

IAEA Safety Standards

for protecting people and the environment

Leadership and Management for Safety

General Safety Requirements

No. GSR Part 2

IAEA SAFETY STANDARDS AND RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish or adopt standards of safety for protection of health and minimization of danger to life and property, and to provide for the application of these standards.

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety. The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

Information on the IAEA's safety standards programme is available on the IAEA Internet site

<http://www-ns.iaea.org/standards/>

The site provides the texts in English of published and draft safety standards. The texts of safety standards issued in Arabic, Chinese, French, Russian and Spanish, the IAEA Safety Glossary and a status report for safety standards under development are also available. For further information, please contact the IAEA at: Vienna International Centre, PO Box 100, 1400 Vienna, Austria.

All users of IAEA safety standards are invited to inform the IAEA of experience in their use (e.g. as a basis for national regulations, for safety reviews and for training courses) for the purpose of ensuring that they continue to meet users' needs. Information may be provided via the IAEA Internet site or by post, as above, or by email to Official.Mail@iaea.org.

RELATED PUBLICATIONS

The IAEA provides for the application of the standards and, under the terms of Articles III and VIII.C of its Statute, makes available and fosters the exchange of information relating to peaceful nuclear activities and serves as an intermediary among its Member States for this purpose.

Reports on safety in nuclear activities are issued as **Safety Reports**, which provide practical examples and detailed methods that can be used in support of the safety standards.

Other safety related IAEA publications are issued as **Emergency Preparedness and Response** publications, **Radiological Assessment Reports**, the International Nuclear Safety Group's **INSAG Reports**, **Technical Reports** and **TECDOCs**. The IAEA also issues reports on radiological accidents, training manuals and practical manuals, and other special safety related publications.

Security related publications are issued in the **IAEA Nuclear Security Series**.

The **IAEA Nuclear Energy Series** comprises informational publications to encourage and assist research on, and the development and practical application of, nuclear energy for peaceful purposes. It includes reports and guides on the status of and advances in technology, and on experience, good practices and practical examples in the areas of nuclear power, the nuclear fuel cycle, radioactive waste management and decommissioning.

LEADERSHIP AND
MANAGEMENT FOR SAFETY

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

LEADERSHIP AND MANAGEMENT FOR SAFETY

GENERAL SAFETY REQUIREMENTS

This publication includes a CD-ROM containing the IAEA Safety Glossary:

2007 Edition (2007) and the Fundamental Safety Principles (2006),
each in Arabic, Chinese, English, French, Russian and Spanish versions.

The CD-ROM is also available for purchase separately.

See: <http://www-pub.iaea.org/MTCD/publications/publications.asp>

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FOREWORD

by Yukiya Amano
Director General

The IAEA's Statute authorizes the Agency to “establish or adopt... standards of safety for protection of health and minimization of danger to life and property” — standards that the IAEA must use in its own operations, and which States can apply by means of their regulatory provisions for nuclear and radiation safety. The IAEA does this in consultation with the competent organs of the United Nations and with the specialized agencies concerned. A comprehensive set of high quality standards under regular review is a key element of a stable and sustainable global safety regime, as is the IAEA's assistance in their application.

The IAEA commenced its safety standards programme in 1958. The emphasis placed on quality, fitness for purpose and continuous improvement has led to the widespread use of the IAEA standards throughout the world. The Safety Standards Series now includes unified Fundamental Safety Principles, which represent an international consensus on what must constitute a high level of protection and safety. With the strong support of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its standards.

Standards are only effective if they are properly applied in practice. The IAEA's safety services encompass design, siting and engineering safety, operational safety, radiation safety, safe transport of radioactive material and safe management of radioactive waste, as well as governmental organization, regulatory matters and safety culture in organizations. These safety services assist Member States in the application of the standards and enable valuable experience and insights to be shared.

Regulating safety is a national responsibility, and many States have decided to adopt the IAEA's standards for use in their national regulations. For parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment of obligations under the conventions. The standards are also applied by regulatory bodies and operators around the world to enhance safety in nuclear power generation and in nuclear applications in medicine, industry, agriculture and research.

