NATIONAL NUCLEAR REGULATOR

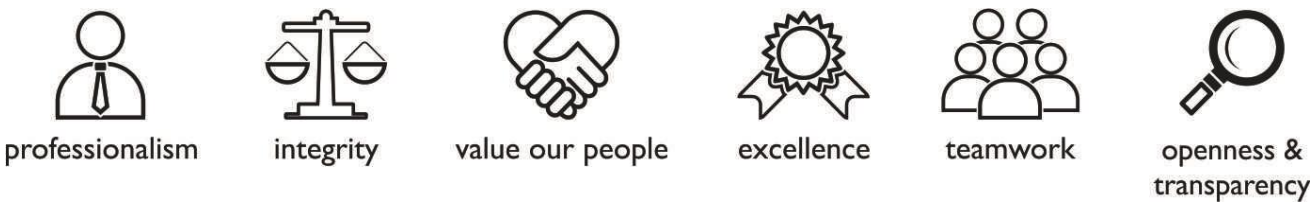
For the protection of persons, property and the environment against nuclear damage

REGULATORY GUIDE

REGULATORY GUIDE ON MANAGEMENT OF SAFETY

RG-0007

Rev 0



UNRESTRICTED

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1 BACKGROUND

Regulations are mandatory and set down specific requirements to be upheld by the authorisation holder or an applicant for a nuclear authorisation. Guidance documents are developed to assist authorisation holders or/and applicant for authorisations in meeting the regulatory requirements. In general guidance documents have to be adhered to by the holder/applicant. Any deviation from NNR guidance has to be justified.

The NNR regulations include a set of draft General Nuclear Safety regulations integrating the following thematic areas in a coherent and harmonized set of regulations that are applicable in a graded approach to activities and facilities being regulated by the NNR:

- Scope of Regulatory Control;
- Management of Safety;
- Authorisation of activities;
- Safety Assessment;
- Radiation Protection, Waste Management and Decommissioning;
- Safe Transportation of Radioactive Material; and
- Emergency Preparedness and Response.

The document provides guidance on the regulatory requirements as contained in Part THREE: Management of Safety of the draft General Nuclear Safety regulations. Due to the lengthy promulgation process for regulations, and the fact that the guidance provided is based in draft regulations, the Executive has resolved to issue the document as INTERIM guidance.

The document will be revised once the regulations in question have been promulgated and circulated to solicit stakeholder comments in accordance with the Regulators document development process.

2 PURPOSE

This document provides guidance for the implementation of the requirements as set out in Part THREE: Management of Safety of the draft General Nuclear Safety regulations on the implementation of the following topics:

1) Graded approach;
2) Management systems;
3) Event management;
4) Limiting conditions of operations;
5) Modifications; and
6) In-service inspection and maintenance

The guidance is applicable to all facilities and activities regulated by the NNR in terms of the provisions of the NNR Act and associated regulations, including applicants, holders of authorisations and suppliers of products and service important to nuclear safety as appropriate.

3 SCOPE

This guidance document clarifies regulatory requirements by providing how-to information, process and procedural guidance, and best practice associated with topics as listed in Section 2 of the document.

The guidance provided on modifications and in-service inspections and maintenance are applicable to nuclear facilities only and considers requirements detailed in the draft Specific Nuclear Safety regulations for Nuclear Facilities.

4 TERMS, DEFINITIONS AND ABBREVIATIONS

In this RG any word or expression to which a meaning has been assigned in the NNRA or the Regulations promulgated in terms of the NNRA, shall have the meaning so assigned. Only additional terms, definitions and abbreviations are provided.

4.1 Terms & Definitions

None

4.2 Abbreviations

IAEA	:	International Atomic Energy Agency
INES	:	International Nuclear and Radiological Event Scale
ISI	:	In Service Inspection
LCO	:	Limiting Condition of Operation
NNR	:	National Nuclear Regulator
NNRA	:	National Nuclear Regulator Act, Act 47 of 1999
OTS	:	Operating Technical Specification
QA	:	Quality assurance
RG	:	Regulatory Guidance Document
SSC	:	Structure, System and Component
SSRP	:	Regulations in terms of section 36, read with section 47 of the National Nuclear Regulator act, 1999 (Act No. 47 of 1999), on Safety Standards and Regulatory Practices

5 GRADED APPROACH

5.1 General considerations

5.1.1 The level of analysis, verification, documentation, regulation, activities, procedures and resources used to comply with a safety requirement, should be commensurate with the potential hazard associated with the facility or activity or consequences if an activity is carried out incorrectly without adversely affecting safety.

5.1.2 A graded approach is applicable to all stages of the lifecycle of an activity or facility. During the lifetime of an activity or facility, any grading that is performed should be such that safety functions and operational limits and conditions are preserved, and such that there are no undue radiological hazards to workers, the public or the environment.

5.1.3 The grading of activities should be based on safety analyses, regulatory requirements and engineering judgement. Engineering judgement implies that account is taken of the safety functions of structures, systems and components (SSCs) and the consequences of failure to perform these functions, and implies that the judgement is documented. Other elements to be considered in grading are the complexity and the maturity of the technology, operating experience associated with the activities and the stage in the lifetime of the facility.

5.1.4 As such, facilities or activities with the potential for offsite consequences should apply the higher and more stringent requirements and codes and standards compared to facilities and activities with on-site radiological hazard potential only.

5.1.5 The complexity of the management system for a particular activity or facility or supplier of services or products important to nuclear safety should also be commensurate with the potential hazard or consequences if an activity is carried out incorrectly.

5.1.6 Management system requirements should be applied to the products and activities of each process in a graded approach such as to deploy appropriate resources, on the basis of consideration of the:

i. Importance to nuclear safety and complexity of each activity;
ii. Hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each activity; and
iii. Possible consequences if an activity is carried out incorrectly.

5.1.7 In general, application of the management system requirements should be most stringent for items, services or processes with the highest safety importance; for the lowest grade, application of the management system requirements may be the least stringent.

5.2 Use of a graded approach in the application of requirements for nuclear facilities

5.2.1 Additional guidance on the implementation for a graded approached to management and verification of safety, site evaluation, design, operation and decommissioning for research reactors can be found in [4]. The principles and guidance provided are generally applicable to activities and facilities.

5.3 Safety classification

5.3.1 All products or services related to an activity or facility should be classified considering the importance of the product or service to nuclear safety.

5.3.2 The safety classification should consider the possible nuclear consequences if the SSC fails to provide its safety function or if a service is carried out incorrectly. At subcomponent level of the SSC, the safety classification should consider the relative importance of the subcomponent on the performance of the safety function of the SSC.

5.3.3 The SSC should be designed, manufactured, installed and subsequently commissioned, operated and maintained to a level of quality and reliability commensurate with their classification.

5.3.4 The categorisation assigned to each safety function should be used to classify SSC required to deliver that function.

5.3.5 Appropriately designed interfaces should be provided between SSC of different classes to ensure that any failure in a lower class item will not propagate to an item of a higher class.

5.3.6 Equipment providing the function to prevent the propagation of failures should be assigned to the higher class.

5.3.7 Auxiliary services that support components of a system important to nuclear safety should be considered part of that system and should be classified as such.

5.3.8 The method for safety classification of SSC's for nuclear facilities should take account taken of factors such as the:

i. Safety function(s) to be performed by the item;
ii. Consequences of failure to perform the safety function;
iii. Frequency at which the item will be called upon to perform a safety function; and
iv. Time following a postulated initiating event at which, or the period for which, the item will be called upon to perform a safety function.

5.3.9 Additional guidance on safety classification of SSC in nuclear power plants can be found in [5].

6 MANAGEMENT SYSTEMS

6.1 General

6.1.1 The management system should provide a single framework for the arrangements and processes necessary to address all the goals of the applicant or authorisation holder as well as organisations of services or products classified as important to nuclear safety. These goals should include aspects such as safety, health, environmental, security, quality and economic elements and other considerations such as social responsibility.

6.1.2 The management system should identify and integrate all applicable regulations, requirements and should enhance safety by:

i. Bringing together, in a coherent manner, all the requirements for managing the organisation;
ii. Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied; and
iii. 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.

6.1.3 The implementation of the management system should be monitored, assessed, maintained and continually improved. For this purpose, management should review, at defined intervals, the performance of the management system by considering experience feedback as well as preventative and corrective actions that have been identified.

6.1.4 The documentation of the management system should include a description of the management system and the organisational structure as well as organisational policies, authorities and responsibilities, competence requirements, management and decision-making procedures and processes.

6.1.5 Quality and safety related procedures within the management system should be defined in the Quality Manual.

6.1.6 The design of the management system should be based on relevant standards such as ISO9001 or equivalent standards and should in addition to the requirements specified in the regulations on Management of Safety comply with requirements of the standards adopted. In addition, the quality management requirements required by codes and standards adopted for the activity or facility need to be implemented in the management systems as appropriate.

6.1.7 Safety and protection should be paramount within the management system, overriding all other demands. The main aim of the management system should be to achieve and enhance safety and protection by:

i. 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;
ii. bringing together in a coherent manner all the requirements for managing the organization; and
iii. describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied.

6.1.8 Applicants and authorisation holders as well as suppliers responsible for products or services of high importance to nuclear safety should integrate safety management and safety culture aspects in the management system. The safety management should focus on organisational structures, processes and procedures and should ensure that safety culture characteristics and attitudes are prevalent throughout the organisations.

