

IAEA Safety Standards

for protecting people and the environment

The Management System for Facilities and Activities

Safety Requirements

No. GS-R-3



IAEA

International Atomic Energy Agency

IAEA SAFETY 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, and also general safety (i.e. all these areas of safety). The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

Safety standards are coded according to their coverage: nuclear safety (NS), radiation safety (RS), transport safety (TS), waste safety (WS) and general safety (GS).

Information on the IAEA's safety standards programme is available at 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 P.O. Box 100, A-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 e-mail to Official.Mail@iaea.org.

OTHER SAFETY 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 and protection in nuclear activities are issued in other publications series, in particular the **Safety Reports Series**. Safety Reports provide practical examples and detailed methods that can be used in support of the safety standards. Other IAEA series of safety related publications are the **Provision for the Application of Safety Standards Series**, the **Radiological Assessment Reports Series** and the International Nuclear Safety Group's **INSAG Series**. The IAEA also issues reports on radiological accidents and other special publications.

Safety related publications are also issued in the **Technical Reports Series**, the **IAEA-TECDOC Series**, the **Training Course Series** and the **IAEA Services Series**, and as **Practical Radiation Safety Manuals** and **Practical Radiation Technical Manuals**. Security related publications are issued in the **IAEA Nuclear Security Series**.

THE MANAGEMENT SYSTEM
FOR FACILITIES AND ACTIVITIES

Safety standards survey

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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".

IAEA SAFETY STANDARDS SERIES No. GS-R-3

THE MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

SAFETY REQUIREMENTS

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2006

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FOREWORD

**by Mohamed ElBaradei
Director General**

The IAEA's Statute authorizes the Agency to establish safety standards to protect health and minimize danger to life and property — standards which the IAEA must use in its own operations, and which a State can apply by means of its regulatory provisions for nuclear and radiation safety. A comprehensive body of safety standards under regular review, together with the IAEA's assistance in their application, has become a key element in a global safety regime.

In the mid-1990s, a major overhaul of the IAEA's safety standards programme was initiated, with a revised oversight committee structure and a systematic approach to updating the entire corpus of standards. The new standards that have resulted are of a high calibre and reflect best practices in Member States. With the assistance of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its safety standards.

Safety standards are only effective, however, if they are properly applied in practice. The IAEA's safety services — which range in scope from engineering safety, operational safety, and radiation, transport and waste safety to regulatory matters and safety culture in organizations — assist Member States in applying the standards and appraise their effectiveness. These safety services enable valuable insights to be shared and I continue to urge all Member States to make use of them.

Regulating nuclear and radiation safety is a national responsibility, and many Member States have decided to adopt the IAEA's safety standards for use in their national regulations. For the Contracting 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 designers, manufacturers and operators around the world to enhance nuclear and radiation safety in power generation, medicine, industry, agriculture, research and education.

The IAEA takes seriously the enduring challenge for users and regulators everywhere: that of ensuring a high level of safety in the use of nuclear materials and radiation sources around the world. Their continuing utilization for the benefit of humankind must be managed in a safe manner, and the IAEA safety standards are designed to facilitate the achievement of that goal.

IAEA SAFETY STANDARDS

SAFETY THROUGH INTERNATIONAL STANDARDS

While safety is a national responsibility, international standards and approaches to safety promote consistency, help to provide assurance that nuclear and radiation related technologies are used safely, and facilitate international technical cooperation, commerce and trade.

The standards also provide support for States in meeting their international obligations. One general international obligation is that a State must not pursue activities that cause damage in another State. More specific obligations on Contracting States are set out in international safety related conventions. The internationally agreed IAEA safety standards provide the basis for States to demonstrate that they are meeting these obligations.

THE IAEA STANDARDS

The IAEA safety standards have a status derived from the IAEA's Statute, which authorizes the Agency to establish standards of safety for nuclear and radiation related facilities and activities and to provide for their application.

The safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment.