Safety is not an end in itself but a prerequisite for the purpose of the protection of people in all States and of the environment — now and in the future. The risks associated with ionizing radiation must be assessed and controlled without unduly limiting the contribution of nuclear energy to equitable and sustainable development. Governments, regulatory bodies and operators everywhere must ensure that nuclear material and radiation sources are used beneficially, safely and ethically. The IAEA safety standards are designed to facilitate this, and I encourage all Member States to make use of them.

THE IAEA SAFETY STANDARDS

BACKGROUND

Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. The radiation risks to workers and the public and to the environment that may arise from these applications have to be assessed and, if necessary, controlled.

Activities such as the medical uses of radiation, the operation of nuclear installations, the production, transport and use of radioactive material, and the management of radioactive waste must therefore be subject to standards of safety.

Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences.

States have an obligation of diligence and duty of care, and are expected to fulfil their national and international undertakings and obligations.

International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection. International safety standards also promote and assure confidence in safety and facilitate international commerce and trade.

A global nuclear safety regime is in place and is being continuously improved. IAEA safety standards, which support the implementation of binding international instruments and national safety infrastructures, are a cornerstone of this global regime. The IAEA safety standards constitute a useful tool for contracting parties to assess their performance under these international conventions.

THE IAEA SAFETY STANDARDS

The status of the IAEA safety standards derives from the IAEA's Statute, which authorizes the IAEA to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property, and to provide for their application.

With a view to ensuring the protection of people and the environment from harmful effects of ionizing radiation, the IAEA safety standards establish fundamental safety principles, requirements and measures to control the radiation exposure of people and the release of radioactive material to the environment, to 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 to mitigate the consequences of such events if they were to occur. The standards apply to facilities and activities that give rise to radiation risks, including nuclear installations, the use of radiation and radioactive sources, the transport of radioactive material and the management of radioactive waste.

Safety measures and security measures¹ have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are issued in the IAEA Safety Standards Series, which has three categories (see Fig. 1).

Safety Fundamentals

Safety Fundamentals present the fundamental safety objective and principles of protection and safety, and provide the basis for the safety requirements.

Safety Requirements

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. Requirements, including numbered ‘overarching’ requirements, are expressed as ‘shall’ statements. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

¹ See also publications issued in the IAEA Nuclear Security Series.

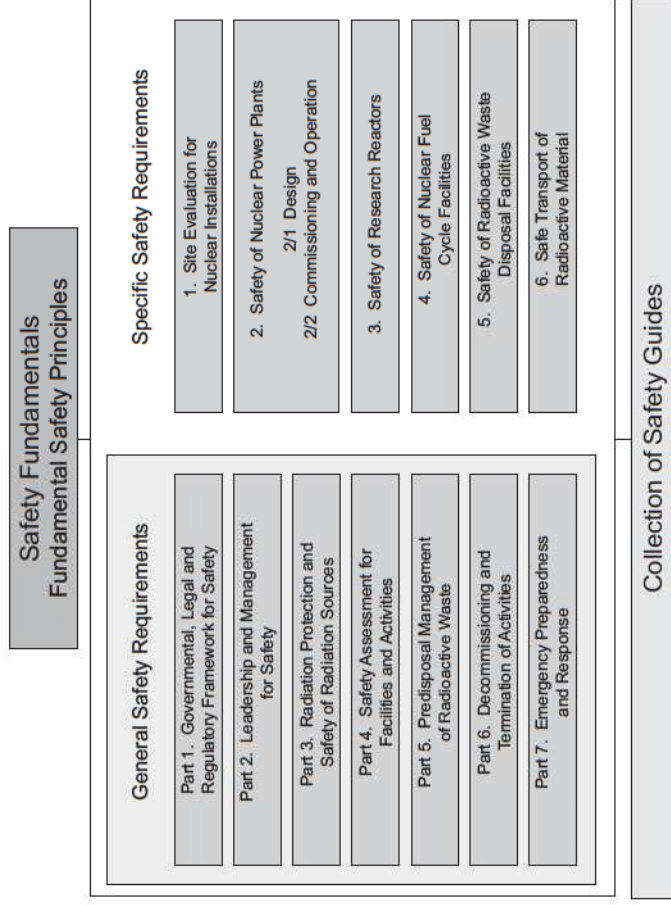


FIG. 1. The long term structure of the IAEA Safety Standards Series.

Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as ‘should’ statements.

APPLICATION OF THE IAEA SAFETY STANDARDS

The principal users of safety standards in IAEA Member States are regulatory bodies and other relevant national authorities. The IAEA safety standards are also used by co-sponsoring organizations and by many organizations that design, construct and operate nuclear facilities, as well as organizations involved in the use of radiation and radioactive sources.

The IAEA safety standards are applicable, as relevant, throughout the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes and to protective actions to reduce existing radiation risks. They can be used by States as a reference for their national regulations in respect of facilities and activities.

The IAEA's Statute makes the safety standards binding on the IAEA in relation to its own operations and also on States in relation to IAEA assisted operations.

The IAEA safety standards also form the basis for the IAEA's safety review services, and they are used by the IAEA in support of competence building, including the development of educational curricula and training courses.

International conventions contain requirements similar to those in the IAEA safety standards and make them binding on contracting parties. The IAEA safety standards, supplemented by international conventions, industry standards and detailed national requirements, establish a consistent basis for protecting people and the environment. There will also be some special aspects of safety that need to be assessed at the national level. For example, many of the IAEA safety standards, in particular those addressing aspects of safety in planning or design, are intended to apply primarily to new facilities and activities. The requirements established in the IAEA safety standards might not be fully met at some existing facilities that were built to earlier standards. The way in which IAEA safety standards are to be applied to such facilities is a decision for individual States.

The scientific considerations underlying the IAEA safety standards provide an objective basis for decisions concerning safety; however, decision makers must also make informed judgements and must determine how best to balance the benefits of an action or an activity against the associated radiation risks and any other detrimental impacts to which it gives rise.

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

The preparation and review of the safety standards involves the IAEA Secretariat and five safety standards committees, for emergency preparedness and response (EPReSC) (as of 2016), nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on Safety Standards (CSS) which oversees the IAEA safety standards programme (see Fig. 2).

All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of

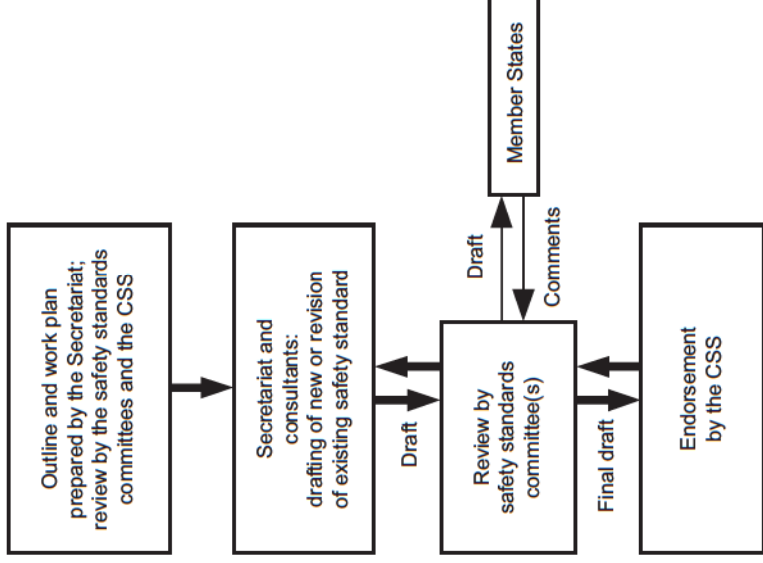


FIG. 2. The process for developing a new safety standard or revising an existing standard.

the Commission on Safety Standards is appointed by the Director General and includes senior governmental officials having responsibility for establishing national standards.

A management system has been established for the processes of planning, developing, reviewing, revising and establishing the IAEA safety standards. It articulates the mandate of the IAEA, the vision for the future application of the safety standards, policies and strategies, and corresponding functions and responsibilities.

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international

expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the IAEA safety standards. Some safety standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

INTERPRETATION OF THE TEXT

Safety related terms are to be understood as defined in the IAEA Safety Glossary (see <http://www-ns.iaea.org/standards/safety-glossary.htm>). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard in the IAEA Safety Standards Series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the body text, or describes methods of calculation, procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the safety standard. Material in an appendix has the same status as the body text, and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. Annexes and footnotes are not integral parts of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material under other authorship may be presented in annexes to the safety standards. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.

