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IAEA SAFETY STANDARDS

for protecting people and the environment

STEP 11:

~~Second review of the draft~~ Incorporation of comments by ~~publication b~~y the review Committees

Leadership and Management for Safety

Draft General Safety Requirements

No. GSR Part 2

DS456

IAEA
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1. INTRODUCTION

BACKGROUND

1.1. This Safety Requirements publication establishes requirements for establishing, assessing, continuously improving and sustaining effective leadership and management for safety in organizations concerned with facilities and activities that give rise to radiation risks. This includes the regulatory body and other competent authorities, and the organization responsible for the facility or activity.

1.2. This Safety Requirements publication supersedes IAEA Safety Standards Series No. GS-R-3 on the Management System for Facilities and Activities[1]. It builds on the concepts of GS-R-3 and emphasizes that leadership for safety, management for safety, and a management system are essential to the specification and application of adequate safety measures and the fostering of a strong safety culture.

1.3. Management systems designed to fulfil the requirements of this Safety Requirements publication integrate safety, health, environmental, security, quality, societal, and economic elements[2]. The management system is based on the fundamental safety objective. Safety is the fundamental objective upon which the management system is based. The experience from Member States of developing, applyingimplementing, maintaining and improving management systems was taken into account in the development of this safety standard.

1.4. Effective application of the requirements of this publication will satisfy the Fundamental Safety Principles [1], and in particular Principle 3, which states that "Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks."

1.5. This publication establishes requirements for ensuring safety on the basis of interrelated concepts of:

a) Lleadership for safety, by establishing and integrating the organization'sa vision, goals, strategies, plans and objectives, and advocating individual commitment to protecting people and the environment from harmful effects of ionizing radiation; and

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-R-3, IAEA, Vienna (2006).

[2] Economic objectives are included in the list of elements that have to be integrated, as it is recognized that economic decisions and actions may introduce or may mitigate potential risks."

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advocating the fundamental safety principles [1]~~;~~ and establishing behavioural expectations and promoting safety culture.

b) Management for safety, which includes establishing and implementing and effective management system. This system has to integrate all elements of management so that requirements for safety are established and applied coherently with other requirements, including those for human performance, quality and security, and so that safety is not compromised by other requirements or demands. The management system also has to ensure the promotion of a safety culture, the regular assessment of safety performance and the application of lessons learned from experience.

~~management for safety, comprising coordinated activities to direct and control an organization, and is a formal, authorized function for ensuring that an organization operates efficiently and that work is completed in accordance with requirements, plans and resources. This includes establishing a management system to achieve the highest standards of safety that can reasonably be achieved [1], and developing and maintaining a strong safety culture to ensure that there are organizational and individual commitments to giving safety issues the attention warranted by their significance.~~

~~b)~~

1.6. Principle 1 of the Fundamental Safety Principles [1] states that "The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks". Leadership and management for safety are therefore of fundamental importance for such organizations. The requirements established in this publication are intended for use in the following ways:

a) By the registrant or licensee, for ensuring leadership and management on the part of organizations and managers responsible for facilities and activities[3] that give rise to radiation risks.[4]

[3] The term 'facilities and activities' is a general term encompassing nuclear facilities, uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other practice or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources: essentially any human activity that may cause people to be exposed to radiation risks.

[4] The term 'radiation risks' is used in a general sense to refer to [1]:

- Detrimental health effects of exposure to radiation (including the likelihood of such effects occurring).

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b) By the registrant or licensee, to specify to a vendor or supplier of products and equipment, or a contractor for services, and to any other relevant organization, any requirements that must be met by the supplier's management system.

~~a)~~c) ~~.~~By the regulatory body, as a part of the basis for the regulation of facilities and activities;

~~b)~~d) By the regulatory body and other relevant governmental organizations, as a basis for meeting their responsibilities for arrangements[5] in relation to leadership and management in conjunction with the requirements established in Ref. [2].

1.7. The requirements established in this Safety Requirements publication apply to all facilities and activities. However, the way in which they are to be met may vary depending on the type and complexity of the facility or activity. Recommendations and guidance on meeting the requirements are provided in related Safety Guides. Other international standards or national standards[6] may be used ~~to supplement~~in addition to the requirements of this publication.

OBJECTIVE

1.8. The objective of this publication is to establish requirements that ~~apply~~ support Principle 3 of the Fundamental Safety Principles [1], in relation to establishing, maintaining and continuously improving leadership and management for safety, and a ~~including a~~ management system, ~~and developing and supporting~~which are key to developing and supporting a strong safety culture, in the organization.