They are issued in the IAEA Safety Standards Series, which has three categories:

Safety Fundamentals

- Presenting the objectives, concepts and principles of protection and safety and providing the basis for the safety requirements.

Safety Requirements

- Establishing the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements, which are expressed as 'shall' statements, are governed by the objectives, concepts and principles of the Safety Fundamentals. If they are not met, measures must be taken to reach or restore the required level of safety. The Safety Requirements use regulatory language to enable them to be incorporated into national laws and regulations.

Safety Guides

- Providing recommendations and guidance on how to comply with the Safety Requirements. Recommendations in the Safety Guides are expressed as 'should' statements. It is recommended to take the measures stated 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. Each Safety Requirements publication is supplemented by a number of Safety Guides, which can be used in developing national regulatory guides.

The IAEA safety standards need to be complemented by industry standards and must be implemented within appropriate national regulatory infrastructures to be fully effective. The IAEA produces a wide range of technical publications to help States in developing these national standards and infrastructures.

MAIN USERS OF THE STANDARDS

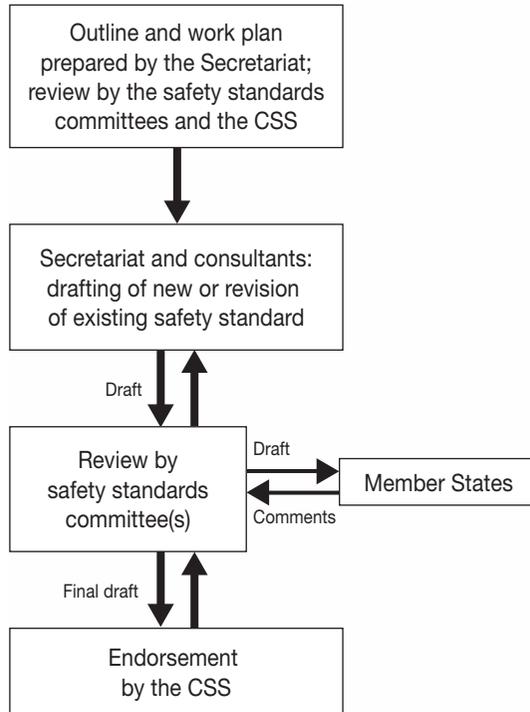
As well as by regulatory bodies and governmental departments, authorities and agencies, the standards are used by authorities and operating organizations in the nuclear industry; by organizations that design, manufacture for and apply nuclear and radiation related technologies, including operating organizations of facilities of various types; by users and others involved with radiation and radioactive material in medicine, industry, agriculture, research and education; and by engineers, scientists, technicians and other specialists. The standards are used by the IAEA itself in its safety reviews and for developing education and training courses.

DEVELOPMENT PROCESS FOR THE STANDARDS

The preparation and review of safety standards involves the IAEA Secretariat and four safety standards committees for safety in the areas of 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 entire safety standards programme. All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of the CSS is appointed by the Director General and includes senior government officials having responsibility for establishing national standards.

For Safety Fundamentals and Safety Requirements, the drafts endorsed by the Commission are submitted to the IAEA Board of Governors for approval for publication. Safety Guides are published on the approval of the Director General.

Through this process the standards come to represent a consensus view of the IAEA's Member States. 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 standards. Some 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 International



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

Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

The safety standards are kept up to date: five years after publication they are reviewed to determine whether revision is necessary.

APPLICATION AND SCOPE OF THE STANDARDS

The IAEA Statute makes the safety standards binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA. Any State wishing to enter into an agreement with the IAEA concerning any form of Agency assistance is required to comply with the requirements of the safety standards that pertain to the activities covered by the agreement.