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1. INTRODUCTION

BACKGROUND

1.1. This Safety Requirements publication establishes requirements for establishing, assessing, sustaining and continuously improving effective leadership and management for safety in organizations concerned with, and facilities and activities that give rise to, radiation¹ risks. This includes the regulatory body and other competent authorities, and the organization responsible for the facility or for the activity.

1.2. This Safety Requirements publication supersedes IAEA Safety Standards Series No. GS-R-3 on the Management System for Facilities and Activities². This Safety Requirements publication develops the concepts of the publication of 2006 and takes into account lessons drawn from experience in events that have occurred. It emphasizes that leadership for safety, management for safety, an integrated management system and a systemic approach (i.e. an approach relating to the system as a whole in which the interactions between technical, human and organizational factors are duly considered) are essential to the specification and application of adequate safety measures and the fostering of a strong safety culture [1].

1.3. Management systems that are designed to fulfil the requirements of this Safety Requirements publication will integrate safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements³. The management system supports the achievement of the fundamental safety objective of protecting people and the environment from harmful effects of ionizing radiation [1], and takes into account the interfaces between safety and security. Experience from Member States in developing, applying, sustaining and improving management systems was taken into account in the development of this safety standard.

¹ 'Radiation' as used here means ionizing radiation.

² INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-R-3, IAEA, Vienna (2006).

³ 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.

1.4. Effective application of the requirements of this Safety Requirements 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 Safety Requirements publication establishes requirements for ensuring safety on the basis of the interrelated concepts of:

- (a) Leadership⁴ for safety: by establishing and integrating the organization’s vision, goals, strategies, plans and objectives; by advocating individual commitment to the protection of people and the environment from harmful effects of ionizing radiation; and by advocating the fundamental safety principles [1], establishing behavioural expectations and fostering a strong safety culture [2].
- (b) Management for safety: this includes establishing and applying an effective management system. This management 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 the need to meet other requirements or demands. Safety measures and security measures must be designed and applied in an integrated manner [1]. The management system also has to ensure the fostering of a strong safety culture, the regular assessment of safety performance and the application of lessons from experience. The management system also supports the development of proactive and responsive management.

1.6. Principle 1 of 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 organizations that are responsible for facilities and activities that give rise to radiation risks and that therefore have the prime responsibility for the safety of such facilities and activities.

⁴ ‘Leadership’ is the use of an individual’s capabilities and competences to give direction to individuals and groups and to influence their commitment to achieving the fundamental safety objective and to applying the fundamental safety principles, by means of shared goals, values and behaviour. ‘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. Managers at all levels need to be leaders for safety.

1.7. The requirements established in this Safety Requirements publication are intended for use in the following ways:

- (a) By the registrant or licensee, for establishing and sustaining leadership and management on the part of organizations and managers responsible for facilities and activities⁵ that give rise to radiation risks⁶ [1–3];
- (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 vendor's or supplier's management system;
- (c) By the regulatory body, as part of the basis for the regulation of facilities and activities;
- (d) By the regulatory body and other relevant governmental organizations, as a basis for meeting their responsibilities for arrangements⁷ in relation to leadership and management, in conjunction with the requirements established in Ref. [4].

1.8. The requirements established in this Safety Requirements publication apply to all types of facilities and activities, as specified in para. 1.11. However,

⁵ 'Facilities' includes: nuclear facilities; irradiation installations; some mining and raw material processing facilities such as uranium mines; radioactive waste management facilities; and 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. 'Activities' includes: the production, use, import and export of radiation sources for industrial, research and medical purposes; the transport of radioactive material; the decommissioning of facilities; radioactive waste management activities such as the discharge of effluents; and some aspects of the remediation of sites affected by residues from past activities.

⁶ The term 'radiation risks' is defined as:

- Detrimental health effects of exposure to radiation (including the likelihood of such effects occurring);
- Any other safety related risks (including those to 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.

