

IAEA Safety Standards

for protecting people and the environment

Application of the Management System for Facilities and Activities

Safety Guide

No. GS-G-3.1



IAEA

International Atomic Energy Agency



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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.

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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**.

APPLICATION OF 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-G-3.1

APPLICATION OF THE MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

SAFETY GUIDE

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

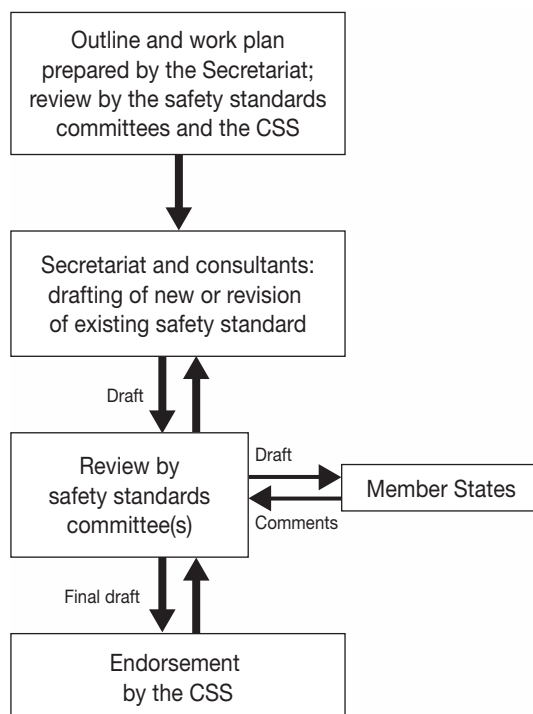
As well as by regulatory bodies and governmental departments, authorities and agencies, the standards are used by authorities and operating organizations in the nuclear industry; by organizations that design, manufacture for and apply nuclear and radiation related technologies, including operating organizations 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 Guide supports the Safety Requirements publication on The Management System for Facilities and Activities [1]. It provides generic guidance to aid in establishing, implementing, assessing and continually improving a management system that complies with the requirements established in Ref. [1]. In addition to this Safety Guide, there are a number of Safety Guides for specific technical areas. Together these provide all the guidance necessary for implementing the requirements of Ref. [1]. This publication supersedes Safety Series No. 50-SG-Q1–Q7 (1996) [2].

1.2. To meet the requirements established in Ref. [1], methods and solutions other than those set out in this Safety Guide may also be acceptable provided that they result in at least the same level of safety.

1.3. The guidance provided here may be used by organizations in the following ways:

- To assist in the development of the management systems of organizations directly responsible for operating facilities and activities and providing services, as described in para. 1.5;
- To assist in the development of the management systems of the relevant regulatory bodies [3];
- By the operator, to specify to a supplier, via contractual documentation, any guidance of this Safety Guide that should be included in the supplier's management system for the supply and delivery of products.

OBJECTIVE

1.4. The objective of this publication is to provide generic guidance for establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security¹, quality and

¹ This Safety Guide 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.

economic elements, in order to meet the requirements established in Ref. [1]. This Safety Guide also provides illustrative examples of the application of the management system requirements.

SCOPE

1.5. 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.

1.6. This Safety Guide 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).

STRUCTURE

1.7. This Safety Guide follows the structure of Ref. [1]. Section 2 provides guidance for implementing the management system, including guidance relating to safety culture, grading and documentation. Section 3 provides guidance on the responsibilities of senior management² for the development and implementation of a management system. Section 4 provides guidance on

² '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.

resource management, including guidance on human resources, infrastructure and the working environment. Section 5 provides guidance on how the processes of the organization can be identified and developed, including guidance on some generic processes of the management system. Section 6 provides guidance on measuring, assessing and improving the management system. The appendices and annexes provide illustrative examples to supplement the text.

2. MANAGEMENT SYSTEM

AN INTEGRATED MANAGEMENT SYSTEM

2.1. An integrated management system should provide a single framework for the arrangements and processes necessary to address all the goals of the organization. These goals include safety, health, environmental, security, quality and economic elements and other considerations such as social responsibility.

2.2. A management system, including organizational models, concepts and tools, should also cover human factor issues and other integrated management approaches that complement the traditional approach to achieving results, which was based on inspections and verification checks.

2.3. Technological innovations have radically altered the interactions between systems and humans, and therefore the management of the entire organization. Complex activities and multiple objectives involve individuals operating at different levels in the organization, while operating processes are modified by the introduction of new management practices and new requirements. Daily practices and the results achieved by the organization, the organizational culture and the management processes are deeply interrelated. The management system should be able to evolve accordingly, to accommodate change and to ensure that individuals understand what has to be done to meet all the requirements applicable and relevant to them.

