Prime Minister Cabinet
Nuclear & Radiological Regulatory Authority
(ENRRA)
Chairman of the Board

رئاسة مجلس الوزراء
هيئة الرقابة النووية والإشعاعية
رئيس مجلس الإدارة

قرار مجلس إدارة هيئة الرقابة النووية والإشعاعية

رقم (٢) لسنة ٢٠١٦

بإصدار وثيقة متطلبات نظم إدارة المنشآت والأنشطة الخاضعة للرقابة

مجلس إدارة هيئة الرقابة النووية والإشعاعية:

بعد الإطلاع علي:

- قانون تنظيم الأنشطة النووية والإشعاعية الصادر بالقانون رقم (٧) لسنة ٢٠١٠،
- وعلي اللائحة التنفيذية لقانون تنظيم الأنشطة النووية والإشعاعية رقم (٧) لسنة ٢٠١٠ الصادرة بقرار رئيس مجلس الوزراء رقم (١٣٢٦) لسنة ٢٠١١،
- وبناءً على ما إنتهت إليه اللجنة المشكلة لإعداد مقترح الوثيقة،
- وبناءً على ما عرضه السيد الأستاذ الدكتور / رئيس الهيئة،
- وعلي موافقة مجلس إدارة هيئة الرقابة النووية والإشعاعية بجلسته رقم (٢) لسنة ٢٠١٦ المنعقدة بتاريخ ٢٠١٦/٢/٢٩.

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مادة (٢): يعمل بهذا القرار اعتباراً من تاريخ صدوره، وعلى جميع المعنيين به – كل فيما يخصه – تنفيذه.

رئيس مجلس إدارة

هيئة الرقابة النووية والإشعاعية

أ.د. محمد رضا عز الدين

٢٠١٦/٣/٨

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REGULATORY REQUIERMENT

Management System Requirements for Regulated Facilities and Activities

متطلبات نظم إدارة المنشآت والأنشطة الخاضعة للرقابة

Egyptian Nuclear and Radiological
Regulatory Authority
Cairo, Egypt

2016

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1. Introduction

1.1 Authorization

In accordance with the provisions of article 12 of the National Nuclear Energy Law No.7/ 2010; the Egyptian Nuclear and Radiological Regulatory Authority (ENRRA) is carrying out all the regulatory and control works related to the nuclear and radiological activities in the Arab Republic of Egypt. Article 25 prohibits any nuclear or radiological activities without getting a license from the Egyptian regulatory body. Article 26 states that it shall be the licensee's obligation to assure the safe and secure operation of the nuclear or radiological facility. Article 17 authorizes the ENRRA board to issue the standards and the regulations that the licensee shall meet to ensure the safety and security of the peaceful use of atomic energy in all fields. Article 38 of the Nuclear Energy Law prescribes that it shall be the licensee's obligation for any nuclear or radiological activities to establish a management system with adequate organizational structure and high quality operation in compliance with the prescribed rules and requirements to protect the people, properties and environment from any risk associated to the activity. The Nuclear Energy Law and its executive regulation highlight the importance of the Management System (MS) within the licensee organizations and provide the basis for this regulatory document.

1.2 Objective

This regulation defines generic safety and quality management requirements affecting the contents, establishment, implementation, evaluation, assessment and continuous improvement of the management system of the licensee that subjected to the regulatory control by the ENRRA. The management system requirements set forth in this document shall be applied to all phases of the lifetime of the facility or the activity in normal, transient and emergency situations, including any subsequent period of institutional control that may be necessary. The main objective of the ENRRA management system requirements is to ensure that all actions not performed within separate management system but with regard to safety, health, environment, security, safeguards, quality, and economic as a whole, and that the safety is not compromised. If deviations are made from the requirements of this regulatory document, ENRRA shall be presented with some other acceptable procedure or solution by which the same safety level set forth in the document is achieved.