⁷ 'Arrangements' in this context means 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.

the way in which the requirements are to be met will vary depending on the safety significance and complexity of the facility or activity. Recommendations and guidance on meeting the requirements are provided in Safety Guides. Other international standards or national standards⁸ may be used in addition to the requirements of this Safety Requirements publication.

OBJECTIVE

1.9. The objective of this Safety Requirements publication is to establish requirements that support Principle 3 of Fundamental Safety Principles [1], in relation to establishing, sustaining and continuously improving leadership and management for safety, and an effective management system. This is essential in order to foster and sustain a strong safety culture in an organization. Another objective is to establish requirements that apply Principle 8, which states that “All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.”

SCOPE

1.10. ‘Safety’ encompasses the protection of people and the environment against radiation risks and the safety of facilities and activities that give rise to radiation risks.

1.11. The requirements in this Safety Requirements publication apply to 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) [5, 6];

⁸ International standards are, for example, those of the International Organization for Standardization or the European Foundation for Quality Management; national standards are, for example, British standards on Occupational Health and Safety Management or the Nuclear Quality Assurance standards of the United States of America.

- (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 the remediation of sites affected by residual radioactive material from past activities [7];
- (e) Any other places where radioactive material is produced, processed, used, handled, stored or disposed of on such a scale that consideration of protection and safety is required, or where a radiation generator is installed;
- (f) Activities involving the production, use, or import and export of sources of ionizing radiation for medical, industrial, agricultural, educational and research purposes;
- (g) The transport of radioactive material [8];
- (h) The decommissioning (or closure) of facilities [9];
- (i) Activities involving the design and manufacture of equipment and other works for and services to facilities or activities that give rise to radiation risks [10];
- (j) Industrial activities involving naturally occurring radioactive material that are, or that may be, subject to the requirements for protection and safety.

1.12. The requirements in this Safety Requirements publication also apply in relation to the functions and activities of the regulatory body, as far as is appropriate. Regulatory bodies and other government organizations may need to adapt the requirements in accordance with their own organizations' accountabilities [4].

1.13. This Safety Requirements publication applies to registrants and licensees throughout the lifetime of facilities and the 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.

1.14. This Safety Requirements publication does not specify all those specific health, environment, security, quality and economic requirements to be addressed that have been established elsewhere (in other IAEA safety standards and in other international codes and standards).

STRUCTURE

1.15. This Safety Requirements publication comprises six sections. Section 2 establishes requirements for the responsibility for safety and for 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 organization to foster and support a culture for safety. Section 6 establishes requirements for measurement, assessment and improvement.

2. RESPONSIBILITY FOR SAFETY

Requirement 1: Achieving the fundamental safety objective

The registrant or licensee — starting 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.

2.1. The registrant or licensee shall ensure that provisions are made to achieve the fundamental safety objective.

2.2. The senior management of organizations, in accordance with their accountabilities:

- (a) Shall ensure the safe siting, design, construction, commissioning, operation and decommissioning (or closure) of facilities [2, 9, 11–14];
- (b) Shall ensure that equipment and activities meet safety standards, quality standards and management standards;
- (c) Shall ensure the safe management and control of all radioactive material and radiation sources that are produced, processed, used, handled, transported, stored or disposed of [5, 15];

- (d) Shall ensure that managers at all levels in the organization develop and maintain an understanding of radiation risks and potential consequences, and of how to manage radiation risks relevant to their responsibilities [16];⁹
- (e) Shall ensure that provision is made for adequate resources and funding, including for the long term management and disposal of radioactive waste, as well as for decommissioning (or closure) of facilities, with due consideration given to the protection of future generations [9, 15, 17];
- (f) Shall ensure that adequate arrangements are made where appropriate for preparedness and response for a nuclear or radiological emergency [18, 19].

3. LEADERSHIP FOR SAFETY

Requirement 2: Demonstration of leadership for safety by managers

Managers shall demonstrate leadership for safety and commitment to safety.