2.4. Organizations should integrate all their components into an integrated management system. These components of the organization include the structure, resources and processes. Individuals, equipment and culture should

therefore be as much a part of the integrated management system as the documented policies and processes.

2.5. In an integrated management system, all goals, strategies, plans and objectives of an organization should be considered in a coherent manner. This implies:

- Identifying their interdependences and their potential to impact on each other;
- Assigning priorities to the goals, strategies, plans and objectives;
- Establishing procedures to ensure that these priorities are respected in decision making.

2.6. Guidance on the transition to an integrated management system is provided in Appendix I.

GENERAL

2.7. A robust and effective management system should support the enhancement and improvement of safety culture and the achievement of high levels of safety performance. The management system should therefore be designed with these purposes in mind and should be implemented in such a way that it is known, understood and followed by all individuals.

2.8. The management system should be designed to enable the organization's objectives to be achieved in a safe, efficient and effective manner.

2.9. The management system should be binding on all individuals.

2.10. The management system should specify all work delegated to external organizations. The lines of communication and the interfaces between internal and external organizations should be specified in the management system, and the responsibility of each organization for work assigned to it should be described.

2.11. The management system should assign responsibility to achieve the organization's objectives and should empower the individuals in the organization to perform their assigned tasks. Managers should be responsible for achieving quality and safety in the final outputs of work under their responsibility within the organization. Individuals should take responsibility

for quality and safety while carrying out the work that is assigned to them. In order to discharge this responsibility, individuals should be technically competent in using the appropriate hardware, equipment, tools and measuring devices and should have a clear understanding of the work processes.

2.12. The management system should ensure that a review of the controls that affect work, such as the training of individuals and the work package that accompanies it, is conducted prior to restarting work after interruptions.

2.13. The management system should provide a common vocabulary consistent with the work being performed. All key terms used in the management system should be defined and should become an integral part of the training programme to ensure that communications and understanding are consistent throughout the organization.

2.14. Senior management should set the goals of the organization and should assign the responsibilities and authorities, define the policies and requirements, and provide for the performance and assessment of work.

2.15. Responsibility and authority to stop unsatisfactory work should be assigned in such a manner that planning, scheduling and other considerations do not override safety requirements.

2.16. The actions of managers and supervisors or team leaders have a strong influence on the safety culture within the organization. These actions should promote good working practices and eliminate poor practices. Managers and supervisors or team leaders should maintain a presence in the workplace by carrying out tours, walk-downs of the facility and periodic observations of tasks with particular safety significance.

2.17. Managers and supervisors should talk to other individuals during workplace tours and should take these opportunities to reinforce awareness of management expectations.

2.18. Managers and supervisors should encourage and welcome the reporting by other individuals of potential safety concerns, incidents and near-misses, and accident precursors, and should respond to valid concerns promptly and in a positive manner. Where appropriate, contractors should give the same high priority to safety, especially when they are working at a facility.

2.19. Strategies to identify, disseminate information on and promote good practices should be adopted, and strategies to eliminate poor practices should be adopted. Such strategies should involve the balanced use of appropriate incentives and sanctions. To be effective, these strategies should be well understood and should be applied consistently and fairly throughout the organization.

2.20. The organization should develop a management system that is appropriate to the stage in the lifetime and the maturity of the nuclear facility or activity.

2.21. All work that is to be done should be planned and authorized before it is commenced. Work should be accomplished under suitably controlled conditions by technically competent individuals using technical standards, instructions, procedures or other appropriate documents.

See Ref. [1], paras 2.1–2.4.

Implementing the management system

2.22. To establish a management system, an organization:

- Should review applicable regulations and standards and the organization's management and technical practices to determine whether the processes adequately address all requirements;
- Should review the Safety Requirements publication [1], the Safety Guides on management systems and other relevant safety related publications to identify shortcomings in the organization and to assign priorities to those areas where improvement or development is necessary;
- Should establish time frames within which the necessary changes are to be implemented.

2.23. The individual in the most senior managerial position in the organization should be responsible for ensuring that the management system is implemented. Implementing the management system demands the collaborative efforts of managers, those performing the work and those assessing the work. For satisfactory implementation, planning and the deployment of adequate resources are necessary. All individuals should be trained to achieve proficiency. It should be ensured that all individuals understand the management processes that apply to the performance of their work. The effectiveness of the management system should be assessed and

reviewed at all stages of implementation. The information gained from assessments should be used to achieve continuing improvements in work performance.

