requirements set for products have been satisfied;
- (j) ensure that product conformity is systematically monitored;
- (k) ensure that the purchasing procedures of the organisation defines the conditions for the use of a sub-contractor by a supplier and for the communication and relaying of relevant requirements within the supply chain; and
- (l) ensure that the management system of the organisation clearly sets out the procedures that should govern the purchase of sets of equipment involving different suppliers and sub-suppliers, the contractual relationships and responsibilities within the entire supply chain.

(3) The authorised person shall

- (a) supervise the suppliers in the supply chain and incorporate the oversight rights of relevant authorities into the supervision procedures;
- (b) in respect of purchases define the documentation to be attached to a product, and control the documentation, during product manufacture and implementation
- (c) ensure that the control procedures are presented in a supplier-specific delivery control plan;
- (d) ensure that the purchasing procedures of the organisation
  - (i) provide for the purchasing of type-approved and serial products for safety-significant components; and

- (ii) define the validation of the suitability and conformity of the products as well as the documentation to be attached to the product;
- (e) require that suppliers draw up a delivery-specific quality plan for the supply of safety-significant and security-significant products which shall be reviewed and approved by the authorised person; and
- (f) establish procedures that reliably prevent the purchasing of counterfeit and fraudulent products.

## **Communication**

### **19. (1) An authorised person shall**

- (a) ensure that the management system of the organisation provides procedures and a means for communicating matters related to nuclear and radiation safety, quality, security and emergency preparedness and response arrangements within the organisation and to interested parties;
- (b) take into consideration, the stage in the lifetime of the facility or activity when planning and implementing communications;
- (c) ensure that any organisational policy on safety, security and quality along with the importance of safety and security are communicated to the personnel;
- (d) ensure that senior management and other managers advocate and support
  - (i) a common understanding of the key aspects of safety culture and security culture within the organisation, including awareness of radiation risks and hazards relating to work and to the working environment, the significance of radiation risks and hazards for safety and the need for a collective commitment to safety and security by teams and individuals;
  - (ii) acceptance by individuals of personal accountability for their attitudes and conduct with regard to safety and security;

- (iii) an organisational culture that supports and encourages trust, collaboration, consultation, trustworthiness and communication;
- (iv) the need for the organisation to provide a means of support for individuals and teams to carry out their tasks safely and securely, report problems relating to the interaction between human, technical and organisational factors and to report any deficiencies in structures, systems and components to avoid degradation of safety, including the timely acknowledgement and report back of actions taken;
- (v) the need to reinforce a learning and questioning attitude at all levels of the organisation and discourage complacency with regard to safety and security;
- (vi) the need to ensure that the management has available safety and security culture expertise in order to foster and sustain a strong safety culture and security culture;
- (vii) the need to provide the means by which the organisation continually seeks to develop and improve its safety culture and security culture, using a systemic approach; and
- (viii) safety oriented decision making in all activities.

(2) The authorised person shall

- (a) establish procedures in the management system for the resolution of conflicts arising in the decision making processes; and
- (b) identify and resolve without unreasonably compromising safety the potential impacts of security measures on safety and of safety measures on security.

### *Measurement Assessment and Improvement of the Management System*

## **Monitoring and Measuring Process**

**20.** An authorised person shall

- (a) monitor and measure the effectiveness of the management system to confirm the ability of the organisation to achieve the results intended and to identify opportunities for improvement of the management system.
- (b) ensure that the management system of the organisation provides procedures for monitoring and measuring processes and for the assessment of the functionality and ability of the procedures to ensure safety and security; and
- (c) ensure that in the timing of self-assessments, independent assessments, and management reviews, the object of the assessment and its impact on nuclear and radiation safety and security are taken into account.

## **Self-Assessment**

**21.** An authorised person shall ensure that

- (a) self-assessments of the management system of the organisation is regularly conducted by using a graded approach to evaluate the effectiveness of the management system and to identify opportunities for the improvement of the management system;
- (b) lessons learnt from the assessment and any resulting significant changes revealed by the assessment are analysed for their implications for safety and security;
- (c) the management system has a defined process for the evaluation and timely use of :
  - (i) lessons from the experience gained and from events that have occurred, both within the organisation and outside the organisation, and lessons from identifying the causes of events;
  - (ii) technical advances and results of research and development; and
  - (iii) lessons from identifying good practices.

## **Independent Assessments**

**22.**An authorised person shall

- (a) assign responsibility for conducting independent assessments of the management system;
- (b) ensure that entities of the organisation, whether in-house or external and individuals assigned independent assessment responsibilities are given sufficient authority to discharge their responsibilities and have direct access to senior management;
- (c) ensure that individuals who conduct independent assessments of the management system are not assigned responsibility to assess areas under the responsibility of their own line management;
- (d) submit to the Authority for approval, a standard to be used for independent assessment; and
- (e) utilise outcomes of assessments conducted by independent external experts to improve the effectiveness of the management system.