– Any other safety related risks (including those to ecosystems in the environment) that might arise as a direct consequence of:
  - Exposure to radiation;
  - The presence of radioactive material (including radioactive waste) or its release to the environment;
  - A loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation.

[5] 'Arrangements' in this context are an integrated set of infrastructural elements necessary to provide the capability for performing a specified function or task. Such elements may include authorities and responsibilities, organization, coordination, personnel, plans, procedures, facilities, equipment, training and contracts.

[6] International standards are, for example, those of the International Standards Organization (ISO 9001, ISO 14001, OHSAS 18001) or the European Foundation for Quality Management; examples of national standards are the Nuclear Quality Assurance standard of the United States of America, ASME NQA-1, or the British standard OHSAS 18001 on Occupational Health and Safety Management.

SCOPE

1.9. The requirements in this publication apply to all types of facilities and activities that give rise to radiation risks, as follows:

a) Nuclear installations (including nuclear power plants; research reactors (including subcritical and critical assemblies) and any adjoining radioisotope production facilities; facilities for the storage of spent nuclear fuel; facilities for the enrichment of uranium; nuclear fuel fabrication facilities; conversion facilities; facilities for the reprocessing of spent nuclear fuel; facilities for the predisposal management of radioactive waste arising from nuclear fuel cycle facilities; and nuclear fuel cycle related research and development facilities);

b) Facilities for the mining or processing of uranium ores or thorium ores;

c) Irradiation installations;

d) Facilities and activities for the management (including disposal) of radioactive waste such as the discharge of effluents; and ~~some aspects of~~ the remediation of sites affected by residual radioactive material from past activities;

e) Any other places where radioactive material is produced, processed, used, handled, stored or disposed of — or where radiation generators are installed — on such a scale that consideration of protection and safety is required;

f) Activities involving the production, use, import and export of sources of ionizing radiation for medical, industrial, agricultural, educational and research purposes;

g) The transport of radioactive material;

h) The decommissioning (or closure) of facilities.

~~h)~~i) i) Design, manufacture of equipment and other works and services to the operating organization, in which is laid the potential impact on the safety of facilities and activities that create risk.

The requirements in this publication also apply in relation to the functions and activities of the regulatory body[2]~~.~~

~~1.10.~~ ‘Safety’ means the protection of people and the environment against radiation risks and the safety of facilities and activities that give rise to the radiation risks [1]. ~~This includes~~

Comment [RH2]: Used the glossary definition

~~the safety of nuclear installations, radiation safety, the safety of disposal facilities for radioactive waste and safety in the transport of radioactive material.~~

~~1.11.~~1.10. This publication is applicable to organizations (registrants and licensees) throughout the lifetime of facilities and for the entire duration of activities, for all operational states and for accident conditions, and in a nuclear or radiological emergency. The lifetime of a facility includes its siting and site evaluation, design, construction, commissioning, operation and decommissioning (or closure and the post-closure period, including any subsequent period of institutional control), until its release from regulatory control.

This publication does not attempt to define all those specific health, environment, security, quality and economic requirements to be addressed that have already been established elsewhere (in other IAEA publications and in international codes and standards). Furthermore, this publication does not set out to duplicate any of the specific requirements for managing their fulfilment in an integrated manner.

Comment [RH3]: Replaced with previous GS-R-3 version

~~1.12. This publication establishes requirements for managing the fulfilment of other requirements in an integrated manner. This publication does not establish specific requirements in relation to nuclear safety, radiation protection, protection of the environment, quality management or quality assurance, nuclear security, or societal and economic requirements and recommendations. Relevant safety requirements are established in other IAEA safety standards [2–14]. See also Refs [15, 16]. Recommendations and guidelines are provided in publications in the IAEA Nuclear Security Series [17–20] and in international codes and standards [21–27]. Terms used in this publication are defined in the IAEA Safety Glossary [28].~~

STRUCTURE

~~1.13.~~1.11. This ~~Safety Requirements~~ publication consists of five sections. Section 2 establishes the responsibility for safety and protecting people and the environment against radiation risks as an overriding priority. Section 3 establishes requirements for leadership for safety. Section 4 establishes requirements for management for safety. Section 5 establishes requirements on the organi~~z~~zation to~~.~~ ~~establish a~~establish a strong safety culture.

