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Regulatory Guide

Application of Leadership and Management for Safety in Nuclear Facilities

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BASIC PRINCIPLE OF REGULATORY GUIDES

Regulatory Guides are issued to provide acceptable methods and guidance to describe methods and/or criteria acceptable to the Authority for meeting and implementing specific requirements in FANR regulations. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods of complying with the requirements in regulations different from the guidance set forth by the regulatory guide can be acceptable if the alternatives provide assurance that the requirements are met.

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Definitions

Article (1)

For the purposes of this regulatory guide, the following terms shall have the meaning ascribed to them in Article 1 of the Federal Law by Decree No. 6 of 2009 Concerning the Peaceful Uses of Nuclear Energy (the Law), and in Article 1 of FANR Regulation for Leadership and Management for Safety in Nuclear Facilities (FANR-REG-01), unless the context requires otherwise: Accident, Authority, Closure, Commissioning, Construction, Counterfeit Item(s), Decommissioning, Design, Disposal, Emergency, Emergency Response, Fraudulent Item(s), Fundamental Safety Objective, Individual(s), Ionising Radiation, Interested Parties, Leadership, Licensee, Management System, Management System Review, Nuclear Facility, Nuclear Fuel, Nuclear Security, Operation, Person, Product, Regulated Activity, Radiation Protection, Radiation Source, Radioactive Material, Radioactive Waste, Radioactive Waste Management, Regulatory Inspection, Safety, Safety Assessment, Safety Culture, Security Culture, Senior Management, Storage, Supply Chain, and Suspect Item(s).

Objective and Scope

Article (2)

This regulatory guide provides guidance and outlines the acceptable methods for implementing the requirements specified in Regulation for Leadership and Management for Safety in Nuclear Facilities (FANR-REG-01, Version 1). In addition to the guidance provided in this regulatory guide, all activities related to ASME Codes should meet requirements specified in ASME NQA-1.

This regulatory guide applies to the Licensee authorised to conduct a Regulated Activity related to a Nuclear Facility and applies over the lifetime of a Nuclear Facility, from siting to Decommissioning or Closure.

Responsibility for Safety

Article (3)

3.1 Achievement of the Fundamental Safety Objective

The Fundamental Safety Objective, as defined in FANR-REG-01 (Version 1), is to protect people and the environment from the harmful effects of Ionising Radiation.

To achieve the highest standard of Safety that can be reasonably achieved, measures should be taken to:

- control radiation exposure of people and the release of Radioactive Material to the environment;
- restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation; and
- mitigate the consequences of events if they were to occur.

The Senior Management of the Licensee's Nuclear Facility maintains the prime responsibility for Safety as fulfilled through the implementation of a Management System which should thus support the Licensee's achievement of the Fundamental Safety Objective.

3.2 Senior Management responsibility

Senior Management should ensure that Safety is incorporated into all aspects of the siting, Design, Construction, and Operation of the Nuclear Facility consistent with a graded approach in accordance with Article 8 of FANR-REG-01 (Version 1). The Senior Management should ensure that ongoing Safety reviews or Safety Assessments are conducted to verify that the Fundamental Safety Objective is being achieved.

a) Safe Siting for a Nuclear Facility should take into account the potential for and effects of external events (e.g. meteorological, seismic, flooding, geotechnical, human-induced events, climate change) on the Nuclear Facility; the characteristics of the site and surrounding environment that could influence the transfer of Radioactive Material released from the Nuclear Facility to persons or the environment; and the population density and distribution surrounding the Nuclear Facility that may affect the ability to implement Emergency Actions.

   Safety in Design should include measures to prevent Accidents that may result in harmful radiological consequences and/or mitigate the consequences thereof; measures to ensure that radiological consequences resulting from a design basis accident remain below regulatory limits and are kept as low as reasonably achievable; and measures to ensure that the potential radiological consequences of plant states with a high likelihood of occurrence are small.

   Achievement of the Fundamental Safety Objective should be demonstrated through a comprehensive Safety Assessment of the Nuclear Facility Design.

   During the Construction of a Nuclear Facility, Senior Management and construction project managers should actively demonstrate Leadership and a commitment to the Fundamental Safety Objective, including radiological, industrial, environmental, and security aspects.

   Guidance applicable to Commissioning and Operation is provided in Article 6 of Regulatory Guide for Operational Safety for Nuclear Facilities (FANR-RG-030, Version 0).

   As specified in Article 6 of FANR-REG-01 (Version 1), Senior Management should ensure that health, environmental, security, quality, human and organisational factors, and economic considerations are not considered separately from Safety requirements so as to preclude their possible negative impact on Safety.

   A Decommissioning plan supported by a Safety Assessment according to the regulation on Decommissioning of Facilities (FANR-REG-21, Version 0) should be prepared by the Licensee for Nuclear Facilities. The Safety Assessment should

address all actions and potential Accidents or situations that may arise during the Decommissioning (or Closure) activities.

b) The types of Products and activities for which quality assurance/quality control, including formal inspection, and verification and validation, should be specified within the Management System.

Product specifications should be in accordance with established standards and incorporate requirements as applicable to the Product safety function.

Procedures should ensure that required inspection, verification and validation are completed prior to Product acceptance, implementation or use with Management System controls in place to ensure Products do not bypass the inspection, verification, and validation requirements.

c) The Licensee should develop processes and procedures for management of Radioactive Waste and disused Radioactive Material during the life cycle of the Nuclear Facility observing its role identified in a strategy for Radioactive Waste Management. Radioactive Waste Management in this regard encompasses phases of pretreatment, treatment, storage, transport and associated conditioning activities for waste and disused material originating from regular and irregular operating conditions.

d) The Licensee should provide all Individuals with information concerning radiation risks and instructional training together with periodic retraining for their radiological protection and Safety. In addition, special training should be provided for Individuals whose functions are relevant to radiological protection of the Individuals and the Safety of the public.

e) Guidance for the development and implementation of a Radiation Protection programme and a pre-disposal Radioactive Waste Management programme is provided in Radiation Protection for Nuclear Power Plants (FANR-RG-033, Version 0).

Sufficient resource allocations and funding should be made available to ensure the Fundamental Safety Objective to protect people and the environment from the harmful effects of Ionising Radiation is met, including during the Decommissioning (or Closure) process and the long-term management and Disposal of Radioactive Waste in a manner that protects future generations.

f) Guidance for development, planning and implementation of an emergency response function is provided in Articles 14 and 15 of Regulatory Guide for Emergency Preparedness for Nuclear Facilities (FANR-RG-035, Version 0).

Sufficient resource allocations and funding should be made available for the development, implementation and periodic review of Emergency Response functions and facilities to ensure that the Emergency Response function supports the Fundamental Safety Objective to protect people and the environment from the harmful effects of Ionising Radiation.

Responsibilities of the Licensee's Board of Directors

Article (4)

4.1 Demonstration by the board of directors of strong and effective Leadership for Safety as well as promotion and support by the board of directors of a strong Safety Culture and Security Culture

The Licensee's board of directors should pursue the following actions with a view to provide directions to the Senior Management and exercise control of the overall performance of the Senior Management and Licensee's organisation as concerns Safety, Safety Culture and Security Culture:

i) ensure that policies, strategies, and plans identifying the values and goals of the Licensee's organisation, which recognise the overarching priority of Safety and promote and support Safety Culture and Security Culture, are established and implemented by the Senior Management and therefore include procedures to hold the Senior Management accountable for their implementation through, but not limited to, the following:

   a. submission of reports on the implementation of the aforementioned policies, strategies and plans to the board of directors and discussion with the board thereof;
   b. ongoing monitoring of Safety performance;
   c. providing the board of directors with results of regular internal and external assessments of the Licensee's performance as concerns Safety, Safety Culture and Security Culture; and
   d. reports on the Management System Reviews;

   The reports and results quoted under (a) to (d) of this Article 4 paragraph 1(i) may be provided for each board of directors meeting, as well as at any other appropriate time, indicating where the board of directors should pay particular focus and attention with respect to Safety, Safety Culture and Security Culture.

ii) review the aforementioned policies, strategies, and plans with a view to enhance Safety, Safety Culture and Security Culture within the Licensee's organisation taking into consideration reports on their implementation, internal and external assessments, best practices, as well as inspection reports from the Authority;
iii) maintain records of discussions and approval of the aforementioned policies, strategies, and plans and amendments thereof;
iv) maintain records of discussion of the reports on the implementation of the aforementioned policies, strategies, and plans.

4.2 Prioritisation of Safety by the board of directors in its decision-making

The Licensee should be able to demonstrate that the decisions of the board of directors affecting Safety are informed, rational, objective, transparent and prudent. Therefore, the board of directors of the Licensee should adopt governance processes for the work of the board of directors to ensure the following in its decision-making:

a) that conflicts between Safety and other business goals are recognised and appropriately resolved;
b) that Safety is given due priority and Safety implications of the Licensee's decisions are evaluated and considered using a robust and systematic process which allows for challenge and scrutiny;
c) that the strategic influence arising from a parent entity of the Licensee does not undermine the prioritisation of Safety;
d) that the interaction of the board of directors with Senior Management gives due priority to Safety in the governance of the Licensee;
e) that significant matters related to Safety reach the board of directors promptly;
f) the timely availability of adequate and sufficient information on Safety as well as sufficient competence or expertise to support its discussion through participation of the Senior Management, in particular the Licensee's chief nuclear officer, in the relevant part of board of directors meetings to foster an independent challenge culture;
g) that results of actions from previous decisions by the board of directors pertinent to Safety are discussed with the board of directors to ensure that such results are taken into consideration in subsequent decision-making.

4.3 Ensuring the provision of adequate competences and sufficient resources in the Licensee's organisation to ensure Safety in its activities

In order to ensure that the Licensee's organisation has adequate competences and sufficient resources to carry out its activities safely, the Licensee's board of directors should pursue the following actions:

a) assess the Safety impact of the organisational structure and the availability of resources, particularly in relation to the roles with Safety significance, when discussing and approving the Licensee's budget as concerns:
    i) staffing programme and recruitment plans;
    ii) competence and resourcing requirements and strategy;
    iii) training programmes in particular those related to Safety, Safety Culture, and Security Culture
b) commission reviews and assessments, through the Licensee's internal audit function or any other appropriate means, of the following:
    i) the organisational structure and the availability of competence and resources on Safety, particularly in relation to the roles with Safety significance;

ii) changes to the organisational structure and staffing arrangements in particular those with the highest Safety significance to check they are suitable and sufficient;

c) identify the Safety significant categories of organisational changes and approve accordingly the competence and resourcing requirements and strategy of the Licensee's organisation;

d) consider the results of the regular monitoring of the Licensee's staffing programme and recruitment plans to ensure they meet the competence and resourcing requirements and strategy, in particular in relation to the roles with Safety significance.

4.4 Monitoring by the board of directors of the overall Safety performance of the Licensee's organisation and actions to achieve and maintain the highest level of Safety within the organisation

The Licensee's board of directors should hold the Licensee's Senior Management accountable through the ongoing monitoring of Safety performance and the results of regular internal and external assessments of the Licensee's Safety performance, including Safety Culture and Security Culture.

The Licensee's board of directors should review and discuss the results of the Management System Reviews, as well as the assessments and findings of the internal audits of the effectiveness and suitability of the Leadership for Safety across the organisation. The Licensee's board of directors should act upon the results of Management System Reviews, and commission, as appropriate, additional reports and internal audits.

Compliance to the above may be met through the following:

a) establishing an independent advisory committee focusing on the Safety performance of the organisation to serve as a committee of the Licensee's board of directors; and

b) providing appropriate information for each board of directors meeting indicating where the board of directors should pay particular focus and attention with respect to Safety, Safety Culture and Security Culture.

Management's Leadership for Safety

Article (5)

5.1 Senior Management's demonstration of Leadership

Senior Management's demonstration of Leadership and commitment to Safety requires the involvement of Senior Management in the Licensee's organisation.

The highest values, attitudes, and expectations at appropriate management levels of the Licensee's organisation should permeate throughout the organisation and extend to external support organisations to ensure the organisation's commitment to Safety.

a) Senior Management should establish and continuously advocate adherence to a Safety policy which gives Safety the highest priority over the competing demands of production.

The Safety policy should promote a Safety Culture with an inherent Safety-conscious work environment that will foster a questioning attitude within the organisation and encourage identification of Safety concerns by all Individuals within the organisation.

b) Management at appropriate levels of the organisation should maintain a level of knowledge and understanding of how human factors mechanisms between the Individual, technology, and the organisation could affect Safety. As such, human factors principles should be developed and applied in relevant organisational activities to ensure Safety outcomes for human-technology-organisation interactions.

c) Senior Management should ensure that the Management System of the Licensee's organisation embodies a strong Safety Culture and Security Culture through ensuring a common understanding of Safety Culture and Security Culture within the Licensee's organisation; reinforcing a learning and questioning attitude at all levels of the Licensee's organisation; and continually seeking to develop and improve its Safety Culture and Security Culture. Additional guidance is provided in Article 19 of this regulatory guide.

d) The Management System should include a full description of the organisational structure including allocation of responsibilities and delegations of authority. All Individuals in the organisation should be made aware of the Safety policy of the Licensee's organisation and of their responsibilities for ensuring Safety.

The organisational Safety Culture should be integrated into the Management System and thereby embody individual accountability for Safety at all levels of the organisation. Individual awareness of personal accountability for Safety can be enhanced by including an assessment of individual Safety and Nuclear Security contributions in periodic Individuals' assessments.

5.2 Leadership of all managers of appropriate functions in the organisation

The key responsibilities of all managers of appropriate functions in the organisation should include implementation of the Licensee's organisation's Safety policy, fostering and sustaining a strong Safety Culture, and controlling and verifying Safety-related activities. Such managers should demonstrate awareness that they are responsible for the Safety of all operations under their control.

a) Such managers should establish organisational goals, strategies, plans, and objectives that support the Safety policy of the Licensee's organisation and should align their priorities and objectives based on Safety being of paramount importance when allocating resources.

Such managers should utilise Nuclear Facility performance indicators, assessment reports, and other available information on Safety performance within their area of responsibility to identify areas for improving Safety performance.

Systematic reviews of the organisational goals, strategies, plans, and objectives should be periodically conducted to assess progress, overall direction and schedule, and effectiveness in improving Safety performance.

b) Such managers should develop organisational values, expectations, and attitudes for Safety that permeate the organisation at every level and extend to external support organisations through their actions, statements and decision-making.

Such managers should ensure their actions and behaviours encourage a questioning attitude and an open exchange of information upward, downward, and laterally within the organisation.

c) Such managers should encourage a questioning and learning attitude and discourage complacency with regard to Safety, and emphasise the accountability of organisations and Individuals under their control.

Such managers should encourage and facilitate the reporting of conditions that may be adverse to Safety and should correct acts by Individuals or conditions that are adverse to Safety.

5.3 Safety responsibilities for managers of appropriate functions

Managers of appropriate functions should be the leading advocates of Safety and demonstrate their commitment to Safety through their words and actions.

a) Such managers should ensure that measurable objectives for achieving Safety goals, strategies and plans are established through the appropriate processes at the various levels of the organisation.

Suitable goals should be established at the departmental level to support the goals, strategies and plans of the Licensee's organisation. Individuals should be held accountable for achievement of the goals assigned to them and be recognised for the actions that they have taken to achieve these goals in a safe manner.

b) Such managers at all levels in the organisation should clearly and routinely communicate the organisation's Safety standards and the need to continually enhance Safety performance to all Individuals within the organisation and ensure that such expectations are fully understood by all those involved in their implementation.

c) The Management System should include an effective communication plan, process or procedure for management to explain policies, issues, and decisions related to Safety. Such communications should encourage feedback and reinforce teamwork within the organisation as a means to improve Safety performance.

Management for Safety

Article (6)

6.1 Senior Management's commitment to the Management System

Senior Management should ensure the implementation of a Management System that addresses all the Safety-related goals, strategies, plans and objectives of the Licensee's organisation and takes into consideration the expectations and requirements of the organisation's Interested Parties and stakeholders.

Article 7 of this regulatory guide provides additional guidance on the implementation of a Management System.

Senior Management should actively and visibly demonstrate a commitment to the success of the Management System and provide the Individuals carrying out the work with the necessary information, tools and support to perform their assigned work responsibilities.

The effectiveness of the Management System should be periodically assessed and the results of the assessments should be used to continually improve the work processes.

Article 23 of this regulatory guide provides additional guidance on the review and continuous improvement of the Management System.

6.2 Senior Management's accountability for the Management System

Senior Management should bear the ultimate responsibility for the Management System and should ensure that it is properly established, implemented, assessed and continually improved.

6.3 Safety policy

Senior Management should ensure that a Safety policy is established and implemented by the Licensee's organisation that gives Safety the required priority, overriding the demands of production.

The Safety policy should promote a strong Safety Culture and a Safety consciousness in the workplace, including a questioning attitude and willingness to raise Safety concerns in line with the organisation's commitment to operational excellence.

a) Senior Management should ensure that the organisational goals, strategies, plans and objectives are consistent with the Safety policy and that they are developed in an integrated manner so that their collective impact does not compromise Safety at the expense of other priorities.

b) Guidance for the implementation of the Management System, including the role of Senior Management, is provided in Article 7 of this regulatory guide.

c) Senior Management should develop the organisational values and behavioural expectations for the organisation to support the implementation of the Management System and should act as a role model for the promulgation of these values and expectations.

d) Senior Management should communicate the provisions of the Safety policy throughout the organisation and ensure all Individuals understand the values, behavioural expectations and their responsibilities for compliance with the requirements of the Management System.

e) Management at all levels in the organisation should ensure the involvement of all Individuals in the implementation and continual improvement of the Management System.

f) Measurable goals and performance indicators in line with the organisation's strategies, plans and objectives should be established to effectively monitor Safety performance in an objective manner. Such objective indicators should be used by management to detect and respond to any shortcomings or deterioration in Safety management.
Article 7 of this regulatory guide provides guidance on the decision-making process within the Management System.

g) Systematic reviews of the goals, strategies, and plans should be carried out periodically at all levels of the organisation to assess progress in achieving the organisation's Safety goals. Such reviews should cover milestone achievement, resource expenditure, and the potential need for redirection, schedule change, or resource allocation in order to address any deviations in either the progress being made or changes to the needs of the organisation.

6.4 Interested Parties

Senior Management should identify the organisation's Interested Parties and gain an understanding of their requirements and expectations in order to ensure mutual expectations are met among the parties.

Communication with Interested Parties is further addressed in Article 17 of this regulatory guide.

6.5 Management System – assignment of responsible Individual

A qualified Individual directly reporting to Senior Management should be assigned the responsibility for and the authority to direct or administer the implementation of the Management System. The responsibilities of the assigned qualified Individual are addressed in Article 6.5 of FANR-REG-01 (Version 1).