6.1.9 The determination of quality management requirements and the associated quality management system for products or services not important to nuclear safety rests with the authorisation holder.

6.2 Leadership and management responsibility

6.2.1 Senior management should ensure that management systems are established, implemented, assessed and continually improved and should demonstrate its commitment to do so.

6.2.2 The commitment of senior management of the organisation to safety and quality of the products or services should be clearly defined, documented and should be communicated to the staff.

6.2.3 The roles and responsibilities as well as the delegation of authority should be clearly defined within the management system of the organisations.

6.2.4 The organisational function and responsibilities for the management system should be clearly defined by the senior management. The overall responsibility for the management system should rest with a member of the senior management.

6.2.5 The authority and responsibilities of the persons and organisational units performing activities affecting quality and/or nuclear safety should be clearly established and defined in writing.

6.2.6 The quality and safety management functions should be independent from operational and line functions. The persons assigned to be responsible for the management system should be suitably qualified and experienced.

6.2.7 Persons and/or organisations performing quality and safety management function should be in a position to report to the management at such a level that the required assurance and oversight function is ensured. The persons and organisations performing quality and safety management functions should therefore have authority and freedom to identify and correct quality problems or safety relevant aspects and prevent repetition. They should ensure the implementation of corrective and preventive measures and verify the introduction and effectiveness of such measures.

6.2.8 The application of management system requirements should be graded based on the safety significance so as to deploy appropriate resources. Reference [3] provides acceptable guidance for the implementation of a graded approach of management system requirements.

6.3 Safety culture

6.3.1 The management system should include those arrangements made by the organisation for safety management in order to promote a strong safety culture and achieve good safety performance.

6.3.2 The management system should provide the framework for promoting, establishing, monitoring for and maintaining a strong safety culture.

6.3.3 A management system should be used to promote and support a strong safety culture by:

(i) Ensuring a common understanding of the key aspects of safety culture within the organisation;

(ii) Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and in accordance with rules, processes and procedures, taking into account the interaction between individuals, technology and the organisation;

(iii) Reinforcing a learning and questioning attitude at all levels of the organisation;

(iv) Providing the means by which the organisation continually seeks to develop and improve its safety culture; and

(v) Leadership and management responsibility.

6.3.4 All organizations involved in implementing nuclear security measures should give due consideration in accordance with NNR requirements and guidance [8] to the development and maintenance nuclear security culture recognizing the synergies between nuclear safety and nuclear security.

6.3.5 Safety culture characteristics

6.3.5.1 Safety culture relates to the characteristics and attitudes of organisations and individuals which ensure that, as an overriding priority, nuclear safety issues receive the attention warranted by their significance.

6.3.5.2 The performance of individuals and teams is strongly influenced by their working environment and atmosphere, particularly the behaviour of leaders. Trust and respect should permeate the organisation.

6.3.5.3 Senior management is responsible for developing the values and behavioural expectations for the organisation, and should be responsible for modelling these through their words and activities.

6.3.5.4 The Regulator requires that an appropriate level of safety culture be adopted within each organisation involved in processes important to nuclear safety and considers the following aspects of a positive safety culture in organisations:

(a) **Leadership:** Management demonstrates a commitment to safety in their decisions and behaviours;

(b) **Conservative decision making:** It is important that there should be a requirement for each individual or team to stop and review safety before starting a piece of work or beginning to carry out a procedure. Various techniques can be used, such as the STAR (Stop, Think, Act, Review) principle;

(c) **Problem identification and resolution:** Issues potentially impacting nuclear safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their importance to nuclear safety;

(d) **Personal accountability:** All individuals take personal responsibility for nuclear safety;
(e) **Work processes:** The process of planning and controlling work activities is implemented so that nuclear safety and quality is maintained.
(f) **Continuous learning:** Opportunities to learn about ways to ensure safety are sought and implemented;
(g) **Environment for raising concerns:** A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination;
(h) **Effective safety communication:** Communications maintain focus on nuclear safety; and
(i) **Questioning attitude:** Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

6.3.6 Quality and safety management

6.3.6.1 Safety management is concerned with the reliability of the products or services with respect to the respective nuclear safety functions. As reliability can only be achieved through adequate performance (quality), the quality of the products or services should be a supporting attribute for safety.

6.3.6.2 Safety management provides for organisational structures and performance measures which, together with the quality management system, ensure that the processes related to the life cycle of the activity or facility are governed by safety aspects including consequences of failures and other occurrences.

6.3.6.3 Safety management should not be managed separately from other activities. Neither should it be seen as an optional extra. Safety management should be an integral component of the way a whole organisation is managed and should have the involvement and active participation of all staff.

6.3.6.4 A written safety policy should be issued by the holder, which should comply with the following:

(a) Nuclear safety have priority, overriding if necessary the demands of production and project schedules and include a commitment to excellent performance in all activities important to safety and encourage a questioning attitude;
(b) Commitment to continuously develop safety;
(c) Communication of the policy to all site personnel with tasks important to safety, in such a way that the policy is understood and applied;
(d) Communication of key elements of the policy to contractors, in such a way that holder's expectations and requirements are understood and applied in their activities;
(e) Requirements on directives for implementing the policy and monitoring safety performance;
(f) Requirements on safety objectives and targets, clearly formulated in such a way that they can be easily monitored and followed up by the plant management; and
(g) Evaluation of the adequacy and the implementation status of the safety policy by the holder on a regular basis.

6.3.6.5 In addition to the above, the following guidance are applicable to applicants for or authorisation holders of nuclear licenses:

(a) A safety policy and safety goals which demonstrates the organisation's commitment to high quality and safety performance and to a strong safety culture should be defined;
(b) The authorisation holder of a nuclear facility should develop and implement a safety management system which should provide the framework for implementation of the aspects of safety culture within the holders' organisation;
(c) Safety management should be implemented for the entire life cycle of a nuclear facility including siting, design, construction, commissioning, operation, decommissioning and decontamination until the end of the period of responsibility as defined by the Regulator;
(d) A safety culture enhancement plan should be implemented specifying activities that will be carried out under the safety management system;
(e) Suppliers of products important to nuclear safety should develop and implement a safety culture enhancement plan for the duration of the service and include the plan as a minimum as part of the project management documentation; and
(f) Training should be provided to vendors and suppliers on the importance of the product to nuclear safety.

6.4 Resource Management

6.4.1 Provision of resources

6.4.1.1 Organisations should provide the resources to carry out the activities of the organisation and to establish, implement, assess and continually improve the management system.

6.4.1.2 The organisation should have adequate competence and clear procedures for the definition and management of outsourced services. The use of outsourced services should be systematic and controllable.

6.4.1.3 For all functions and processes necessary for siting, design, construction, manufacturing, commissioning, operation and decommissioning, including regulatory and supporting processes, the authorisation holder should ensure that sufficient resources are available to respond to all foreseeable circumstances, including normal operations, abnormal and emergency conditions, maintenance and inspection.

6.4.1.4 The organisation's structure, tasks, the number of necessary personnel, competence requirements and employment should be planned in adequate detail during the facility's design phase already.

6.4.2 Financial resources

6.4.2.1 Resource management should include activities for determining the needs for, and sources of, financial resources. The control of financial resources should include activities for comparing actual usage against plans and for taking necessary action.

6.4.2.2 Authorisation holders should plan for, make available and control the financial resources necessary for:

(a) meeting safety standards;
(b) maintaining the safety culture;
(c) implementing and maintaining an effective and efficient management system; and
(d) achieving the organisation's goals.

6.4.3 Training and qualification

6.4.3.1 All organisations should select their personnel and should implement training programmes to ensure and maintain the required levels of qualification and experience. It should be ensured that all staff has the competence to carry out their tasks safely and effectively.

6.4.3.2 The organisations should include a systematic process to establish technical and behavioural competence requirements which should consider the following aspects as a minimum:

(a) determination of training methods to ensure awareness of the relevance and importance of their actions to the achievement of safety goals;

(b) formal assessment of competence of individuals;

(c) evaluation of training actions; and

(d) supervision and monitoring of the individuals until full competence is achieved.

6.4.3.3 To achieve quality and to maintain safety, individuals should be capable of performing their assigned tasks. Training should emphasize the correct performance of work and should provide an understanding of:

(a) the principles of the management system and the relevant management processes and procedures;
(b) accountabilities and responsibilities in the organization;
(c) individual and organizational values and behavioural standards;
(d) the relationship between the management system and the development of a strong safety culture;
(e) key characteristics and attributes of safety culture; and
(f) importance of involving interested parties and how to best involve them.

6.4.3.4 Training should be designed to ensure that the training content addresses the specific needs of individuals and the overall organisation. This means that training should be planned and carried out using a systematic approach, with established measurable objectives and with a means of evaluating its effectiveness.

6.4.3.5 Technically competent individuals and instructors who are competent in the necessary instructional techniques should be involved in the analysis, design, development, implementation and evaluation of training.

6.4.3.6 Training is crucial to the continuing development of personnel. Senior management should therefore also allocate technically competent experts in the subject matter to develop the training curricula necessary for the achievement of the organisation’s objectives and to enhance the development of personnel.

6.4.3.7 Line managers should participate personally in the analysis of training needs, in the review and approval of training programmes and plans (as well as in the delivery of some parts of the training), and in the evaluation of the effectiveness of the training.

6.4.3.8 Training in the application of procedures and instructions should be given to those individuals who have to apply the procedures to do their work. Additional training should be given when procedures or instructions undergo major revision.