2. RES~~P~~ONSIBILITY FOR SAFETY

Requirement 1: Achieving the fundamental safety objective

The licensee with the senior management shall ensure that the fundamental safety objective of protecting people and the environment from harmful effects of ionizing radiation is achieved

~~**Senior management shall ensure that the fundamental safety objective of protecting people and the environment from harmful effects of ionizing radiation is achieved without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks.**~~

2.1 Senior management of organizations in accordance with their ~~shall be responsible, as appropriate,~~accountabilities ~~for~~ shall:

a) Ensure~~ing~~ the safe siting~~ and site evaluation~~, design, construction, commissioning, operation and decommissioning (or closure~~)of~~) of facilities. Also ensuring the quality of the associated equipment, and activities important to safety.

b) Ensure~~ing~~ the safe management and control of all radioactive material that is produced, processed, used, handled, transported, stored, or disposed. ~~of or transported.~~

~~c) Ensuring the safe management and control of all radioactive sources and radiation generators;~~

~~d)~~c) Ensure~~ing~~ that managers at all levels in the organization develop ~~an understanding~~an understanding of radiation risks and ~~–~~potential consequences, and how to manage radiation risks relevant to their responsibilities.

~~e)~~d) Ensure~~ing~~ the provision for adequate resources and funding for the long term management (including disposal) of radioactive waste and decommissioning of facilities, with due consideration given to the protection of future generations;

e) Ensure~~ing~~ that arrangements are made for preparedness and response for a nuclear or radiological emergency.[7]

2.2 Regulatory bodies and other government organisations shall interpret the requirements in accordance to their own organization's accountabilities and in their interactions with operational organisations.

2.3 All safety requirements in this document should form part of the integrated managements systems for all organizations.

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~~f) [GSR Part 7].~~

3. LEADERSHIP FOR SAFETY

Requirement 2: Demonstration of leadership by senior management

The senior management of the organization shall demonstrate leadership for safety. ~~Senior management[7] shall advocate an approach to safety that encompasses all interactions between human, technology and the organization~~.

3.1 The difference between management and leadership can be stated simply; Management is a formal, authorized function for ensuring that an organization operates efficiently and that work is completed in accordance with requirements, plans and resources; while leadership is the use of capabilities to give direction, to influence and communicate with the aim of achieving the commitment of all individuals to appropriate goals, shared values and behaviors. Managers at all levels need also to be leaders.

3.2 ~~3.1~~ Senior management shall develop an organization that is able to:

(a) Advocate an approach to safety that encompass interactions between human, technology and the organization.

~~(a)~~(b) Establish, adhere to and advocate individual and ~~institutional~~ organizational values that demonstrate leadership for safety.

~~(b)~~(c) Establish behavioural expectations and promote safety culture, as part of establishing and ~~a~~ maintaining a strong safety culture and implementing the organizations safety policy.

~~(c)~~(d) ~~Ensure~~ Establish the acceptance of personal accountability in relation to safety on the part of all individuals in the organization.

~~(d)~~ Establish and communicate that the policy on safety ~~is an~~ which shall establish that as an overriding priority, protection and safety issues receive

~~[7] 'Senior management' means the person or persons who are accountable for meeting the terms established in the licence, and/or who direct, control and assess an organization at the highest level. Several different terms are used, including, for example: board of directors, chief executive officer (CEO), director general, executive team, plant manager, top manager, chief regulator, site vice president, managing director and laboratory director and owner.~~

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the attention warranted by their significance~~, overriding priority of the organization, in accordance with the highest standards of safety that can reasonably be achieved.~~

(e) Ensure that responsibilities and accountabilities are in line with the organization's policies, strategies, plans and objectives, to ensure that safety requirements are met and goals are achieved.

(f) ~~Ensure~~ Establish that decision making at all levels are guided by the priorities and accountabilities for safety~~. guide decision-making at all levels.~~

(g) Develop and maintain leadership competences at all levels in the organization, including competences for leadership in dealing with incidents and nuclear and radiological emergencies as well as unanticipated events.

~~(g)~~(h) Support the leaders at all levels in their promotion of safety and development of a strong safety culture.

~~(h) Senior management, shall develop an organization that is able to appropriately prepare and respond to incidents and accidents,~~Ensure that the organization structure is in line with the management for safety.

(i) ~~3.2 Senior management shall e~~

(j) Encourage open communication within the organization.

(k) ~~Senior management shall s~~Seek information on ~~the effectiveness of~~ manager's effectiveness of actions at all levels in the organization in achieving, ensuring and enhancing safety, and shall take action as appropriate.

~~3. 3 Senior management shall ensure that there is timely and effective communication and consultation with interested parties[8] and shall ensure that relevant information is disseminated to them.~~

~~[8] Interested parties may include: customers, owners, operators, employees, suppliers, partners, trade unions, the regulated industry or professionals; scientific bodies; governmental agencies or regulators (local, regional and national) whose responsibilities may cover nuclear energy; the media; the public (individuals, community groups and interest groups); and other States, especially neighbouring States that have entered into agreements~~

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Requirement 3: Demonstration of leadership for safety by managers at all levels

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Managers at all levels in the organization shall demonstrate leadership for safety in application of the management system, establishing continuous improvement, and in the fostering of a strong safety culture.