Implementation plan

2.24. Senior management should prepare a plan to achieve full implementation of the management system. The implementation plan should be subject to approval and monitoring by the most senior manager assigned the responsibility for development and implementation of the management system.³

2.25. The implementation plan should include provisions for recruiting, selecting, training, assigning and retraining adequate numbers of individuals, in a manner consistent with schedules for implementation and workloads. Consideration should be given to needs for special skills and training. Such provisions should take into account demographic and economic conditions.

2.26. Work plans, schedules, instructions, technical specifications and drawings that are necessary to define the specific actions to perform work should be developed, should be subject to approval, and should be used or referred to as necessary in the processes of the management system. Their preparation should be planned and scheduled so that individuals have clear instructions on how to sequence and perform their work correctly.

2.27. Plans should be prepared for assessing the effectiveness of instructions and their implementation in relation to the performance of work, and for assessing the results achieved in relation to quality and safety. Implementation of these plans should commence as soon as possible. Frequent early assessments may be necessary to ensure the adequacy of instructions and to prevent the endorsement of poor practices. The involvement of individuals in the development of these procedures and instructions should be considered to ensure the usefulness and ease of application of these documents.

³ In some Member States the individual in the most senior position appoints a full time management system manager (see para. 3.18). This management system manager may be supported by a team composed of representatives of all organizational units that meets regularly to exchange experience and good practices and to resolve any problems or difficulties that arise during the development of the management system.

Interface arrangements

2.28. There should be a clear understanding of the division of responsibilities and the working relationships between all organizational units participating in or supporting the management system. Such units include centralized corporate and technical departments providing support, and company safety committees. They also include public services such as fire services and medical services.

2.29. Consistent methods of defining relative responsibilities and lines of communication between organizational units should be implemented.

2.30. Interface agreements, sometimes referred to as ‘memoranda of understanding’, or equivalent formal agreements that define interfaces between organizational units should be developed where appropriate. For example, such agreements may be appropriate where safety could be affected, where the working arrangements are complex or where the interfaces involve several organizations. Their acceptance by the managers of the interfacing organizations and units should be obtained in writing. The interface agreements should be distributed to all affected participants.

2.31. In the preparation of interface documents, the following points should be addressed:

- The participating units should be identified and included on the circulation list.
- The prime responsibilities, authority and accountability for the work should be stated clearly.
- The responsibilities for review and comment, approval of technical issues, implementation, reporting, verification and audit should be specified where appropriate.
- Key positions within each unit to act as focal points for communication should be specified.
- The contents of the documents necessary to carry out the activity or convey technical information across the interface (typically programmes, plans, specifications, procedures, instructions, drawings and records) should be defined.
- The flow of documents across organizational interfaces and the schedules for actions by interfacing units or groups should be specified.

See Ref. [1], paras 3.12–3.14.

SAFETY CULTURE

2.32. The management system should provide structure and direction to the organization in a way that permits and promotes the development of a strong safety culture together with the achievement of high levels of safety performance. The management system should establish a working environment in which staff can raise safety issues without fear of harassment, intimidation, retaliation or discrimination.

2.33. The management system will both influence and be influenced by the overall culture of the organization. The relationship between the management system and the culture of the organization should be understood by all individuals of the organization.

2.34. Senior management should have an understanding of the key characteristics and attributes that support a strong safety culture and should provide the means to ensure that this understanding is shared by all individuals. Senior management should provide guiding principles and should reinforce behavioural patterns that promote the continual development of a strong safety culture.

2.35. Management at all levels should promote the types of behaviour, values and basic beliefs that lead to the development of a strong safety culture. Managers should monitor and reinforce the attributes that have been identified as essential for achieving a strong safety culture and should pay attention to early signs of decline in these attributes and thus in the safety culture.

2.36. A strong safety culture has the following important attributes:

- Safety is a clearly recognized value:
 - The high priority given to safety is shown in documentation, communications and decision making.
 - Safety is a primary consideration in the allocation of resources.
 - The strategic business importance of safety is reflected in the business plan.
 - Individuals are convinced that safety and production go hand in hand.
 - A proactive and long term approach to safety issues is shown in decision making.
 - Safety conscious behaviour is socially accepted and supported (both formally and informally).