6.4.4 Working environment

6.4.4.1 It should be ensured that the working environment is in compliance with all requirements, including Occupational, Health and Safety, the personnel has available the necessary facilities, work can be performed safely, and that the goals set for work can be achieved.

6.4.4.2 It should be ensured that the working environment has a positive influence on the motivation, satisfaction and performance of individuals so as to enhance the performance of the organization. A suitable working environment depends on a combination of human and physical factors.

6.5 Organisational Management

6.5.1 The applicant or authorisation holder should ensure that changes within their own organisation and suppliers providing products or services of high importance to nuclear safety, including structure, staffing levels and resources, are evaluated to ensure that the changes will not adversely affect nuclear safety. Organisational changes within the authorisation holder that could potentially impact nuclear safety should be submitted to the regulator for acceptance prior to implementation.

6.5.2 Where there is collaboration between different organisations involved in the performance of design, manufacturing and/or construction tasks, responsibilities and tasks should be defined and documented. The authorisation holder should ensure that interfaces between these organisations are clearly defined, specified and described.

6.6 Process management

6.6.1 The processes of the management system should be planned and implemented in a controlled manner. The development of each process should ensure that requirements, interfaces and interactions with other processes as well as risks relating to operation have been identified and taken into consideration. The process flow and phases as well as the measurement and assessment procedures necessary for continuous improvement should be determined.

6.6.2 In the definition of processes and the activities contained in them, provision should be made for human error in work performance. Processes should be planned to identify and disclose possible errors as early in the process as possible.

6.6.3 Responsibilities and procedures for process implementation, evaluation and development should be determined for each process.

6.6.4 For each process, any activities for inspection, testing, verification and validation, their acceptance criteria and the responsibilities for carrying out these activities should be specified. For each process, it should be specified if and when these activities are to be performed by designated individuals or groups other than those who originally performed the work.

6.6.5 The work performed in each process important to nuclear safety should be planned and carried out under controlled conditions using only approved instructions and procedures as well as appropriate working tools. Each individual should be responsible for the quality of his work and should be provided with adequate training, tools and instructions prior to starting the work.

6.6.6 The management system should have established requirements for the control of outsourced processes and activities.

6.6.7 The processes of the management system should be defined for each phase in the lifetime of an activity or facility. In determining and establishing the processes, requirements specific to each phase should be identified and implemented.

6.7 Regulatory Processes

6.7.1 Applicants for new authorisations should submit to, and agree with, the regulator a project management plan defining the authorisation schedule and activities. In developing the authorisation schedule the tasks of the regulator should also be considered. The project management plan should be reviewed regularly and revised as necessary to reflect any changes considering the status of authorisation as well as the different authorisation stages.

6.7.2 The applicant or authorisation holder is responsible for the definition and introduction of the authorisation documentation. This includes any design, manufacturing, installation, construction and commissioning documents which are determined to be part of the supporting documents for the authorisation holder.

6.7.3 Authorisation documents should be identifiable, should be submitted to the NNR for review and acceptance and should be periodically reviewed to confirm their continued suitability.

6.7.4 The applicant or authorisation holder should ensure that authorisation documents, including changes, are independently reviewed by themselves and approved for release by authorised personnel.

6.8 Design and development

6.8.1 The conditions for application of the selected codes and standards as prescribed by the authority which released the code / standard should be complied with by the organisations involved in the process. Any deviations should be justified and presented to the regulator for acceptance.

6.8.2 Quality assurance (QA) measures should be defined that are compatible with the technical requirements of the selected codes and standards. The involvement of the authorisation holder in the quality assurance measures should be commensurate with the safety and quality classification of the product or service being delivered. Quality assurance measures, including responsibilities to ensure compliance thereto, should be included in design specifications.

6.8.3 All SSC's important to nuclear safety should be designed according to the latest or applicable approved standards as at the time of authorisation of the nuclear facility.

6.8.4 If possible the SSC should be of a design proven in previous equivalent applications, and should be consistent with the reliability goals determined for the respective plant SSC. Where new or innovative design or features are used, the authorisation holder should provide the results of the investigations on applicability of the codes and standards to the regulator. It should be demonstrated that the selected codes and standards are fully applicable to the plant SSC. In any other case a revised code, standard or specification should be developed and approved.

6.8.5 Design and development outputs should contain the information necessary for verification and validation to pre-determined requirements and/or design criteria. The authorisation holder should ensure that the outputs are reviewed against inputs as part of a design review process to provide objective evidence that the requirements /or design criteria have been met.

6.8.6 Validation of the output of the design and development processes should be performed in a controlled manner to ensure that the resulting product or service is capable of meeting the requirements for the specified use. A test programme should be implemented to demonstrate the safe performance of new safety features. It should be ensured that the safety features will perform as predicted, to provide sufficient data to validate analytical codes, and that the effects of systems interactions are acceptable. The test program should include suitable qualification testing of a prototype simulating the most adverse design conditions. The test programme should be defined in writing and make provision for sign-offs as the test programme conditions are met.

6.8.7 The verification or checking process should be performed by individuals, departments or organizational units other than those who have performed the original design. Design changes should be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes should include evaluation of the effect of the changes on constituent parts and product already delivered and relevant records maintained.

6.8.8 Human factors should be systematically considered at all stages of the life cycle of the nuclear facility or activity. These considerations include the allocation of functions to humans and technology, the identification and analysis of tasks important to nuclear safety (including human error potential), the design of the work environment, user interface design, training and procedures.

6.8.9 Human and organisational failures should be prevented in the design and operation of nuclear facilities by ensuring that:

(a) Sound ergonomic principles are followed in the design of equipment and the development of operating procedures;

(b) Appropriate equipment, safety systems and procedural requirements are provided and other necessary provisions are made to-

i. reduce, as far as practicable, the possibility that human error or inadvertent action could give rise to accidents or other incidents leading to the exposure of any person;

ii. provide means for detecting human errors and for correcting them or compensating for them; and

iii. facilitate protective actions and corrective actions in the event of failures of safety systems or failures of protective measures.

6.9 Procurement

6.9.1 The organisation should ensure that purchased products/services conform to specified purchase requirements which should include all technical specifications as well as relevant statutory and regulatory requirements. The type and extent of control applied to the supplier and the purchased product should be commensurate with the importance to nuclear safety of the purchased product/service on subsequent product/service realisation or the final product/service.

6.9.2 The applicant or authorisation holder should establish a graded supplier qualification process based on importance to nuclear safety of the product or service to be delivered by the supplier.

6.9.3 The regulator may observe the implementation of the supplier qualification process of the authorisation holder of products/services important to nuclear safety. The authorisation holder should therefore ensure that the following information will be made available to the regulator as a minimum the:

i. product/service to be delivered or scope of work to be performed;
ii. management system documentation, facilities and production processes;
iii. contractual agreements and the interface arrangements; and
iv. product/service related deliverables already provided and a list of those scheduled for future delivery.

6.9.4 All suppliers of products or services important to nuclear safety should have a current quality management system appropriate to the scope of supply and could submit a product related management system confirmation issued by a certification or conformity assessment organisation, which is accepted in the South African legal framework, in support. The certificate / confirmation should contain a statement of the scope of application, which should be appropriate to the scope of supply, and should be within its stated period of validity.

6.9.5 Suppliers should implement procedures to ensure that product/service specific requirements and any other requirements affecting the achievement of quality are clearly defined.

6.9.6 The applicant or authorisation holder should as perform an evaluation of the suppliers' ability to comply with the requirements specified (compliance audits) and to perform the required tasks (technical process evaluations and/or audits).

6.9.7 It should be ensured that the required reviews, tests and inspections are carried out where procurement documents and / or codes standards require an Authorised Inspection Agency (AIA) or an Independent Inspection company to undertake surveillance during the manufacturing and assembly of products or the construction activities.

6.9.8 The applicant or authorisation holder should ensure that procedures are established within their own organisation or at the suppliers to ensure that purchased material, equipment and services, whether purchased directly or through suppliers, conform to the requirements specified in procurement documents. Objective evidence should be available covering inspections at the supplier and at the supplier's sources for accessory parts and examination of materials, parts and equipment up to delivery.

6.9.9 It should be ensured by the applicant or authorisation holder and its suppliers that materials, parts and equipment are not used until documentary evidence is available confirming that they conform to the procurement documents.

6.9.10 The applicant or authorisation holder and its suppliers should ensure that materials, parts and equipment are inspected before use to identify any damage occurred during transport and to determine whether the delivered products conform to the procurement documents.

6.9.11 The applicant or authorisation holder and its suppliers should ensure that documentary evidence is retained confirming that products conform to the design requirements specified in the procurement documents.

6.9.12 Procurement documents for material, equipment and services should include or reference the procedures and/or standards required to be applied by the supplier.

6.9.13 The list of suppliers should include at least the following information:

i. product or services to be delivered;
ii. supplier of the product/service and sub-supplier of components;
iii. safety and quality classification of the SSC;
iv. selected codes and standards; and
v. status of qualification / certification.

6.9.14 The list should be submitted to the regulator in accordance with agreed processes whenever changes involve suppliers of products or services of importance to nuclear safety and should be available in general for inspection, review and audit.

6.9.15 The procurement documents and design specifications of important to nuclear safety products should specify the required codes and standards, materials, duties and capacities, operational and environmental parameters, loads, safety margins, settings, design limits, acceptable tolerances as well as quality and safety management requirements. These requirements should be consistent with the safety assessment submitted in support of an application or modification.