~~3.1~~3.3 Managers at all levels in the organization shall ensure that their leadership includes:

(a) The involvement of teams and individuals in the organization in the application and continuous improvement of the management system to ensure safety

(b) The advocacy of adherence to the management system and development of individual and institutional values and expectations for safety, throughout the organization by means of their decisions, statements and actions.

~~3.2~~3.4 Managers at all levels in the organization shall actively seek information on safety ~~related~~ performance within their area of responsibility with appropriate monitoring, and shall share this information within the organization and shall demonstrate commitment to improving safety ~~related~~ performance.

~~3.3~~3.5 Managers at all levels in the organization shall ensure that their actions serve to encourage the reporting of safety ~~related~~ issues, develop questioning attitudes ~~and~~, and to ~~oppose~~ correct acts or conditions adverse to safety.

~~3.4~~3.6 Managers at all levels in the organization:

(a) Shall encourage all individuals to achieve their work goals and to perform their tasks safely, and shall support them in this;

(b) Shall engage all individuals in enhancing safety ~~related~~ performance;

(c) Shall communicate ~~the~~ to make transparent the basis of safety ~~related~~ decisions.

~~providing for an exchange of information concerning possible transboundary impacts, or States involved in the export or import of certain technologies or materials.~~

4. MANAGEMENT FOR SAFETY

RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM ~~FOR SAFETY~~

Requirement 4: Senior management's responsibility for the management system

~~4.1~~ **Senior management shall establish, ~~apply~~implement, maintain and continuously improve a management system for ensuring safety.**

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4.1 Senior management shall retain overall accountability for the management system.

4.2 Senior management shall establish, ~~apply~~ implement and maintain the management system, in order to ensure safety and to meet regulatory and other requirements.

~~4.2 Senior management shall retain overall responsibility for the management system.~~

4.3 Senior management shall assign to a designated individual the responsibility for coordinating the development, application and maintenance of the management system. The designated individual shall be given the necessary authority to discharge this responsibility and shall be given direct access to senior management. This assignment of responsibility to an individual shall not detract from the line management's responsibility and accountability for safety. ~~of line management[9] for safety.~~

Requirement 5: Goals, Strategies, plans, and objectives.

Senior management shall establish goals, strategies, plans and objectives for the organization that are consistent with the organization's safety policy.

4.4 Senior management shall establish ~~arrangements for the development of~~ goals, strategies, plans and objectives, ~~with~~ in consultation ~~of~~ and with feedback of information from individuals in the organization. The goals, strategies, plans and objectives of the organization shall be developed in such a manner that safety is not compromised by other priorities.

4.5 Senior management shall ~~ensure that, where relevant,~~establish measurable safety objectives in line with the goals, strategies and plans are established at various levels in the organization.

~~[9] The 'line management' is the directing or supervisory chain or hierarchy of management accountable for the performance of activities.~~

4.6 Senior management shall ensure that the execution of plans is periodically reviewed against the safety objectives and goals, and that actions are taken where necessary to address any deviations from the plans.

Requirement 6: Interactions with interested parties

Interactions with interested parties shall be integrated into the management system.

4.7 Senior management shall identify the 'interested parties' for their organisation and the appropriate strategy for interaction with them. Senior management shall ensure that there is appropriate timely and effective communication and consultation with interested parties[10] and shall ensure that relevant information is disseminated to them.

~~4.7~~4.8 Senior management shall make arrangements to ensure that processes for meeting legal and regulatory requirements and/or taking initiatives for interactions with interested parties are specified in the management system, and are understood and acted on by all individuals in the organization.

~~4.8~~4.9 Senior management shall establish appropriate means of informing and consulting interested parties with regard to radiation risks associated with the operation of facilities or the conduct of activities.

~~4.9~~4.10 Senior management shall make arrangements to consider in its decision making processes the concerns and expectations of interested parties in relation to safety and to take appropriate actions.

[10] Interested parties may include: customers, owners, operators, employees, suppliers, partners, trade unions, the regulated industry or professionals; scientific bodies; governmental agencies or regulators (local, regional and national) whose responsibilities may cover nuclear energy; the media; the public (individuals, community groups and interest groups); and other States, especially neighbouring States that have entered into agreements providing for an exchange of information concerning possible transboundary impacts, or States involved in the export or import of certain technologies or materials.