1.3 Scope

The present requirement is applicable to the management system of all nuclear and radiological facilities, activities and practices in all fields in Egypt particularly that related to all the stages of the nuclear fuel cycle through all phases (siting, design, construction, commissioning, operation, decommissioning, and release from regulatory control). Including, nuclear fuel plants, research and test reactors, super- critical and sub-critical assemblies, nuclear power reactors, spent nuclear fuel repositories, nuclear transformation plants, nuclear enrichment plants and spent nuclear fuel retreatment plants. In addition, it is applied on the activities related to fabrication, use and handle

of radioactive sources, radioactive waste management activities, transport of radioactive material and any other practice or circumstances in which people, properties and environment may be exposed to ionizing radiation from natural or artificial source except activities involving the use of X-ray equipment in the medical field.

Structure

The ENRRA requirement consists of six sections. Section1 represents an introduction of the document; section 2 establishes the general requirements for the MS; section 3 establishes the requirements for and responsibilities of senior management. Section 4 establishes the requirements for resource management and section 5 establishes the requirements for the processes of the organization. Section 6 establishes the requirements for measuring, assessing and improving the Management System.

2. The Management System

2.1 Planning, implementation and improvement of the management system

2.1.1 The licensee shall establish, implement, assess, maintain and continually improve a Management System. The system shall be well- balanced and aligned with the goals of the facility or activity and shall fulfill the nuclear and radiation safety requirements.

2.1.2 The management system shall identify and integrate all statutory and regulatory requirements that apply to the regulated activities and facilities of the licensee.

2.1.3 The Licensee shall introduce a set of objectives for the Management System to enhance safety through:

a. Bringing together in a coherent manner all the requirements for managing the facility or activity;
b. Describing the planned and systematic actions (processes, procedures and work instructions) necessary to provide adequate assurance that all the requirements are satisfied and covering the organizational structure, personnel responsibility and authority, decision making and managing safety and security risks.
c. Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.

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

2.1.5 The licensee shall demonstrate to the ENRRA, upon request for authorization, that it has an effective management system that fulfills the requirements.

2.1.6 All the published documents of the International Atomic Energy Agency (IAEA) related to the management system requirements, and describe acceptable methods and guidance for

implementing these requirements are to be taken into account in the licensee management system.

2.2 Safety Culture

2.2.1 The licensee management system shall promote and support a strong safety culture by ensuring a common understanding between all the individuals and teams of the safety culture key aspects and support them to carry out their tasks safely and successfully.

2.2.2 The management system procedures shall strengthen vigilant, questioning and initiative attitude at all levels of the organization.

2.2.3 The management system shall contain a policy level statement on safety and quality management that defines safety as paramount in the licensee's operation and decision making. The management policy shall establish strategy and generic safety-related goals as well as quality-related generic goals and shall reflect the licensee's commitment for both the development of nuclear and radiation safety and for the high quality and its continuous improvement.

2.2.4 The licensee shall provide adequate resources for the identification and continuous promotion of safety culture.

2.2.5 Senior management shall develop shared values for safety and establish behavioral expectations to shape a strong safety culture, encourage acceptance of personal responsibility for safety, as well as shall develop and maintain leadership capabilities at all levels in the organization.

2.3 Graded Approach

2.3.1 The applying of management system requirements shall be graded for all the products and activities of each process on the basis of the following considerations:

a. The safety significance and complexity of each product or activity.
b. The hazards and the magnitude of the potential impact associated with the safety, health, security, safeguards, and environmental, quality and economic elements of each product or activity.
c. The possible consequences if a product fails or an activity is carried out incorrectly.

2.4 Management System Documentation

2.4.1 The management system shall be described in specific document that is adequate for the application.

2.4.2 The management system documentation shall include the following:

a. The policies' statements of the organization.
b. A description of the management system.

c. A description of the organizational structure related to the facility or the activity that describe clearly the reporting lines between the functional department mangers and senior managers.
d. A description of the functional responsibilities, general responsibilities, accountabilities, competence requirements, levels of authority, decision-making procedures, and interactions of those in charge of the management, performance and evaluation of the work.
e. A description of the processes and complementary information explaining how the work will be prepared, revised, performed, recorded, evaluated and improved.

2.4.3 Quality and safety related procedures within the management system shall be defined in the organization management system manual.

2.4.4 The documentation of the management system shall be developed to be understandable to those required to use it. Documents shall be readable, readily identifiable and available at the point of use.

2.4.5 The documentation of the management system shall reflect the characteristics of the facility, its activities and the complexities of the processes to be carried.