6.9.16 The applicant or authorisation holder should ensure that the procurement documents for materials, items and equipment of the nuclear facility or activity reflect the requirements established for the respective life cycle stage. Procurement documents should provide the following minimum information:

i. intended application and operating conditions;
ii. quality characteristics and safety classifications;
iii. performance requirements;
iv. surveillance of in-process, final and functional tests and inspections;
v. documentation and submission requirements for design and analyses, manufacturing, assembly and installation of parts, components and systems and the construction of structures, including the associated tests and inspections;
vi. requirements for handling, storage, conservation, transportation and packaging;
vii. identification coding for documents and for procured items; and
viii. product identification and traceability.

6.10 Production and service provision

6.10.1 Procedures should be established to ensure compliance with relevant requirements and acceptance criteria during manufacturing, construction and commissioning activities.

6.10.2 Special processes used during manufacturing, installation and construction of nuclear facilities including welding, heat treatment, inspection and non-destructive testing should be documented and controlled and should be performed by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications or any other specific requirements or criteria.

6.10.3 Procedures should be established for the identification and control of materials, parts, and components important to nuclear safety, including partly fabricated assemblies. These procedures should ensure where relevant the identification of the items, either on the item or on records traceable to the item, throughout manufacturing, construction, installation and use of the item.

6.10.4 A configuration management system should be established to indicate, by the use of markings such as stamps, tags, labels, route cards or other suitable means, the status of inspections and tests performed upon individual items.

6.10.5 Procedures should be established to control the handling, storage, shipping, cleaning and preservation of materials, components and equipment important to nuclear safety to prevent damage or deterioration. Surveillance measures must be applied to ensure that the requirements regarding marking, handling, storage, transportation and packaging are met.

6.10.6 In-process inspections of processed material, items or products important to nuclear safety should be performed for each work step at suppliers where it is necessary to ensure quality. Where direct inspection of processed material, items or products is impossible or disadvantageous, statistical process control and/or indirect controls should be provided by monitoring processing equipment and personnel.

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6.10.7 Mandatory hold and/or witness points, beyond which work should not proceed without the consent of the applicant or authorisation holder, the regulator or another authority as required by the applied standards and/or design specifications, should be specified in documents. Tests and inspections should be performed at specified hold points during, and at completion of manufacturing, assembly and construction.

6.10.8 The production and inspection steps should be coordinated (e.g. by using an inspection sequence plan or quality plan) such that the tests and inspections are performed at a stage when the required quality characteristics can still be verified without restriction.

6.10.9 Qualification and test programmes should be established to ensure the execution of all testing required to demonstrate that products important to nuclear safety will perform their functions satisfactorily. Procedures should be used in the test programme and should incorporate the requirements and acceptance criteria contained in the applicable design documents.

6.10.10 Qualification and test procedures should include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and was used and that the test was performed under testing conditions.

6.10.11 The qualification, test and inspection results should be documented, evaluated and accepted by the authorisation holder or another authority as required by the applied standards and/or design specifications to provide assurance that test requirements have been satisfied.

6.10.12 In case products are sourced from the original equipment manufacturer it should be demonstrated by the authorisation holder that the product conforms to the design specification, and that the relevant quality assurance measures were implemented.

6.11 Control of monitoring and measuring devices

6.11.1 The organisation should determine the monitoring and measurement to be undertaken and the equipment needed to provide evidence of conformity to requirements.

6.11.2 The organisation should establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

6.11.3 Where necessary to ensure valid results, measuring equipment should:

i. be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification should be recorded;
ii. be adjusted or re-adjusted as necessary;
iii. have identification in order to determine its calibration status;
iv. be safeguarded from adjustments that would invalidate the measurement result; and
v. be protected from damage and deterioration during handling, maintenance and storage.

6.11.4 In addition, the organisation should assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements and should take appropriate action on the equipment and any product affected.

6.11.5 Records of the results of calibration and verification should be maintained.

6.12 Measurement, assessment and improvement

6.12.1 General

6.12.1.1 Measurement, assessment and improvement should be part of the establishment of a learning culture in the organisation. Individuals at all levels should review their work critically on a routine basis to identify areas needing improvement and the means of achieving it.

6.12.2 Measurement

6.12.2.1 The management system should ensure that standards of performance are established.

6.12.2.2 These standards should be directly related to the product provided by the organization and based on the objectives set by senior management.

6.12.2.3 Once the standards have been established, performance should be measured against them. These measurements should be monitored at regular intervals to ascertain whether or not improvements in the quality of the product or process are necessary.

6.12.2.4 Performance indicators should be used and other appropriate methods of measurement should be developed.

6.12.3 Self-assessment

6.12.3.1 Senior management and management at all other levels in the organisation of authorisation holders should periodically perform self-assessments to evaluate and improve performance of work and safety culture. Self-assessment means that the organisation's own personnel evaluates performance of work or a process against pre-determined criteria.

6.12.3.2 The personnel should be able to contribute to assessment and improvement and the feedback provided by them should be collected and processed.

6.12.4 Independent assessment

6.12.4.1 The management system should include requirements and procedures for the regular, independent assessment of the system's conformity, performance and effectiveness.

6.12.4.2 These assessment may be conducted by an own organisational unit with sufficient authority and independence to discharge its responsibilities. Individuals participating in independent assessments should not assess their own work.

6.12.4.3 International peer review missions should be arranged by authorisation holders of nuclear facilities where appropriate.

6.12.4.4 For the improved effectiveness of the management system, assessments conducted by external independent experts should be utilised by authorisation holders.

6.12.5 Control of non-conforming products and corrective actions

6.12.5.1 Non-conformances should be regarded as opportunities for improvement and as such should be used as an input to the management system improvement process.

6.12.5.2 Senior management should ensure that those performing work are aware of and use the process for prompt notification and reporting of non-conformances.

6.12.5.3 All individuals should have the opportunity to identify, and should be encouraged to identify, non-conforming products and processes, and should have the opportunity to identify improvements and suggest them via the management system.

6.12.5.4 Senior management should allocate responsibilities so that non-conformances are monitored and followed up until it has been verified that the agreed corrective actions have been completed, including the provision of feedback to the individuals who identified the non-conformances.

6.12.5.5 Determination of the cause of a non-conformance may require a thorough investigation by technically qualified and experienced individuals. The investigation may need to include the participation of the individuals involved and those who identified the non-conformance, to

gain a complete understanding of the problem. The managers responsible for the determination of the cause of the non-conformance should assign sufficient resources to the task.

6.12.5.6 Non-conforming products should be properly identified, segregated, controlled, recorded and reported. The impact of the non-conformance should then be evaluated and reviewed and the non-conforming product should be accepted; or reworked or corrected within a specified time period; or rejected and discarded or destroyed to prevent its inadvertent use.

6.12.5.7 Any individual, who finds products or processes that do not meet specified requirements, or who observes abnormal behaviour, should be obliged to report the matter formally using the appropriate process.

6.12.5.8 The objective of a corrective action process should be to identify, document, evaluate and trend non-conformances and to take actions to correct non-conformances.

6.12.5.9 The degree of evaluation used for non-conformances that have been reported and are subject to the corrective action process can vary widely. Because of the time and effort involved in the evaluation of non-conformances, a graded approach should be applied to ensure that the most intensive evaluation is reserved for the problems of highest significance.

6.12.5.10 Senior management should ensure that corrective actions are subject to approval, prioritized and completed in a timely manner, on the basis of their significance. Managers should be held accountable for meeting due dates for corrective actions. Extensions or exceptions to due dates for completing corrective actions should be controlled and should be made only in response to new issues of higher priority.

6.12.5.11 Non-conformances and associated causes should be trended to identify repeat occurrences, generic (common) issues and weaknesses while the weaknesses are still at a level at which they do not pose a significant hazard

6.12.5.12 Corrective actions designed to prevent any recurrence of significant non-conformances should be reviewed for effectiveness. These reviews help to determine whether corrective actions are also effective in preventing recurrence.

6.12.5.13 Senior management should monitor the status of corrective actions.

6.12.5.14 The purpose of preventive actions is to prevent the potential causes of non-conformances from occurring and to maintain safety and performance. A process for preventive actions should:

(a) take proactive steps to ensure that a potential non-conformance does not occur; and
(b) use process analysis to determine how to build in process changes.

6.12.5.15 Preventive actions should include, but should not be limited to, the following:

(a) changing processes or the organizational structure;
(b) retraining and requalifying individuals;
(c) improving safety culture;
(d) changing or modifying documents;
(e) improving the management system;
(f) enforcing requirements for documents; and
(g) issuing new documents.

6.13 Monitoring and measurement of the management system

6.13.1.1 The applicant or authorisation holder should monitor and measure the effectiveness of the management system to confirm ability of the process to achieve the intended results and to identify opportunities for improvement.

6.13.1.2 The frequency of review should be determined by the needs of the organisation. Inputs to the review process should result in outputs that provide data for use in planning for improvements in the performance of the organisation.

6.13.1.3 Inputs that will allow the evaluation of the efficiency and effectiveness of the management system in the review should cover:

(a) the status and the organisation's objectives and the results of improvement activities;
(b) the status of actions from past management system reviews;
(c) the performance of the organization in achieving its objectives, plans and goals;
(d) the results of assessments of all types;
(e) feedback on the satisfaction of interested parties;
(f) advances in technology, research and development;
(g) results from benchmarking activities;
(h) the performance of suppliers;
(i) new opportunities for improvement;
(j) the control of process and product non-conformances;
(k) the status of activities in strategic partnerships;
(l) other factors that may impact the organization, such as financial, social or environmental conditions; and
(m) relevant statutory and regulatory changes.