International conventions also contain similar requirements to those in the safety standards, and make them binding on contracting parties. The Safety Fundamentals were used as the basis for the development of the Convention on Nuclear Safety and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. The Safety

Requirements on Preparedness and Response for a Nuclear or Radiological Emergency reflect the obligations on States under the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

The safety standards, incorporated into national legislation and regulations and supplemented by international conventions and detailed national requirements, establish a basis for protecting people and the environment. However, there will also be special aspects of safety that need to be assessed case by case at the national level. For example, many of the safety standards, particularly those addressing planning or design aspects of safety, are intended to apply primarily to new facilities and activities. The requirements and recommendations specified in the IAEA safety standards might not be fully met at some facilities built to earlier standards. The way in which the safety standards are to be applied to such facilities is a decision for individual States.

INTERPRETATION OF THE TEXT

The safety standards use the form 'shall' in establishing international consensus requirements, responsibilities and obligations. Many requirements are not addressed to a specific party, the implication being that the appropriate party or parties should be responsible for fulfilling them. Recommendations are expressed as 'should' statements in the main text (body text and appendices), indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures) for complying with the requirements.

Safety related terms are to be interpreted as stated in the IAEA Safety Glossary (<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 within the 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 main text, is included in support of statements in the main text, or describes methods of calculation, experimental 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 standard. Material in an appendix has the same status as the main 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 published in standards that is under other authorship may be presented in annexes. 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 defines the requirements for establishing, implementing, assessing and continually improving a management system. A management system designed to fulfil these requirements integrates safety, health, environmental, security¹, quality² and economic³ elements. Safety is the fundamental principle upon which the management system is based. These requirements must be met to ensure the protection of people and the environment and they are governed by the objectives, concepts and principles of the IAEA Safety Fundamentals publication [1].

1.2. The standards of the International Organization for Standardization on environmental management systems [2] and on quality management systems [3] were considered in developing this publication. The experience of Member States in developing, implementing and improving management systems was also taken into account.

1.3. The content of this publication supports the achievement of the two general aims of the management system, as stated by the International Nuclear Safety Group (INSAG) [4]:

- “To improve the safety performance of the organization through the planning, control and supervision of safety related activities in normal, transient and emergency situations;
- “To foster and support a strong safety culture through the development and reinforcement of good safety attitudes and behaviour in individuals and teams so as to allow them to carry out their tasks safely.”

¹ This Safety Requirements publication covers the security of facilities, nuclear material and sources of radiation only to the extent that security measures for physical protection are essential to safety and the failure of such measures has consequences for safety.

² Quality refers to the degree to which a product, process or service satisfies specified requirements.

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. This Safety Requirements publication supersedes the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations [5]. It uses the term ‘management system’ rather than ‘quality assurance’. The term management system reflects and includes the initial concept of ‘quality control’ (controlling the quality of products) and its evolution through quality assurance (the system to ensure the quality of products) and ‘quality management’ (the system to manage quality). The management system is a set of interrelated or interacting elements that establishes policies and objectives and which enables those objectives to be achieved in a safe, efficient and effective manner.

1.5. The content of this publication is based on two key concepts: that work may be structured and interpreted as a set of interacting processes; and that all individuals involved contribute to achieving safety and quality objectives.

1.6. The requirements established in this publication may be used by organizations in the following ways:

- As the basis for the management systems of organizations directly responsible for operating facilities and activities and providing services, as described in para. 1.8;
- As the basis for the regulation of these facilities and activities by the regulatory body;
- As the basis for the management systems of the relevant regulatory bodies [6];
- By the operator, to specify to a supplier, via contractual documentation, any specific requirements of this Safety Requirements publication that must be included in the supplier’s management system for the supply and delivery of products⁴.

1.7. A Safety Guide in support of this publication provides generic guidance on the application of the management system for all facilities and activities and for their regulation [7]. In addition to the generic guidance, there are several specific Safety Guides that provide additional guidance on implementing these requirements in specific areas.

⁴ A product is the result or output of a process. Examples include a radionuclide, a waste package and electricity.