- 3.1. The senior management of the organization shall demonstrate leadership for safety by:
 - (a) Establishing, advocating and adhering to an organizational approach to safety that stipulates that, as an overriding priority, issues relating to protection and safety receive the attention warranted by their significance;
 - (b) Acknowledging that safety encompasses interactions between people, technology and the organization [2];
 - (c) Establishing behavioural expectations and fostering a strong safety culture;
 - (d) Establishing the acceptance of personal accountability in relation to safety on the part of all individuals in the organization and establishing that decisions taken at all levels take account of the priorities and accountabilities for safety.

⁹ Some personnel are accredited or authorized by means of a regulatory process that may be separate or partly separate from the organization's management. However, the maintenance of skills and knowledge, and the continued eligibility for accreditation or authorization, will be the responsibility of the senior management throughout the period of time for which a person is employed by the organization.

3.2. Managers at all levels in the organization, taking into account their duties, shall ensure that their leadership includes:

- (a) Setting goals for safety that are consistent with the organization's policy for safety, actively seeking information on safety performance within their area of responsibility and demonstrating commitment to improving safety performance;
- (b) Development of individual and institutional values and expectations for safety throughout the organization by means of their decisions, statements and actions;
- (c) Ensuring that their actions serve to encourage the reporting of safety related problems, to develop questioning and learning attitudes, and to correct acts or conditions that are adverse to safety.

3.3. Managers at all levels in the organization:

- (a) Shall encourage and support all individuals in achieving safety goals and performing their tasks safely;
- (b) Shall engage all individuals in enhancing safety performance;
- (c) Shall communicate clearly the basis for decisions relevant to safety.

4. MANAGEMENT FOR SAFETY

RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

Requirement 3: Responsibility of senior management for the management system

Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety.

4.1. Senior management shall retain accountability for the management system even where individuals are assigned responsibility for coordinating the development, application and maintenance of the management system [1, 2].

4.2. Senior management shall be responsible for establishing safety policy.

Requirement 4: 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.

- 4.3. Goals, strategies, plans and objectives for the organization shall be developed in such a manner that safety is not compromised by other priorities.
- 4.4. Senior management shall ensure that measurable safety goals that are in line with these strategies, plans and objectives are established at various levels in the organization.
- 4.5. Senior management shall ensure that goals, strategies and plans are periodically reviewed against the safety objectives, and that actions are taken where necessary to address any deviations.

Requirement 5: Interaction with interested parties

Senior management shall ensure that appropriate interaction with interested parties takes place.

- 4.6. Senior management shall identify interested parties for their organization and shall define an appropriate strategy for interaction with them.
- 4.7. Senior management shall ensure that the processes and plans resulting from the strategy for interaction with interested parties include:
 - (a) Appropriate means of communicating routinely and effectively with and informing interested parties with regard to radiation risks associated with the operation of facilities and the conduct of activities;
 - (b) Appropriate means of timely and effective communication with interested parties in circumstances that have changed or that were unanticipated;
 - (c) Appropriate means of dissemination to interested parties of necessary information relevant to safety;
 - (d) Appropriate means of considering in decision making processes the concerns and expectations of interested parties in relation to safety.

THE MANAGEMENT SYSTEM

Requirement 6: Integration of the management system

The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised.

4.8. The management system shall be developed, applied and continuously improved. It shall be aligned with the safety goals of the organization.

4.9. The management system shall be applied to achieve goals safely, to enhance safety and to foster a strong safety culture by:

- (a) Bringing together in a coherent manner all the necessary elements for safely managing the organization and its activities;
- (b) Describing the arrangements made for management of the organization and its activities;
- (c) Describing the planned and systematic actions necessary to provide confidence that all requirements are met;
- (d) Ensuring that safety is taken into account in decision making and is not compromised by any decisions taken.

4.10. Arrangements shall be made in the management system for the resolution of conflicts arising in decision making processes. Potential impacts of security measures on safety and potential impacts of safety measures on security shall be identified and shall be resolved without compromising safety or security [20–23].

4.11. The organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations shall be clearly specified in the management system.

4.12. Regulatory requirements shall be reflected in the management system.

4.13. Provision shall be made in the management system to identify any changes (including organizational changes and the cumulative effects of minor changes) that could have significant implications for safety and to ensure that they are appropriately analysed.

4.14. Arrangements shall be established in the management system for an independent review to be made before decisions significant for safety are made.