6.6 Delegation of Management System activities

Management System processes that are delegated to others (e.g. agents, contractors, consultants) should be controlled to ensure the processes are established and implemented in accordance with the Licensee's Management System procedures. The Licensee retains the primary responsibility for the establishment and implementation of the Management System processes.

Management System

Article (7)

7.1 Establishment and implementation of an integrated Management System

The Licensee authorised to conduct a Regulated Activity should establish and implement a comprehensive integrated Management System comprising policies, programmes, processes, and procedures. The requirements for managing and monitoring the Safety-related operational activities of the Nuclear Facility should be in a planned and systematic manner so as to minimise possible adverse impacts on Safety.

Overall, the Management System should effectively sustain the organisation's Safety Culture and continually improve the Safety performance of the organisation, and enable the organisation to achieve its policies, goals, strategies, and objectives in a safe, efficient and effective manner.

The Management System should be founded upon clearly defined organisational values with supporting policies, and be developed, maintained and implemented in keeping with the goals, strategies, objectives and plans of the organisation that include:

- clear identification of the interdependencies of the organisational goals, strategies, and plans;
- assignment of priorities to organisational goals, strategies, and plans;
- establishment of policies, programmes, processes, and procedural controls to ensure organisational goals, strategies, and plans are accomplished according to the assigned priorities of the organisation.

The Management System should clearly identify Safety as its principal purpose, which includes nuclear and radiological Safety, environmental protection, and the Nuclear Security of the Nuclear Facility.

The Management System should emphasise and support a strong Safety Culture throughout every level of the organisation, and include the establishment and implementation of a Safety policy that gives Safety the highest priority over the competing demands of production and schedule requirements. Safety Culture should be continuously reinforced throughout the organisation to ensure a common understanding and behavioural commitment to the organisation's Safety policy, encourage a questioning attitude, and to promote excellence in the performance of all activities important to Safety.

The Management System should be continuously monitored for its effectiveness and for improvement opportunities. Further guidance on reviews and assessments of the Management System is provided in Articles 20, 21, 22 and 23 of this regulatory guide.

7.2 Assurance and demonstration of the effective implementation of a Management System

The Licensee's organisation should be able to demonstrate an effective fulfilment of its Management System requirements for example through:

- Senior Management Leadership, including demonstration of their personal commitment to the Management System, and the fostering of everyone's participation in the use and continuous improvement of the Management System;
- Managers and Senior Management of appropriate functions of the organisation setting an example for Safety through oversight and walk downs in the field and direct involvement in training;
- prevalence of a strong organisational Safety Culture and a questioning attitude at all levels of the organisation;
- housekeeping and material conditions that reflect a commitment to operational excellence;
- clear documentation of the functional responsibilities, interface definitions, and communications within the organisation;
- documented evidence of a well-defined procedural work sequence of controlled process steps and interactions, inputs and outputs, and process measurement criteria;
- ongoing assessment activities coupled with continuous improvement initiatives; and
- high-level achievement as verified by organisational goal attainment and key performance indicator (KPI) metrics.

7.3 The main objective of the Management System is to enhance Safety and support a strong Safety Culture

Safety is the fundamental principle upon which the Management System should be based. The Management System has two general objectives:

- To improve the Safety performance of the organisation through a planned and controlled conduct of Safety-related activities of all phases of facility operations.
- To foster and support a strong Safety Culture through the establishment and reinforcement of positive Safety attitudes and behaviours in Individuals and team

structures to give Safety the highest priority in accordance with the organisation's Safety policy.

(a) The Management System should be an integrated system of policies, programmes, processes and procedures bringing together the organisational goals and all the functions and responsibilities in a coherent manner to achieve and enhance Safety.

(b) The Management System should provide a planned and coherent systematic sequence of activities to ensure that the organisational objectives can be achieved in a safe, efficient, and effective manner. Senior Management should prepare a plan to achieve full implementation of the Management System. The implementation plan should be subject to approval and monitoring by the most senior manager assigned the responsibility for the development and implementation of the Management System.

(c) and (d) Safety should be clearly designated to be of paramount importance in the Management System and be integrated into all activities of the organisation.

The organisation's goals, objectives, strategies, and plans should be developed in an integrated manner so that their collective impact on Safety is understood and managed.

7.4 Identification and integration of legislative and regulatory requirements

The Management System should acknowledge the Licensee's obligation to comply with the applicable laws and regulations of the UAE, the Authority regulations, the applicable Licences, as well as the applicable international codes and standards.

The Management System should be reviewed against the applicable Authority regulations, Licences, and international codes and standards to ensure that all its operating programmes, processes and implementing procedures address all the requirements adequately.

The Management System should specifically identify the applicable UAE and Authority statutory and regulatory requirements that apply to its products and process activities.

7.5 Establishment of an independent review committee

The arrangements for the Management System should include provisions for an independent operational Safety review committee. The committee should periodically review and evaluate decisions pertaining to Products, items or activities important to Safety and to formulate recommendations to the Senior Management and the board of directors of the Licensee's organisation, as required.

The independent review committee should provide an in-depth, independent, senior-level review of Nuclear Facility performance in areas related to Nuclear Safety. This independent review should focus on Nuclear Facility Operation, operational readiness, areas of concern and operational activities, with a view towards challenging Senior Management to remain self-critical.

Periodic external reviews may be conducted by experienced industry peers using well-established and proven processes.

The independent review committee may be supported by subcommittees reporting to the Licensee's senior manager (i.e. Plant Manager) that focus on the following areas:

- Operations
- Maintenance
- Organisational Effectiveness
- Engineering.

These subcommittees may be supported by additional staff as necessary to review the topical areas chosen for each meeting. For areas of improvement or gaps in performance that describe a problem or condition that currently exists and needs to be resolved, or needs more attention to enhance the ability of the Licensee to safely operate the Nuclear Facility, each subcommittee liaison should ensure all areas for improvement and recommendations are entered into the Licensee's corrective action programme.

7.6 Specification of requirements for the review committee

(a) A review committee at the Senior Management level to review on-site operations should be established to perform cross-disciplinary reviews of Nuclear Facility operations, proposed Products, items or activities that may impact Safety.

(b) The independent review committee should include outside experts with extensive experience (i.e. 20 years' experience) in Nuclear Facility Design and/or operations. The committee will advise Senior Management, the chief nuclear officer, and, as necessary, the Licensee's board of directors.

(c) The independent review committee chairman should remain engaged as required with the Senior Management and board of directors for the recommendation of decisions significant to Safety.

7.7 Establishment of a clear, systematic, timely and transparent decision-making process

The Management System should clearly delineate the authorities and decision-making responsibilities within the organisation in decision-making pertaining to Nuclear Safety-related matters.

The Management System should promote a continual effort to strive for openness and good communication throughout the organisation.

The decision-making process should be systematic, transparent and timely, the rigour of which should be commensurate with its Safety significance.

7.8 Conflict resolution arising from the decision-making process

The Management System should include a formal conflict resolution procedure or guidance document that may be used to address any conflicts arising from the decision-making process in a manner that does not compromise Nuclear Safety.

Nuclear Safety and Nuclear Security measures should be designed and implemented in such a manner that they do not compromise each other. The Management System should establish mechanisms to resolve potential conflicts and to manage interfaces between Nuclear Safety and Nuclear Security.

Where conflicts between Nuclear Safety and Nuclear Security are identified, a Management System procedure should include appropriate compensatory and/or mitigating actions as necessary to maintain Nuclear Safety and Nuclear Security.

7.9 Identification and analysis of impacts and potential impacts of any changes on Safety, including organisational changes and cumulative effects of minor changes

Proposed changes to the Nuclear Facility, including modifications, operational procedures, and changes to the Licensee's organisation should be classified according to Safety significance and evaluated to ensure no degradation in Safety.

Guidance for managing organisational changes is provided in Screenings and Evaluations for Modifications to Operating Nuclear Facilities (FANR-RG-029, Version 0).

The overall integration of multiple changes, and the interactions of separate changes, or the effects of an accumulation of minor changes, should be carefully evaluated for any adverse impact on Safety.

Graded Approach

Article (8)

8.1 Development and implementation of a Management System using a graded approach

The Licensee's grading process should determine the extent of the application of the requirements of the Management System to the Products, services, items and activities of the organisation. A graded approach to the Management System should be documented and applied to the requirements of a Product, service, item or activity. The controls of a process commensurate with its relative significance, complexity and its potential impact on Safety, Nuclear Security, and the environment should take the following into consideration:

(a) The application of controls demands resources. The application of a graded approach is to deploy appropriate resources based on the following:

- the significance and complexity of each Product or activity; and

- the possible consequences if a Product fails, a regulated activity is performed incorrectly, or the step of an operating procedure is performed incorrectly in the Operation of a Nuclear Facility.

The graded approach should be developed and implemented through the application of a structured grading methodology whereby, for example, a numeric grade is assigned to the Product, service, item or activity. The grading methodology may be developed and applied as follows:

- identify the areas of anticipated significant impact associated with a Product, service, item or activity, e.g. impacts on Nuclear Safety, Radiation Protection, plant Nuclear Security and safeguards, and the environment;
- evaluate the hazards and develop criteria for determination of relative significance for each of the above areas of anticipated significant impact;
- determine the optimum number of grades accordingly, typically three or four grades, with grade one being the highest level;
- evaluate the complexity and the risk significance (likelihood and possible consequences of failure or occurrence of an unanticipated event) of the Product, service, item or activity.

The grading process should also take into consideration other factors associated with the Product, service, item or activity, such as:

  - Safety classification of associated Structures, Systems and Components (SSCs);
  - operational characteristics and location of the Nuclear Facility;
  - relationship of the particular Product, service, item or activity to statutory and regulatory requirements and Licence conditions; and
  - functional interfaces within the organisation (potential for organisational failure).

- The evaluation of the proposed Product, service, item or activity and final grade determination should also include a review of available industry-wide operating experience to identify potentially adverse conditions or unanticipated events that may be associated with the proposed Product, service, item or activity.
- Utilising the grading process as developed above, assign a grade to the Product, service, item or activity and determine the degree of Management System requirements (e.g. analysis, review, testing, control, documentation, and training). This should include any preventive or mitigating measures that may relate to Nuclear Safety, Radiation Protection, Nuclear Security and safeguards, protection of the environment, quality assurance, and economic viability.

- The Management System should include a Senior Management-level cross-functional safety review of proposed Products, services, items or activities, including modifications to Nuclear Facility equipment or procedures, to ensure their impact on Nuclear Safety has been adequately evaluated.

(b) The graded approach should be applied to Safety and non-Safety related SSCs that support safe and reliable operations. This includes evaluating:

- the risks and uncertainties including hazards associated with Safety, Nuclear Security, safeguards, Radiation Protection, environmental, and quality elements of each Product, SSC or activity;
- the importance and complexity of each Product, SSC, programme, process, procedure and activity.

(c) Emergency measures in place and potential consequences in the event of Product, programme, process or procedure failures.

8.2. Application of the graded approach to Management Systems to each process within the organisation

Each of the Management System processes within the organisation should be developed and implemented utilising the graded approach.

- The graded approach as applied to a process should take into consideration the level of risk associated with a loss of control of the process activities and consequential impact on the Product.
- Grading of a process should consider the complexities inherent in the process, including complexity in the Design, procurement, manufacturing, Construction or installation, and the operational and management aspects of the process.
- The graded approach to a process may include added controls such as in-process reviews and authorisations, special training, added resource allocations, installation testing and quality control hold points, and/or other applicable controls.

Documentation

Article (9)

9.1 Documentation of the Management System

No additional guidance is considered necessary for FANR-REG-01 (Version 1), Article 9, paragraph 1.

9.2 Management System documentation description

A typical three-level structure of information may be taken into account for providing a description of Management System documentation, which may consist of:

- Level 1: an overview of how the Licensee organisation and its Management System are designed to adhere to its policies and meet its objectives;
- Level 2: a description of the processes to be implemented to achieve the policies and objectives and the designation of which organisational unit is to carry them out;
- Level 3: detailed instructions and guidance that enable the processes to be carried out and the designation of the Individual or unit that is to perform the work.

All Individuals responsible for preparing or revising documents of the Management System should be competent to perform the tasks and should be given access to appropriate information on which to base their work, input or decisions.

Level 1

Level 1 should provide an overview of the policies and objectives of the Licensee organisation and should describe the Management System that addresses the requirements that apply to the organisation's work. The information at this level of the Management System should be the most senior manager's primary means of communicating to Individuals the expectations of the management, their strategies for success and the methods for achieving the organisation's objectives.

Information on the following should be provided at Level 1:

- vision, mission and goals of the Licensee organisation;
- the Fundamental Safety Objective;
- policy statements of the Licensee organisation (i.e. policies on values and behavioural expectations);
- organisational structure, including the governance and structure thereof;
- levels of authority and responsibilities and accountabilities of Senior Management and organisational units;
- structure of the Management System documentation;
- an overview of the Licensee organisation's operating programmes and processes;
- responsibilities of owners of the processes;
- arrangements for measuring and assessing the effectiveness of the Management System;
- levels of authority, including all interactions of those managing, performing and assessing work and all processes;
- compliance of the Management System with the legislative and regulatory requirements that apply to the Licensee's organisation; and
- interactions with external organisations and Interested Parties.

The most senior manager in the organisation should ensure that Level 1 information is distributed to Individuals for the purpose of implementation and that its contents are effectively understood and implemented.

Level 2

This level of information should describe the processes of the Licensee organisation and provide specific details on which activities should be performed and which organisational unit should carry them out. This information:

- should define the process map of the Management System including the interactions between processes;
- should define the responsibilities and lines of communication that are internal and external to the organisation in each area of activity, for example in processes and interface arrangements; and
- should define measurable objectives and specify which activities are to be carried out and controlled and who is responsible and accountable, and, where appropriate, should refer to supporting information.

Information at this level should provide administrative direction to managers in all positions. It should not be used to provide the details of how technical tasks are to be performed. Technical tasks should be detailed in information at Level 3. To avoid unnecessary detail, cross-reference should be made to Level 3 information such as supporting guidance or detailed working documents.

Level 3

Level 3 information consists of detailed working level documents, which also include procedures, work instructions, technical instructions and drawings and typically cover the tasks within a process that are carried out within a department or by an Individual. A writer's guide may be developed to ensure the consistency of the style and appearance of documents. Detailed working documents are used to describe specific work activities and to convey administrative and technical information to the Individuals performing the work. The type and format of these documents may vary considerably depending on their application. The detailed working documents may include the following instructions:

a) *Purpose:* provide a clear, concise statement explaining the specific purpose of the document.

b) *Scope:* define the type and the scope of work and the places to which the document applies and define the boundaries of the functions, systems and areas addressed in the document.

c) *Responsibilities:* define the duties of the Individuals who are to apply the document. Identify these Individuals and specify their responsibilities and when any necessary action should be taken.

d) *Definitions:* define words and terms used in the document that could potentially be misunderstood which, therefore, need clarification.

e) *References:* provide a bibliography of specifications, standards and other documents referenced in the document. Documents that are referenced may also include applicable Design documents or other source documents such as vendor's literature, engineering drawings or Nuclear Facility specifications.

f) *Prerequisites:* state any independent actions that should be performed, and by whom they should be performed, prior to the use of procedure or instruction. State any spare parts, special tools or instruments that are necessary (e.g. scaffolding or services), state also the necessary state of the Nuclear Facility, if relevant, and any special condition necessary to simulate normal or abnormal operating conditions.

g) *Precautions:* state what precautions are necessary to protect equipment, Individuals, the public and the environment or to avoid abnormal conditions or an Emergency. Such precautions can be highlighted in this section or they may be identified in the relevant steps of the procedures or instructions.

h) *Limitations:* consider whether there are any limitations on the parameters being controlled. Identify the corrective measures that may be used to restore such parameters to within the normal limits.

i) *Actions:* include a description of functions or tasks to be performed in a process. Provide sufficient detail so that a competent Individual can perform the functions or tasks without direct supervision. In some cases, it may be appropriate to provide step-by-step instructions.

j) *Verification:* identify any work activity that requires verification, including independent verification. Highlight the verification points at the relevant step in the procedure.

k) *Acceptance criteria:* state the criteria for the satisfactory completion of a task or function. If tolerances within prescribed limits are permissible, they should be specified together with any requisite actions (i.e. reporting). Specify the method of verification to be used.

l) *Records:* clarify which documents or forms are to be used and retained. A list should be added which specifies, by title, the records necessary to certify or provide evidence that the tasks required in the document have been accomplished and verified. Identify records as permanent or non-permanent in accordance with specified criteria, and specify the retention times for non-permanent records. Record the date and identify the Individuals performing the work and, where appropriate, the 'as found' condition, the corrective action performed and the 'as left' condition.

9.3 Requirements for Individuals responsible for reviewing and approving documents

Documents are reviewed for adequacy by qualified Individuals other than the preparer. During the operational phase, documents affecting the configuration or Operation of the Nuclear Facility as described in the application documents may be screened to identify those that require review by the Nuclear Safety review board or plant manager, for example, prior to implementation.

To ensure effective and accurate procedures during the operational phase, applicable procedures should be reviewed and updated as necessary in particular following:

- any modification to a system;
- any unusual incident, such as an Accident, significant operator error or equipment malfunction; and/or
- upon discovery of procedure discrepancies.

Prior to issuance or use, documents, including revisions thereto, should be approved by the designated function within the Licensee's organisation. A list of all controlled documents identifying the most up-to-date, approved version should be maintained so Individuals can readily determine the appropriate document for use.

Resource Management

Article (10)

10.1 Determination of competences and resources required to carry out the activities of the organisation

The Senior Management should develop a long-term staffing plan that is linked to the long-range objectives developed by the Licensee's organisation to anticipate future personnel needs based on determination of the competences and resources necessary to carry out the activities of the organisation safely. This plan should be reviewed and updated periodically to ensure that it is consistent with and supports the long-range objectives of the Licensee's organisation and the needs of the Nuclear Facilities. The staffing plan should include anticipated changes in authorised staffing levels and a forecast of personnel needs, taking into account losses due to retirement and attrition. The long-term staffing plan should allow sufficient time for Individuals to turn over job responsibilities and should allow for continuity in the conduct of duties.

On the basis of the objectives, functions and responsibilities of the Licensee's organisation, proper definitions should be provided and a detailed analysis of tasks and activities should be performed so that activities of the organisation are carried out safely. The appropriate staffing and qualification requirements at different levels in the organisation should be determined, and the selection, training and retraining requirements should be specified.

The Senior Management should ensure that the Licensee's organisation is staffed with competent managers and a sufficient number of qualified and experienced Individuals to perform the activities of the Licensee. It should also ensure that a sufficient number of experienced staff is supplemented, as necessary, by consultants or contractors to ensure the safe Operation of the Nuclear Facility so that duties important to Safety may be carried out without undue pressure (i.e. vendor-supplier support).