OBJECTIVE

1.8. The objective of this publication is to define requirements for establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security, quality and economic elements to ensure that safety is properly taken into account in all the activities of an organization.

1.9. The main objective of the requirements for the management system is to ensure, by considering the implications of all actions not within separate management systems but with regard to safety as a whole, that safety is not compromised.⁵

SCOPE

1.10. This publication is applicable to the establishment, implementation, assessment and continual improvement of management systems for:

- Nuclear facilities;
- Activities using sources of ionizing radiation;
- Radioactive waste management;
- The transport of radioactive material;
- Radiation protection activities;
- Any other practices or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources;
- The regulation of such facilities and activities.

1.11. This Safety Requirements publication is applicable throughout the lifetime of facilities and for the entire duration of activities in normal, transient and emergency situations. This includes any subsequent period of institutional control that may be necessary. For a facility, these phases usually include siting, design, construction, commissioning, operation and decommissioning (or close-out or closure).

1.12. This publication does not attempt to define all those specific health, environmental, security, quality and economic requirements to be addressed

⁵ There have been many instances in which decisions have been taken without considering the impact on safety (e.g. economic decisions such as reducing costs by cutting staff), which has led to safety related problems.

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 those specific requirements; rather, it defines the requirements for managing their fulfilment in an integrated manner.

1.13. The integrated management system requirements defined in this publication cover topics that either relate directly to safety or are part of the managerial framework without which safety cannot be ensured and maintained. Thus topics such as management commitment, communications and other aspects are included from the perspective of seeking to enhance safety as well as performance.

STRUCTURE

1.14. This Safety Requirements publication consists of six sections. Section 2 establishes the general requirements for the management system, including those relating to safety culture, grading and documentation. Section 3 establishes the requirements for and responsibilities of senior management⁶ for the development and implementation of a management system. Section 4 establishes the requirements for resource management. Section 5 establishes the requirements for the processes of the organization — their specification, development and management — and for the generic processes of the management system. Section 6 establishes the requirements for measuring, assessing and improving the management system.

2. MANAGEMENT SYSTEM

GENERAL REQUIREMENTS

2.1. A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and

⁶ ‘Senior management’ means the person who, or group of people which, directs, controls and assesses an organization at the highest level. Many different terms are used, including, for example: chief executive officer (CEO), director general, executive team, plant manager, top manager, chief regulator, site vice-president, managing director and laboratory director.

shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:

- Bringing together in a coherent manner all the requirements for managing the organization;
- Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;
- Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.

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

2.3. The management system shall identify and integrate with the requirements contained within this publication:

- The statutory and regulatory requirements of the Member State;
- Any requirements formally agreed with interested parties (also known as ‘stakeholders’⁷);
- All other relevant IAEA Safety Requirements publications, such as those on emergency preparedness and response [8] and safety assessment [9];

⁷ Stakeholder: interested party; concerned party. ‘Stakeholder’ means an interested party – whether a person or a company, etc. – with an interest or concern in ensuring the success of an organization, business, system, etc. To ‘have a stake in’ something figuratively means to have something to gain or lose by, or to have an interest in, the turn of events. The term stakeholder is used in a broad sense to mean a person or group having an interest in the performance of an organization. Those who can influence events may effectively become interested parties – whether their ‘interest’ is regarded as ‘genuine’ or not – in the sense that their views need to be considered. Interested parties have typically included the following: 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.

- Requirements from other relevant codes and standards adopted for use by the organization.

2.4. The organization shall be able to demonstrate the effective fulfilment of its management system requirements.

SAFETY CULTURE

2.5. The management system shall be used to promote and support a strong safety culture by:

- Ensuring a common understanding of the key aspects of safety culture within the organization;
- Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;
- Reinforcing a learning and questioning attitude at all levels of the organization;
- Providing the means by which the organization continually seeks to develop and improve its safety culture.

GRADING THE APPLICATION OF MANAGEMENT SYSTEM REQUIREMENTS

2.6. The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:

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

2.7. Grading of the application of management system requirements shall be applied to the products and activities of each process.