The requirements on the independent nature of the review and on the necessary competences of the reviewers shall be specified in the management system.

Requirement 7: Application of the graded approach to the management system

The management system shall be developed and applied using a graded approach.

4.15. The criteria used to grade the development and application of the management system shall be documented in the management system. The following shall be taken into account:

- (a) The safety significance and complexity of the organization, operation of the facility or conduct of the activity;
- (b) The hazards and the magnitude of the potential impacts (risks) associated with the safety, health, environmental, security, quality and economic elements of each facility or activity [16, 24–26];
- (c) The possible consequences for safety if a failure or an unanticipated event occurs or if an activity is inadequately planned or improperly carried out.

Requirement 8: 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.

4.16. The documentation of the management system shall include as a minimum: policy statements of the organization on values and behavioural expectations; the fundamental safety objective; a description of the organization and its structure; a description of the responsibilities and accountabilities; the levels of authority, including all interactions of those managing, performing and assessing work and including all processes; a description of how the management system complies with regulatory requirements that apply to the organization; and a description of the interactions with external organizations and with interested parties.

4.17. Documents shall be controlled. All individuals responsible for preparing, reviewing, revising and 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.

4.18. Revisions to documents shall be controlled, reviewed and recorded. Revised documents shall be subject to the same level of approval as the initial documents.

4.19. Records shall be specified in the management system and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable.

4.20. 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.

MANAGEMENT OF RESOURCES

Requirement 9: Provision of resources

Senior management shall determine the competences and resources necessary to carry out the activities of the organization safely and shall provide them.

4.21. Senior management shall make arrangements to ensure that the organization has in-house, or maintains access to, the full range of competences and the resources necessary to conduct its activities and to discharge its responsibilities for ensuring safety at each stage in the lifetime of the facility or activity, and during an emergency response [13, 14, 18].¹⁰

4.22. Senior management shall determine which competences and resources the organization has to retain or has to develop internally, and which competences and resources may be obtained externally, for ensuring safety.

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

¹⁰ 'Resources' includes individuals (the number of individuals and their competences), infrastructure, the working environment, knowledge and information, and suppliers, as well as material and financial resources.

4.24. Competences to be sustained in-house by the organization shall include: competences for leadership at all management levels; competences for fostering and sustaining a strong safety culture; and expertise to understand technical, human and organizational aspects relating to the facility or the activity in order to ensure safety.

4.25. Senior management shall ensure that individuals at all levels, including managers and workers:

- (a) Are competent to perform their assigned tasks and to work safely and effectively;
- (b) Understand the standards that they are expected to apply in completing their tasks.

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

4.27. The knowledge and the information of the organization shall be managed as a resource.

MANAGEMENT OF PROCESSES AND ACTIVITIES

Requirement 10: Management of processes and activities

Processes and activities shall be developed and shall be effectively managed to achieve the organization's goals without compromising safety.

4.28. Each process shall be developed and shall be managed to ensure that requirements are met without compromising safety. Processes shall be documented and the necessary supporting documentation shall be maintained. It shall be ensured that process documentation is consistent with any existing documents of the organization. Records to demonstrate that the results of the respective process have been achieved shall be specified in the process documentation.

4.29. The sequencing of a process and the interactions between processes shall be specified so that safety is not compromised. Effective interaction between

interfacing processes shall be ensured. Particular consideration shall be given to interactions between processes within the organization, and to interactions between processes conducted by the organization and processes conducted by external service providers.

4.30. New processes or modifications to existing processes shall be designed, verified, approved and applied so that safety is not compromised. Processes, including any subsequent modifications to them, shall be aligned with the goals, strategies, plans and objectives of the organization.

4.31. 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, and verification and validation are required to be conducted.

4.32. Each process or activity that could have implications for safety shall be carried out under controlled conditions, by means of following readily understood, approved and current procedures, instructions and drawings. These procedures, instructions and drawings shall be validated before their 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 11: Management of the supply chain

The organization shall put in place arrangements with vendors, contractors and suppliers for specifying, monitoring and managing the supply to it of items, products and services that may influence safety.

4.33. The organization shall retain responsibility for safety when contracting out any processes and when receiving any item, product or service in the supply chain¹¹.