6.14 Document and records management

6.14.1 Systematic procedures should be in place for the control of documents. Document control should cover documents needed in the operation of the facility, such as the plant documentation as well as its design, construction, commissioning, operation and decommissioning documents. In addition, procedures and requirements for the storage of documents should be determined.

6.14.2 All individuals involved in preparing, revising, reviewing or approving documents should be specifically assigned and competent to perform the tasks.

6.14.3 All documents should be unambiguously marked for identification and should contain the revision status. Documents of external origin should also be identified and their distribution controlled. The identification code should allow an unambiguous coordination between areas, parts, items etc. and the respective documents throughout the planning, design, procurement, manufacturing, assembly, construction, operation and maintenance phases.

6.14.4 The document control procedures should be described including, among others, the specification, preparation, review, approval, promulgation, revision, dissemination, archiving and disposal of documents. The documents to be kept permanently and temporarily as well as the storage times should be defined. The materials and recording methods used should meet the requirements for storage. The document control system should take into account data security requirements.

6.14.5 The compilation, revision, review and approval of a document should be based on a defined authorisation level. The management system should ensure the use of correct documents.

6.14.6 The documents to be updated and the updating procedures should be determined, considering the documents' safety significance and regulatory requirements.

6.14.7 Procedures, specifications, instructions or drawings should include quantitative and/or qualitative acceptance criteria where appropriate.

6.14.8 All departments and organisations impacted should be informed of any revisions of procedures, specifications, instructions or drawings without delay. The organisations should ensure that the use of incorrect or invalid documents is prevented and that the tasks are performed in accordance with valid documents.

6.14.9 Records should be retained as evidence of activities affecting quality and safety. Records should be readable, complete, identifiable, classified, stored and easily retrievable. Retention times of records should be defined.

7 EVENT MANAGEMENT

7.1 General

7.1.1 A system and procedure for data collection, registration, classification, investigation, analysis, assessment and reporting of all events, which are associated with the activity being undertaken, should be established. Engineering analysis and assessment and/or management judgment should be taken into account when applying the events classification criteria effectively and to determine a scheme of situations or events that complies with regulatory criteria.

7.1.2 Other events, which are not classified into the categories in Appendices 1 and 2, may be considered should it be concluded that such events are of potential significance. The examples in Appendices 1 and 2 are illustrative and regarded as the minimum events that should be reported. Events emanating from the safety, hazard and risk assessments as well as other applicable laws and regulations should also be considered and catered for.

7.1.3 In developing the classification scheme, events in the following key safety and security areas should be considered:

i. management systems
ii. human performance management
iii. operating performance
iv. safety analysis
v. physical design
vi. fitness for duty
vii. radiation protection
viii. conventional health and safety
ix. environmental protection
x. emergency management
xi. fire protection
xii. waste management
xiii. transport safety
xiv. external events

7.2 Notification

7.2.1 A Category 4 event should be verbally communicated to the Regulator immediately upon the discovery or occurrence of the event by a duly authorised official.

7.2.2 Verbal notification of a Category 4 event shall be followed by written notification to the Regulator within 24 hours after the discovery or occurrence of the event.A Category 3 event

should be verbally communicated to the Regulator within 24 hours upon the discovery or occurrence of the event by a duly authorised official.

7.2.3 Verbal notification of a Category 3 event shall be followed by written notification to the Regulator within 48 hours after the discovery or occurrence of the event.

7.2.4 A Category 2 event should be communicated to the Regulator verbally or in writing within 3-5 days upon the discovery or occurrence of the event by a duly authorised official.

7.2.5 For the purpose of verbal reporting telephonic means (the telephone or cellphone network/system) should be utilized to alert the Regulator with sufficient information of an event.

7.2.6 Each event should be recorded and reported separately as discreet events, however where several incidents have occurred and are seen to be linked, a single report may be submitted to the NNR, which should include clarification on the connection of the events.

7.2.7 The verbal reporting of any event should as a minimum contain the following information:

i. the site, location or premises at which the event occurred;
ii. date and time of the discovery or occurrence of the event;
iii. the Category under which the event is being classified;
iv. details of any casualties or otherwise affected persons;
v. brief description of the nature of the event, including current status;
vi. provisional International Nuclear and Radiological Event Scale (INES) rating as stipulated in the regulation; and
vii. what mitigating action has been taken to restore safe conditions .

7.2.8 The written notification of events should be provided to the Regulator by a duly authorised official of the authorisation holder and should include as a minimum the following information:

i. full name and operative indication of the facility or the name of the site;
ii. date and time of occurrence and discovery of the event;
iii. status of facility or the site before the event;
iv. brief description of the event;
v. presumable causes for the event, including a description of violations if any;
vi. status of the facility or the site at the time of occurrence of the event;
vii. preliminary rating of the event according to the International Nuclear and Radiological Event scale (INES);
viii. identification of the likely or possible impact of the event;
ix. if there has been a release of radioactivity, an estimate of the amount and the nature;
x. details of any casualties or otherwise affected persons;
xi. potential consequences for the safety of affected operations; and
xii. if known, the potential impact on other operations or for other facilities.

7.2.9 After providing the written notification, if necessary or on request by the Regulator, the authorisation holder should inform additionally the NNR about the development of the event and in particular in relation to any subsequent reduction of the safety level, and the effectiveness of the corrective measures undertaken.

7.3 Investigation and corrective actions

7.3.1 On the basis of the root causes for the occurrence of the event, revealed in the course of the analysis, the authorisation holder should determine the corresponding corrective actions that are appropriate for preventing recurrence.

7.3.2 The time limit and the responsibilities for implementation should be determined for each corrective action.

7.3.3 The authorisation holder should provide the necessary arrangements for the control and supervision of the implementation of the corrective measures.

7.4 Reporting

7.4.1 A close-out report should be submitted to the Regulator within 30 days of the discovery or occurrence of an event classified in Category 4 or 3.

7.4.2 A close-out report should be submitted to the Regulator within 45 days upon the discovery or occurrence of an event classified in Category 2.

7.4.3 The format of the close-out report to the Regulator, which should include the results of the investigation and analysis of the event, should be determined by the authorisation holder and include as a minimum the following information as well those specified in Part FOUR in the Management of Safety Regulation:

i. detailed description of the event, which should include the operational state of the facility or site preceding the event, means of identification and/or registering of the event, description of the chronological sequence of the development of the event, diagrams and tables, illustrating the changes in the key parameters;
ii. evaluation of the event from safety point of view (safety assessment) including the consequences of the event, analysis of the safety importance of the event (INES rating), influence of the event on the provision of the basic safety functions and on the defence-in-depth potential consequences of the event under different operational circumstances, reference to other similar events, which have occurred earlier at similar facilities or sites;
iii. causes of the event including a list of the system and component failures, personnel errors or violations of the personnel, and direct (immediate) causes thereof, as well as root causes for the system and component failures and for the errors and violations of the personnel;
iv. corrective measures, including restoring, short-term and long-term corrective measures, including schedule of implementation, responsible parties, measures for prevention of the recurrence of the event, also under other possible circumstances; and
v. list of the annexes to the report on the results of the investigation and analysis of the event.

7.5 International Nuclear and Radiological Event Scale

7.5.1 The INES level should be determined according to the IAEA INES User's Manual.

7.5.2 In some instances, when a longer time scale is required to know or estimate the actual consequences of the event, a provisional rating should be given with a final rating provided at a later date.

7.5.3 For an event rating during evolving severe accident situations, the notification of an INES rating should be delayed until sufficient information becomes available. A provisional INES rating or a likely range of INES ratings should then be provided. The INES rating should be updated as soon as new information becomes available. An explanation of reasons for the revised rating should be provided as well as information on whether and when the next rating can be expected.

7.5.4 The authorisation holder should file written documents used as the basis of the determination of the INES rating.

7.5.5 Required INES ratings should be determined and provided to the Regulatory Body in accordance with holder procedures by a duly authorised official of the authorisation holder and should include the Event Rating Form as shown in Appendix 3.

7.5.6 Responsible persons should be appointed within the authorisation holders organisation for the INES ratings, and all relevant staff should be trained and competent in the application of the INES User's Manual.

7.5.7 For events attracting national and international interest, the holder should develop criteria to determine whether the event warrants reporting to the NNR, based on communication of such events to the public/media, and the associated interest/responses.

8 LIMITING CONDITIONS OF OPERATIONS

8.1 General guidance

8.1.1 Limiting conditions of operation should be developed and implemented to ensure that the nuclear facility is operated in accordance with design assumptions and intentions as documented in the safety assessment.

8.1.2 The Operating Technical Specification (OTS) should:

i. define the conditions that shall be met to prevent situations that might lead to accidents or to mitigate the consequences of accidents should they occur;
ii. be kept updated and reviewed in the light of experience, developments in science and technology, and every time modifications in the facility or in the safety analysis warrant it, and changed if necessary;
iii. define a process for making modifications or temporary modifications of OTS. Such modifications should be adequately justified by safety analysis and independent safety review;
iv. be readily accessible to control room personnel and control room operators should be highly knowledgeable of the OTS and the associated technical basis;
v. cover all operational plant states including where applicable power operation, shutdown and refuelling, any intermediate conditions between these states and temporary situations arising due to maintenance and testing; and
vi. include minimum staffing levels for shift staff in the OTS.