DOCUMENTATION OF THE MANAGEMENT SYSTEM

2.8. The documentation of the management system shall include the following:

- The policy statements of the organization;
- A description of the management system;
- A description of the structure of the organization;
- A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;
- A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.

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

2.10. The documentation of the management system shall reflect:

- The characteristics of the organization and its activities;
- The complexities of processes and their interactions.

3. MANAGEMENT RESPONSIBILITY

MANAGEMENT COMMITMENT

3.1. Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities.

3.2. Senior management shall develop individual values, institutional values and behavioural expectations for the organization to support the implementation of the management system and shall act as role models in the promulgation of these values and expectations.

3.3. Management at all levels shall communicate to individuals the need to adopt these individual values, institutional values and behavioural expectations as well as to comply with the requirements of the management system.

3.4. Management at all levels shall foster the involvement of all individuals in the implementation and continual improvement of the management system.

3.5. Senior management shall ensure that it is clear when, how and by whom decisions are to be made within the management system.

SATISFACTION OF INTERESTED PARTIES

3.6. The expectations of interested parties shall be considered by senior management in the activities and interactions in the processes of the management system, with the aim of enhancing the satisfaction of interested parties while at the same time ensuring that safety is not compromised.

ORGANIZATIONAL POLICIES

3.7. Senior management shall develop the policies of the organization. The policies shall be appropriate to the activities and facilities of the organization.

PLANNING

3.8. Senior management shall establish goals, strategies, plans and objectives⁸ that are consistent with the policies of the organization.

3.9. Senior management shall develop the goals, strategies, plans and objectives of the organization in an integrated manner so that their collective impact on safety is understood and managed.

3.10. Senior management shall ensure that measurable objectives for implementing the goals, strategies and plans are established through appropriate processes at various levels in the organization.

⁸ These goals, strategies, plans and objectives are sometimes collectively referred to as a 'business plan'.

3.11. Senior management shall ensure that the implementation of the plans is regularly reviewed against these objectives and that actions are taken to address deviations from the plans where necessary.

RESPONSIBILITY AND AUTHORITY FOR THE MANAGEMENT SYSTEM

3.12. Senior management shall be ultimately responsible for the management system and shall ensure that it is established, implemented, assessed and continually improved.

3.13. An individual reporting directly to senior management shall have specific responsibility and authority for:

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

3.14. The organization shall retain overall responsibility for the management system when an external organization is involved in the work of developing all or part of the management system.

4. RESOURCE MANAGEMENT

PROVISION OF RESOURCES

4.1. Senior management shall determine the amount of resources necessary and shall provide the resources⁹ to carry out the activities of the organization

⁹ 'Resources' includes individuals, infrastructure, the working environment, information and knowledge, and suppliers, as well as material and financial resources.

and to establish, implement, assess and continually improve the management system.

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

HUMAN RESOURCES

4.3. Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained.

4.4. Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organization's objectives.

INFRASTRUCTURE AND THE WORKING ENVIRONMENT

4.5. Senior management shall determine, provide, maintain and re-evaluate the infrastructure and the working environment necessary for work to be carried out in a safe manner and for requirements to be met.

5. PROCESS IMPLEMENTATION

DEVELOPING PROCESSES

5.1. The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of

the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved.

5.2. The sequence and interactions of the processes shall be determined.

5.3. The methods necessary to ensure the effectiveness of both the implementation and the control of the processes shall be determined and implemented.

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

- Process requirements, such as applicable regulatory, statutory, legal, safety, health, environmental, security, quality and economic requirements, are specified and addressed.
- Hazards and risks are identified, together with any necessary mitigatory actions.
- Interactions with interfacing processes are identified.
- Process inputs are identified.
- The process flow is described.
- Process outputs (products) are identified.
- Process measurement criteria are established.