The staffing arrangements should take into account:

- the need to involve the Licensee's organisation in the review of activities, including those that are conducted during the Design, Construction and Commissioning stages;
- the need to establish timely liaison with the Authority, public authorities and other stakeholders;
- the minimum number of Individuals necessary for performing all functions with respect to Nuclear Facility Operation and Emergency situations;
- the need for adequate expertise particularly in the case of a remotely located Nuclear Facility;
- the turnover of personnel in the Licensee's organisation;
- the minimum number of Individuals required to support maintenance (such as the extent of maintenance carried out on shift, the extent of employment of contractors etc.); and
- the need for training the Individuals and retraining Licensee staff.

10.2 (a) Specification of competence requirements

The Senior Management should ensure that for Individuals at all levels who may be required to perform duties that affect Safety, their competence requirements should be specified. For each category of Individuals, the necessary competence may be defined by means of:

- educational level (academic qualification);
- previous experience (including direct and related experience); and/or
- training and continuing training.

Qualification is a formal statement resulting from an assessment of an Individual's competence to fill a position and perform all duties assigned to that position in a responsible manner. Competence is the ability to apply skills, knowledge and attitudes in order to perform an activity or job to specified standards in an effective and efficient manner. Experience is the knowledge gained and the skills developed while performing the duties of a position. Competence may be sustained by regular and continuing training and the availability of competent staff to meet the needs of the organisation taking into account the turnover of operating staff, retirements and promotions.

10.2 (b) Required training to achieve the proficiency level of Individuals' competence

Competence may be developed through education, experience and formal training. The responsibility of ensuring that Individuals remain appropriately qualified should rest with the Licensee. The Senior Management should ensure that an overall training policy is in place, which represents a commitment by the Licensee and Senior Management to the training of personnel and an acknowledgement of the critical role that training plays in the safe, reliable Operation and maintenance of the Nuclear Facility. A training plan should be prepared on the basis of the long-term needs and goals of the Nuclear Facility. This plan should be evaluated periodically in order to ensure that it is consistent with current and future needs and goals. The training needs for duties important to Safety using the Systematic Approach to Training (SAT) process should be considered a priority. The relevant Nuclear Facility procedures, references, resources, tools, equipment and standards should be used in the training process to ensure, as practicable, that errors, omissions and poor practices are not accepted. The SAT process should include the following phases:

- Analysis: this should comprise the identification of training needs and of the competences required to perform a particular job.
- Design: in this phase, competences should be converted into training objectives. These objectives should be organised into a training plan.
- Development: in this phase, training material should be prepared so that training objectives can be achieved.
- Implementation: in this phase, training should be conducted by using the training materials developed.
- Evaluation: in this phase, all aspects of the training programmes should be evaluated on the basis of data collected in each of the other phases. This should be followed by feedback leading to improvements in the training programmes and to Nuclear Facility improvements.

It should be the responsibility of the managers of appropriate functions, with reference to each position important to Safety, to ensure that:

- training needs are continuously analysed and an overall training programme is developed;
- the performances of all trainees are assessed at various stages of the training;
- the effectiveness of the training is evaluated;
- the competence of the Individuals occupying such positions is periodically checked, and continuing training or retraining is provided on a regular basis so that their level of competence is maintained; and
- in allocating resources, the implementation of training programmes is given high priority.

Line managers and supervisors should be accountable for the qualification of their personnel; they should be involved in defining training needs, evaluating the job performance of personnel, providing feedback to the training department and ensuring that the training provided reflects operating experience.

A lack of full-time training staff should not relieve managers of the responsibility of ensuring that their staff are adequately trained and qualified.

10.2 (c) Maintenance of required proficiency level of Individuals

The training plan should be periodically reviewed and modified as necessary. Such a review should be undertaken by Individuals other than those directly responsible for the training. Nuclear Facility management should be directly involved in the evaluation of training programmes to ensure that the required proficiency level of Individuals is achieved and maintained. Close cooperation should be maintained in the training evaluation process between the Nuclear Facility management, individual departments and training department.

10.3 Licensee arrangements to ensure accessibility to a full range of competences and resources required to discharge its responsibilities

The Senior Management should provide or make accessible a full range of competences and the resources required to conduct its activities and discharge its responsibilities during all phases of a Nuclear Facility, as well as during any subsequent period of institutional control or during a nuclear or radiological Emergency, such as:

- adequate arrangements for response to all kinds of anticipated operational occurrences and Accident conditions to protect the health and safety of the site personnel and the public and for protection of the environment; and
- adequate facilities and services that are made available in a timely manner during normal Operation and for responding to all kinds of anticipated operational occurrences, design basis accidents and postulated severe accidents.

10.4 Determination of development of required competences and resources

To ensure the continuous availability of competent staff to meet the needs of the organisation based on a resource plan, the Senior Management should determine which resources will be developed internally based on a Licensee training plan and which competences and resources will be obtained through external contracts.

10.5 Determination of arrangements to retain staff in the organisation

Arrangements should be established to ensure that an adequate number of competent staff are available at all times to operate the Nuclear Facility safely in both normal and abnormal conditions. A long-term succession plan for staff should be put in place supported by reviews of career development, associated action plans and recruitment plans supported by human resources policies to avoid a high turnover of staff in the Licensee's organisation.

10.6 Determination of requirements to sustain in-house capabilities

The Senior Management should ensure that competences to be sustained in-house include competences of all Individuals who may be required to perform duties that affect Safety. In-house capabilities should be qualified or have a sufficient understanding through training in team work management and supervision, understanding of the Nuclear Facility (i.e. technical, human and organisational aspects related to Nuclear Facility), and the safety management principles that are relevant to their work. In-house capabilities should also include competences in how to promote Safety and Nuclear Security and conservative decision-making in terms of attitudes, as well as skills in communications.

10.7 Assessment of staff and line management competences

For every position in the Licensee's organisation that is important to Safety, the Senior Management should establish a series of requirements for initial and continuing training in order to establish and maintain competence. These requirements should vary according to the individual position, level of responsibility and specific level of competence required, and should be prepared by persons having specific competence in Nuclear Facility Operation and experience in developing training activities. The established requirements should relate to the tasks, the standards expected to be applied and activities to be performed.

10.8 Staff training in the relevant requirements of the Management System

Managers should be held responsible for ensuring that all Individuals working under their supervision have been provided the necessary training in the relevant requirements of the Management System. Training should be conducted to ensure that Individuals are capable of performing their tasks and should have a good understanding of:

- the principles of the Management System and the relevant programme descriptions, process descriptions and implementing procedures;
- Individuals and organisational values and behavioural standards;
- the relationship between the Management System and the development of a strong Safety Culture;
- key characteristics and attributes of Safety Culture; and

- the goals, strategy, plans and objectives of the Licensee's organisation.

Knowledge Management

Article (11)

11.1 Management of knowledge as a resource

The Management System should include and continually maintain a system for the management of records, reports, and experiences within the Licensee's organisation for Safety-related activities thus making up the knowledge base of the Licensee's organisation.

An integrated systematic approach to knowledge management should be taken within the Licensee's organisation, and information should be treated as an organisational resource necessary for Safety-related decision-making and continuous improvement.

(a) To manage information and knowledge, the Licensee's Senior Management should include provisions for:

- identification of information needs of the Licensee's organisation;
- identification and access to internal and external sources of information;
- using the data, information and knowledge to set and meet the organisation's strategies and objectives;
- ensuring appropriate Nuclear Security and confidentiality;
- ensuring the preservation of organisational knowledge and capturing tacit knowledge for appropriate conversion to explicit knowledge;
- identification, creation and/or collection of knowledge materials (i.e. Nuclear Facility Design and operational information, reports, and other important information, knowledge and experiences) for the retention of knowledge in an organised indexed system, which, as applicable, is searchable in electronic form; and
- efficient dissemination of knowledge within the Licensee organisation.

(b) The management of knowledge within the organisation should include an appropriate document control system to retain and facilitate easy retrieval of information to enhance process workflow and decision-making, and to encourage knowledge sharing across the organisation.

The retention times of Management System information should be established consistent with the knowledge management obligations of the Licensee's organisation. Information should be stored in secure facilities that protect against loss, damage or deterioration.

The organisational knowledge base should facilitate the assimilation of new personnel and advance the skills and knowledge of existing personnel.

Senior Management should ensure that organisational knowledge is preserved and that tacit knowledge is captured and converted into explicit knowledge. The debriefing of retiring

personnel should be considered. The incorporation of senior Individuals in training sessions on organisation processes should be considered with the objective of knowledge preservation.

11.2 Maintenance of knowledge

The Licensee's Senior Management should establish, maintain and re-evaluate as necessary the organisational knowledge base, infrastructure and the working environment necessary for work to be carried out in a safe manner and for all the process objectives to be met.

The knowledge base should be maintained in readily accessible form, electronically searchable as applicable, updated in a timely manner, and classified and indexed to make the information easily accessible to users.

Process Implementation

Article (12)

12.1 General requirements for process implementation

Processes should be developed and implemented within the Management System to describe the sequence and interactions necessary to effectively and efficiently achieve the organisational goals, strategies and objectives. The processes should meet all the applicable requirements of the Fundamental Safety Objective during the siting, Design, Construction, Commissioning, Operation, Closure, and Decommissioning of a Nuclear Facility, and support and improve the Safety performance of the organisation such as:

- continuous review of applicable regulations and standards, Safety requirements publications, Safety guides and the organisation's management and technical practices ensuring processes adequately address all current applicable requirements to the extent practicable.

The methods necessary to ensure the effectiveness of both the implementation and the control of processes for all phases of the organisation's activities during the siting, Design, Construction, Commissioning, Operation, Closure, and Decommissioning of a Nuclear Facility should be planned, implemented and improved in accordance with established and documented processes.

The processes should provide a structured and systematic approach to decision-making that meets the needs of the Licensee's organisation, and should include all review, assessment and oversight activities to ensure continuous improvement in the organisational processes.

The Senior Management in the Licensee's organisation should be responsible for ensuring that the Management System is implemented. For satisfactory implementation, planning and the deployment of adequate resources are necessary. All Individuals should be trained to achieve proficiency. It should be ensured that all Individuals understand the management processes that apply to the performance of their work. Senior Management should prepare a

plan to achieve full implementation of the Management System. Consideration should be given to needs for special skills and training.

12.2 Sequence and interactions of Management System processes

The Management System processes should be developed to identify the process inputs and outputs and to explicitly describe the sequence of work activities, interactions, and interfaces.

The activities and interfaces between or among various functional groups within a single process should be planned and managed so as to ensure clear division of responsibility and effective communication.

Processes should be defined and documented based on regulatory and statutory Safety requirements and the nature of the Licensee's organisational structure and functional work activities. The processes should be documented utilising appropriate techniques such as graphical representations, flow charts, checklists, written instructions, or media.

The Management System processes should be organised in a hierarchical manner, typically grouped as core processes, support processes, and management processes, generally as follows:

- core processes including key operational, maintenance, work management, materials and services and technical support processes;
- support processes including cross-functional or generic processes such as training, information technology, emergency preparedness and response, loss prevention, Nuclear Fuel and licensing services; and
- management processes including management oversight and independent assessment, human resources services and business administration.

The interfaces between the core processes and the support and management processes should be clearly specified including the specific information flow and the inputs/outputs necessary to support achievement of the organisational objectives and to support and continuously improve organisational Safety performance.

For each process, a designated owner should be given the authority and responsibility to:

- explicitly determine that there is effective interaction between interfacing processes;
- explicitly determine that process documentation is consistent with any existing documents;
- ensure that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the Licensee organisation including Authority regulations; and
- monitor and report on the performance of the process.

The work performed in each process should be carried out under controlled conditions by using approved current procedures, instructions, and drawings that are periodically reviewed to ensure their adequacy and effectiveness. The control of processes contracted to external organisations should be identified within the Management System. The Licensee's organisation should retain overall responsibility when contracting any processes.

12.3 Methods to ensure effectiveness of the Management System processes

The Management System processes should be continually monitored and assessed to ensure the effectiveness of their implementation and control in achieving the desired results and to identify opportunities for improvement.

The following methods or data sources may be utilised to assess and/or measure the effectiveness of the Management System processes to identify areas for improvement:

- Management Oversight

  Managers should normally perform oversight reviews and assess the performance of activities through their day-to-day line management activities.
  Line management monitoring:
  - should observe the work being carried out to ensure that the applicable standards are being met;
  - should be visibly present and available and should listen to suggestions and complaints from Individuals;
  - should examine trends in performance indicators;
  - should review the results and lessons learnt from self-assessments, independent assessments, observation and surveillance programmes;
  - should carry out pre-job briefings and post-job briefings where necessary;
  - should coach and mentor Individuals to improve their performance;
  - should review the achievement of goals, strategies, plans and objectives; and
  - should hold oversight meetings such as operational meetings, management team meetings, and Nuclear Safety oversight meetings.

- Self-Assessment:

  Senior Management and management at all other levels in the Licensee's organisation should carry out self-assessments to evaluate the performance of work and improvement of Safety Culture.

- Independent Assessment:

  Independent assessments should be conducted regularly on behalf of Senior Management:

- to evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives;
- to determine the adequacy of work performance and leadership;
- to evaluate the Licensee organisation's Safety Culture; and
- to identify opportunities for improvement.

- Management System Review:

  A Management System Review should be conducted at planned intervals to ensure the continuing suitability and effectiveness of the Management System and its ability to enable the objectives set for the Licensee organisation to be accomplished.
- Non-conformance Reports and Corrective Action Programmes

  Articles 20 to 24 of FANR-REG-01 (Version 1) provide requirements for using measurement, assessments, the Management System Review, and input from non-conformance and corrective action programmes for the identification of improvements to the Management System processes.

12.4 Development of each Management System process

The Management System processes should be developed to achieve the following:

(a) Each Management System process should identify the legal and regulatory requirements, including licensing conditions, and other obligations or commitments applicable to the particular process. A single matrix layout of processes versus requirements may be used to present the process requirements with reference to the matrix in each of the individual process documents.

The process requirements should cover the applicable legislative and regulatory requirements including Safety, Nuclear Security, radiological, safeguards, environmental, quality, and economic requirements.

(b) The hazards and risks associated with each process should be identified, and precautionary and/or appropriate control measures should be specified to ensure such hazards or risks are effectively managed.

The identification of hazards and risk should include, as applicable for the particular process, an assessment of workplace risk where the work activities might pose a risk of injury, harm or damage.

Individual processes may necessitate the inclusion of a risk management plan depending on the nature of the process and inherent hazards or risk.

(c) The processes within the Management System may be illustrated by flowcharts, and the interactions and interfaces with other processes should be clearly identified.

The interfaces between or among processes should include identification of the data and/or information exchanges expected among the processes along with any limitations or provisions for use of such data or information by the recipient process.

There should be a clear understanding of the division of responsibilities and the working relationship between all organisational units participating in or supporting the Management System.

(d) The processes within the Management System should include inputs that are clearly specified and qualified for use within the intended process flow.

(e) The process flow should describe how work progresses and integrates throughout the organisation as well as interfaces with other organisational units and suppliers. The process flow should also incorporate the relevant expectations and reference the related documentation and records requirements.

The process flow may be described through flowcharts, checklists, descriptive instructional procedures, or other visual media.

The process flow may be developed using a top-down, hierarchically linked set of flowcharts with more detail provided the closer they are to the technical task level. At the technical task level, the process may be better described utilising instructional procedures.

(f) The output of a process should identify the specific product or result that is expected to be produced by a process. Process outputs may serve as an input to another process or be a contributing component or factor of a Management System programme.

(g) The Management System processes should be monitored and measured to continually assess their effectiveness in achieving the Licensee organisation's goals and objectives, and to continuously improve the Safety performance of the organisation.

Measurement criteria should be established to assess process effectiveness, for example to measure timeliness and Product quality (e.g. based on input from the Authority, rework, quality assurance findings or non-conformances).

12.5 Activities and interfaces within a single process

For each process, an Individual should be designated as a process owner with the responsibility and authority to manage the process.

The assigned process owner should ensure effective interaction and communication among the Individuals or teams involved in the process with clear assignment of responsibilities. The work is planned and performed under controlled conditions utilising approved up-to-date procedures, instructions, specifications or other appropriate means that are periodically assessed to ensure their adequacy and effectiveness.

Process Management

Article (13)

13.1 Effective management of processes

Processes and activities should be developed and effectively managed within the Management System with clear assignment of responsibilities to achieve the organisational goals and objectives, meet all applicable requirements, and to support and continuously improve the Safety performance of the Licensee organisation. The overall focus of goals, strategies, and plans should be to meet the Fundamental Safety Objective as defined in Article 1 of FANR-REG-01 (Version 1), in addition to other business objectives.

The Management System processes should provide the means to meet all applicable requirements and deliver the products or services of the Licensee's organisation. To manage the processes of the Licensee's organisation, the organisation should determine:

- the processes that implement the vision, goals, strategy, policies and the Fundamental Safety Objective of the organisation;
- the requirements for the input to the processes and output from the processes; and
- how the processes interact to enable the organisation's objectives to be achieved.

Methods should be established to ensure the effective and efficient implementation of the Management System processes, for example line management oversight, in-process technical review and assessment, and self-assessment, all of which should also be used to identify opportunities to further advance the performance of the Licensee organisation.

13.2 Leadership of Management System processes

Each process should have an Individual assigned as a process owner with the authority and responsibility as described in the paragraphs below.

The responsibilities of a process owner are to:

(a) develop and maintain the process, including process documentation and records management, in keeping with the goals, objectives, and strategies of the Licensee's organisation. The scope, level of detail, inputs, outputs, and interface requirements should define the amount of supporting documentation necessary for the Management System;

(b) ensure effective interaction between interfacing processes, including interfaces within their assigned process and interfaces with other processes and operating programmes within the Management System;

(c) ensure the documented process is consistent with other processes including support processes and interfacing processes, and other documentation within the

Management System, e.g. organisational vision and mission statements, strategic objectives, performance indicators, operating programmes, processes and implementing procedures;

(d) ensure that records demonstrating the performance of the process are included in the process documentation and are controlled so that they are readily retrievable, readable, and complete with established retention times consistent with regulatory requirements and the organisation's knowledge management obligations;

(e) monitor the performance of the process, including interactions with other processes, the internal process flow of information, and the quality and timeliness of the process output, e.g. through tracking the applicable performance indicators, management oversight and observation, and self-assessment;

(f) based on the performance monitoring above, advance the continuous improvement of the process through the development of improvements and preventive measures and foster a learning and questioning attitude within the Licensee organisation; and

(g) ensure the process, including any subsequent changes to it, remains aligned with the organisational goals, strategic objectives, and the organisation's Fundamental Safety Objective to ensure that nuclear and radiological Safety, the Nuclear Facility's physical security, and protection of the environment are at all times maintained.