8.1.3 The nuclear facility should not be returned to service following unplanned shutdown until it has been shown to be safe to do so.

8.1.4 The authorisation holder should ensure that an appropriate surveillance program is established and implemented to ensure compliance with OTS and should ensure that results are evaluated and retained.

8.1.5 In cases of non-compliance, remedial actions should be taken immediately to re-establish OTS requirements.

8.2 The Limiting Conditions of Operation (LCO)

8.2.1 Each established LCO should be justified based on facility design, safety analysis with due account taken of the uncertainties in the safety analysis process as well as the results of commissioning tests.

8.2.2 Limits and conditions for normal operation should include limits on operating parameters, stipulation for minimum amount of operable equipment, actions to be taken by the operating staff in the event of deviations from the LCO and time allowed to complete these actions.

8.2.3 Each LCO should have associated surveillance requirements that support the operating personnel in ensuring compliance with the LCO.

8.2.4 The LCO should include the following:

(i) Requirements for all operational states, including shutdown, and temporary situations arising during maintenance and testing;
(ii) Where operability requirements cannot be met, the actions to bring the plant to a safer state;
(iii) Operability requirements for the various modes of normal operation the number of systems or components important to safety that should be in operating condition or standby condition;
(iv) Minimum staffing levels for shift staff; and
(v) Actions to be taken and limitations to be observed by the operating personnel.

8.2.5 If operating personnel cannot ascertain that the nuclear facility is operating within operating limits, or the facility behaves in an unexpected way, measures should be taken without delay to bring the facility to a safe and stable state.

8.2.6 Adequate margins should be ensured between operational limits and the established safety systems settings, to avoid undesirably frequent actuation of safety systems.

8.2.7 The operational limits and conditions should reflect the provisions made in the final design, taking into account the results of the commissioning tests.

8.2.8 The operational limits and conditions should be reviewed over the operating life of the facility in the light of experience, developments in technology and safety, and changes in the plant, and should be modified if it is considered appropriate by the operating organization and approved by the Regulator.

8.3 Safety Limits

8.3.1 Safety limits should be established to protect the integrity of certain physical barriers that guard against the uncontrolled release of radioactive material.

8.3.2 The safety limits should be established by means of a conservative approach to ensure that all the uncertainties of safety analyses are taken into account.

8.3.3 Adequate margins should be ensured between operational limits and the established safety systems settings, to avoid undesirably frequent actuation of safety systems.

8.3.4 Safety limits should be established using a conservative approach to take uncertainties in the safety analyses into account.

8.4 Operability requirements

8.4.1 Operability requirements should state for the various modes of normal operation the number of systems or components important to nuclear safety that should be in operating condition or standby condition.

8.4.2 Where operability requirements cannot be met, the actions to bring the plant to a safer state should be specified, and the time allowed to complete the action shall be stated.

8.4.3 If operating personnel cannot ascertain that the power plant is operating within operating limits, or the facility behaves in an unexpected way, measures should be taken without delay to bring the plant to a safe and stable state.

8.4.4 The allowable periods of inoperability and the cumulative effects of these periods should be assessed in order to ensure that any increase in risk is kept to acceptable levels. Methods of probabilistic safety or reliability analysis should be used as the most appropriate means for this purpose. Shorter inoperability periods than those derived from a probabilistic safety analysis may be stipulated in the LCO on the basis of other information such as pre-existing safety studies or operational experience.

8.5 Additional guidance

Additional guidance on the development, content and implementation of LCO's for nuclear power plants and research reactors are provided in [6] and [7] respectively.

9 MODIFICATIONS

9.1 The following guidance are applicable to holder of nuclear licenses

9.1.1 All modifications classified as important to nuclear safety or where a modification results in a revision of the safety assessment, or current licensing basis should be accepted by the Regulator prior to the implementation of the modification.

9.1.2 The modification process should not allow for downgrades of the safety classification of the modification. The applicable safety classification of the modification should be used in a structured and approved process to determine factors such as the required qualifications and capability of design and implementation staff, the levels of review required, and related requirements such as the application of quality control verification.

9.1.3 Before commissioning a modified facility or putting the facility back into operation after modification, personnel should have been trained, as appropriate to ensure responsible personnel are capable of operating, testing and maintaining the modified facility. All relevant documents necessary for operation should have been updated.

9.1.4 Temporary changes should be managed according to specific procedures and should be clearly identified at the point of application and at any relevant control position. Operating personnel should be clearly informed of these modifications and of their consequences for the operation of the facility.

9.1.5 The number of simultaneous temporary modifications should be kept to a minimum. The duration of a temporary modification should be limited. The authorisation holder should periodically review outstanding temporary modifications to determine whether they are still needed.

9.1.6 The modification process should consider the long term health of new components installed during a modification. Where new components have been assigned safety functions by the design, the authorisation holder should submit its functional testing programme to the Regulator as part of the modification proposal.

9.1.7 Installed modifications classified as important to nuclear safety should be assessed to determine if the modification has met the original stated objectives and requirements.

9.1.8 The authorisation holder should establish and implement documented processes to ensure proper design, safety assessment, review, control and implementation of all permanent and temporary modifications. These processes should ensure that the requirements of the plant safety assessment and applicable codes and standards are met.

9.1.9 Safety and enhancement of safety should be considered in connection with all actions causing plant modifications. Modifications should not reduce the level of safety.

9.1.10 The authorisation holder should establish a procedure for updating documents as soon as possible after modification implementation. Responsibilities for the revision of all affected documents such as drawings, procedures, safety analysis report, operational limits and conditions, system description, training material including simulator, vendor equipment manuals and spare parts lists should be clearly assigned in the modifications process.

9.1.11 Implementation and testing of plant modifications should be performed in accordance with the authorisation holder's work control system and appropriate testing procedures.

9.1.12 A modification effectiveness report should be submitted to the Regulator for information within 2 years of completion of the installation of the modification. The report should also provide evidence that code required inspections and commissioning tests were comprehensive and correctly implemented, and that all documentation relevant to the plant change are appropriately revised and implemented and/or archived.

10 IN-SERVICE INSPECTION AND MAINTENANCE

The following sections provides guidance on the in-service inspection and maintenance requirements as contained in Section 9 of Part THREE: Management of Safety of the draft General Nuclear Safety regulations and Section 8(12) of the draft Specific Nuclear Safety regulations: Nuclear Facilities and are applicable to holder of nuclear licenses.

10.1 General

10.1.1 All structure, system or component important to nuclear safety should be maintained, tested and inspected to appropriately justified and accepted or benchmarked codes, standards and practices.

10.1.2 Administrative and engineering controls designed to prevent and mitigate hazards should be tailored to the work being performed and the associated hazards. Protecting the public, workers, and the environment should be a priority when work activities are planned and performed.

10.1.3 Following any event due to which the safety functions and functional integrity of any component or system may have been challenged, the authorisation holder should investigate to establish their direct and root causes and should revalidate the safety functions and functional integrity of any component or system which may have been challenged by the event.

10.1.4 The validity of equipment qualification for structures, systems or components important to nuclear safety should not be unacceptably degraded by any modification or by the carrying out of any maintenance, inspection or testing activity.

10.1.5 The authorisation holder should carry out such tests, inspections and examinations in connection with any structure, system or component as the Regulator may, after consultation with the authorisation holder, specify.

10.1.6 When any examination, inspection, maintenance or test of any part of a plant reveals any matter or condition indicating that the safe operation or safe condition of that plant may be affected, the suitably qualified and experienced person appointed to control or supervise any such examination, inspection, maintenance or test should bring it to the attention of the authorisation holder forthwith who should take appropriate action and ensure the matter is appropriately recorded, investigated and corrected.

10.1.7 The authorisation holder should establish procedures for all maintenance, testing, surveillance and inspection tasks.

10.1.8 Any proposed changes to the in-service inspection or maintenance programme should be assessed to analyse their effects on system availability, their impact on plant safety, and their conformance with applicable requirements.

10.1.9 Before equipment is removed from service for maintenance, testing, surveillance and inspection tasks, full compliance of the resultant plant configuration to the operational limits and conditions should be ensured. Following maintenance, it should be ensured that the plant is not returned to service before completion of documented confirmation of its correct configuration and the implementation of the appropriate functional testing.

10.1.10 The authorisation holder should ensure that a full and accurate report of every examination, inspection, maintenance or test of any part of a plant indicating the date thereof and signed by the suitably qualified and experienced person appointed by the authorisation holder to control and supervise such examination, inspection, maintenance or test is made to the authorisation holder forthwith upon completion of the said examination, inspection, maintenance or test.

10.2 Reliability programme

10.2.1 The reliability programme designed to ensure that SSC important to nuclear safety function reliably should -

(a) Include periodic inspections or tests of structure, system or component in order to demonstrate their reliability and operability to determine whether they are acceptable for continued safe operation of the plant or whether any remedial measures are necessary;
(b) Take into account operational limits and conditions;
(c) Be periodically re-evaluated to incorporate operational research and other relevant experience;
(d) Take into account vendor recommendations and the results of condition monitoring; and
(e) Take into account the potential for degradation due to fatigue, corrosion, ageing, thermal effects, irradiation effects, and other factors.