5.5. The activities of and interfaces between different individuals or groups involved in a single process shall be planned, controlled and managed in a manner that ensures effective communication and the clear assignment of responsibilities.

PROCESS MANAGEMENT

5.6. For each process a designated individual shall be given the authority and responsibility for:

- Developing and documenting the process and maintaining the necessary supporting documentation;
- Ensuring that there is effective interaction between interfacing processes;
- Ensuring that process documentation is consistent with any existing documents;
- Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation;

- Monitoring and reporting on the performance of the process;
- Promoting improvement in the process;
- Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the organization.

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

5.8. Each process shall be evaluated to ensure that it remains effective.

5.9. The work performed in each process shall be carried out under controlled conditions, by using approved current procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness. Results shall be compared with expected values.

5.10. The control of processes contracted to external organizations shall be identified within the management system. The organization shall retain overall responsibility when contracting any processes.

GENERIC MANAGEMENT SYSTEM PROCESSES

5.11. The following generic processes shall be developed in the management system.

Control of documents

5.12. Documents¹⁰ shall be controlled. All individuals involved in preparing, revising, reviewing or approving documents shall be specifically assigned this work, shall be competent to carry it out and shall be given access to appropriate information on which to base their input or decisions. It shall be ensured that document users are aware of and use appropriate and correct documents.

¹⁰ Documents may include: policies; procedures; instructions; specifications and drawings (or representations in other media); training materials; and any other texts that describe processes, specify requirements or establish product specifications.

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

Control of products

5.14. Specifications and requirements for products, including any subsequent changes, shall be in accordance with established standards and shall incorporate applicable requirements. Products that interface or interact with each other shall be identified and controlled.

5.15. Activities for inspection, testing, verification and validation shall be completed before the acceptance, implementation or operational use of products. The tools and equipment used for these activities shall be of the proper range, type, accuracy and precision.

5.16. The organization shall confirm that products meet the specified requirements and shall ensure that products perform satisfactorily in service.

5.17. Products shall be provided in such a form that it can be verified that they satisfy the requirements.

5.18. Controls shall be used to ensure that products do not bypass the required verification activities.

5.19. Products shall be identified to ensure their proper use. Where traceability is a requirement, the organization shall control and record the unique identification of the product.

5.20. Products shall be handled, transported, stored, maintained and operated as specified, to prevent their damage, loss, deterioration or inadvertent use.

Control of records

5.21. Records shall be specified in the process documentation and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable.

5.22. Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and knowledge management obligations 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.

Purchasing

5.23. Suppliers of products shall be selected on the basis of specified criteria and their performance shall be evaluated.

5.24. Purchasing requirements shall be developed and specified in procurement documents. Evidence that products meet these requirements shall be available to the organization before the product is used.

5.25. Requirements for the reporting and resolution of non-conformances shall be specified in procurement documents.

Communication

5.26. Information relevant to safety, health, environmental, security, quality and economic goals shall be communicated to individuals in the organization and, where necessary, to other interested parties.

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

Managing organizational change

5.28. Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified.

5.29. The implementation of such changes shall be planned, controlled, communicated, monitored, tracked and recorded to ensure that safety is not compromised.

6. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

MONITORING AND MEASUREMENT

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

SELF-ASSESSMENT

6.2. Senior management and management at all other levels in the organization shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture.

INDEPENDENT ASSESSMENT

6.3. Independent assessments shall be conducted regularly on behalf of senior management:

- To evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives;
- To determine the adequacy of work performance and leadership;
- To evaluate the organization's safety culture;
- To monitor product quality;
- To identify opportunities for improvement.

6.4. An organizational unit shall be established with the responsibility for conducting independent assessments.¹¹ This unit shall have sufficient authority to discharge its responsibilities.

6.5. Individuals conducting independent assessments shall not assess their own work.

¹¹ The size of the assessment unit differs from organization to organization. In some organizations, the assessment function may even be a responsibility assigned to a single individual or to an external organization.