13.3 Inspection, testing, verification and validation activities

Each Management System process should include as applicable, specifications for inspection, testing, verification and/or validation, as well as their acceptance criteria as applicable to the process output Product or service. The specifications should include the following:

- identification of the specific parameters to be inspected, tested, and verified and/or validated;
- the associated acceptance criteria;
- the applicable process stages or conditions, hold points, and the applicable sequence of inspection, testing, and verification and/or validation, required independence at various stages; and
- identification of the organisational unit or Individuals assigned and his/her responsibilities to perform the inspection, testing, and verification and/or validation.

Individuals should not inspect, test, verify or validate their own work Product; however, they are expected to perform self-checking prior to Product or service delivery.

13.4 Periodic evaluation of processes

The effectiveness of the Management System processes should be monitored and periodically evaluated to ensure its continued effectiveness and alignment with the organisational goals,

strategic objectives, and the Licensee organisation's Fundamental Safety Objective (see Article 13.2 e, f, and g above).

The periodic evaluations may be conducted as self-assessment under the direction of the process owner, an independent assessment by either an internal assessment organisation or cross-functional team of Individuals, or as part of a broader Management System Review. Articles 21, 22, and 23 of this regulatory guide respectively provide guidance for the conduct of these types of periodic evaluations.

13.5 Use of approved procedures, instructions and drawings

The Management System Products, services, and processes that have implications on Safety should be developed and/or carried out under controlled conditions following Licensee document management processes and implementing procedures utilising approved current procedures, instructions and drawings. The procedures, instructions and drawings should be reviewed and validated by the Individuals responsible for implementation of the process and/or the process owner.

Procedures, instructions, and drawings should be periodically reviewed to ensure their continued applicability and effectiveness, and the results of the periodic review evaluated against expectations to determine the need for revision.

13.6 Processes implemented by a third party

Management System processes or tasks outsourced to a third party, such as processes in relation to Nuclear Fuel, Nuclear Security, Safety Assessment or the calibration of Safety equipment, should be clearly identified within the Management System documentation. The Licensee's organisation should retain overall responsibility for management of the process.

The outsourced process or tasks should be controlled to ensure the process or task is conducted in accordance with the applicable Management System requirements, e.g. specifications and validation requirements, regulatory requirements, monitoring and measuring of the process, and applicable documentation requirements.

Interfaces or interactions of the outsourced process or task within Management System processes should be managed as part of the Licensee's approved Management System.

13.7 Process sequencing and interfaces

The sequence of workflow within a process and the interactions among processes should be developed to achieve the following:

- process requirements including statutory, regulatory, legal, Safety, health, security, environmental, quality, and economic requirements are identified and addressed;
- hazards and risks are identified, along with mitigation measures;

- process inputs, outputs and interfaces with other processes are identified and fully described; and
- process measurement techniques and criteria are established to monitor the performance of the process.

The sequencing of a process and interfaces with other processes should be specified so as to not compromise Safety, for example, by ensuring that the output transferred from one process is fully compatible with its intended use in the other process and that the limitations or range of the transferred data or information is clearly identified.

Effective interactions between interfacing processes within the organisation's Management System and with processes or tasks provided by an outside third party should be developed and maintained. The interactions with an outside third party may include the following:

- clarification of the inputs from the Licensee's organisation to the outside third party and the outputs from the third party to the Licensee's organisation;
- arrangements for the transfer of information between the Licensee's organisation and the outside third party;
- arrangements for outside third-party monitoring and oversight by the Licensee's organisation for process validation; and
- establishment of communication channels between the Licensee's organisation and the outside third party, including periodic status reporting.

13.8 New processes or modifications to existing processes

New processes or modifications to existing processes should be developed as described under Article 13.7 above and verified so that Safety is not compromised. Such changes in the Management System should be planned, controlled, communicated (i.e. to the Authority as applicable), monitored and tracked during the development and early stage of implementation to ensure Safety is not compromised.

Depending upon the significance of a new process or extent of a modification to an existing process, Senior Management may elect to have an independent assessment performed to confirm the effectiveness of the new or modified process and to verify that Safety is not compromised.

Control of Documents and Records

Article (14)

14.1 Control and use of Management System documents

The information technology (i.e. Electronic Document Management System) necessary to support an integrated Management System, including configuration management, should be

planned from the Design stage of the Nuclear Facility. Such data should be readily accessible for use during the lifetime of the Nuclear Facility. The documents should be suitable for use by the appropriate Individuals and the content should be clear, concise and unambiguous.

The Management System should ensure that records and other documents (including electronic documents) relevant to the safe and reliable Operation of the Nuclear Facility, including Design documents, Commissioning documents and documents relating to the operational history of the Nuclear Facility, are properly managed. Such documentation should record all the changes in Nuclear Facility configuration. Only correct, up-to-date versions of documents should be available to operating personnel. Previous versions of these documents should be appropriately archived and maintained for reference purposes.

The types of documents that should be controlled, taking into consideration the graded approach described in Article 8 of this regulatory guide, include:

- documents that define the Management System;
- Safety requirements;
- work instructions;
- training materials;
- assessment reports;
- drawings;
- data files;
- specifications;
- computer codes;
- non-conformance reports;
- test results;
- receipt and storage inspection reports;
- purchase orders and related documents; and
- supplier documents.

14.2 Approval and recording of document changes

Senior Management should ensure that provisions are in place to control revision, review and maintaining records of documents. Revised documents should be subject to the same level of approval as the initial documents. If it becomes necessary to correct errors, any revisions of records should be controlled and tracked.

A modification to one document may affect other documents and affected documents should be revised accordingly. Where practicable, modifications to documents should be highlighted in the documents by suitable means.

The Electronic Document Management System should be used to manage documents during the lifetime of the Nuclear Facility to include:

- identifying the originator of the document;
- identifying the approver of the document;
- keeping track of when the document was created and last modified, for each version of the document;
- distinguishing whether the document is present in a draft version or its approved version;
- keeping track of any form template that is associated with the document; and
- managing document security with access provisions for approved documents.

14.3 Data security policies, processes, procedures and instructions

Senior Managers should ensure that policies, processes, procedures and instructions are put in place to designate the importance to Nuclear Security of various classes of documents and protect information in documents as appropriate to meet applicable requirements for data security. This should include educating Individuals about the vulnerability of non-encrypted information held on networked computers and making all authorised users aware of their responsibility to maintain the confidentiality of documents, to protect their passwords, to abide by the organisation's security policy and to report any breaches of which they become aware.

Documents can be lost or corrupted due to unauthorised access, malicious interference or system failure. Breaches may originate from within or external to an organisation and standard security tools should be adopted and used to counteract these threats and vulnerabilities.

The Management System should include computer security measures to ensure the appropriate protection (including traceability) of sensitive information, sensitive information assets and sensitive digital assets. Computer security measures should ensure confidentiality, integrity and availability as well as meeting any other requirements specified by the competent authorities.

14.4 Usability of records

Senior Management should ensure that relevant physical and digital records meeting regulatory and the Licensee's records management requirements are specified in the Management System and controlled. Both physical and digital records should be readable, complete, identifiable and easily retrievable.

The Licensee should ensure in the record process that records are specified, prepared, authenticated and maintained as required by the applicable codes, standards and specifications.

The Management System should specify that physical and digital records are:

- categorised, including retention times;
- registered upon receipt;
- readily retrievable;
- indexed and located in physical or digital files;
- stored in a controlled and safe environment;
- stored in appropriate storage media; and
- remain unchanged under normal circumstances.

An index or digital programme should provide sufficient information to identify the topic or asset and the relevant associated records.

Documents from external sources should be reviewed to ensure their suitability before acceptance and use in the Management System.

Senior managers should ensure that physical and digital records are indexed, filed, stored and maintained in facilities that allow their retrieval when necessary. The preparation and storage requirements for different media should reflect the manufacturer's guidance for the media. The records should be accessible at all times during the specified retention periods. Access to locations where records are retained should be controlled. Responsibilities for maintaining and operating the record process and the facilities for the storage of records should be clearly defined and documented. Consideration should be given to the need to access information in Emergency conditions at a location away from the Nuclear Facility. If it becomes necessary to correct errors, any revisions of records should be approved by the same level of authority as the original record and tracked.

14.5 Maintenance of records as evidence of performance

The Management System implementing procedures for a task should define which records need to be retained as evidence that the task was completed in accordance with the requirements of quality and Safety. The implementing procedures should also specify the retention time.

Records provide objective evidence of activities performed or results achieved. The processes or procedures or assessments of an organisation generate a range of information, such as:

- specifications;
- assessment reports;
- Safety reports;
- procurement documents;
- non-conformance reports;

- receipt and storage inspection reports;
- test results;
- calibration data for measuring and testing equipment.

The requirements for the management of records, such as statutory obligations, codes and standards, and the Authority expectations, should be identified and understood to ensure that they are addressed by the applicable Management System processes.

14.6 Document retention periods

The applicable Management System process/implementing of procedures should include provisions that specify the retention times of records and associated test materials and specimens that are consistent with the Authority requirements, codes and standards, safety quality requirements and specification.

The manner in which the retention of documentation is controlled depends on its type, use and significance to Safety. The retention period for each document should be based on the organisation's needs, the consequences of not having the information available at a future time, and related regulations. Records should be categorised in accordance with these needs and the retention periods that have been determined for the various categories. The media in which documentation is recorded should also reflect these considerations.

Records that should be considered for long-term storage should be based on the Licensee's quality assurance programme, ASME codes, and regulatory requirements, which may include:

- approved specifications of Products;
- records of the condition of Products;
- records demonstrating that Individuals are competent to perform their work;
- records demonstrating compliance with codes, standards, statutory and regulatory requirements;
- configuration management records; and
- records of the investigation of an Accident, malfunction, event or non-conformance.

Relevant operating experience information of the Nuclear Facility should be retained for use throughout the Nuclear Facility's operating lifetime and used as input for periodic Safety reviews, deterministic and probabilistic Safety Assessments, the Design and implementation of modifications to the Nuclear Facility, and ageing management.

Senior Management should specify responsibility for the transfer or disposal of records. Disposal of records should be with the concurrence of relevant organisational units at the time of disposal in compliance with applicable quality assurance, codes and standards requirements.

14.7 Durability of records

The Management System should specify appropriate storage conditions in terms of fire protection, Nuclear Security and environmental conditions.

All records should be readable, complete and identifiable with the Product or process involved and should be preserved in media that resists deterioration for the necessary retention times. Records that need special processing and control, such as computer codes and software and information stored on high density media or optical discs, should be maintained and controlled to ensure that they are readily retrievable and usable.

To prevent the deterioration of records during the retention period, it may be necessary to transfer records to a different medium. The transfer process should include control and verification that the information has been transferred accurately. If any copying is necessary to maintain image quality during the retention period, this should also be controlled and the quality of the copied image verified.

Control of Products and Services

Article (15)

15.1 Assessment of Products and services that may affect Safety

The Management System should include a process for the control of Products and services to ensure that such Products and services meet all the specified requirements, including Design, functional, environmental qualification and quality.

The assessment of quality should include both quality assurance to provide confidence in fulfilling the specified requirements for the Products and services and quality control to verify conformity with the specified requirements for the Products and services.

The control process should include the following types of requirements, as applicable to the particular Product or service:

- Product or services specifications and requirements;
- inspection, testing, verification and validation requirements; and
- documentation of all pertinent records, e.g. specifications, assessment and Safety reports, procurement documents, non-conformance reports, inspection and test plans, inspection reports, testing results, and certificate of conformance.

Products and services that may interact or interface with each other should be identified and their functional design specifications thoroughly reviewed for compatibility, and their interface functions tested prior to use to ensure adequately controlled implementation of the interfaced Product and/or services.

Use of an enterprise IT system (Electronic Document Management System) could improve the efficiency of and coordination among interfacing Management System processes and facilitate the configuration management process.

15.2 Inspection, testing, verification and validation of Products and services

Inspection, testing, verification and validation provide a measure of assurance, control, and documented evidence that the supplied Products or services meet the specified acceptance criteria and are acceptable for use.

Applicable inspection, testing, verification and validation of Products and services should be completed prior to acceptance and installation or implementation of the Product or service. A process should be established to determine the types of inspection, testing, verification and/or validation required to be performed for the given Product or service, for example:

- quality control source inspection conducted at the supplier facility prior to shipment to determine conformity of the Product;
- quality control receipt inspection to verify conformance of the Product with specifications and to check for visible damage, defects, or other discrepancy, as well as detection of Counterfeit or Fraudulent Items;
- factory acceptance testing performed at the supplier facility to verify functionality, including hardware and software functions of the Product;
- review of the quality management documentation provided by the supplier to verify the adequacy of the quality assurance and quality control processes as applied to the Product or service;
- review of the Design documents, drawings, and supporting analyses to verify compliance with the Product specifications and regulatory requirements; and
- Product testing using established and proven test requirements, procedures, and criteria to demonstrate that the Product equipment, component, or material performs as intended, including safety function performance that conforms to regulatory commitments, and the licensing basis.

Test requirements and acceptance criteria should be developed based on the Product specifications and Design documents. Inspections and test planning should address such aspects as Product characteristics, inspection techniques, hold and witness points, acceptance criteria and Individuals responsible for conducting the inspections.

The tools and the measurement and test equipment used to perform the inspection, testing, verification and validation activities important to Safety should be of the proper type and range and should be maintained and calibrated to ensure consistent and accurate results.

A process should be established for the calibration and control of test and measurement tools, gauges, instruments and other tools or devices used for test and measurement activities important to Safety.

15.3 Meeting specified requirements

The quality control process should include requirements to confirm the Products and services meet their specifications and requirements, including quality requirements, and that they will perform satisfactorily in service.

The inspection, testing, verification and validation activities described in Article 15, paragraph 2, may be augmented with a design review or quality assurance audit as a means to thoroughly evaluate the Product or service for conformance with the specifications and requirements. The extent of any design review or audit may be determined through application of the grading process described in Article 8 of this regulatory guide and such design review or audit should be conducted early in the Product or service development cycle.

15.4 Compliance with design, quality and service requirements

The Products provided for use should be supplied in such manner or form that compliance with their design, quality, and services requirements can be verified prior to their use or installation.

Products should undergo a material inspection directly upon receipt at the Licensee's Nuclear Facility and therefore be accessible for checks and visual examination, including: verification of item identity and quantity; confirmation of receipt of required documentation, including Product certificates; and checks for shipping damage or foreign material. Receipt inspection personnel should be trained in the detection of Counterfeit or Fraudulent Items.

Technical inspections should also be conducted to confirm that all the Product specifications, in-service requirements, quality requirements, and acceptance criteria are met.

Any non-conformances should be documented and non-conforming items should be segregated from accepted items.

15.5 Ensuring that Products and services do not bypass verification activities

The Products and services quality control process should include appropriate controls and indicators to ensure that the required verification activities are not inadvertently bypassed.

Proper planning, training and management oversight, plus the use of administrative measures such as checklists, inspection traveller tags, and inspection hold-point signoffs may be used to provide assurance that the required verifications are performed prior to acceptance and implementation of Products and services.

15.6 Identification and traceability of Products

Products should be identified to ensure proper use and where traceability is required, the identification of the Product should be uniquely recorded and controlled.

15.7 Damage, deterioration, loss prevention and prevention of inadvertent use

Following receipt and inspection, Products should be stored in the organisation's secure storage and warehousing system. The Products that would be installed in the Nuclear Facility should be stored in accordance with the specification until their installation.

Products should be securely stored under the required environmental conditions with in-storage maintenance, traceability, shelf-life monitoring, and configuration control measures compliant with the Product storage and handling specifications in order to prevent damage, deterioration, or inadvertent use.

Handling, transport and operation of Products should take into consideration the Product susceptibility to damage, the need for Product identification and traceability, and other factors such as the need for frequent handling and protection of Individuals.

Non-conforming Products should be stored physically separate from Products that are acceptable for use in the Nuclear Facility to minimise the inadvertent use of a non-conforming Product.

Purchasing

Article (16)

16.1 Process and oversight for procurement of Products and services that may influence Safety

The Management System should include arrangements for qualification, selection, evaluation, procurement, and oversight of the Supply Chain. The Individuals carrying out procurement activities:

- should ensure, as basis for selection, that the supplier is capable of supplying the Products and services as specified;
- should monitor suppliers to confirm that they continue to perform satisfactorily;
- should ensure that the Products and services conform to the requirements of procurement documents and perform as expected;
- should specify the contact Individual for all communications on the procurement with the supplier; and
- should define, where necessary, the interfaces between the organisation and suppliers to ensure that the key dates for the supply are met.

The Supply Chain typically includes designers, vendors, manufacturers and constructors, employers, contractors, subcontractors, and consignors and carriers who supply Safety-related items. The Supply Chain can also include other parts of the Licensee's organisation.

The Management System should specify the responsibilities for review and approval of procurement documents within the organisation and the processes for review and approval before issuance to ensure that all requirements have been included and are in accordance with the specified procedures and regulatory requirements.

Changes to procurement documents should be undertaken in a controlled manner and be subject to the same level of control as the original documents.

All suppliers and contractors involved in Products or services that may influence Safety, including relevant Design, engineering, manufacturing, Construction, Operation, maintenance or other related activities, should be made aware of the applicable Safety requirements and expectations of the Licensee's organisation. Suppliers and contractors of Safety-related Products and services should be made aware of the Safety Culture of the Licensee's organisation and expectations in this area for suppliers.

The contractors selected for specific Safety-related activities should provide documentary evidence to the Licensee's organisation that they and their personnel have the appropriate training and qualifications to perform the assigned work. This information should be provided before contractor personnel start such work and should include confirmation of relevant experience in performing similar work.

The Licensee's organisation should make clear in procurement documents that, during the entire period of the contracted work, contractor personnel involved in Safety-related activities should be competent and qualified to perform their assigned tasks.

The above applicable requirements should be cascaded to the sub-contractors in the Supply Chain by purchasing contract provisions.

In order for suppliers to improve their services, feedback from evaluations of measured and perceived performance may be provided by the Licensee.

Products should not be released for use or installation until all inspections have been satisfactorily concluded and all specified documents have been received and checked.

16.2 Selection and performance evaluation of suppliers

The Management System should specify that the selection of suppliers for Products and services that may influence Safety should be based on an evaluation of the supplier's capability to provide Products or services in accordance with the requirements of the procurement documents. Managers of appropriate functions and at appropriate levels should use specified criteria to evaluate and select suppliers. Responsibilities in the Licensee's organisation for determining suppliers' capabilities should be identified and methods to be used in evaluating prospective suppliers may include:

- evaluating the prospective supplier's history of providing a Product that performs satisfactorily in actual use;

- review of records that have been accumulated in connection with previous procurement actions and operating experience with the Product;
- evaluating the prospective supplier's Management System or quality assurance programme as applicable; and
- evaluating the capability of the prospective supplier by investigating samples of current production.

Submitted quotations (bids or tenders) from prospective suppliers should be evaluated in a logical manner to ensure that they conform to the requirements of the procurement documents. The evaluation of quotations carried out by the Licensee's organisation should be a team effort involving the organisational units responsible for the technical and procurement activities.