10.2.2 The authorisation holder should establish a programme that has the objective of ensuring that the structures, systems and components important to nuclear safety function reliably and in accordance with the relevant design, performance and safety criteria. The programme should:

(a) identify, using a systematic method, all structures, systems and components important to safety associated with the initiation, prevention, detection or mitigation of any failure sequence which could lead to damage of fuel or associated release of radionuclide or both;
(b) specify reliability targets for the identified structures, systems and components;

(c) identify and describe the potential failure modes of the identified structures, systems and components;
(d) specify the minimum capabilities and performance levels that the identified structures, systems and components should attain to achieve reliabilities that are consistent with the safety targets and regulatory requirements;
(e) provide information to the maintenance program to maintain the effectiveness of the identified systems;
(f) provide for periodic inspections, tests, modelling, monitoring or other measures to effectively assess the reliability of the identified systems;
(g) include provisions to assure, verify and demonstrate that the reliability program is implemented effectively;
(h) include provisions for recording and reporting the results of program activities, including the results of reliability assessments, inspections, tests, or monitoring of the reliability of the identified structures, systems and components; and
(i) document, clearly and comprehensively, the activities, attributes, elements, results and administration of the reliability program.

10.3 Maintenance programme

10.3.1 Co-ordination should be established among different maintenance groups (for mechanical, electrical, instrumentation and control, and civil maintenance), and with operations and support groups (groups for fire protection, radiation protection, physical protection and industrial safety). The potential impact of maintenance upon plant safety (such as system availability) should be assessed.

10.3.2 The plant management should ensure the effective performance and control of maintenance activities during planned and forced outages. The tasks and responsibilities of different organizational units and persons in outages should be clearly defined in writing.

10.3.3 Arrangements should be made to procure, receive, store and issue parts and materials for use in the plant.

10.3.4 The maintenance programme should be periodically reviewed in light of operating experience, and any proposed changes to the programme should be assessed to analyse their effects on system availability, their impact on plant safety, and their conformance with applicable requirements.

10.4 In-service inspection

10.4.1 The test results may not be accepted by the person who performed the test.

10.4.2 The (up-to-datedness and) adequacy of the periodic testing programme and procedures should be periodically assessed against the design bases and predefined criteria. The programme and procedures should be revised and supplemented where necessary.

10.4.3 The actions to be taken in response to deviations from the acceptance criteria in the maintenance, testing, surveillance and inspection tasks should be defined in the procedures.

10.4.4 Repairs to structure, system or component should be performed as promptly as practicable after discovery. Priorities should be established with account taken first of the relative importance to nuclear safety of the defective structure, system or component.

10.5 Codes and standards

10.5.1 Codes and standards should be applied consistently, without omission of conditions or embedded requirements. Any deviation to the code should be justified and accepted by the Regulator.

10.5.2 Codes and standards should be nuclear-specific codes or standards. The codes and standards should be evaluated to determine their applicability, adequacy and sufficiency and should be supplemented or modified as necessary to a level commensurate with the importance of the safety function(s) being performed.

10.5.3 Compliance with the National Legislation and applicable Regulations is required.

10.6 Ageing management

10.6.1 The ageing management programme should identify all ageing mechanisms relevant to structures, systems or components important to nuclear safety, determine their possible consequences, and determine necessary activities in order to maintain the operability and reliability of these structures, systems or components, (and to ensure that the most exposed component is detected before it can lead to failure).

10.6.2 The authorisation holder should assess structures, systems or components important to nuclear safety taking into account relevant ageing and wear-out mechanisms and potential age related degradations in order to ensure the capability of the plant to perform the necessary safety functions (as determined in the safety analysis report) throughout its planned life, under design basis conditions.

10.6.3 Long term effects arising from operational and environmental should be evaluated and assessed as part of the ageing management programme.

10.6.4 In its ageing management programme, the authorisation holder should take account of environmental conditions, process conditions, duty cycles, maintenance schedules, service life, testing schedules and replacement strategy.

10.6.5 The ageing management programme should be coordinated with, and be consistent with, other relevant programmes, including the programme for periodic safety review. A systematic approach should be taken to provide for the development, implementation and continuous improvement of ageing management programmes.

10.6.6 The ageing management programme should be reviewed and updated as a minimum with the periodic safety reassessment, in order to confirm whether ageing and wear-out mechanisms have been correctly taken into account.

10.6.7 The authorisation holder should provide monitoring, testing, sampling and inspection activities to assess ageing effects to identify unexpected behaviour or degradation during service.

10.6.8 Surveillance of major structures and components should be carried out to timely detect the inception of ageing effects and to allow for preventive and remedial actions.

11 REFERENCES

The following references were consulted during the compilation of this document:

[1] Act No. 47, 1999, National Nuclear Regulator Act
[2] Regulations in terms of section 36, of the National Nuclear Regulator Act, 1999 (Act no. 47 of 1999), on Safety Standards and Regulatory practices (GN R388).
[3] Application of the Management System for Facilities and Activities, IAEA Safety Guide No. GS-G-3.1 or as amended from time to time
[4] Use of a Graded Approach in the application of safety requirements for research reactors, IAEA Safety Guide No. SSG-22 or as amended from time to time.
[5] Safety Classification of Structures, Systems and Components in Nuclear Power Plants, draft IAEA Safety Guide No. SSG-22 or as amended from time to time.
[6] Operational limits and conditions and operating procedures for Nuclear Power Plants, IAEA Safety Guide No. NS-G-2.2 or as amended from time to time.
[7] Operational limits and conditions and operating procedures for Research Reactors, IAEA Safety Guide No. NS-G-2.4 or as amended from time to time.
[8] RG-0006 (draft), Guidance on the Nuclear Security Measures or Physical Protection Systems for Nuclear Facilities

APPENDIX 1: CRITERIA FOR THE CLASSIFICATION OF EVENTS AT NUCLEAR FACILITIES

CATEGORY 4
a) Activation of emergency plan or any event that could compromise the effectiveness of the arrangements for emergency preparedness and response.
b) Violation of legislation related to Safety, Health and Environment.
c) Any fatality or serious injury involving over-exposure to radiation.
d) Any fatality or serious occupational injury
e) Release of radioactive material which exceeds annual authorized discharge quantities per nuclide.
f) Any instance where it has been established that a member of the public has been exposed to a dose in excess of the dose limit.
g) Personnel actions or deviant behaviour of a psychological or medical nature (including alcohol/drug related).
h) An uncontrolled or unplanned criticality excursion.
i) Entry into any incident, accident or abnormal event procedure.
j) Exceeding any safety limits or violating any requirement in the operating technical specifications or authorization.
k) Any instance when a qualified expert in radiological protection (including environmental/emergency planning) with licence binding responsibilities is overruled on a matter pertaining to radiological safety.
l) Any transport incident or accident involving the conveyance of nuclear hazard material on and off site.
m) An event that results in a worker or visitor receiving a dose in excess of the dose limits.
n) Hazards originating either on-site or off-site which affects nuclear safety related systems and equipment.
o) Any explosion or outbreak of fire on a licensed site affecting or likely to affect the safe working or safe condition of the nuclear facility.
p) Any event in which the integrity of safety control features has degenerated to the extent that exposure to radiation or loss of property in the public domain, attributable to the event, has occurred or involves equipment damage, defects, or non-conformance, in which the health and safety of plant personnel or members of the public could be at risk (radiological or otherwise).
q) Degradation of protective systems (discovered during testing or operation) which did not lead to an incident (either because another system afforded protection or an operator intervened).
r) Total failure of any safety related system as referenced in the Operating Technical Specifications.
s) Contamination by radioactive material off site resulting in public dose limit has been exceeded.
t) Contamination of personnel by radioactive material of which personal contamination has resulted in dose exceeding the annual dose limits for a consecutive period of 12 months.
u) Discovery of an area on the authorised site, which has not previously been subjected to radiation hazard assessments.
v) Unauthorised release of equipment potentially contaminated with radioactive material as scrap or for repair or refurbishment (excluding theft).
CATEGORY 3
a) Inadvertent activation of a public warning system such as the off-site warning siren.

b) Any unauthorised, incorrectly authorised or unquantified discharge of radioactive effluents. ("Unquantified" includes those not analysed, not monitored for radioactivity, flow or volume, or for which the analysis is invalid).
c) Any instance where levels of radioactivity in environmental samples are detected in excess of the reporting levels.
d) Any event that causes off-site public exposure of the order of one half of the prescribed dose limits.
e) Personnel actions or deviant behaviour of a psychological or medical nature (including alcohol/drug related) having the potential to cause nuclear damage.
f) Non-compliance with procedures that results in loss of plant capability to perform essential nuclear safety functions.
g) Failure to comply with the instruction for a Limiting Condition for Operation, as defined in the Operating Technical Specifications.
h) Any event where radioactive material or waste was inadvertently brought onto or transported off the licensed site.
i) An event that results in worker dose higher than 20mSv/annum.
j) Significant hazards originating either on-site or off-site which could affect or affecting nuclear safety related systems and equipment.
k) Fire that requires mobilisation of the site fire brigade, excluding fire practices.
l) Any event that causes the spread of radioactive contamination on site.
m) Any event that renders access to Important to Safety (ITS) equipment inaccessible as a result of a release of radioactivity material.
n) Any event that could have led to a degeneration of the integrity of safety control features to the extent that life-threatening exposure to radiation or loss of use of property in the public domain could have occurred, but where the possible consequences of the event were prevented by appropriate control.
o) Failures of safety related equipment discovered during testing, requalification or pre-commissioning.