Comment [RH4]: Moved to this section. From 3.3

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Requirement 7: Integration ~~of all elements of management in~~of the the management system

The management system shall integrate all elements of management, including safety, health, environmental, security, quality, societal and economic elements, so that safety is not compromised.

~~4.10~~4.11 The management system shall be ~~applied~~implemented, assessed and continuously improved. It shall be aligned with the goals of the organization and shall contribute to their achievement.

~~4.11~~4.12 The management system shall be ~~applied~~ implemented to achieve safety and to enhance safety ~~related~~ performance by:

(a) Bringing together in a coherent manner all the requirements and processes for managing the organization and its activities for safety;

(b) Describing the arrangements made for management ~~for safety~~of the organization and its activities as part of the integrated management system, in order to achieve a high level of safety ~~related~~ performance, and describing the planned and systematic actions necessary to provide confidence that all requirements are met;

(c) Ensuring that safety is taken into account ~~in~~ during decision making and is not compromised by any decisions taken.

~~(c)~~(d) Promoting safety culture

~~4.12~~4.13 Provision shall be made in the management system to identify potential impacts of security measures on safety and potential impacts of safety measures on security, in order to plan and integrate measures to be taken without compromising safety or security.

~~4.13~~4.14 The ~~management and~~ organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations, including with a parent organization, shall be clearly specified in the management system.

~~4.14~~4.15 Any proposed significant changes, (including organizational changes and cumulative changes), shall be analysed with regard to their implications for safety.

~~4.15~~4.16 Arrangements shall be established in the management system for independent review before decisions ~~important~~ significant for~~to~~ safety are made. The requirements on the independent nature of the review and on the competences of the reviewers shall be specified in the management system.

~~4.16~~4.17 Arrangements shall be established in the management system for the resolution of conflicts in decision making processes that affect safety..

Requirement 8: Graded approach to the ~~application~~ definition and implementation of the requirements for the management system

The requirements for the management system shall be ~~applied~~ implemented by using a graded approach, based on the safety significance of each activity and process.

~~4.17~~4.18 The criteria for grading the application of the management system requirements shall be documented in the management system [34]. The following shall be taken into account:

(a) The significance for safety and the complexity of the process, activity, structure, system, component, item of equipment, product or service;

(b) The hazards and the magnitudes of the radiation risks, including potential radiological consequences, associated with the safety, health, environmental, security, quality, societal, economic and other elements of each activity or product;

(c) The possible consequences if a failure or an unanticipated event ~~occurs,~~occurs or if an activity is inadequately planned or improperly carried out.

Requirement 9: Documentation of the management system

The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use.

~~4.18~~4.19 The documentation of the management system shall include, as a minimum, the following:

(a) The policy statements of the organization; that includes a statement of the values and behavioural expectations as defined by senior management.

(b) A safety policy, stating that achieving the fundamental safety objective of protecting people and the environment from harm is an overriding priority.

~~(b) harmful effects of ionizing radiation has an overriding priority;~~

~~(c) A statement of the values and expectations of senior management;~~

~~(d)~~(c) A description of the structure of the organization;

~~(e)~~(d) A description of how the management system complies with ~~the~~ all regulatory requirements that apply to~~on~~ the organization;

~~(f)~~(e) A description of the responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;

~~(g)~~(f) A description of 'when, how and by whom' decisions are to be made;

~~(h)~~(g) A description of the organizational processes, with supporting information that explains how work is to be ~~prepared, reviewed~~planned, performed, verified, recorded and assessed and how safety, quality and security are to be assured.

~~(i)~~(h) A description of the interactions with interested parties and with external organizations, including interactions with the parent organization, if any, and interactions with the regulatory body, as applicable.

~~4.19~~4.20 Documents shall be controlled. All individuals involved in preparing, revising, reviewing or approving documents shall be competent to perform the tasks and shall be given access to appropriate information on which to base their input or decisions. It shall be ensured that users of documents ~~are aware of and use appropriate and~~use the correct documents.

~~4.20~~4.21 Changes to documents shall be reviewed and recorded and shall be subject to the same level of approval as the documents themselves.

~~4.21~~4.22 Records shall be specified in the ~~process documentation~~management system, and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable.

~~4.22~~4.23 Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and with the obligations for knowledge management of the organization. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record.

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MANAGEMENT OF RESOURCES

Requirement 10: Provision of resources[11]

Senior management shall determine and shall ensure the availability of, the competences and resources necessary to carry out the activities of the organization to ensure safety.