3. The Management Responsibility

3.1 Management commitment

3.1.1 The licensee's management at all levels shall demonstrate their commitment to the establishment, implementation, assessment, and continual improvement of the management system and shall assign the resources required to carry out these activities.

3.1.2 The licensee's senior management shall develop individual and institutional values and behavioral expectations for the organization, and communicates it to the employees to support the implementation of the management system and shall act as role models in the promulgation of these values and expectations.

3.1.3 The licensee's senior management shall foster the involvement of all employees in the implementation and continual improvement of the management system and shall ensure that there is a clear definition for when, how and by whom decisions are to be made within the management system.

3.2 Satisfaction of interested parties

3.1.4 The licensee's senior management shall consider the expectation of the interested parties in the activities and parties in the activities and interactions in the processes of the management system in a way that to ensure that safety is not compromised.

3.3 Organizational policies

3.2.1 The Senior management shall establish the organizational policies that shall be appropriate for the organization's activities and facilities.

3.4 Planning

3.3.1 The Senior management shall establish goals, strategies, plans and objectives (business plans, strategic plans, operating plans,.. etc.) that are consistence with the policies of the organization and an integrated manner, so that their collective impact on safety be adequately understood and managed.

3.3.2 The Senior management shall ensure that measurable objectives are established at different levels of the organization and by appropriate means for implementation goals, strategies and plans.

3.3.3 The Senior management shall ensure that implementation of the plans is periodically revised on the basis of these objectives and that the measures necessary to correct deviations from the plans are adopted when necessary.

3.5 Responsibilities and authority relating to the management system

3.4.1 The ultimate responsibility for the management system rests with the licensee even if any other technical support organizations are involved in the work. The licensee is responsible for ensuring that regulatory requirements of the management system are complied with.

3.4.2 The licensee shall ensure that senior management designates accountable individual reporting directly to senior management with the following authority and responsibility:

a. Coordinating the development and implementation of the management system, and its assessment and continual improvement.
b. Reporting on the performance of the management system, including its influence on safety and safety culture, and any need for improvement.
c. Resolving any potential conflicts between requirements and within the processes of the management system.

4. The Resource Management

4.1 Provision of resources

4.1.1 The licensee shall ensure the availability of adequate resources to carry out the activities of the organization and to establish, apply, evaluate and continuously improve the management system.

4.2 .Human resources

4.2.1 The licensee shall ensure the availability of adequate resources to carry out the activities of the organization and to establish, plan, implement, assess and continually improve the management system.

4.2.2 The Senior management shall determine the degree of competence required for individual at all levels and shall provide training and adopt adequate measures to achieve and maintain the required level of competence. The effectiveness of the actions adopted shall be evaluated.

4.2.3 The Senior management shall ensure that the employees have the competence required for the performance of the tasks assigned to them and that they understand the impact of their activities on safety. The personnel shall have received appropriate training and preparation and shall have acquired the skills, knowledge and experience required to ensure their competence. Training shall be used to ensure that the personnel are aware of the interest and importance of their activities and how they affect safety.

4.3. Infrastructure and working environment

4.3.1 The licensee shall ensure that the senior management determine, provide, maintain and re-evaluate the infrastructure and the working environment required for the activities to be performed safely and a manner such that compliance with the ENRRA's requirements is ensured.

4.4 Knowledge Management

4.4.1 The information and Knowledge (know-how) shall be managed as a resource within the management system of the organization.

5. Process Implementation

5.1 Process Development

5.1.1 The processes of the management system required to achieve the objectives, provide the resources for compliance with the requirements, generate the products of the organization and safely operate the facility or activity shall be identified.

5.1.2 The sequence of interfaces and interactions of the processes as well as risks relating to each process within the management system shall be determined.

5.1.3 The development of the processes shall be planned, evaluated and continuously improved. The methods necessary to ensure the effectiveness of both the implementation and the control of all processes shall be determined and implemented.

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

a. Process requirements, such as applicable regulatory, statutory, legal, safety, radiation protection, environmental, security, quality and economic requirements are addressed.
b. Hazards and risks are identified; together with any necessary mitigation actions.
c. Interactions with interfacing processes are identified.
d. Process inputs are identified.
e. The process flow is described.
f. Process outputs (products) are identified.
g. Process measurement criteria are established.