OR

p) Incorrect maintenance or operating instructions leading to the inability of a safety system to perform its intended function.
q) The use of nuclear fuel handling equipment which is known to be defective or the use of associated procedures that are known to have anomalies, the results of which could impair continued safe nuclear fuel handling operations.
r) On-site handling damage to new or irradiated enriched fuel.
s) Failure to use a properly prepared written directive or failure to develop, implement, or maintain procedures as required by the regulator.
t) A breakdown of a licensee's QA program and /or treatment and management of information.
u) Management's failure to comply with policies and procedures.

CATEGORY 2

a) Any off-site warning siren found to be inoperable.
b) Exceeding one half of the annual authorised discharge quantities per nuclide in any three-month period.

OR

c) Failure to comply with the surveillance requirements for gaseous and liquid effluent monitoring instrumentation.
d) Any event that causes off-site public exposure in the order of one quarter of the prescribed dose limits.
e) Human performance error that leads to death of an employee.
f) Unexplained control circuit transients affecting normal plant operations.

g) Any natural phenomenon or other external condition that posed a potential threat to the safety of the nuclear facility or that significantly distracted site personnel in the performance of duties necessary for safe operation.
h) A fire or other internal hazard that posed a potential threat to safety of the nuclear facility or that significantly distracted site personnel in the performance of duties necessary for safe operation.
i) Discovery outside a controlled area boundary of radiation or contamination, including contamination on equipment, clothing or skin, significantly above that permitted by the local arrangements.
j) Any other event which could not give rise in the short term to life-threatening exposure to radiation, or loss of use of property in the public domain, but which would indicate a degraded level of assurance in the adequacy of safety control features, or could be a precursor to an event falling into the above two categories.
k) Minor failures associated with safety related systems.

OR

l) Failures of the secondary system pressure boundary.
m) In the event that the total gamma activity in sewage sludge exceeded the requirements.
n) Radiation levels, measured in a workplace or other on-site area or contamination by radioactive material of a workplace or other on-site area of which investigation level has been exceeded.
o) Contamination of personnel by radioactive material of which investigation level has been exceeded.
p) Contamination by a hazardous chemical substance, of a workplace or other on-site area of which the contamination level was in excess of the prescribed limits but nobody was endangered as a result; or facility control limit was exceeded.

CATEGORY 1

a) Any event that causes off-site public exposure of the order of one tenth of the prescribed dose limits.
b) An event or deficiency in physical protection which threatens safety.
c) A condition which has prevented or could have prevented the intended functioning of equipment which is of importance for safety,
d) A deviation from specified system or component performance,

APPENDIX 2: CRITERIA FOR THE CLASSIFICATION OF EVENTS AT NORM FACILITIES

CATEGORY 4
a) Declaration of an accident. b) Any instance where it has been established that a member of the public has been subjected to a dose in excess of the annual dose limit. c) Any other event in which the integrity of safety control features has degenerated to the extent that serious exposure to radiation or loss of use of property in the public domain, attributed to the event, has occurred or is about to occur. d) Transport Accidents or incidents during the transport of material or equipment in which some material or equipment was released and individuals became contaminated. e) Any major accident in a processing plant or storage area where highly active radioactive material is present that has resulted in the spread of contamination as well as individuals (workers or members of the public) becoming contaminated. f) Discovery of an area off the authorised site where radioactive material from the site is present to which a member of the public has reasonably free access. g) Discovery of an area on the authorised site, which has not previously been subjected to radiation hazard assessments and where the dose levels exceed allowable levels. h) Where it is suspected or known that an occupationally exposed person has exceeded the annual dose limits. i) Unauthorised release of equipment, potentially contaminated with radioactive material, as scrap or for repair or refurbishment (excluding theft) exceeding 10 times the prescribed limits. j) Failure of dams, vessels or pipes which could have resulted, or has resulted, in material contaminated to above prescribed limit per radionuclide being released into areas to which members of the public has reasonably free access and where individuals would be present on a daily basis. k) Any instance when the radiation protection function is overruled. l) Any instance when the transport off the authorised site of radioactive material or any equipment or objects contaminated with radioactive material was not in accordance with Regulations for the Safe Transport of Radioactive Material. m) The violation of any operational limitation identified in the nuclear authorisation. n) Unauthorised entry into an area with radiation levels in excess of those prescribed for controlled areas. o) Release of radioactive material which exceeds annual authorized discharge quantities. p) A licensee fails to implement or substantially maintain reasonable assurance of fitness for duty program.
CATEGORY 3
a) Any other event which could have led to a degeneration of the integrity of safety control features to the extent that serious exposure to radiation or loss of use of property in the public domain could occur, but where the possible consequences of the event were prevented by appropriate mitigatory actions. b) Transport Accidents or incidents during the transport of material or equipment in which some material or equipment was released but no individuals became contaminated. c) Any major accident in a processing plant or storage area where highly active radioactive material is present that has resulted in the spread of contamination but in which individuals did not become contaminated. d) Incidents where it is suspected or known that an occupationally exposed person has exceeded a dose of 20mSv/annum. e) Unauthorised release of equipment potentially contaminated with radioactive material, as scrap or for repair or refurbishment (excluding theft) exceeding the prescribed contamination levels. Failure of dams, vessels or pipes which could have resulted, or has resulted, in material contaminated to above prescribed limit per radionuclide being released into areas to

which members of the public has reasonably free access and where individuals would not normally occupy.

f) Unauthorised entry into an area with radiation hazards in excess of those prescribed for suspended areas.
g) Any instance where greater than one half of any annual authorized discharge quantity has been discharged in any three month period.
h) Any instance where it has been established that a member of the public has been subjected to a dose in excess of 20µSv/annum.
i) Any instance where levels of activity in environmental samples are detected in excess of specified reporting levels.
j) Discharge of any radioactive effluent which has not passed through the appropriate waste treatment facility, is unqualified ("unqualified" includes those not analysed, not monitored for, radioactivity, flow or volume, or for which the analysis is invalid), is unauthorized or incorrectly authorized.
k) Violation of the limiting conditions in respect of monitoring liquid and gaseous effluents.
l) Fire which affects the facility operation.
m) Any instance where a ventilation system controlling the airborne levels of nuclear-hazard material within the facility or airborne discharges from the facility has become inoperable.
n) Failure to use a properly prepared written directive or failure to develop, implement, or maintain procedures as required by the regulator.
o) A breakdown of a licensee's QA program and /or treatment and management of information.
p) Management's failure to comply with policies and procedures.

CATEGORY 2

a) Any other event which could not give rise in the short term to serious exposure to radiation, or loss of use of property in the public domain, but which would indicate a degraded level of assurance in the adequacy of safety control features, or could be a precursor to an event falling into the above two categories.
b) Any major accident in a processing plant or storage area where highly active radioactive material is present but there was no release of contamination.
c) Any instance where it has been established that a member of the public has been subjected to a dose in excess of 100µSv/annum.
d) Discovery of a working area with a low occupancy for all persons on the authorised site, which has not previously been subjected to radiation hazard assessments and where the gamma dose rate is or the potential alpha energy concentration of the radon potential concentration is more than the prescribed limit.
e) Unauthorised entry into an area with radiation levels exceeding those prescribed for uncontrolled areas.
f) Failure to comply with the surveillance requirements for airborne and liquid effluent monitoring equipment.

CATEGORY 1

a) Transport Accidents or incidents during the transport of material or equipment in which no material or equipment was released.
b) Any minor accident in a processing plant or storage area where highly active radioactive material is present.

APPENDIX 3: EVENT RATING FORM

Further Info on Web (URL):	Click here to enter text.

Annexes:

Title	**Category**	**Description** *(optional)*
Click here to enter text.	Choose an item.	Click here to enter text.
Click here to enter text.	Choose an item.	Click here to enter text.

Event Title:	Click here to enter text.
Date of Event:	Click here to enter a date.
Event Location / Facility Name:	Click here to enter text.
Event Country:	Click here to enter text.
Type of Event:	Choose an item.

INES Rating:	Choose an item.
Status of Rating:	Choose an item.
Date of Rating:	Click here to enter a date.

Impact on People and Environment		
Release beyond authorized limits?	☐	
Overexposure of a member of the public?	☐	
Overexposure of a worker?	☐	
Impact on the Radiological Barriers and Controls at Facilities		
Contamination spread within the facility?	☐	
Damage to radiological barriers (incl. fuel damage) within the facility?	☐	
Degradation of Defence In-Depth?	☐	
Person injured physically or casualty?	☐	
Is there a continuing problem?	☐	

Event Description[1]:
Click here to enter text.

Justification of INES Rating[2]:
Click here to enter text.

Contact Person for Further Information	
Name:	Click here to enter text.
Affiliation/Organization:	Click here to enter text.
Email:	Click here to enter text.
Telephone:	Click here to enter text.
Organization Website (URL):	Click here to enter text.

Further Info on Web (URL):	Click here to enter text.

Annexes:

Title	**Category**	**Description** *(optional)*
Click here to enter text.	Choose an item.	Click here to enter text.
Click here to enter text.	Choose an item.	Click here to enter text.

[1] If/when the ERF is published on the IAEA NEWS website, the first 300 characters of the event description will appear on the front page of the website.
[2] If/when the ERF is published on the IAEA NEWS, the contents of the Justification of the INES Rating field will not appear to users from the general public.