6.6. Senior management shall evaluate the results of the independent assessments, shall take any necessary actions, and shall record and communicate their decisions and the reasons for them.

MANAGEMENT SYSTEM REVIEW

6.7. A management system review shall be conducted at planned intervals to ensure the continuing suitability and effectiveness of the management system and its ability to enable the objectives set for the organization to be accomplished.

6.8. The review shall cover but shall not be limited to:

- Outputs from all forms of assessment;
- Results delivered and objectives achieved by the organization and its processes;
- Non-conformances and corrective and preventive actions;
- Lessons learned from other organizations;
- Opportunities for improvement.

6.9. Weaknesses and obstacles shall be identified, evaluated and remedied in a timely manner.

6.10. The review shall identify whether there is a need to make changes to or improvements in policies, goals, strategies, plans, objectives and processes.

NON-CONFORMANCES AND CORRECTIVE AND PREVENTIVE ACTIONS

6.11. The causes of non-conformances shall be determined and remedial actions shall be taken to prevent their recurrence.

6.12. Products and processes that do not conform to the specified requirements shall be identified, segregated, controlled, recorded and reported to an appropriate level of management within the organization. The impact of non-conformances shall be evaluated and non-conforming products or processes shall be either:

- Accepted;
- Reworked or corrected within a specified time period; or
- Rejected and discarded or destroyed to prevent their inadvertent use.

6.13. Concessions granted to allow acceptance of a non-conforming product or process shall be subject to authorization. When non-conforming products or processes are reworked or corrected, they shall be subject to inspection to demonstrate their conformity with requirements or expected results.

6.14. Corrective actions for eliminating non-conformances shall be determined and implemented. Preventive actions to eliminate the causes of potential non-conformances shall be determined and taken.

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

6.16. Potential non-conformances that could detract from the organization's performance shall be identified. This shall be done: by using feedback from other organizations, both internal and external; through the use of technical advances and research; through the sharing of knowledge and experience; and through the use of techniques that identify best practices.

IMPROVEMENT

6.17. Opportunities for the improvement of the management system shall be identified and actions to improve the processes shall be selected, planned and recorded.

6.18. Improvement plans shall include plans for the provision of adequate resources. Actions for improvement shall be monitored through to their completion and the effectiveness of the improvement shall be checked.

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GLOSSARY

facilities and activities. 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.

independent assessment. Assessments such as audits or surveillances carried out to determine the extent to which the requirements for the management system are fulfilled, to evaluate the effectiveness of the management system and to identify opportunities for improvement. They can be conducted by or on behalf of the organization itself for internal purposes, by interested parties such as customers and regulators (or by other persons on their behalf), or by external independent organizations.

management system. A set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective way.

The management system integrates all elements of an organization into one coherent system to enable all of the organization's objectives to be achieved. These elements include the structure, resources and processes. Personnel, equipment and organizational culture as well as the documented policies and processes are parts of the management system. The organization's processes have to address the totality of the requirements on the organization as established in, for example, IAEA safety standards and other international codes and standards.

management system review. A regular and systematic evaluation by senior management of an organization of the suitability, adequacy, effectiveness and efficiency of its management system in executing the policies and achieving the goals and objectives of the organization.

operator. Any organization or person applying for authorization or authorized and/or responsible for nuclear, radiation, radioactive waste or transport safety when undertaking activities or in relation to any facilities or sources of ionizing radiation. This includes, inter alia, private individuals, governmental bodies, consignors or carriers, licensees, hospitals, self-employed persons, etc.

regulatory body. An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating nuclear, radiation, radioactive waste and transport safety. The national competent authority for the regulation of radioactive material transport safety is included in this description, as is the Regulatory Authority for radiation protection and safety.

(nuclear) safety. The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards.

safety culture. The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.

self-assessment. A routine and continuing process conducted by senior management and management at other levels to evaluate the effectiveness of performance in all areas of their responsibility.

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