The managers of appropriate functions and at appropriate levels of the Licensee's organisation should monitor, evaluate and verify how the supplier performs against the procurement requirements. Managers should identify notification points for evaluation as early as practicable in the procurement process. These should be documented and agreed between the Licensee's organisation and the supplier. The Licensee's quality assurance department should develop a schedule of supplier assessments. The frequency of assessments should be determined by factors such as the importance of Products and performance of supplier.

Supplier assessments may be carried out when:

- it is necessary to determine the capability of a supplier and the adequacy of its Management System or quality assurance programme;
- after the award of a contract, it is necessary to determine whether the supplier is appropriately performing the functions as defined in the Management System/quality assurance programme, applicable codes and standards and other contract documents.

16.3 Development and documentation of Products and services requirements

The Licensee's Management System should include the following topics in a supplier contractual agreement:

- specification, verification and validation requirements for the Product or service;
- any statutory or regulatory requirements to be met;
- Management System requirements, including requirements on process monitoring and methods of measurement, performance targets for processes and the reporting of results; and
- audits to be performed by the Licensee's organisation.

Licensee procurement documents should generally cover the points below.

- Scope of work: a full description of the work to be undertaken by a supplier, including interfaces with other work, so that intent is clearly understood.
- Technical requirements: the technical requirements for Products or services should be specified with reference to technical documents such as codes, specifications, regulatory requirements, standards, design basis documents and drawings, process requirements and requirements for the approval or qualification of Products, procedures or processes.
- Qualification requirements: needs and requirements should be identified and necessary resources should be provided.
- Inspection and testing requirements: when inspection or testing of Products is necessary, this should be specified. Acceptance criteria for the requirements should also be specified.
- Access to the supplier facilities: conditions of access to the supplier's premises to carry out activities such as inspections, audits and surveillance should be defined.
- Identification of the standards applicable to the Management System and quality assurance: when international standards other than those of the IAEA or applicable ASME are quoted, these additional requirements should be adequately complied with in their Management System manual and quality assurance manual as applicable.
- Document requirements: the documents that the supplier is required to submit to the organisation for approval or comments should be clearly identified in the procurement documents.
- Record requirements: requirements on supply of records after completion of all activities of the procured Product or services contract and on material samples should be made clear to the supplier prior to concluding the contract.
- Timing of submissions: clear instructions should be given to suppliers regarding the times when the necessary documents and records should be submitted.
- Non-conformance reporting: the supplier should have a clear understanding of the non-conformance control process. It should be made clear which party may sanction which type of non-conformance.
- Subsidiary supplier controls: unless otherwise specified by the Licensee's organisation, the supplier should be responsible for the control of subsidiary suppliers.

16.4 Licensee competence for procurement and assessment of suppliers and Products

The Senior Management should ensure that the Licensee's organisation has a clear understanding and knowledge of the Product or service being supplied. The Licensee's organisation should itself retain the competence to specify the scope and standard of a

required Product or service, and subsequently to assess whether the Product or service supplied meets the applicable Safety requirements.

Individuals carrying out procurement activities, in conjunction with the relevant technical personnel, should have the capabilities to:

- ensure that the information provided to suppliers is clear, concise and unambiguous, fully describes the Products and services necessary, and includes technical and quality requirements;
- ensure, as a basis for selection, that the supplier is qualified and fully capable of supplying the Products and services as specified;
- monitor suppliers to confirm that they continue to perform satisfactorily;
- ensure that the Products and services conform to the requirements of procurement documents and perform as expected;
- specify the contact Individual for all communications on procurement with the supplier; and
- define, where necessary, the interfaces between the organisation and suppliers and between different suppliers to ensure that key dates for supply are met.

16.5 Specifications in procurement documents for non-conformance reporting including CFSI

The Licensee's procurement management and supplier should establish and document methods for the disposition of items and services that do not meet procurement documentation requirements. These methods should contain the following provisions:

- evaluation of non-conforming items;
- submittal of non-conformance notice to the Licensee by the supplier (i.e. use as-is or repair);
- Licensee disposition of supplier recommendation;
- verification of the implementation of disposition; and
- maintenance of records of supplier-submitted non-conformances.

Non-conformances of Products or services, including Counterfeit, Fraudulent and Suspect Items (CFSI), identified by the Licensee or the supplier during the procurement process should be handled in accordance with Article 16.7 and Article 24 of this regulatory guide.

The identity of the Individual responsible for assigning each level of non-conformance should be made clear to the supplier. Non-conformances identified by the Licensee's organisation should be reported to the supplier immediately for processing through the supplier's non-conformance control process.

16.6 Licensee responsibility for all Products and services

The Management System directives should make clear that the Licensee's organisation retains responsibility for Safety when contracting out any processes and when receiving any item, Product or service in the Supply Chain. In this regard, the Licensee should make arrangements for ensuring that suppliers of items, Products and services important to Safety adhere to Safety requirements. They should meet the Licensee's expectations of safe conduct in their delivery and that these provisions should be cascaded to the sub-contractors in the Supply Chain.

An important aspect of safe operation is ensuring that Safety-related components continue to meet their original design requirements so that they operate as intended throughout the lifetime of the Nuclear Facility. Procurement contracts for Products and services that may influence Safety therefore should specify that defects in components or computer codes discovered by the supplier after delivery are reported to the Licensee.

The Licensee, when purchasing items or services that can affect Safety, still retains responsibility for that Safety and needs to have processes in place to maintain Nuclear Safety and Nuclear Security throughout the lifetime of the Nuclear Facility. This prime responsibility cannot be transferred or delegated to suppliers.

16.7 Licensee oversight of suppliers to detect and prevent CFSI

Contracts with suppliers known to have supplied CFSI or the procurement of items that are known to have been counterfeited in the past should be conducted with increased rigour and attention to quality requirements. The supplier needs to be made aware of their accountability for providing the correct items and the consequences of supplying CFSI.

The Licensee's procurement staff training should include consideration that CFSI potentially include a wide range of items, such as threaded fasteners, piping components and electrical components, and include familiarity with the Licensee's inspection procedure for CFSI. The oversight of suppliers should include assessment of their measures to detect and prevent the introduction of CFSI.

CFSI are more likely to appear when:

- the items are manufactured and procured outside of the quality assurance programme (commercial grade items);
- the items are expensive to manufacture;
- the items are expensive to test;
- the procurement requirements are poorly defined;
- the method for verifying that the procurement requirements are met is inadequate;
- the urgent replacement of a failed item is required.

Processes should be set up in advance for addressing suspected CFSI incidents. This is to ensure that staff members are aware of the importance of reporting such incidents and

quarantining Suspect Items, including their packaging and supporting documentation, to allow for a full and effective investigation with the original equipment manufacturer, the supplier, and potentially with law enforcement authorities. Such processes should be integrated with a site's normal corrective action programme and include reporting mechanisms to the wider nuclear and non-nuclear industry.

When a potential CFSI is identified that is important to Safety, consideration should be given to reporting the issue to the Authority at an early stage. It may also be beneficial to involve the Authority in plans to assess the extent of the problem and the evaluation and disposition activities as per the Authority's licence conditions.

Communication

Article (17)

17.1 Internal communication

(a) Communication related to Safety and Nuclear Security

The information communicated to Individuals in the organisation by Senior Management with regard to the requirements related to Safety and Nuclear Security should include:

- the Licensee's objective of meeting the Fundamental Safety Objective defined in Article 1 of FANR-REG-01 (Version 1);
- the importance of management at all levels instilling an attitude among the Individuals in the Licensee's organisation that encourages the reporting of all conditions, issues and concerns including events and near misses, potential problems relating to equipment failures, shortcomings in human performance, procedural deficiencies, or inconsistencies in documentation that are relevant to Safety;
- the shared aim of Safety and Nuclear Security measures of protecting human life, health and the environment and that changes in Safety measures and Nuclear Security measures should be assessed in an integrated manner so that Nuclear Security measures do not compromise Safety and Safety measures do not compromise Nuclear Security;
- the results of self-assessments of Leadership for Safety and Nuclear Security with the objectives of sustaining a strong Safety and Security Culture, improving leadership for Safety, and promoting a continuous improvement philosophy and a learning attitude within the organisation;

In communication, the full description of any Nuclear Facility item should be given using the phonetic alphabet. In both the Nuclear Facility and in control rooms, training should be provided in the use of three-way communication.

Periodic performance evaluations of Individuals and Licensee organisation units provide an opportunity to communicate and reinforce the Licensee's emphasis on Safety as a paramount objective.

(b) Communication related to policies, goals, strategies, plans, objectives and processes on Safety, security and quality

The information communicated to Individuals in the organisation by Senior Management with regard to the Licensee's policies, goals, strategies, plans, objectives and processes on Safety, security and quality should include:

- vision, mission and goals of the Licensee organisation;
- policy statements of the Licensee organisation;
- organisational structure;
- levels of authority and responsibilities and accountabilities of Senior Management and organisational units;
- structure of the Management System and quality assurance documentation;
- an overview of the Licensee organisation's Management System operating programmes and processes;
- responsibilities of owners of the Management System operating programmes and processes; and
- arrangements for measuring and assessing the effectiveness of the Management System.

Communications should be designed to engage internal Interested Parties to improve their performance by making sure that they:

- know how their everyday actions relate to the Licensee organisation's objectives and policies;
- have the information they need to guide their actions; and
- know they will share in success on the basis of their individual and team contributions.

17.2 Communication strategy for Interested Parties and the public

Every organisation has Interested Parties, all of whom have needs and expectations. In order to ensure that formally agreed expectations of Interested Parties are determined and met and to enhance their satisfaction, Senior Management should identify all of the organisation's Interested Parties and should understand their interests and their requirements, needs and expectations.

The following groups should be considered when identifying Interested Parties: customers, owners, operators, employees, suppliers, the regulated industry, and governmental entities. These groups' responsibilities cover nuclear energy or environmental impacts, the media, the public, other states concerning possible trans-boundary impacts, states involved in the export or import of certain technologies or materials, and relevant international organisations.

A communication strategy could have the following purposes:

- to share relevant information;
- to involve all relevant organisations; and
- to raise issues and resolve them.

The communication strategy that should be implemented for interactions with Interested Parties and the public should seek approval from the board of directors. All Interested Parties should be made aware that ensuring Safety overrides all other demands, especially in the event of contrary expectations on the part of different Interested Parties.

17.3 Purposes of the communication strategy with Interested Parties and the public

The processes and plans resulting from the communication strategy should facilitate the following:

(a) Communication of radiation risks

The Management System should include provisions to ensure that Interested Parties, including the local population, are informed of radiation risks associated with the operation of a Nuclear Facility and related activities and that any necessary information relevant to Safety is disseminated.

The Licensee should provide information on the status of the radiation risks associated with the Operation of a Nuclear Facility to the public in a regular and timely manner. The public should be informed of any significant event on the International Nuclear and Radiological Event Scale (INES) and of any corrective actions taken at the Nuclear Facility.

The public should also be provided with clear, objective and understandable information during and after a nuclear or radiological Emergency.

(b) Timely communication in circumstances that have changed or were unanticipated

Timely communication should be recognised as important when new or changed management processes are being developed or circumstances have changed. This should involve Individuals at all relevant levels of the organisation and, where appropriate, external Interested Parties, to ensure that the process addresses their needs and they are given notification of any changes in the operating environment that impacts Safety.

The communication should:

- explain what is happening and why,
- address the effects on Interested Parties,
- describe what impact the activity or change will have on Safety and on the Licensee organisation's Management System processes, and
- include training for those who are involved in the communication of changes.

(c) Dissemination of necessary information

For additional guidance see FANR-REG-01 (Version 1), Article 17.3 (c).

(d) Considering Safety-related concerns of Interested Parties

Verbal or written Safety or Nuclear Security concerns expressed by Interested Parties, including members of the public, should be documented and their disposition recorded. If warranted, the item should be entered into the Licensee's corrective action programme and notification to the Authority considered. When the source of the concern is known, a response describing the disposition should be provided to the individual or organisation expressing the concern. Provisions should be made to provide anonymity should the source of the concern desire this following Licensee process.

Safety concerns may be potential or actual Safety issues including the areas of Design, Construction, Operation, maintenance, Radiation Protection, safeguards, security, emergency preparedness, harassment, intimidation, retaliation, discrimination, wrongdoing, or a work environment that discourages workers from raising Safety concerns.

(e) Communication of Safety, Nuclear Security, and quality policies and related goals, strategies, objectives and plans to all Interested Parties

The information communicated to Interested Parties with regard to the Licensee's policies, goals, strategies, plans, objectives and Management System processes on Safety, Nuclear Security and quality should include the items listed in Article 17.1 (b) above, namely:

- vision, mission and goals of the Licensee organisation;
- policy statements of the Licensee organisation;
- organisational structure;
- levels of authority and responsibilities and accountabilities of Senior Management and organisational units; and
- arrangements for measuring and assessing the effectiveness of the Management System.

In addition, the Licensee's objective of meeting the Fundamental Safety Objective defined in Article 1 of FANR-REG-01 (Version 1), should be emphasised as well as the policy established and implemented by the Licensee that gives Safety the highest priority, overriding the demands of production and project schedules.

Organisational Changes

Article (18)

18.1 Classification of organisational changes, disposition of evaluation, documentation and reporting to the Authority

Refer to guidance provided in Screenings and Evaluations for Modifications to Operating Nuclear Facilities (FANR-RG-029, Version 0), Article 9, Modifications to the Organisational Arrangements as described in the Application Documents.

18.2 Reporting changes to key Safety positions within the Licensee's organisation to the Authority

Any planned changes to the key Safety positions as described in the Licence application documents should be communicated to the Authority at least 30 calendar days in advance of appointment to the Authority for review and comments if needed. The notification should be directed to the Authority's Deputy Director General for Operations or his delegate as advised by the Authority from time to time.
The Authority may provide comments, if any, based on review of appointments for key Safety positions reporting to Senior Management within 7 (seven) working days of receiving the notification of such proposed changes.

The Licensee ensures that its employees have a clear understanding of the key Safety positions within its organisation, and Senior Management can assess whether they have the necessary expertise to support and oversee those positions effectively. They should be selected on the basis of the Licensee's defined criteria (i.e. job description and Nuclear Safety Roles and Responsibilities Manual) and their capability to be competent in the position. Competence criteria should be determined for the position based on the work to be performed, which includes education, experience, knowledge and performance requirements.

Safety Culture and Security Culture

Article (19)

19.1 Role of the Management System

The Management System should integrate and promote a strong Safety Culture and a strong Security Culture throughout all levels of the Licensee organisation.

Article 7 of this regulatory guide provides guidance for establishing and maintaining a Management System for Safety Culture within the Licensee's organisation.

A robust Security Culture should be developed, fostered and maintained in order to prevent, detect, and respond to malicious acts against Nuclear or Radioactive Material, or a Nuclear Facility or associated activities.

Nuclear Safety and Nuclear Security should be a fundamental and integral part of the Licensee organisation's overall Safety Culture.

19.2 Role of Individuals

Senior Management should establish clear, written policies aligned with and supportive of a strong Safety and Security Culture and should ensure effective communication of commitment and adherence to such policies within the Licensee's organisation.

Senior Management should be the leading advocate of Safety and should continuously demonstrate its commitment through both words and actions. Leaders throughout the Licensee organisation should set an example for Safety and should actively engage the workforce to create a Safety-conscious work environment with active involvement of all Individuals in identifying and resolving Safety and Nuclear Security issues.

A commitment to Safety and Nuclear Security should be evident at all levels of the organisation. Managers should treat supervisors as a crucial part of the management team to put Safety Culture and Security Culture into practice at the working levels of the organisation.

Individuals should maintain a commitment to a Safety-conscious work environment that promotes Safety both individually in their work practices and behaviours, and collectively within the organisation.

A common understanding by all Individuals of the characteristics and attributes of a strong Safety Culture is a prerequisite, so that everyone can seek and identify strengths and weaknesses and thus enhance the Safety and Security Culture. Ownership of Nuclear Safety and Nuclear Security should be evident at all levels of the organisation collectively and by all Individuals and teams within the organisation.

Individuals should maintain vigilance for assumptions, conditions, or behaviours that could adversely affect Safety. They should discourage complacency and raise any concerns as appropriate.

19.3 Role of management

Senior Management and all levels of management should have a clear understanding of the fundamental aspects and characteristics that support a strong Nuclear Safety and Nuclear Security Culture and should ensure that such understanding is communicated throughout the organisation.

The principle that Nuclear Safety and Nuclear Security are of the highest priority and considered essential for the success of the organisation should be conveyed and continually promoted by management throughout the Licensee's organisation. Safety and Nuclear Security should be paramount within the Management System overriding all other demands.

a) Training should be provided within the organisation to familiarise all Individuals with the effects of Ionising Radiation and the Safety and Nuclear Security hazards associated with their work environment at the Nuclear Facility. The basic principles of Safety and Security Culture should be taught to all Individuals, with refresher training and updates on general topics periodically conducted.

b) Senior Management should ensure that Safety, including Nuclear Safety, environmental Safety and Nuclear Security, is incorporated into all activities within the organisation.

c) Managers of appropriate functions and levels should spend time in the field to observe work practices and to communicate the principle of Nuclear Safety, coach and reinforce standards and expectations, and listen to concerns and feedback from the workforce.

19.4 Responsibility of management

Senior Management and managers at all levels of the organisation should actively promote and support a strong Safety Culture and Security Culture on a regular basis.

a) The Safety Culture and Security Culture should include the commitment to and accountability for Safety and Nuclear Security by Individuals at all levels of the organisation.

   Senior Management and other managers should empower Individuals, holding them accountable for adhering to the Licensee organisation's Safety Culture and Security Culture and encourage Individuals to continually seek improvement in the organisation's Safety and Nuclear Security performance.

b) Senior Management should provide the necessary resources for the Licensee organisation to carry out its tasks safely and successfully, including equipment, information, procedures, knowledge, infrastructure, working environment and taking into account interaction between the human, technical and organisational factors.

   Training and management briefings should ensure that Individuals understand the relevance and importance of their work activities and how they affect the Licensee organisation's Safety performance and achievement of the organisation's goals, plans and objectives.

c) Senior Management and managers at all levels of the Licensee organisation should actively and visibly foster the long-term commitment and engagement of all Individuals within the organisation and their adherence to the Safety Culture and Security Culture through the processes of employee participation, consultation, and recognition.

   Senior Management should support a strong Safety Culture by reinforcing a learning and questioning attitude at all levels of the Licensee organisation through the creation of an environment of trust, transparency, collaboration and open communication.

d) Senior Management and other managers should establish a respectful work environment where communication and a high level of trust is cultivated, and differing opinions are encouraged and thoughtfully considered by management.

e) The Management System should include a process to allow employees to freely raise concerns without fear of retaliation, intimidation, harassment, or discrimination.