5.1.5 In the developing of processes; provisions shall be made for human error in work performance. Processes shall be planned to identify and disclose possible errors as early in the process as possible.

5.1.6 The activities of the different individuals or groups participating in a single process, along with the interrelations between them, shall be planned, controlled and managed to assure efficient communications and clearly assignment of responsibilities.

5.2 Process Management

5.2.1 The licensee shall designate a qualified Individual for each process as a process owner with authority and responsibilities for the following:

a. Establishment and documentation of the process and maintenance of the necessary support documentation.
b. Ensuring of efficient interaction between interfacing processes.
c. Ensuring that the documentation relating to the process is coherent with the existing documents.
d. Ensuring that the records required to demonstrate achievement of the results of the process are specified in the pertinent documentation.
e. Monitoring and reporting on the performance of the process.
f. Promoting improvements in the process.
g. Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the organization.

5.2.2 For each process the inspection, testing, verification and validation activities, acceptance criteria and responsibilities for the performance shall be specified. Also for each process specification shall be clear for what activities to be carried out by persons or groups of persons different from those responsible for their initial performance and when. For each individual shall be responsible for the quality of his work, he shall be given adequate training, tools and instructions prior to starting the work.

5.2.3 Each process shall be periodically evaluated to ensure that its efficiency is maintained.

5.2.4 In each process the activities shall be carried out under controlled conditions, using appropriate procedures, instructions, drawings or other resources, which shall be revised periodically to ensure their suitability and efficiency. The results shall be compared with the expected values.

5.2.5 The licensee management system shall identify and establish requirements for the control of subcontracted processes and activities by external organizations. Meanwhile for the licensees organization shall retain overall responsibility when contracting for any subcontracted processes.

5.3 Generic Management System Processes

5.3.1 The following generic management system processes shall be included among the processes to be implemented:

a) Control of Documents

5.3.2 All documents (including policies; procedures; work instructions; specifications and drawings, training materials; and any other texts that describe processes, specify requirements or establish product specifications) that are in any storage format shall be controlled in appropriate manner.

5.3.3 The Senior management shall ensure that all individuals participating in the preparation, revision, examination or approval of documents shall have been expressly appointed, shall be competent in the performance of these tasks and shall have access to appropriate information on which to base their contributions or decisions. There shall be assurance that the users of the documents have knowledge of and use appropriate and correct documents.

5.3.4 Changes to documents shall be reviewed and recorded and shall be subject to the same level of approval as the documents themselves.

5.3.5 The materials and recording methods used shall meet the requirements for defined retention periods and the document control system shall comply with all relevant data security requirements.

5.3.6 The licensee shall establish policies and plans to protect information pertaining to the security of facility or activity from public disclosure.

b) Control of Products

5.3.7 Product specifications and requirements, including subsequent product modifications, shall be in accordance with the established standards and incorporate all the applicable requirements. Products having interfaces or mutually interacting shall be determined and controlled.

5.3.8 Inspection, testing, verification and validation activities shall be completed prior to the acceptance, implementation, use or operation of the products. The tools, instruments and equipment used for these activities shall be appropriate as regards range, type accuracy and precision.

5.3.9 Compliance of the products with the specified requirements shall be confirmed and the tests and preventive maintenance activities required to ensure their satisfactory operation shall be scheduled and performed.

5.3.10 The licensee shall assure that the products are supplied in such a form that they can be verified, satisfied their design and service requirements. Controls shall be applied to ensure that the products do not bypassed and subjected to the necessary inspection, testing, verification and validation activities.

5.3.11 Each product shall be identified in order to ensure that it is used properly. When traceability is a requirement, unique identification shall be assigned to each product, controlled and recorded throughout the complete life cycle of the product.

5.3.12 Products shall be handled, transported, stored, maintained and used as specified to prevent them from sustaining damage, being lost, becoming deteriorated or being used incorrectly.

c) Control of Records

5.3.13 Records shall be specified, developed and controlled in the documentation of the process. All the records shall be complete, readable, identified and easily retrievable.

5.3.14 The management system records shall be maintained as furnish evidence that activities affecting quality were performed consistent with established procedures and specifications.