- Leadership for safety is clear:
 - Senior management is clearly committed to safety.
 - Commitment to safety is evident at all levels of management.
 - There is visible leadership showing the involvement of management in safety related activities.
 - Leadership skills are systematically developed.
 - Management ensures that there are sufficient competent individuals.
 - Management seeks the active involvement of individuals in improving safety.
 - Safety implications are considered in change management processes.
 - Management shows a continual effort to strive for openness and good communication throughout the organization.
 - Management has the ability to resolve conflicts as necessary.
 - Relationships between managers and individuals are built on trust.
- Accountability for safety is clear:
 - An appropriate relationship with the regulatory body exists that ensures that the accountability for safety remains with the licensee.
 - Roles and responsibilities are clearly defined and understood.
 - There is a high level of compliance with regulations and procedures.
 - Management delegates responsibility with appropriate authority to enable clear accountabilities to be established.
 - ‘Ownership’ for safety is evident at all organizational levels and for all individuals.
- Safety is integrated into all activities:
 - Trust permeates the organization.
 - Consideration of all types of safety, including industrial safety and environmental safety, and of security is evident.
 - The quality of documentation and procedures is good.
 - The quality of processes, from planning to implementation and review, is good.
 - Individuals have the necessary knowledge and understanding of the work processes.
 - Factors affecting work motivation and job satisfaction are considered.
 - Good working conditions exist with regard to time pressures, workload and stress.
 - There is cross-functional and interdisciplinary cooperation and teamwork.
 - Housekeeping and material conditions reflect commitment to excellence.
- Safety is learning driven:
 - A questioning attitude prevails at all organizational levels.

- Open reporting of deviations and errors is encouraged.
- Internal and external assessments, including self-assessments, are used.
- Organizational experience and operating experience (both internal and external to the facility) are used.
- Learning is facilitated through the ability to recognize and diagnose deviations, to formulate and implement solutions and to monitor the effects of corrective actions.
- Safety performance indicators are tracked, trended, evaluated and acted upon.
- There is systematic development of individual competences.

See Ref. [1], para. 2.5.

GRADING THE APPLICATION OF MANAGEMENT SYSTEM REQUIREMENTS

Graded approach

2.37. A structured approach to determining how the management system requirements are to be applied to products and activities should be developed and implemented.

2.38. The degree to which the management system requirements are applied to a product or activity should reflect the importance of the product or activity to safety, health, environmental, security, quality and economic expectations, the complexity of the product or activity, and the possible consequences if the product fails or if the activity is carried out incorrectly.

2.39. Grading the application of the management system requirements should enable valuable resources and attention to be targeted at the products or activities of greater significance. This can result in minimizing total costs while improving safety.

2.40. For all products and activities within a process, all the requirements of and demands on the relevant process should first be considered. By using the grading methodology it may be possible to identify products and activities of lesser significance within a process. For products and activities of lesser significance, it is then possible to determine whether all the controls and checks of the process are necessary. Controls and checks that could be graded include, for example, aspects such as qualification and training for individuals, type and

format of procedures, and requirements on verification, inspection, testing, material, records and the performance of suppliers.

Grading process

2.41. The grading process should determine the extent of the application of the requirements of the management system to the products and activities of the organization.

2.42. Applying controls demands resources. Resources should be applied and focused where they are necessary on the basis of aspects such as safety significance and risks. They should be applied to a lesser degree for less important products or activities. Errors in more significant products or activities could potentially lead to the diversion of large amounts of resources, could shut down a facility or production line, and could cause a threat to individuals and the environment. Introducing additional controls that may reduce or eliminate such errors is therefore highly beneficial.

2.43. It is common sense to apply tighter controls to more important products and activities. A methodology for grading should be developed that ensures that all individuals in the organization apply this common sense approach in a uniform manner.

2.44. Examples of the controls that could be graded are:

- For the document and records management process:
 - Preparation of documents and records;
 - Need for and extent of validation;
 - Degree of review and the individuals involved;
 - Level of approval to which documents are subjected;
 - Need for distribution lists;
 - Types of document that can be supplemented by temporary documents;
 - Need to archive superseded documents;
 - Need to categorize, register, index, retrieve and store document records;
 - Retention time of records;
 - Responsibilities for the disposal of records;
 - Types of storage medium, in accordance with the specified length of time of storage.
- For the procurement process:
 - Expectations of suppliers for assessment, evaluation and qualification;

- Scope and level of detail of the procurement specification;
- Need for and scope of supplier quality plans;
- Extent of inspection, surveillance and audit activities for suppliers;
- Scope of documents to be submitted by the supplier and approved by the organization;
- Records to be provided or stored and preserved.

The selected grading process should be consistent with the applicable codes and standards, local rules and regulatory requirements.

See Ref. [1], paras 2.6–2.7.

DOCUMENTATION OF THE MANAGEMENT SYSTEM

General

2.45. The management system should be described by a set of documents that establish the overall controls and measures to be developed and applied by an organization to achieve its goals. These controls and measures should apply to every unit and individual within the organization.