~~4.23 Senior management shall determine the competences and resources necessary to ensure safety and shall ensure the availability of these competences and resources in a timely manner for conducting the activities of the organization.~~

Comment [RH5]: Repetition of the requirement

4.24 Senior management shall make arrangements to ensure that the organization ~~has and~~ maintains access to the full range of competences and resources necessary ~~, including resources from providers of external expert support~~ to conduct its activities and to discharge its responsibilities for ensuring safety at each stage in the lifetime of the facility or activity.

4.25 Senior management shall determine which competences and resources it has to retain or to develop internally, and which competences and resources may be obtained externally to maintain safe operations.

4.26 Senior management shall ensure that the competence requirements for individuals at all levels are specified, and shall ensure that training is conducted or other actions are taken to achieve and sustain the required levels of competence. An evaluation shall be conducted of the effectiveness of the training and of the actions taken.

4.27 Competences to be maintained in-house by the organization shall include competences for leadership at all levels and for developing and sustaining a safety culture, and expertise to understand and maintain the design ~~basis and the safety case of the facility or activity~~and operation for safety of the facility or activity. Senior management shall ensure:

a) that individuals at all levels, including managers and workers, are competent to perform their assigned tasks and work;

b) ~~that~~that individuals at all levels, including managers and workers understand the standards expected in the completion of their tasks.

[11] 'Resources' includes individuals (number of individuals and their competences), infrastructure, the working environment, information and knowledge, and suppliers, as well as material and financial resources.

4.28 All individuals in the organization shall be trained in relevant requirements of the management system. Such training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to ensuring safety in the achievement of the organization's objectives.

4.29 ~~Senior management shall ensure that expertise in human factors and organizational factors is applied as part of the development of leadership and management for safety, and of process and plant safety requirements.~~ The information and knowledge of the organization shall be managed as a resource that includes supporting safety and promote a strong safety culture.

~~4.29 The information and knowledge of the organization shall be managed as a resource in a knowledge management system.~~

MANAGEMENT OF PROCESSES AND ACTIVITIES

Requirement 11: Management of processes and activities

Processes and activities shall be developed and managed to achieve the organization's ~~goals safely.~~safety goals.

4.30 The management of processes and activities shall ensure that there are measures in place for :

~~4.30 For each process of the organization, a designated individual shall be given the authority and responsibility for:~~

~~(d)~~(a) Developing and documenting the process and maintaining the necessary supporting documentation;

~~(e)~~(b) Ensuring that there is effective interaction between interfacing processes;

~~(f)~~(c) Ensuring that process documentation is consistent with any existing documents;

~~(g)~~(d) Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation;

~~(h)~~(e) Monitoring and reporting on performance ~~in~~ of the process;

~~(i)~~(f) Bringing about improvements in the process;

~~(j)~~(g) Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the organization.

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4.31 Each process shall be developed and managed to ensure requirements are met without compromising safety.~~Each process shall be developed and managed so that safety is not compromised and safety requirements are met.~~

~~4.31 The processes, including feedback mechanisms for obtaining information on the effectiveness of the management system, shall be applied, assessed and continuously improved.~~

4.32 The sequencing of a process and the interactions between processes shall be specified so that safety is not compromised. Particular consideration shall be given to interactions between processes within the organization and interactions with processes conducted by external service providers.

4.33 New processes or changes to existing processes shall be designed, verified, approved and ~~applied~~ implemented so that safety is not compromised.

4.34 ~~For each process, a~~Any activities for inspection, testing, and verification and validation, their acceptance criteria and the responsibilities for carrying out such activities shall be specified. It shall be specified when and at what stages independent inspection, testing, verification and validation are required to be conducted.

4.35 Each activity that could have implications for safety shall be carried out under controlled conditions, by using readily understood, approved and current procedures, instructions and drawings, or by other appropriate means. These means shall be validated before first use and shall be periodically reviewed to ensure their adequacy and effectiveness. Individuals carrying out such activities shall be involved in the validation and the periodic review of such procedures, instructions and drawings.

Requirement 12: Management of the supply chain

The organization shall put in place arrangements with vendors, contractors and suppliers to specify, monitor and control the supply of items, products and services that may influence safety.

4.36 The organization shall retain responsibility for safety when contracting any processes and/or when receiving any item, product or service in the supply chain[12].

[12] The supply chain, described as 'suppliers', typically includes: designers, vendors, manufacturers and constructors, employers, contractors, subcontractors, and consigners and carriers who are supplying safety ~~related~~ items. The supply chain can also include other parts of the organization and/or parent organizations.

4.37 The organization shall have a clear understanding ~~and knowledge~~ of the product or service being supplied[13]. The organization shall 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 safety requirements.