5.3.15 The period of retention, test and maintain the records shall be established in accordance with the applicable requirements and commitments of the organization regarding knowledge management obligations. There shall be assurance that the records in all storage formats are kept readable for the duration of the retention times specified for each record.

d) Purchasing

5.3.16 The licensee shall ensure that; suppliers of products are selected on the basis of specified criteria and their performance is evaluated periodically.

5.3.17 Adequate quality requirements shall be developed as purchasing requirements in procurement documents for the products and it shall be controlled. Evidence that products meet these requirements shall be available to the organization before the product is used. Qualified personnel shall be available to determine the quality requirements for purchases and control suppliers.

5.3.18 Systematic procedures shall be in place to define purchasing requirements and to resolve and report non-conformances specified in procurement documents.

e) Communication

5.3.19 Information relevant to safety, health, environmental, security, quality and economic goals shall be communicated to individuals in the organization and to other interested parties upon necessity.

5.3.20 The licensee shall communicate with all interested parties (suppliers, subcontractors…..etc) to ensure that they are familiar with the organizational safety, security and quality policies, the related management system goals to ensure that they understand its expectations and requirements.

5.3.21 Internal communication concerning the implementation and effectiveness of the management system shall take place between the various levels and functions of the organization.

f) Organizational Change

5.3.22 The licensee shall ensure that all organizational change objectives are defined and each change shall be assessed and classified depending on its safety significance and shall be justified prior to its implementation.

5.5.23 The implementation of organizational changes shall be planned, controlled, communicated, monitored, tracked and recorded in order to ensure that safety is not compromised.

6. Monitoring, Assessment and Improvement

The characteristics of an evolved management system are the gathering of information relating to quality and safety management, active monitoring and analysis, regular self-assessment, and independent assessment, and based on these the need of continual improvement of the management system processes and procedures is identified to ensure its continuing suitability and effectiveness.

6.1 Monitoring and Measurement

6.1.1 The effectiveness of the management system shall be monitored and measured in order to confirm that the processes are capable to achieve the intended results and identify improvement options.

6.2 Self Assessment

6.2.1 Senior management and the management personnel at all levels of the organization shall perform self-assessments to evaluate the performance of the work, the process and the improvement the safety culture. The self assessment shall be performed against pre-determined criteria to identify the non- conformities and propose required improvements. The feedback provided by the individuals responsible for activities and processes analysis at all levels of the organization shall be collected and processed.

6.2.2 Periodic and programmed self assessment exercises shall be conducted at planned intervals in compliance with the expectations applicable to the activities and processes related to the safety of the facility or activity.

6.3 Independent Assessment

6.3.1 The Licensee shall have periodic independent assessments conducted on behalf of the senior management to:

a. Evaluate and improve the effectiveness of the management system in ensuring that processes are meeting and fulfilling the goals, strategies, plans and objectives.
b. Determine the adequacy of work performance and leadership.
c. Evaluate the organization's safety culture and security culture.
d. Monitor the product quality.
e. Identify opportunities for improvement.

6.3.2 The Licensee shall establish an organizational unit and assign qualified personnel with the adequate training and experience for the responsibility for conducting independent assessments. This unit shall have sufficient authority and freedom to act to fulfill its responsibilities.

6.3.3 Individuals participating in independent internal assessments shall not assess their own work. Their work shall not be limited to the independent internal assessment activities but shall include the following: internal audits, external audits, supervisions and documentary reviews.

6.3.4 Independent external assessments shall be systematically performed for high safety significant and complex facilities and activities. The assessments could cover all the safety significant aspects or specific assessments dealing with specific aspects.

6.3.5 Senior management shall evaluate the results of the independent assessments and take necessary actions to drive improvements and take into consideration the best national and international practices. They shall record and communicate their decisions and the reasons for them.

6.3.6 The outcome of the licensee periodical assessment of the functionality and coverage of the management system shall be submitted to ENRRA for information.

6.3.7 ENRRA shall oversight the management system implementation and its effectiveness of the licensee and the organizations participating in the safety significant actions within the licensed facility or activity, either by document review or by graded inspection. Inspection on the system functionality is contained in the periodic inspection program during all phases of the licensed facility.