## **Management System Review**

**23.**An authorised person shall ensure that

- (a) the senior management conducts a review of the management system at planned intervals, taking into account new requirements and changes in the organisation, to confirm the suitability and effectiveness of the management system, and the ability of the management system to enable the objectives of the organisation to be accomplished;
- (b) the review includes the objectives of the management system and incorporates matters that pertain to the safety, security and quality policy and to nuclear and radiation safety and quality as well as an assessment of opportunities for improvement and needs for change;
- (c) the following are used as input data for the reviews:
  - (i) the results of self-assessment and independent audits;

- (ii) process assessments;
- (iii) realization of safety, security and quality objectives;
- (iv) status of corrective and preventive actions;
- (v) follow-up measures taken after previous management reviews;
- (vi) lessons from experience gained and from events;
- (vii) suggestions for improvement; and
- (viii) changes that could affect the management system.

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

### **24. An authorised person shall**

- (a) evaluate the causes of non-conformances of processes and the causes of safety and security related events that could give rise to radiation risks, manage and mitigate any consequences that may arise from those causes;
- (b) determine the corrective actions required to eliminate the causes of non-conformances, and to prevent the occurrence of, or to mitigate the consequences of, similar safety related events and take corrective actions in a timely manner; and
- (c) ensure that the status and effectiveness of the corrective actions and preventive actions taken are monitored and reported to the management at an appropriate level in the organisation.

## **Improving the Management System**

### **25. An authorised person shall**

- (a) define, collect, and analyse appropriate information about its operation or activity;
- (b) review the results of assessments of the effectiveness, quality of performance and safety management of the management system and plan and systematically implement the necessary improvements, based on their safety and security significance without undue delay;

- (c) ensure that the action plan includes provision of the necessary resources for implementation;
- (d) communicate the results of self-assessments and independent assessments to leadership for safety, security, safety culture and of security culture at all levels in the organisation;
- (e) ensure that the results of the assessments are acted upon to foster and sustain a strong safety culture and security culture, to improve the leadership for safety and security, and to foster a learning attitude within the organisation; and
- (f) monitor the progress of improvements and verify the completion and effectiveness of the improvements.

### *Miscellaneous*

#### **Penalties**

26. A person who contravenes any of the provisions of these Regulations commits an offence and is liable to penalty provision in Regulation 80 of the *Basic Ionising Radiation Control Regulations*.

#### **Appeals**

27. A person who is not satisfied with a decision taken by the Authority may appeal in accordance with sections 81, 82, 83, 84 and 85 of the Nuclear Regulatory Authority Act, 2015 (Act 895).

#### **Interpretation**

28. In these regulations, unless the context otherwise requires,

“auditing” means a documented activity performed to determine by investigation, examination and evaluation of objective evidence the adequacy of, and adherence to, established procedures, instructions, specifications, codes, standards, administrative or operational programmes and other applicable documents, and the effectiveness of their implementation;

“competence” means a demonstrated ability to apply knowledge, skills and attitudes appropriate to carry out a specific role successfully;

“Document control” means tracking documents to ensure that employees who refer to them always have the correct documents available;

“independent assessment” means appraisal in the nature of audits or surveillance carried out to determine the extent to which the requirements for the management system are fulfilled, to evaluate the effectiveness of the management system and to identify opportunities for improvement;

“lifetime” means the span of life of a facility commencing from siting, through site evaluation, design, construction, commissioning, operation and decommissioning, or closure and the post-closure period, and any subsequent period of institutional control, until the facility is released from regulatory control;

“management of radioactive waste” means the process of safely handling, storing, transporting and disposing of waste that contains radioactive materials.

“management system” means a set of interrelated or interacting elements for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner;

“management system review” means a regular and systematic evaluation by senior management of an organisation of the suitability, adequacy, effectiveness and efficiency of the management system of the organisation in executing the policies and achieving the goals and objectives of the organisation;

“process” means a set of interrelated or interacting activities which transforms inputs into outputs;

“product” means a result of a process;

“requirement” means a need or expectation of which a special mention is made, or one which is generally implied or obligatory;

“resources” includes individuals, infrastructure, the working environment, information and knowledge, and suppliers, as well as material and financial resources.

“safety culture” means the assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance;

“safety significant” means the ability to have an impact on safety, whether determined through risk analysis or other means that exceeds a predetermined significance criterion.

“security culture” means the characteristics and attitude in organisations and of individuals which establish that security issues receive the attention warranted by their significance;

“self-assessment” means a routine and continuing process conducted by senior management and management at other levels to evaluate the effectiveness of performance in all areas of their responsibility;

“senior management” means the person or the group of persons who directs, controls and assesses an organisation at the highest level;

“sub-contractor” means a supplier that is not in a direct contractual relationship with the licensee or licence applicant; and

“supplier” means a person or an organisation to whom an authorised person delegates duties, totally or partially, in relation to its activities and they may be designers, vendors, manufacturers and constructors, employers, contractors, subcontractors, and consigners and carriers who supply safety related items.