4.38 The management system shall include arrangements for:

(a) Qualification of vendors, contractors and suppliers of items, products and services

(b) Selection of vendors, suppliers and contractors on the basis of the effectiveness of their management systems and their performance;

(c) Verification that vendors, suppliers and contractors understand and are in compliance with, safety requirements relating to the items, products or services that they provide;

~~(c)~~(d) Verification that vendors suppliers and contractors have arrangements for the control and supervision of their sub-contractors with respect to safety.

~~(d)~~(e) Specification of contractual requirements, including safety ~~related~~ requirements;

~~(e)~~(f) Provision, where appropriate, of advice, information and training to suppliers and their staff;

~~(f)~~(g) Appropriate arrangements for communication and supervision;

~~(g)~~(h) Periodic assessment of the management system of suppliers and of their performance using a graded approach;

~~(h)~~(i) Verification ~~and validation~~ that items, products and services supplied meet the organization's specifications and are authentic. [35] ~~.~~

~~4.39 The organization shall communicate to each supplier the principles and the requirements for a graded approach that are required to be included in the supplier's management system.~~

~~4.40~~4.39 The organization shall make arrangements for ensuring that suppliers of items, products and services important to safety, adhere to ~~the contracted~~ safety requirements, and meet the organization's expectations of safe behaviour in their delivery.

Comment [RH6]: Removed in accordance to MS comments and that this is superfluous to requirements as paragraph below covers what is needed.

[13] The capability of the organization to have a clear understanding and knowledge of the product or service to be supplied is sometimes termed an 'informed customer' (or 'intelligent customer' or 'knowledgeable customer') capability.

MEASUREMENT, ASSESSMENT AND IMPROVEMENT OF THE MANAGEMENT SYSTEM

Requirement ~~—~~13: Measurement, assessment and improvement of the management system

The effectiveness of the management system shall be measured, assessed and improved so as to enhance safety ~~related~~ performance.

~~4.41~~4.40 The effectiveness of the management system shall be monitored and measured to confirm the ability of the organization to achieve the results intended, to share feedback on and to learn from successes and strengths and weaknesses, and to identify opportunities for its improvement.

~~4.42~~4.41 Performance indicators shall be developed and used in order to ~~measure~~ assess the effectiveness of the management system and to confirm the suitability of processes or activities for achieving the intended ~~results~~outcomes. Trends in performance indicators shall be analysed and evaluated at regular intervals.

~~4.43~~4.42 All processes shall be periodically evaluated for their effectiveness and ability to ensure safety. Performance indicators should be used. Assessments shall be made of radiation risks arising from particular processes and activities and used to decide when significant revision of the management system is required.

~~4.44~~4.43 The causes of non-conformances, events and safety ~~related~~ issues that arise shall be determined and the potential consequences shall be evaluated, managed and mitigated. Corrective actions for eliminating the causes of non-conformances and preventative actions to avoid the recurrence of the same or similar safety ~~related~~ issues shall be determined and shall be taken in a timely manner. The status and effectiveness of all corrective ~~actions~~ and preventive ~~measures~~ actions taken shall be monitored and shall be reported to management at an appropriate level in the organization.

~~4.45~~4.44 Self-assessment of the management system ~~for safety~~ shall be performed periodically by managers and by individuals at all levels in the organization with the following purposes:

(a) to identify and to learn from successes and strengths, and to correct weaknesses that hinder the achievement of the organization's safe delivery of objectives as part of continuous improvement.~~;~~

(b) to confirm that the management system is delivering to the required standard for safety;

(c) to enhance leadership and safety culture and to ensure the effectiveness of processes and activities;

~~(c)~~(d) to participate in the sharing of experience with the nuclear industry.

~~4.46~~4.45 Independent assessments (including audits) of the management system ~~for safety~~, shall be conducted regularly ~~on behalf of~~by senior management to evaluate its effectiveness, and identify opportunities for improvement. Independent assessments of the management system shall critically evaluate the following:

(a) The fulfilment of requirements, goals, strategies, plans and objectives;

(b) Delivery of the required standards for safety, and the integration of safety requirements by the management system

(c) Leadership performance and safety culture;

(d) The adequacy of resources provided for individuals to be able to meet requirements, and to achieve goals and objectives in accordance with strategies and plans;

~~4.47~~4.46 Senior management shall evaluate the results of the independent assessments and self-assessments of the management system, shall take any necessary actions, and shall record and communicate within the organization their consequent decisions and the reasons for them.

~~4.48~~4.47 Plans for the conduct of independent assessments and self-assessments of the management system shall be reviewed and adjusted to reflect concerns of management and problems with performance as well as opportunities for improvement.