6.4 Management System Reviews

6.4.1 The Licensee shall conduct management system review at scheduled intervals, in order to ensure its continuous suitability and effectiveness of the management system and its ability to enable the objectives set for the organization to be accomplished.

6.4.2 The review shall cover, but limited to, the following items:

a. Results of all forms of assessments.
b. Results obtained and objectives covered by the organization and its processes.
c. Non-conformities and corrective, preventive or improvement actions.
d. Lessons learned from other organizations.
e. Opportunities for improvement.

6.4.3 Weaknesses and obstacles shall be identified, assessed, and solved in a timely manner.

6.4.4 The review shall determine the need to introduce changes or improvements in the policies, goals, strategies, plans, objectives, processes, organization structure, and staffing.

6.5 Non-Conformities, Corrective and Preventive Actions

6.5.1 The licensee shall ensure that the management system contains procedures for the identifying, evaluating, handling of non-conforming processes and products in an open atmosphere that improves the work performance and identify the opportunities for improvements.

6.5.2 The causes of non-conformances shall be determined and the corrective actions required for their eliminating shall be determined and implemented. Preventive measures to avoid their recurrence and eliminate their causes shall be determined and implemented. The significance of

non-conformances shall be evaluated, root causes identified, corrective and preventive action is documented.

6.5.3 Products and processes that do not conform to specified requirements shall be identified, separated, controlled, registered, and reported to management within the organization. The impact of non-conformances shall be evaluated and followed by decisions in the form of:

a. Acceptance.
b. Rework and correction in a specified time period.
c. Rejection and discard or eradication in order to prevent their unintended use.

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

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

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

6.6 Improvements

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

6.6.2 Plans for improvement shall include assurance for adequate resources. Actions for improvement shall be monitored until their completion, and the effectiveness of the improvement shall be checked.

7. Definitions

Institutional control	Control of a radioactive waste site by the ENRRA according to the nuclear law 7/2010. This control may be active (monitoring, surveillance, remedial work) or passive (land use control) and may be a factor in the design of the facility.
Facilities and activities	A term encompassing all activities related to nuclear and radiation facilities, fabrication, use or handle of radioactive sources in addition to radioactive waste management activities, transport of radioactive material and any other practice or circumstances in which people, properties and environment may be exposed to ionizing radiation from natural occurring or artificial sources.
Management system	A set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective way. 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 structure, resources and processes. Personnel, equipment and organizational culture as well as the documented policies and processes are parts of the management system.
Management system review	A regular and systematic evaluation by Senior Management of an organization of the suitability, adequacy, effectiveness and efficiency of its Management System in executing the policies and achieving the goals and objectives of the organization
Safety culture	The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.
Security culture	Characteristics and attitude in organizations and of individuals which establish that security issues receive the attention warranted by their significance.
Self-assessment	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	The person who, or group of people which, directs, controls and assesses an organization at the highest three levels. Many different terms are used, including, for example: chief executive officer (CEO), director general, executive team, plant manager, Senior manager, chief regulator, site vice-president, managing director and laboratory director.
Nuclear facilities	A term encompassing facilities related to the nuclear fuel cycle including nuclear fuel plants, research and test reactors, super- critical and sub-critical assemblies, nuclear power reactors, spent nuclear fuel repositories, nuclear transformation plants, nuclear enrichment plants and spent nuclear fuel retreatment plants.
Radiation facilities	A term encompassing facilities use or handle radioactive source, and any other activity or practice related to all sources of ionizing radiation, except activities involving the use of X-ray equipment in the medical field.

Graded Approach	A process or method in which the stringency of the ENRRA's 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.
Interested Parties	A person, company, etc., with a concern or interest in ensuring the success of an organization. Interested parties have typically included customers, owners, operators, employees, suppliers, partners, trade unions; the regulated industry or professionals; scientific bodies; governmental agencies or regulators (local, regional and national) whose responsibilities may cover nuclear energy; the media; the public (individuals, community groups and interest groups); and others.
Process owner	The designated individual who has the authority and responsibility for each process. Process owner should have a good understanding of the process and be concerned when the process does not work well. He should have the authority to assess the impact of the process on safety and on the plans and objectives of the organization, and to monitor the effectiveness of the process. He Should have the authority to propose and initiate changes in it, and to monitor and control the major resources for it.