   Senior Management should implement a clearly written policy and process that supports Individuals' rights and responsibilities to raise Safety or Nuclear Security concerns, including concerns related to retaliation or discrimination when such issues are raised.

f) Senior Management and other managers should promote continuous learning and constant examination of the Licensee organisation's performance through self-assessment, independent assessment, lessons learnt from experience, and benchmarking in order to further develop and improve its Safety Culture and Security Culture.

g) Safety and Nuclear Security should be managed together within the Management System, with the recognition that actions or requirements of one can have implications on the other. As such, potential conflicting actions or requirements should be carefully analysed to ensure that Safety is not compromised. Such cross-reference reviews should be addressed in the applicable Management System processes.

h) The Management System should include processes for effectively communicating the following within the Licensee's organisation:
   i. problems relating to internal human, technical and organisational factors;
   ii. deficiencies in structures, systems, and components to avoid degradation of Safety or Nuclear Security;
   iii. issues affecting Safety or Security that should be identified, acknowledged, and promptly evaluated and resolved according to their significance to Nuclear Safety and Nuclear Security.

   The process should include requirements for immediate corrective actions or compensatory measures, determine the extent of condition and cause, and corrective actions and actions to prevent recurrence.

   The Management System should include mechanisms for management, including Senior Management, to promptly acknowledge both the Individuals who report significant issues and the corrective actions taken within the organisation to address the reported issues.

Measurement, Assessment and Continuous Improvement

Article (20)

General Requirements

20.1 Effectiveness of the Management System

Senior Management should conduct a review of the Management System at planned intervals to confirm its suitability and effectiveness, and its ability to enable the objectives of the Licensee organisation to be accomplished with account taken of new requirements and changes in the organisation. While aspects of this review may be performed by Nuclear Facility staff or outside experts, the personal involvement of senior managers in the scheduled periodic reviews of the Management System is important.

Senior Management and management at all levels in the Licensee's organisation should regularly perform oversight reviews and assess the performance of activities through their day-to-day line management activities. This includes confirming the ability of the Licensee's

organisation to achieve the intended results and identifying opportunities for improvement of the Management System, including minimising the occurrence of problems relating to Safety. In addition to day-to-day interactions, more structured interactions should be used such as:

1) line management monitoring;

2) reviewing the achievement of goals, strategies, plans and objectives; and

3) oversight meetings.

Line management monitoring necessitates that managers be individually involved in assessing the performance of work, posing informed and probing questions and reviewing the results of work completed.

Goal achievement reviews can be implemented by a series of planned and systematic reviews (periodic accountability or performance reviews) to assess the progress of Individuals in their achievement of the goals, strategies, plans and objectives relevant to them. Managers at an appropriate level should review the effectiveness of the performance of each Individual or functional unit. Some organisations include within the individual reviews an element related to the demonstrated priority given to Safety by the Individual.

Oversight meetings enable managers to obtain information and to take any immediate corrective action. Oversight meetings can include:

a) operational meetings, often on a daily basis, to ensure appropriate daily resource allocation;

b) management team meetings to make decisions to confirm the ability of the Licensee's organisation to achieve the intended results on the basis of feedback from internal and external sources;

c) Nuclear Safety oversight meetings to ensure that management continually maintains an awareness of, and responds appropriately to, Nuclear Safety issues; and

d) corporate oversight to ensure that the Management System at the Nuclear Facility meets the management needs of the corporation, and to initiate changes to the Management System, as indicated by line management feedback and by the results of the self-assessment and independent assessment processes described in Articles 21 and 22 of this regulatory guide.

Nuclear Safety and corporate oversight should include a Safety committee independent review of performance and activities that relate to the safe Operation of the Nuclear Facility. Safety committees comprise senior managers and consultants with extensive experience of Nuclear Facilities or other industries.

Senior Management should ensure that both self-assessments and independent assessments of leadership for Safety, of Safety Culture, and of Security Culture are carried out at all organisational levels and for all functions in the Licensee's organisation. The culture assessments should make use of recognised experts in the respective areas and be focused

on the enhancement of the organisational culture in these areas. The assessments should include establishing that Safety and Nuclear Security measures are designed and implemented in such a manner that they do not compromise each other and that mechanisms are in place to resolve potential conflicts and to manage Safety–security interfaces.

20.2 Feedback and analysis of operating experience

The Licensee's organisation should establish an operating experience programme to learn from Nuclear Safety and Nuclear Security events at the Nuclear Facility. An effective operating experience programme should include the following main elements:

- Identification and reporting of internal operating experience
- Collection of available external operating experience
- Screening of operating experience, including immediate review of events related to Nuclear Safety
- Investigation and in-depth analysis of relevant operating experience
- Trending and review for timely recognition of developing issues
- Management of corrective actions resulting from investigation and analysis of operating experience, including approval, implementation, tracking and evaluation of their effectiveness
- Use, dissemination and exchange of operating experience, including through national and international reporting systems
- Review of the effectiveness of the operating experience programme
- Lessons from identifying good practices
- Maintenance of a storage, retrieval and documentation system for operating experience.

The Management System should include procedures for the provision of feedback on operating experience from activities undertaken at the operating Nuclear Facilities as part of the operating experience programme implemented to prevent recurrence of events and to enhance Safety.

The Licensee is responsible for instilling an attitude among the Individuals that encourages the reporting of all events, including low-level events and near misses, potential problems relating to equipment failures, shortcomings in human performance, and procedural deficiencies or inconsistencies in documentation that are relevant to Safety.

The causes of non-conformances of processes and the causes of Safety-related events that could give rise to radiation risks should be evaluated and any consequences managed and mitigated. The corrective actions necessary for eliminating the causes of non-conformances and for preventing the occurrence of, or mitigating the consequences of, similar Safety-related

events should be determined. The corrective actions should be taken in a timely manner commensurate with the Safety significance and potential for recurrence.

Criteria and performance indicators for assessing the effectiveness of the main elements of the operating experience programme should be developed and implemented. Performance indicators should include both process-based and result-based indicators.

Progress in taking the corrective actions should be monitored to ensure that actions are completed within appropriate timescales. The completed corrective actions should be reviewed to assess whether they have adequately addressed the issues identified in audits and reviews.

Management should monitor and review the effectiveness of the operating experience programme on a regular basis and at a frequency commensurate with the number and significance of the arising operating experience issues. This review should include the status of corrective actions that have not been completed and the effectiveness of those that have.

20.3 Assessments to support the continuous improvement of the Management System and Leadership for Safety

As noted above in 20.2 and as discussed in Articles 21 and 22 of this regulatory guide, Senior Management should ensure that both self-assessments and independent assessments of Leadership for Safety, of Safety Culture, and of Security Culture are carried out at all organisational levels and for all functions in the Licensee's organisation.

The Licensee's organisation can benefit from the use of a set of tools that are aimed at enabling continuous improvement. These tools consist of a corrective action programme, self-assessment and benchmarking programmes, an operating experience feedback programme, an observation and coaching programme, performance assessment and identification of trends, and performance indicators. Independent oversight organisations, safety committees, regulatory bodies and organisations such as the IAEA and the World Association of Nuclear Operators (WANO) also provide input to continuous improvement. Collectively, these provide the means by which the Licensee's organisation can assess performance and enable continuous improvement.

20.4 Performance-based measures and criteria to monitor the requirements for Safety, Nuclear Security, safeguards and Radiation Protection during the lifetime of the Nuclear Facility

The Senior Management of the Nuclear Facility should develop performance-based measures and criteria to monitor the requirements for Safety, Nuclear Security, safeguards and Radiation Protection during siting, Design, Construction, Commissioning, Operation and Decommissioning or Closure of the Nuclear Facility.

Design: the Management System should include provisions for ensuring the quality of the Design of each structure, system and component, as well as of the overall Design of the

Nuclear Facility during its lifetime. This includes the means for identifying and correcting Design deficiencies, for checking the adequacy of the Design and for controlling Design changes as per the applicable regulatory requirements, and the terms and conditions of the Licence.

Construction: items important to Safety for a Nuclear Facility should be designed so that they can be manufactured, constructed, assembled, installed and erected in accordance with established processes that ensure the achievement of the Design specifications and the required level of Safety meeting the applicable regulatory requirements and the terms and conditions of the Licence.

Operation: the assessments during the Operation phase of the Nuclear Facility are discussed in Article 20.1. In addition, senior managers should develop, on the basis of best international practice, a set of performance indicators (objective standards and criteria) against which performance could be evaluated. For a Nuclear Facility, objective standards and criteria that specify performance requirements in areas such as Operation, maintenance, chemistry, engineering, Radiation Protection, protection against fires and emergency planning should be developed.

Decommissioning: the Licensee should be aware, over the operating lifetime of the Nuclear Facility, of the needs in relation to future Decommissioning. Experience and knowledge with regard to contaminated or irradiated structures, systems and components gained in modification and maintenance activities at the Nuclear Facility should be recorded and retained to facilitate the planning of Decommissioning. Complete and reviewed information should be compiled to be transferred to the organisation responsible for managing the Decommissioning phase. For a Nuclear Facility with multiple units, appropriate measures should be put in place to ensure that common systems and common equipment remain fully available to support the safe Operation of all the generating units during a unit Decommissioning.

Safeguards: Safety measures, Nuclear Security measures, and arrangements for the State system of accounting for and control of nuclear material for a Nuclear Facility should be designed and implemented in an integrated manner so that they do not compromise one another.

20.5 Analysis, actions, and communications of findings regarding the Management System and Leadership for Safety

Corrective actions as a result of the assessments and findings of the effectiveness and suitability of the Management System should be evaluated using risk assessment techniques to ensure that any risks are identified and mitigated.

It is important that the results of the assessments for leadership in Safety, Safety Culture, and Security Culture described in Article 20, paragraph 2.1 of this regulatory guide, be communicated at all levels in the organisation, including the board of directors, and acted upon

to foster and to improve leadership in these areas and to promote a learning attitude in the Licensee's organisation.

Self-Assessment

Article (21)

21.1 Periodic self-assessments of the Management System

Senior Management should ensure that self-assessments of the Management System are regularly conducted to evaluate its effectiveness and to identify opportunities for improvement. These assessments should address the overall effectiveness of programmes, work processes and performance areas, unresolved significant Safety issues, specific events and new regulatory requirements. Such assessments should be carried out by management at all levels on a regular basis by experienced personnel who are familiar with the Management System operating programmes, processes and procedures being assessed.

Self-assessments should be initiated in response to situations that indicate a need for a closer review of performance, such as:

- adverse trends in performance data or problems tracked in the corrective action programme;
- indications of a decline in Safety Culture or Security Culture of the Licensee's organisation;
- indications of Management System operating programmes and process deficiencies or inefficiencies;
- input from ongoing management oversight, self-assessment activities, employee concerns programme, or information provided by independent or external assessment groups;
- inputs from ongoing security programme drills and exercises, issues from processes and protocols for classifying and handling of information both inside and outside the Licensee's organisation, maintenance of cyber security systems, implementation of contingency plans to address the defined threats and responses, interface with law enforcement bodies and coordination with off-site organisations;
- significant changes for which an early progress check is necessary;
- implementation of new operating programmes or revisions to existing operating programmes or processes; and
- new or recent issues or problems.

The self-assessment process should be used to evaluate Management System operating programmes, processes and performance areas against specific criteria by the examples of technique identified below. Self-assessment may be carried out periodically (e.g. every two years).

When selecting the individuals to participate in self-assessments, the following should be considered:

- technical expertise in the area being assessed;
- ability in applying the techniques of interviewing, observing and analysing;
- open-mindedness and the ability to accept different approaches.

In addition, concerns expressed by the Authority should be considered in selecting self-assessment topics. The Licensee may elect to conduct pre-Regulatory Authority inspection self-assessments to prepare the Individuals for regulatory inspector questions and to self-identify problems in the areas to be inspected.

Examples of self-assessment areas may include the following:

- inspections of the Nuclear Facility including observations of work conduct and housekeeping; documentation reviews; procedure update status checks; and routine communications with Individuals, including informal interviews and group break-out sessions to determine whether expectations are understood;
- review of the results of staff surveys and questionnaires;
- review of work backlogs and rates of maintenance rework;
- review of international operating experience reports;
- coaching and observation programmes in which weaknesses in performance are documented for further action;
- review, analysis and trending of important performance and Safety data;
- review of new corrective action programme entries (e.g. non-conformances, condition reports) and corrective action/root cause analysis reports;
- review of the operation of the Licensee's Management System processes against appropriate process performance measures relative to effectiveness and efficiency;
- review of the Licensee's Management System operating programmes relative to achieving operating programme objectives and compliance with regulatory requirements;
- benchmarking to identify opportunities for improvements in performance; and
- periodic reviews of performance by Senior Management, such as management review meetings in which managers provide a summary of key performance weaknesses or strengths in areas for which they are responsible.

The results of various assessments should be used to identify areas for improvement and to address them by appropriate measures. The assessments should also be used to determine whether previous improvement measures have been effective in addressing specific performance gaps.

Managers should verify that issues for resolution that are identified in the self-assessment process are promptly entered in the Licensee's corrective action programme to ensure that resolution of the issue is timely and is prioritised on the basis of their potential consequences for Safety.

Results of the self-assessments should be communicated to the groups and Individuals who are affected by the actions to be taken. The results of the self-assessments should be shared with:

- the manager being evaluated;
- the groups being evaluated, and
- other groups that can use the information to improve their performance.

Senior Management should retain the overall responsibility for carrying out self-assessments of the overall Management System. Direct participation by Senior Management and management at all levels is essential to the success of the process since senior managers are in a position to have an overview of the organisation as a whole. The results and decisions of self-assessments by Senior Management should be recorded and related actions resulting from the recommendations taken promptly. Senior Management should also evaluate the effectiveness of these actions.

21.2 Self-assessment of Leadership for Safety Culture and Security Culture

Senior Management should ensure that self-assessments of leadership for Safety Culture and Security Culture are carried out at all organisational levels and for all functions in the Licensee organisation. These self-assessments should make use of recognised experts in the assessment of leadership, Safety Culture and Security Culture. The strength of a culture in an organisational unit is not necessarily revealed by assessments of equipment, documentation and procedures. A specialist should be included in the self-assessment team to ensure that appropriate assessment tools are developed and applied, as well as for carrying out an analysis of the results (including a statistical analysis of the results of questionnaires) and their interpretation. In addition, the effect of interfaces with other components of the Licensee's organisation and the Authority on the assessed Safety Culture should be addressed.

Safety measures and Nuclear Security measures have in common the aim of protecting human life, health and the environment. Changes in Safety measures and security measures resulting from self-assessments should be assessed in an integrated manner so that Nuclear Security measures do not compromise Safety and Safety measures do not compromise Nuclear Security.

The results of self-assessments of leadership for Safety and Security Culture should be communicated at all levels in the organisation. The results of such assessments should be acted on to foster and sustain a strong Safety and Security Culture, to improve leadership for Safety, and to promote a continuous improvement philosophy and a learning attitude within the organisation. The self-assessment team should summarise the results and identify areas for improvement and may suggest actions to be taken. The results should be reported to the

management at an appropriate level, one that is responsible for the implementation of the improvement actions. A follow-up assessment should be performed, taking into account the time needed for improvement actions to have their full effect on the Safety Culture.

Senior Management should also regularly commission assessments of leadership for Safety and of Safety Culture in its own organisation. More information on assessment of Safety Culture and Security Culture is provided in Article 19 of this regulatory guide.

21.3 Analysis of significant changes and/or findings for their implications on Safety

Self-assessments of Management Systems should not only determine whether previous improvement measures resulting from self-assessment findings have been effective in addressing specific performance gaps but also whether any adverse implications for Safety have been inadvertently introduced by the improvement measures.

As noted in Article 21.2 above, Safety measures and Nuclear Security measures have in common the aim of protecting human life, health and the environment. Changes in Safety measures and/or Nuclear Security measures resulting from self-assessment findings should be assessed in an integrated manner so that Nuclear Security measures do not compromise Safety and Safety measures do not compromise Nuclear Security.

Independent Assessments

Article (22)

22.1 Internal organisational unit for independent assessments

The independent assessment unit to be established under the Licensee's organisation to conduct periodical independent assessments on behalf of the Senior Management may be composed of Licensee staff assigned to the assessment unit or brought together for a specific assessment that includes members of the assessment unit and other Individuals in the organisation. The independent assessment unit may also assign an external organisation the task of conducting a specific assessment.

A schedule of internal audits should be established by the assessment unit and endorsed by the Senior Management of the organisation.

22.2 Purposes of independent assessments

The periodical independent assessments should carry out the following:

(a) Independently evaluate the effectiveness of the Management System

The overall goal of independent assessments of the Management System is to evaluate the effectiveness of Management System processes in meeting and fulfilling goals, strategies, plans and objectives of the organisation in the areas of Safety, Nuclear Security, safeguards, Radiation Protection, Safety Culture and Security Culture.

Independent assessments of the Management System should consider:

- outputs from Licensee operating programmes and processes assessments;
- results delivered and objectives achieved by the organisation and its processes, considering results in the context of the performance measures that have been established;
- problem identification and corrective and preventive actions; and
- lessons learnt from other organisations.

Significant changes in the Licensee's organisation or processes should be considered when determining the need for an independent assessment. When major organisational changes are planned, they should be rigorously and independently scrutinised. The drive to improve efficiency and reduce costs can result in organisational changes that can have significant Safety implications. Examples of such changes are:

- mergers of organisations, leading to a drive for harmonised standards and procedures;
- changes in the arrangements for providing central support services;
- reassignment of work activities, thereby increasing the likelihood that expertise in critical areas will be lost;
- changes in the policies for recruitment, selection, induction and training of individuals; and
- reductions in the number of management levels and in the grades of Individuals carrying out activities in the organisation.

(b) Independently evaluate the effectiveness of processes

The schedule of independent assessments should include assessments of all major processes of the Management System over a defined period. For each assessment, a plan should be established to select areas from the Management System on its operating programmes, processes or activities and requirements to be assessed in fulfilling goals, strategies, plans and objectives of the Licensee's organisation.

The independent assessments for the attributes of the processes described in Articles 12 and 13 of this regulatory guide should be focused on areas where problems have been found in work processes and the scope adjusted to reflect management concerns.

A combination of various types of independent assessments may be used to provide a balanced evaluation of performance, and may include technical inspections (for example Design modification calculations), work surveillance, and procedure adequacy. Information on the qualification and training of Individuals performing the processes should be examined. The independent assessor may need to ask

Individuals specific questions to determine, for example, their experience or knowledge of procedures.

The independent assessment should be primarily focused on the evaluation of the effectiveness of the processes in meeting the goals, strategies, plans and objectives of the Licensee's organisation. In cases where the assessment detects ineffectiveness in processes or implementing procedures, the focus should be on corrective actions and opportunities for improvements.

Problems and good practices identified in the independent assessments should be reported in a way that will help Senior Management understand what actions are needed.