~~4.49~~4.48 An organizational entity shall be established or an individual shall be appointed with the responsibility for conducting independent assessments of the management system. This entity or individual shall have sufficient authority to discharge these responsibilities and shall have direct access to senior management. Individuals conducting independent assessments of the management system shall not assess areas of responsibility of their own line management.

~~4.50~~4.49 Senior management shall 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 organization to be accomplished, with account taken of new requirements and changes in the organization. This review and subsequent improvements shall cover all significant sources of information on safety ~~related~~ performance, including the following outputs from different forms of assessment;

~~(k)~~(a) Results delivered and objectives achieved by the organization by means of its processes and activities;

~~(l)~~(b) Non-conformances and the progress and effectiveness of corrective actions and preventive measures;

~~(m)~~(c)Operating experience, including lessons and good practices from other organizations;

~~(n)~~(d) Opportunities for improvement.

~~4.51~~4.50 The management system shall include evaluation and timely use of the following:

(a) Lessons from experience gained and events occurring, both within the organization and outside the organization, and from the causes of events;

(b) Technical advances and research and development;

(c) Methods for identifying good practices.

5. SAFETY CULTURE

Requirement14: Fostering and c~~C~~ontinuous improvement of safety culture

Individuals in the organization, from senior management downwards, shall promote a strong safety culture. ~~Individuals in the organization, from senior management downwards, shall demonstrate leadership by fostering safety culture~~. The leadership for safety and the management system shall be used to foster and support a strong safety culture.

5.1. Attitudes and behaviours that contribute to a strong safety culture shall be ~~specified~~ defined and developed through leadership and use of the management system.

5.2. All individuals in the organization shall contribute to fostering and supporting a strong safety culture.

~~5.2.~~5.3. Managers and leaders~~, by using the management system~~ shall ~~to provide and~~ advocate and support the following:

(a) A collective commitment to safety by teams and individuals;

(b) Acceptance by individuals of personal accountability for attitudes and behaviour with regard to safety;

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(c) A common understanding of safety and safety culture;

(d) A culture that encourages trust, collaboration and communication, and that values the reporting of issues relating to human and organizational factors;

~~(d)~~ Measures to encourage a questioning and learning attitude at all levels in the organization and to discourage complacency with regard to safety;

(e)

(f) The reporting of any deficiencies in structures, systems and components to avoid degradation of safety;

(g) The timely acknowledgement and feedback of information on problems identified and suggestions made;

(h) The means by which the organization seeks to enhance safety and safety culture;

(i) Responsibility and accountability of organizations and of managers at all levels for safety;

(j) ~~Measures to encourage a questioning and learning attitude at all levels in the organization and to discourage complacency with regard to safety;~~

(k) A common understanding of the key ~~aspects~~ elements of safety and safety culture within the organization;

(l) An awareness of radiation risks and hazards relating to the work and to the work environment, and an understanding of their significance for safety;

(m) Risk ~~informed~~ based and conservative decision making in all activities.

~~5.3. The management system shall include arrangements to ensure the participation and visible presence in the field activities of management at all levels in the organization.~~ The management system shall include arrangements to ensure the participation and visible presence of management at all level, in the activities of the organisation (including field activities).

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5.4. The management system shall include arrangements to support teams and individuals in carrying out ~~successfully~~ their tasks successfully with regard to safety, with account taken of interactions between human, technology and the organization[14].

Requirement15: Assessment, ~~-~~ continuous improvement and maintenance of leadership for safety and safety culture

Senior management shall regularly commission independent assessments of, and shall provide for self-assessments of, leadership and safety culture.

5.5. Senior ~~managers~~ management shall designate a team representing all organizational levels and functions in the organization, and with expertise in the assessment of leadership and safety culture, to carry out a self-assessment to inform the basis of continuous improvement of safety culture .

5.6. Senior ~~managers~~ management shall ensure that the independent assessment of leadership and safety culture is conducted including experts in the sciences of applying leadership and safety culture independent assessments methods to inform the basis of continuous improvement of safety culture . .

5.7. The results of independent assessments and self-assessments of leadership and safety culture[15] shall be communicated at all levels in the organization and shall be acted upon to enhance safety culture and to foster a learning attitude within the organization.

[14] Human, technology, and organization (HTO) term is the same as the older terms Man, technology and organization (MTO) and the Individual, technology and organization (ITO).

[15] Assessment of leadership and safety culture is a form of assessment requiring a specific approach and perspective on how human and organizational factors such as values, attitudes and behaviour can affect safety. Assessments of leadership and safety culture and of human factors and organizational factors make use of particular methods such as surveys, interviews, focus groups, field observations and reviews of documents.

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[[Consideration to be given to whether and which conventions can be mentioned in the text and how; see para. 1.5.]]

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