¹¹ The supply chain, described as 'suppliers', typically includes: designers, vendors, manufacturers and constructors, employers, contractors, subcontractors, and consigners and carriers who supply safety related items. The supply chain can also include other parts of the organization and parent organizations.

4.34. The organization shall have a clear understanding and knowledge of the product or service being supplied¹². 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 the applicable safety requirements.

4.35. The management system shall include arrangements for qualification, selection, evaluation, procurement, and oversight of the supply chain.

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

5. CULTURE FOR SAFETY

Requirement 12: Fostering a culture for safety

Individuals in the organization, from senior managers downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture.

5.1. All individuals in the organization shall contribute to fostering and sustaining a strong safety culture [1, 2].

5.2. Senior managers and all other managers shall advocate and support the following:

- (a) A common understanding of safety and of safety culture, including: awareness of radiation risks and hazards relating to work and to the working environment; an understanding of the significance of radiation risks and hazards for safety; and a collective commitment to safety by teams and individuals;
- (b) Acceptance by individuals of personal accountability for their attitudes and conduct with regard to safety;

¹² 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' capability.

- (c) An organizational culture that supports and encourages trust, collaboration, consultation and communication;
- (d) The reporting of problems relating to technical, human and organizational factors and reporting of any deficiencies in structures, systems and components to avoid degradation of safety, including the timely acknowledgement of, and reporting back of, actions taken;
- (e) Measures to encourage a questioning and learning attitude at all levels in the organization and to discourage complacency with regard to safety;
- (f) The means by which the organization seeks to enhance safety and to foster and sustain a strong safety culture, and using a systemic approach (i.e. an approach relating to the system as a whole in which the interactions between technical, human and organizational factors are duly considered);
- (g) Safety oriented decision making in all activities;
- (h) The exchange of ideas between, and the combination of, safety culture and security culture.

6. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

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

The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety.

6.1. The effectiveness of the management system shall be monitored and measured to confirm the ability of the organization to achieve the results intended and to identify opportunities for improvement of the management system.

6.2. All processes shall be regularly evaluated for their effectiveness and for their ability to ensure safety.

6.3. The causes of non-conformances of processes and the causes of safety related events that could give rise to radiation risks shall be evaluated and any consequences shall be managed and shall be 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, shall be determined, and corrective actions shall be taken in a timely manner.

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

6.4. Independent assessments and self-assessments of the management system shall be regularly conducted to evaluate its effectiveness and to identify opportunities for its improvement. Lessons and any resulting significant changes shall be analysed for their implications for safety.

6.5. Responsibility shall be assigned for conducting independent assessments of the management system. The organizations, entities (in-house or external) and individuals assigned such responsibilities shall be given sufficient authority to discharge their responsibilities and shall have direct access to senior management. In addition, individuals conducting independent assessments of the management system shall not be assigned responsibility to assess areas under the responsibility of their own line management.

6.6. 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.

6.7. The management system shall include evaluation and timely use of the following:

- (a) Lessons from experience gained and from events that have occurred, both within the organization and outside the organization, and lessons from identifying the causes of events;
- (b) Technical advances and results of research and development;
- (c) Lessons from identifying good practices.

6.8. Organizations shall make arrangements to learn from successes and from strengths for their organizational development and continuous improvement.

Requirement 14: Measurement, assessment and improvement of leadership for safety and of safety culture

Senior management shall regularly commission assessments of leadership for safety and of safety culture in its own organization.

6.9. Senior management shall ensure that self-assessment of leadership for safety and of safety culture includes assessment at all organizational levels and for all functions in the organization. Senior management shall ensure that such self-assessment makes use of recognized experts in the assessment of leadership and of safety culture.

6.10. Senior management shall ensure that an independent assessment of leadership for safety and of safety culture is conducted for enhancement of the organizational culture for safety (i.e. the organizational culture as it relates to safety and as it fosters a strong safety culture in the organization).

6.11. The results of self-assessments and independent assessments of leadership for safety and of safety culture [1] shall be communicated at all levels in the organization. The results of such assessments shall be acted upon to foster and sustain a strong safety culture, to improve leadership for safety and to foster a learning attitude within the organization.

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Director General

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