(c) Independently evaluate the effectiveness of work performance and Leadership for Safety Culture and Security Culture

The purpose of the independent assessment of the attributes described in Article 5 of this regulatory guide is for enhancement of the Licensee's organisation as it fosters a strong Safety Culture and Security Culture in the organisation. The results of independent assessments of Leadership for Safety and of Safety Culture therefore should be communicated at all levels in the organisation.

Independent assessments should be focused on the following important attributes of a strong Safety Culture:

- Safety is clearly recognised as a paramount value
- Leadership for Safety is clear
- Accountability for Safety is clear
- Safety is integrated into all activities
- Safety is learning driven.

The planning and conduct of independent assessments of Safety Culture and Security Culture should include the participation of specialists in behavioural science with knowledge of statistical methods of analysis.

(d) Independently monitor the quality, compliance and conformity of Products and services

The independent assessments for the attributes of the control of Products and services described in Article 15 of this regulatory guide should be focused on areas where problems have been found in delivered Products and services and the scope adjusted to reflect management concerns.

Problems and good practices identified in the independent assessments should be reported in a way that will help Senior Management understand what actions are needed.

(e) Independently identify opportunities for improvement

Independent assessments in all areas should identify both good practices and opportunities for improvements.

Contributors to learning and performance improvement are corrective action programmes, benchmarking, and information exchange and training. Independent assessments focused on the implementation of these programmes can reinforce areas where good practices are leading to organisational learning and improvement.

(f) Independently determine the adequacy and implementation of processes and programmes for the detection, prevention and elimination of Counterfeit, Fraudulent and Suspect Items (CFSI).

For identification and disposition of CFSI, the Licensee should establish a process and procedure in the quality assurance programme. CFSI are potential non-conforming items and therefore their treatment can be integrated into normal non-conformance process. Some non-conforming conditions may be recorded in the receipt documents and be endorsed by the supplier, or may be recorded in receipt inspection documents. All non-conforming items, including CFSI, should be addressed by the quality assurance procedures for non-conformance control and corrective actions.

The Licensee should take into consideration that CFSI include a wide range of items, such as threaded fasteners, piping components and electrical components. The Licensee's inspection procedure for CFSI should provide guidance to determine the detection, prevention and elimination of CFSI including for the oversight of contractors and suppliers. CFSI are more likely to appear when:

- the items are manufactured and procured outside of the quality assurance programme (commercial grade items);
- the items are expensive to manufacture;
- the items are expensive to test;
- the procurement requirements are poorly defined;
- the method for verifying that the procurement requirements are met is inadequate;
- the urgent replacement of a failed item is required.

The tracking of CFSI should use methods and processes similar to those used for the tracking of non-conformances.

When a CFSI is identified and the item is important to Safety, consideration should be given to reporting the issue to the Authority at an early stage. It may also be beneficial to involve the Authority in plans to assess the extent of the problem and the evaluation and disposition activities as per the Authority's licence conditions.

Senior Management should be responsible for providing the resources necessary to ensure personnel have the knowledge and capability to prevent CFSI from entering the Nuclear Facility, and to identify and disposition CFSI that already exist in the Nuclear Facility.

Specific CFSI training should be considered for:

- the detection of installed CFSI;
- identifying CFSI during receipt and inspection;
- using CFSI information within the procurement process.

The most effective processes should be followed in detecting CFSI within the Nuclear Facility:

- involvement of appropriate departments that serve in a leadership role responsible for tracking and evaluation of CFSI;
- appropriate staff involvement in procurement and Product acceptance;
- effective source inspection, receipt inspection, and testing programmes; and
- thorough engineering-based programmes for review, testing, and dedication of commercial grade Products for suitability in Safety systems.

The procurement of CFSI should be avoided. Contracts with suppliers known to have supplied CFSI or the procurement of items that are known to have been counterfeited in the past should be conducted with increased rigour and attention to quality requirements. The supplier needs to be made aware of their accountability for providing the correct items and the consequences for supplying CFSI. The normal non-conformance disposition process should be applied for the evaluation and removal of the CFSI.

Independent assessment should evaluate the adequacy and implementation effectiveness of the organisation processes for the prevention and elimination of CFSI. The potential assessment scope should include suppliers as well as the Nuclear Facility programme related to CFSI.

22.3 Individuals assigned to independent assessments

Individuals assigned to perform Independent Assessments should have qualifications and competence in the areas assessed, and should be trained in observation and interview techniques and in objective reporting.

The independent assessment unit should screen prospective independent assessors to verify that they would not be assessing their own work or areas under responsibility of their own line management and should have direct access to Senior Management.

22.4 Use of performance-based measures in independent assessments

The Management System should ensure that standards of performance are established. These standards should be directly related to the Product provided by the organisation and based on the objectives set by Senior Management. Once the standards have been established, performance should be measured against them. Performance indicators should be used and other appropriate methods of measurement should be developed.

Management System Review

Article (23)

23.1 Management System Review by Senior Management

The Management System should be continuously monitored and periodically assessed to confirm its effectiveness in achieving the organisational objectives and to identify opportunities for improvement.

An organisation-wide Management System Review sponsored by Senior Management should be conducted periodically to affirm the continued effectiveness and efficiency in achieving the organisation's goals, strategies and objectives.

The Management System Review should take into account any new requirements, changes in organisational goals, strategies, plans or objectives, and reorganisation of the management structure.

The Management System Review should also provide a forum for the exchange of ideas, Licensee organisational performance feedback, and open discussion among all the participants within the organisation. The results of the Management System Review should be documented and required improvements communicated to organisational units.

23.2 Scope of Management System Review

The extent of Management System Review should be established by the Licensee's Senior Management, dependent upon the particular needs at the time, e.g. recent changes, new requirements, and reorganisation.

In general, the Management System Review should consider the following:

(a) results of recently completed self-assessments and independent assessments, including assessment findings and recommendations, as well as Regulatory Inspection findings and observations, results of benchmarking activities, and the feedback on the satisfaction of Interested Parties;

(b) process metrics indicating the level of success of the Management System in achieving organisational goals, strategies, plans and objectives, e.g. performance indicators, applicable deficiency reports, cost and delivery schedule data;

(c) process flows, including inputs, outputs, and interfaces;

(d) corrective action programme data, including condition reports and non-conformance reports, and the associated root cause determinations, corrective actions and actions to prevent recurrence;

(e) input from operational experience programme reviews, including lessons learnt from other organisations, and the follow-up remedial actions taken by the organisation to address any Design or operational issues, near misses, or other applicable deficiencies,

as well as whether corrective actions or improvement initiatives have resulted in inadvertent adverse Safety consequences;

(f) the status of improvement opportunities that may have been identified earlier;

(g) advances in technology including research and development initiatives that may be considered for implementation or further study; and

(h) changes to relevant statutory and regulatory requirements.

23.3 Identification of weaknesses in the Management System

The results of the Management System Review should provide inputs to the organisation's corrective action programme for improvement. Any weaknesses or impediments in the Management System should be prioritised and promptly addressed by Senior Management in a timely manner. Senior Management should use this review as a powerful tool in the identification of opportunities for improvement in the performance of the Licensee's organisation.

23.4 Identification of changes in the Management System

The results of the Management System Review should be evaluated by Senior Management to determine the need for revisions to the Licensee organisation's policies, goals, strategies, plans and objectives, processes, or organisational structure and staffing levels.

The results of the Management System Review may also provide:

- information for strategic planning for the future needs of the organisation;
- objectives of improvements in performance and Safety for the organisation;
- appraisals of the suitability of the organisation's structure and resources; and
- loss prevention and mitigation plans for identified risks.

Non-conformance and Corrective and Preventive Actions

Article (24)

24.1 Mechanisms to identify, evaluate and correct non-conforming processes, Products or services

The Management System should include a corrective action programme (e.g. a condition reporting system) with a process to identify and evaluate conditions, issues and concerns for resolution and ensure that non-conforming Products, services, processes or other conditions adverse to quality are appropriately dispositioned prior to use or implementation.

The corrective action programme should also include provisions to verify the effectiveness of corrective actions and prevent recurrence of conditions adverse to Safety.

The prevention of conditions adverse to Safety should include an ongoing operating experience programme working in combination with the corrective action programme to identify potential weaknesses for corrective or preventive action, including the identification, control, and correction of design and operational deficiencies and non-conformances in Products, services or processes. Conditions and events to be handled by the non-conformance control process should include delivery or procurement of items or services that do not meet requirements.

Internal conditions and events to be handled by the corrective action programme process should include:

- deviations from approved process parameters or procedures;
- failures of Individuals to implement work instructions;
- inadequate documentation containing incorrect or incomplete information; and
- inadequate training of Individuals to perform the Safety-related tasks for which they have been given responsibility.

Concession granted to allow acceptance of a non-conforming Product or process should be subject to authorisation by the Senior Management of the related organisation. When non-conforming Products or processes are reworked or corrected, they should be subject to inspection to demonstrate their conformity with applicable requirements or expected results.

On being advised of a non-conformance or condition adverse to Safety, managers should promptly:

- ensure that the non-conformance or condition adverse to Safety has been entered into the corrective action programme;
- initiate any necessary immediate compensatory action to minimise the effect of the non-conformance or condition adverse to Safety;
- confirm that the Product, service or process has been identified (physically marked, labelled, segregated or otherwise controlled) as non-conforming;
- determine what restrictions on further use of the Product, service, or process should be put in place;
- arrange for a review of the non-conformance, and other related non-conformances (extent of condition).

Corrective actions for eliminating non-conformances should be determined and implemented. The status and effectiveness of all corrective and preventive actions should be monitored and reported to management at an appropriate level in the Licensee's organisation.

For operations, an operating experience programme should include methods to analyse both in-house events and events in the nuclear industry generally so as to identify the actions needed to prevent the occurrence of similar events. These events include initiating events, Accident precursors, near misses, Accidents and Nuclear Security events. In-house events of

interest to other Nuclear Facilities should be shared within national and international feedback systems.

The operating experience programme elements should include those discussed in the guidance for Article 20 of this regulatory guide.

The Licensee's organisation should maintain liaison, as appropriate, with support organisations (e.g. manufacturers, research organisations and designers) involved in the Design, Construction, Commissioning and Operation of the Nuclear Facility in order to feed back experience information and to obtain advice, if necessary, in the event of equipment failure or other events.

Issues reported in the corrective action process should be reviewed promptly for their possible effect on Safety, reliability and operability and to determine whether they meet the threshold criteria for reporting to the Authority as per operating licence requirements.

Individuals should be trained in the techniques of root cause analysis for reviewing significant issues, using a well-defined method to identify root causes, contributory causes and corrective actions needed to prevent recurrence. Contributory causes may include not only errors made by Individuals, but also leadership and organisational factors and behaviours.

Trending should be used to identify categories of issues such as those associated with procedures, human performance, operations, maintenance, training and equipment. Trend coding could be used to assist in trend analysis, provided that is applied consistently.

24.2 Identification and mitigation of causes and impacts potentially involving radiation risks

The Licensee's Senior Management should ensure that the causes of non-conformances and the causes of Safety-related events that could give rise to radiation risks are evaluated and any consequences managed and mitigated. The corrective actions necessary for eliminating the causes of non-conformances, and for preventing the occurrence of, or mitigating the consequences of, similar Safety-related events should be determined. The corrective or preventive actions should be taken in a timely manner commensurate with the Safety significance and potential for recurrence.

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.

The process for corrective actions should require corrective actions to be evaluated using risk assessment techniques to ensure that any risks are identified and mitigated.

Those events with significant implications for Safety should be investigated to identify their direct and root causes, including causes relating to equipment Design, operation and maintenance, or to human and organisational factors. The results of such analyses should be included, as appropriate, in relevant training programmes and used in reviewing procedures

and instructions. Nuclear Facility event reports and non-radiation-related Accident reports should identify tasks for which inadequate training may be contributing to an unplanned event, equipment damage, excessive unavailability of equipment, the need for unscheduled maintenance work, the need for rework, unsafe practices, or lack of adherence to approved procedures. Evaluation of issues of lower significance should be focused on correcting the immediate (or apparent) cause and may not need to address the root cause.

Consideration of preventive measures should include the following:

- changing the Licensee's Management System operating programmes or processes or implementing procedures or the organisational structure;
- retraining and requalifying Individuals in the Licensee's organisation;
- improving Safety Culture and Security Culture;
- changing or modifying documents (e.g. Design, operating procedures, maintenance);
- improving the Management System;
- enforcing procedural adherence; or
- issuing new documents.

As a result of the investigation of events, clear recommendations should be developed for the responsible managers so that they can take appropriate corrective actions in due time to avoid any recurrence of the events. Corrective actions should be prioritised, scheduled and effectively implemented and reviewed for their effectiveness. Operating personnel should be briefed on events of relevance so that they can take the necessary corrective actions to prevent their recurrence.

24.3 Documentation of non-conformances and preventive and corrective actions

The Licensee's Senior Management should ensure that processes are in place to control and document non-conforming Products, processes and services.

A formal template of non-conformance should:

- identify who is reporting the non-conformance, when it was found and to whom it was initially reported; (identification of the Individual reporting the non-conformance is not required whenever anonymity is to be maintained)
- identify the non-conforming Product, service or process and state its location and the method used to physically mark, label, segregate or otherwise control the Product or process to prevent its inadvertent use;
- include a description of the non-conformance; and
- describe the immediate action taken by the Individual reporting the non-conformance, or by others, to minimise the adverse effects of the non-conformance.

Non-conformances should be reported in sufficient detail to allow proper review. Unique identification should be given to each report to allow effective tracking of the non-conforming Product, service or process.

The Licensee's organisation should establish and maintain a system for the storage, retrieval (i.e. track, select, evaluate, trend and resolve) and searching of operating experience, as well as other non-conformances. The system should be able to be effectively searched using an appropriate coding or keyword system.

Relevant operating experience information should be retained for use throughout the Nuclear Facility's operating lifetime, including as input for periodic safety review, deterministic and probabilistic Safety Assessment, the design and implementation of modifications to the Nuclear Facility, and ageing management.

The status and effectiveness of all corrective actions and preventive actions taken should be monitored and should be reported to the management at an appropriate level in the organisation.

Information that could affect Nuclear Security should be identified, and its confidentiality should be protected as required by UAE law or relevant regulation (i.e. Information Protection Program (IPPOM).

24.4 Control and disposition of non-conformances

The Licensee's non-conformance procedure should provide guidance that during the analysis of non-conformances, the process for identification of non-conforming items, segregation, control, recording and reporting is provided. The impact of the non-conformance should then be evaluated and reviewed and the non-conforming Product should be accepted, reworked or corrected within a specified time period, or rejected and discarded or destroyed to prevent its inadvertent use.

Consideration should be given to physically segregating a non-conforming item or process to ensure that it is not used before any agreed and approved corrective action has been taken. Segregation may be achieved by removal to a secure area, placing behind barriers, isolating the non-conforming item, or stopping the service or process, or by administrative control.

An example classification of the disposition of non-conforming physical Products is:

Reject: the non-conforming Product, service or process is not fit for the intended use.

Repair: the non-conforming item, when repaired (or in the case of documents, revised) is capable of functioning in accordance with the design requirements, although it does not fully conform to the original design specification. Temporary repairs normally have a prescribed period of validity.

Rework: the item is capable of being fully restored to the original specification requirements (some additional rework carried out under suitable conditions will correct the non-conformance).

Accept with Conditions: it is likely that the non-conforming item, service or process will be fit for use under special, specified conditions.

Use as-is: in this instance, it is likely that the non-conforming item, service or process deviates marginally from the specified requirements but is still declared fit for use.

For Products or calculations of safety systems that are involved in the dispositions above, the design authority should be consulted.

Where corrective action is not appropriate or acceptable then a process needs to be defined to reject and scrap an item and preclude its future use. Any such process needs to clearly define the control, identification and segregation of the non-conforming Product.

24.5 Open atmosphere for reporting and identification of opportunities for improvement; relevant procedure development

The Licensee's Senior Management should be responsible for instilling an attitude among Individuals that encourages the reporting of all conditions, issues and concerns including events and near misses, potential problems relating to equipment failures, shortcomings in human performance, process or procedural deficiencies or inconsistencies in documentation that are relevant to Safety.

The implementation of corrective actions stemming from a non-conformance may represent improvement opportunities for work processes. Procedures should be developed defining the process for processing non-conformances and implemented for submitting improvement proposals based on the lessons learnt from both the non-conformance analysis and the corrective actions developed.

24.6 Objectivity and competence in non-conformance assessments

The Licensee's senior managers should ensure that Individuals responsible for classifying and analysing non-conformances have adequate understanding of the area in which they are working and access to pertinent background information concerning the non-conformance. Assessors of non-conformances should be technically qualified, experienced Individuals, who do not review their own work, and are adequately independent from cost and schedule considerations. The analysis should include the participation of the Individuals involved, such as craftsmen, operators and those identifying the deficiency, in order to gain a complete understanding of the problem.

The managers responsible for the determination of the cause of non-conformances should assign sufficient resources to the task.

Information regarding the non-conformance or experience should be examined for any precursors to, or trends in, adverse conditions for Safety, so that any necessary corrective actions can be taken before serious conditions arise.

24.7 Validation of decisions to accept non-conforming Products or services

When Products from an outside organisation are found to be in non-conformance with the purchase specifications, the determination of the acceptance of corrected Products, services, or processes should be verified as acceptable by the Licensee's organisation in addition to any certification of correction by the outside organisation. In cases involving items in safety systems, the design authority of the Licensee's organisation should be consulted.

Information about the non-conformance, and its implications to Safety, should be used to determine the impact on affected activities until the agreed and approved corrective action is verified as having been satisfactorily completed. The following are typical measures that should be considered:

- requirements to carry out additional inspection or testing, in order to obtain higher levels of confidence in items
- restrictions on further processing of items or services during manufacture or construction
- restriction on the use of other components from the same supplier
- restriction on documents use
- restrictions on operation regimes through changes in operating limits and conditions on approval from the Authority based on operating licence or amendments to maintenance schedules
- stoppage of the work if it is determined that its continuation would lead to an unsafe condition
- retraining of operating staff.

24.8 Status and effectiveness of corrective and preventive actions

The Licensee's Senior Management should ensure that criteria and performance measures for assessing the effectiveness of the main elements of the non-conformance and corrective actions programme are developed and implemented. Performance measures should include both process-based and result-based indicators.

Progress in taking corrective and preventive actions should be monitored to ensure that actions are completed within appropriate timescales. The completed corrective actions should be reviewed to assess whether they have adequately addressed the issues identified in applicable non-conformances, audits and reviews.

Management should monitor and review the effectiveness of the non-conformance and corrective actions programme on a regular basis at a frequency commensurate with the number and significance of the arising operating experience issues. This review should include the status of corrective actions that have not been completed and the effectiveness of those that have been completed.

The Licensee should establish a trending and review process to allow recognition of developing or emerging problems so that proactive measures can be taken before serious conditions arise. Trending and review should be performed at the Nuclear Facility level and at the operating organisation level.

24.9 Opportunities for Individuals to identify non-conformances and be informed of resolutions

As noted in Article 24.5 of this regulatory guide, the Licensee is responsible for instilling an attitude among the Individuals that encourages the reporting of all conditions, issues, and concerns including events and near misses, potential problems relating to equipment failures, shortcomings in human performance, procedural deficiencies, or inconsistencies in documentation that are relevant to Safety.

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 Licensee's non-conformance and corrective action processes, as appropriate.

References

Article (25)

3.1 Achievement of the Fundamental Safety Objective

- IAEA SF-1, Fundamental Safety Principles, section 2

3.2 Senior Management responsibility

- IAEA SF-1, Fundamental Safety Principles, section 2, 3.15
- IAEA NS-R-3, Site Evaluation for Nuclear Installations, sections 2.1, 3
- IAEA SSR 2/1, Safety of Nuclear Power Plants: Design, sections 2.8. 2.9
- IAEA SSR 5, Disposal of Radioactive Waste, sections 2.1-2.14, 3.12-3.20
- IAEA NG-T-1.6, Management of Nuclear Power Plant Projects, section 3.1.1,
- IAEA GSR Part 2, Leadership and Management for Safety, Requirements 1, 2
- IAEA GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, sections 3.110, 3.127, 3.131
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.29-5.31
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 5.12

5.1 Senior Management's demonstration of Leadership

- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, sections 2.5, 3.2a, 3.14, 5.1-5.4, 5.5-5.9,
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 3.2
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 2.4, 2.6-2.9, 2.31-2.36

5.2 Leadership of all managers of appropriate functions in the organisation

- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, sections 3.7, 3.16-3.19, 5.3-5.4
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 2.14, 6.3
- IAEA GSR Part 2, Leadership and Management for Safety, Requirement 3.2

5.3 Safety responsibilities for managers of appropriate functions

- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, sections 3.16-3.19, 5.1, 5.8, 6.1-6.3
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 2.15
- IAEA GSR Part 2, Leadership and Management for Safety, Requirement 3.3

6.1 Senior Management's commitment to the Management System

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 2.1-2.2, 2.22-2.24, 3.2-3.3

6.2 Senior Management's accountability for the Management System

- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 3.27-3.29

6.3 Safety policy

- SSR-2/2, Safety of Nuclear Power Plants: Commissioning and Operation, Requirement 5, sections 4.1, 4.2
- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, sections 5.22-5.23
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 3.1, 3.19, 3.25, 6.3
- IAEA GSR Part 2, Leadership and Management for Safety, Requirement 3.3

6.4 Interested Parties

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 3.8
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 3.5-3.6

6.5 Management System – assignment of responsible Individual

- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 3.29

6.6 Delegation of Management System activities

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.18-5.19

7.1 Establishment and implementation of an integrated Management System

- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 6.1, 6.4, 6.24, 6.40
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 2.1, 2.5, 2.7, 2.8, 2.10
- IAEA Safety Fundamentals SF-1, Fundamental Safety Principles, Principle 3: Leadership and Management for Safety
- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, sections 2.3 – 2.5, 5.5 – 5.6

7.2 Assurance and demonstration of the effective implementation of a Management System

- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 2.15, 3.1
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 2.5, 2.7, 2.10, 2.36

7.3 The main objective of the Management System is to enhance safety and support a strong Safety Culture

- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 2.8, 2.17, 3.1
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 2.24, 2.5, 2.7, 2.10, 2.17, 2.36,3.9
- IAEA SSR-2/2, Safety of Nuclear Power Plants: Commissioning and Operation, section 3.2

7.4 Identification and integration of legislative and regulatory requirements

- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 2.1
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 2.22, 3.9
- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, sections 4.1, 4.2

7.6 Specification of requirements for the review committee

- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, sections 7.53, and A-12
- IAEA SSR-2/1, Safety of Nuclear Power Plants: Design, sections 2.15 – 2.18 (Maintaining the Integrity of Design of the Plant)

7.7 Establishment of a clear, systematic, timely and transparent decision-making process

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 2.36, 4.3, 4.4, 5.64
- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, sections 3.2 – 3.4

7.8 Conflict resolution arising from the decision-making process

- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, section 7.58

7.9 Identification and analysis of impacts and potential impacts of any changes on safety, including organisational changes and cumulative effects of minor changes

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.56- 5.71
- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, sections 2.16, 5.11, 5.14, 5.27, 7.97
- IAEA NG-T-1.1, Managing Organizational Change in Nuclear Organizations, sections 2.2, 3.

8.1 Development and implementation of a Management System using a graded approach

- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 2.38 – 2.40

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 2.37 – 2.43
- IAEA TECDOC – 1740, Use of a Graded Approach in the Application of the Management System Requirements for Facilities and Activities, section 2. 3
- IAEA Safety Fundamentals SF-1, Fundamental Safety Principles, Principle 3: Leadership and Management for Safety

8.2. Application of the graded approach to Management Systems to each process within the organisation

- IAEA TECDOC – 1740, Use of a Graded Approach in the Application of the Management System Requirements for Facilities and Activities, section 2.3

9.2 Management System documentation description Article items a to g

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections - 2.45 to 2.61

10.1 Determination of competences and resources required to carry out the activities of the organisation

- IAEA Safety Guide, NS-G-2.4, The Operating Organization for Nuclear Power Plants, sections 6.11 to 6.15

10.2 (a) Specification of competence requirements

- IAEA Safety Guide, NS-G-2.8, Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, sections 3.1 to 3.11

10.2 (b) Required training to achieve the proficiency level of Individuals' competence

- IAEA Safety Guide, NS-G-2.8, Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, sections 4.13, 4.14

11.1 Management of knowledge as a resource

- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, sections 7.102, 7.103
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 4.4, 5.26, 5.40, 5.43 – 5.46
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 4.8, 4.10, 4.13 – 4.14

11.2 Maintenance of knowledge

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 4.4
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 4.14

12.1 General requirements for process implementation

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 5.2

- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 5.1

12.2 Sequence and interactions of Management System processes

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.4, 5.5
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 5.5, 5.6
- IAEA TEDOC-1252, Information Integration in Control Rooms and Technical Offices in Nuclear Power Plants, sections 1, 2, 3.1

12.3 Methods to ensure effectiveness of the Management System processes

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.8, 6.3
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 6.2, 6.3

12.4 Development of each Management System process

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.4, 5.5, 5.8, 5.9
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 2.1, 5.1, 5.57, 5.65 – 5.67

12.5 Activities and interfaces within a single process

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.14 – 5.17
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 5.7

13.1 Effective management of processes

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 5.12
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 6.1 – 6.34

13.2 Leadership of Management System processes

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.7, 5.17, 6.1
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 5.31, 6.1

13.3 Inspection, testing, verification and validation activities

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.29, 5.30
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 5.12, 5.14 – 5.18

13.4 Periodic evaluation of processes

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 6.1 – 6.3

- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 6.8 – 6.32

13.5 Use of approved procedures, instructions and drawings

- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 5.7

13.6 Processes implemented by a third party

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.18, 5.22
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 5.7

13.7 Process sequencing and interfaces

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 5.22
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 5.10

13.8 New processes or modifications to existing processes

- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 5.1, 5.40

14.1 Control and use of Management System documents

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, sections 4.16, 4.17
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 2.60, 5.24, 5.35, 5.26, 5.27
- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, September 2022, sections 7.98, 7.102, 7.103

14.2 Approval and recording of document changes

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, section 4.18
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 5.39, Appendix II.22

14.3 Data security policies, processes, procedures and instructions

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section Annex I-19
- IAEA Nuclear Security Series No. 17-T (Rev. 1), Computer Security Techniques for Nuclear Facilities, Technical Guidance, 2021, section 3.4

14.4 Usability of records

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, section 4.19
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.39, 5.45, 5.46, Appendix II.26

14.5 Maintenance of records as evidence of performance

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 2.58, 5.35, 5.36

14.6 Document retention periods

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, section 4.20
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.42, 5.43, 5.44, 5.49, Annex III-1
- IAEA SSG-50, Operating Experience Feedback for Nuclear Installations, section 2.80
- IAEA TECDOC-1510, Knowledge Management for Nuclear Industry Operating Organizations, section 3.2
- IAEA TECDOC-1910, Quality Assurance and Quality Control in Nuclear Facilities and Activities, Good Practices and Lessons Learned, section 3.3

14.7 Durability of records

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, section 4.20
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.40, 5.41, 5.47, 5.48
- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, section 7.105

15.1 Assessment of Products and services that may affect Safety

- IAEA NP-T-3.21, Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities, section 2.1
- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, sections 7.39, 7.41
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.29 – 5.33, 5.35
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 5.12

15.2 Inspection, testing, verification and validation of Products and services

- IAEA NP-T-3.21, Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities, sections 3.5.1.2, 3.5.2.2
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.29, 5.34
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 5.16, 5.20, 5.21, 5.24, 5.26, 5.28, 5.29

15.3 Meeting specified requirements

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.29, 5.35
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 5.16, 5.22, 5.23

15.4 Compliance with design, quality and service requirements

- IAEA NP-T-3.21, Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities, section 3.10
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 5.12

15.5 Ensuring that Products and services do not bypass verification activities

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 5.31
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 5.17

15.6 Identification and traceability of Products

- IAEA NP-T-3.21, Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities, section 3.11.5
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 5.12

15.7 Damage, deterioration, loss prevention and prevention of inadvertent use

- IAEA NP-T-3.21, Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities, section 3.1
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 5.12

16.1 Process and oversight for procurement of Products and services that may influence Safety

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, sections 4.33, 4.35
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.51, III.3, III.4, Appendix III
- IAEA SSG-75, Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, sections 3.35 -3.37
- IAEA TECDOC-1910, Quality Assurance and Quality Control in Nuclear Facilities and Activities, Good Practices and Lessons Learned, 2020, section 3.6
- IAEA NP-T-3.21, Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities, section 3.17.1

16.2 Selection and performance evaluation of suppliers

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 5.51, III.5 - III.15, III.19, III.20

16.3 Development and documentation of Products and services requirements

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 5.19

16.4 Licensee competence for procurement and assessment of suppliers and Products

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, sections 4.34, 5.50

16.5 Specifications in procurement documents for non-conformance reporting including CFSI

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section III.16

16.6 Licensee responsibility for all Products and services

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, sections 4.33, 4.36

- IAEA NP-T-3.21, Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities, sections 1.1.2, 2.1

16.7 Licensee oversight of suppliers to detect and prevent CFSI

- IAEA Nuclear Energy Series No. NR-G-3.1, Sustaining Operational Excellence at Nuclear Power Plants, Principles and Challenges, p.17
- IAEA NP-T-3.21, Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities, section 7.4.17
- IAEA-TECDOC-1169, Managing Suspect and Counterfeit Items in the Nuclear Industry, 2000, sections 1.1,2.1,2.2,2.3, 3.1, 3.3 and 4

17.1 Internal communication

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, section 6.11
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 2.54, 5.55
- IAEA SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation, section 5.31
- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, p viii

17.2 Communication strategy for Interested Parties and the public

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 3.8, 5.53
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 3.5

17.3 Purposes of the communication strategy with Interested Parties and the public

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections, 5.52, 5.55
- IAEA SSG-50, Operating Experience Feedback for Nuclear Installations, section 2.74
- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, sections 4.10, 4.11, 4.12, 4.13
- USNRC NUREG-BR 0204, Rev. 8, Reporting Safety Concerns to the NRC, Introduction

19.1 Role of the Management System

- IAEA Nuclear Security Series 28-T, Self-assessment of Nuclear Security Culture in Facilities and Activities, section 2
- IAEA Nuclear Security Series 7, Nuclear Security Culture, sections 1, 2

19.2 Role of Individuals

- GS-G-3.1, Application of the Management System for Facilities and Activities, sections 3.10-3.12
- IAEA GS-G-3.5, The Management System for Nuclear Installations, Appendix I, section 1

19.3 Role of management

- GS-G-3.1, Application of the Management System for Facilities and Activities, sections 2.34-2.36
- IAEA SSG-75, Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, sections 5.1-5.2
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 2.8-2.12, 2.14

19.4 Responsibility of management

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 3.7, 3.17-3.18, 6.69-6.77
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 2.6, 2.10, 2.22-2.26
- IAEA SF-1, Fundamental Safety Principles, section 3

20.1 Effectiveness of the Management System

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, sections 6.6, 6.9, 6.10
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 5.51
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 6.3
- IAEA SSG-72, The Operating Organization for NPPs, section 7.58

20.2 Feedback and analysis of operating experience

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, sections 6.3, 6.7
- IAEA SSG-72, The Operating Organization for NPPs, sections 7.93, 7.94, 7.95, Annex A, A-12
- IAEA SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design, section 3.2
- IAEA SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation, sections 4.37, 5.27-5.33
- IAEA SSG-50, Operating Experience Feedback for Nuclear Installations, sections 2.4, 2.53, 2.64, 2.70, 2.71, 2.74, 2.77

20.3 Assessments to support the continuous improvement of the Management System and Leadership for Safety

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, sections 6.9, 6.10
- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, sections 7.58, Annex A, A-1

20.4 Performance-based measures and criteria to monitor the requirements for Safety, Nuclear Security, safeguards and Radiation Protection during the lifetime of the Nuclear Facility

- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 6.28
- IAEA SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design, sections 2.15, 2.16, 3.2, Requirement 8, Requirement 11, 4.19
- IAEA SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation, sections 6.1, 6.10, 9.4, 9.5
- WANO Performance Indicators 2021, April 2022

20.5 Analysis, actions, and communications of findings regarding the Management System and Leadership for Safety

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, section 6.11

21.1 Periodic self-assessments of the Management System

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, section 6.4
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 3.16, 6.6, 6.8, 6.10, 6.19, 6.20, 6.21
- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 6.6, 6.8
- IAEA SSG-50, Operating Experience Feedback for Nuclear Installations, section 2.76, 2.78

21.2 Self-assessment of Leadership for Safety Culture and Security Culture

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, sections 6.9, 6.11, Requirement 14
- IAEA TECDOC 1141, Operational Safety Performance Indicators for Nuclear Power Plants, p. 26
- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, p.viii
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 6.36

21.3 Analysis of significant changes and/or findings for their implications on Safety

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, section 6.4
- IAEA SSG-72, The Operating Organization for NPPs, p.viii

22.1 Internal organisational unit for independent assessments

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, section 6.5
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 6.36

22.2 Purposes of independent assessments

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, sections 6.9, 6.10, 6.11
- IAEA-TECDOC-1169, Managing Suspect and Counterfeit Items in the Nuclear Industry, sections 1.1, 2.1, 2.2, 2.3, 3.1, 3.3 and 4
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 2.36, 5.57, 5.58, 6.22, 6.24, 6.25, 6.26, 6.27, 6.36, 6.42, Appendix IV

- IAEA GS-G-3.5, The Management System for Nuclear Installations, sections 2.6-2.37, 6.38, 3.40, Appendix I
- IAEA Nuclear Energy Series No. NR-G-3.1, Sustaining Operational Excellence at Nuclear Power Plants, Principles and Challenges, sections 2.2, 3.3.1

22.3 Individuals assigned to independent assessments

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 6.43
- GS-G-3.5, The Management System for Nuclear Installations, section 6.34

22.4 Use of performance-based measures in independent assessments

- WANO Performance Indicators 2021, April 2022

23.1 Management System Review by Senior Management

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 6.45 – 6.49
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 6.40

23.2 Scope of Management System Review

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 6.45 – 6.47
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 6.40

23.3 Identification of weaknesses in the Management System

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 6.48
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 6.40

23.4 Identification of changes in the Management System

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 6.48, 6.49
- IAEA GS-G-3.5, The Management System for Nuclear Installations, section 6.40

24.1 Mechanisms to identify, evaluate and correct non-conforming processes, Products or services

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, section 6.7
- IAEA SSG-72, The Operating Organization for Nuclear Power Plants, section 7.93
- IAEA SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design, section 3.2
- IAEA SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation, sections 5.27, 5.32
- IAEA SSG-50, Operating Experience Feedback for Nuclear Installations, sections 2.4, 2.70,

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 6.60, 6.63

24.2 Identification and mitigation of causes and impacts potentially involving radiation risks

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, section 6.3
- IAEA SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation, sections 5.28, 5.30
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 6.68, 6.77

24.3 Documentation of non-conformances and preventive and corrective actions

- IAEA GSR Part 2, Leadership and Management for Safety, 2016, section 6.3
- IAEA SSG-50, Operating Experience Feedback for Nuclear Installations, sections 2.74, 2.79, 2.80
- IAEA-TECDOC-1910, Quality Assurance and Quality Control in Nuclear Facilities and Activities, Good Practices and Lessons Learned, section 3.9
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, sections 6.61, 6.62

24.4 Control and disposition of non-conformances

- IAEA-TECDOC-1910, Quality Assurance and Quality Control in Nuclear Facilities and Activities, Good Practices and Lessons Learned, 2020 section 3.9
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, July 2006, section 6.58
- IAEA Safety Guides, Quality Assurance for Safety in Nuclear Power Plants and Other Nuclear Installations, Code and Safety Guides Q1-Q14, Safety Guide Q2, Non-Conformance Control and Corrective Actions, Safety Series No. 50-SG-Q2, section 307.

24.5 Open atmosphere for reporting and identification of opportunities for improvement; relevant procedure development

- IAEA SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation, section 5.31
- IAEA-TECDOC-1910, Quality Assurance and Quality Control in Nuclear Facilities and Activities, Good Practices and Lessons Learned, section 3.9

24.6 Objectivity and competence in non-conformance assessments

- IAEA SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation, section 5.29
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 6.57

- IAEA Safety Guides, Quality Assurance for Safety in Nuclear Power Plants and Other Nuclear Installations, Code and Safety Guides Q1-Q14, 1996, Safety Guide Q2, Non-Conformance Control and Corrective Actions, Safety Series No. 50 SG-Q2, Introduction, Basic Requirement 3

24.7 Validation of decisions to accept non-conforming Products or services

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 6.58
- IAEA Safety Guides, Quality Assurance for Safety in Nuclear Power Plants and Other Nuclear Installations, Code and Safety Guides Q1-Q14, 1996, Safety Guide Q2, Non-Conformance Control and Corrective Actions, Safety Series No. 50-SG-Q2, section 312.

24.8 Status and effectiveness of corrective and preventive actions

- IAEA SSG-72, The Operating Organization for NPPs, section 7.94
- IAEA SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation, section 4.37
- IAEA SSG-50, Operating Experience Feedback for Nuclear Installations, sections 2.53, 2.64

24.9 Opportunities for Individuals to identify non-conformances and be informed of resolutions

- IAEA SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation, section 5.31
- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities, section 6.59

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