2.46. The documentation of the management system should be appropriate to the organization and to the work that it performs and should be readily understandable to users. The documentation should also be flexible enough to accommodate changes in policy; in strategic aims; in safety, health, environmental, security, quality and economic considerations; and in regulatory requirements and other statutes. It should also accommodate the feedback of experience from implementation and from internal and external lessons learned.

2.47. The management system should adopt a vocabulary that is coherent, makes sense, and is clear, unambiguous and readily understandable. To this end, each document should be written in a manner appropriate to the level of expertise of its users and in a manner that reflects the correct ways of working (i.e. ‘user friendly’).

2.48. The management system should include measures to ensure that documentation is available in a language appropriate to the user. Management should state the languages to be used for the work instructions and procedures

and should specify measures to ensure that individuals understand what they are asked to do.

2.49. Documents that have been translated should be reviewed to ensure that the text reflects the intent of the original document and is not just a literal translation. Vocabulary that is internal to an organization should be made available to contractors and subcontractors who are engaged by the organization to carry out work or to provide services.

2.50. The content of documents should be determined with the participation of the individuals who will use them to do their work and of other individuals whose work will be affected by the documents. These individuals should also be consulted during subsequent revisions of the documents. For detailed working documents, there should be a period of trial use, and validation should be carried out and recorded to determine the accuracy of the documents. Changes should then be made, as necessary, to ensure the effective communication of expectations.

2.51. An organization may operate facilities at several sites, or it may operate a facility or activity using nuclear or radiation technology that is part of a large organization (e.g. a radiotherapy department may be part of a hospital or a research reactor may be part of a research centre). In such cases, the management system for the whole organization should be established to integrate the objectives common to both the facility and the whole organization, and the mission and work of the facility. To complement such management systems, specific local processes may be necessary and should be used to address work that is unique to one or more of the organization's facilities, sites or organizational units.

Information structure

2.52. A three level structure of information promotes clarity and avoids repetition by establishing the amount of information and the level of detail appropriate to each type of document and by using cross-references between specific documents at the different levels. A typical three level structure consists of:

- Level 1: An overview of how the organization and its management system are designed to meet its policies and objectives;

- Level 2: A description of the processes to be implemented to achieve the policies and objectives and the specification of which organizational unit is to carry them out;
- Level 3: Detailed instructions and guidance that enable the processes to be carried out and specification of the individual or unit that is to perform the work.

Level 1

2.53. Level one should provide an overview of the policies and objectives of the organization and should describe the management system that addresses the requirements that apply to the organization's work. The information at this level of the management system should be the most senior manager's primary means of communicating to individuals the expectations of management, their strategies for success and the methods for achieving the organization's objectives.

2.54. Information on the following should be provided at level 1:

- Vision, mission and goals of the organization;
- Policy statements of the organization;
- Organizational structure;
- Levels of authority and responsibilities and accountabilities of senior management and organizational units;
- Structure of the management system documentation;
- An overview of the organization's processes;
- Responsibilities of owners of the processes (see para. 5.14);
- Arrangements for measuring and assessing the effectiveness of the management system.

2.55. The most senior manager in the organization should ensure that level 1 information is distributed to individuals for the purposes of implementation and that its contents are effectively understood and implemented.

Level 2

2.56. This level of information describes the processes of the organization and provides specific detail on which activities should be performed and which organizational unit should carry them out. This information:

- Should define the process map of the management system, including the interactions between processes;
- Should define the responsibilities and lines of communication that are internal and external to the organization in each area of activity, for example in processes and interface arrangements;
- Should define measurable objectives and specify which activities are to be carried out and controlled and who is responsible and accountable, and, where appropriate, should refer to supporting information;
- Should identify and plan activities to ensure that work is dealt with in a safe, systematic and expeditious manner.

2.57. Information at this level should provide administrative direction to managers in all positions. It should outline the actions that managers should take to implement the organization's management system. It should not be used to provide the details of how technical tasks are to be performed. Technical tasks should be detailed in information at level 3.

2.58. The contents of sections typically contained in documents at level 2 are:

- Purpose: Why does the document exist? The specific objectives of the document should be stated clearly and concisely.
- Scope: What management actions are addressed by the document and who is supposed to use it? The type of work and situations to which the document applies should be defined. The boundaries of application of the document should be stated.
- Responsibilities: Who is responsible for the document and for the activities described within the document? The individuals should be identified by title and their responsibilities should be defined.
- Definitions and abbreviations: What words or acronyms are used in the document that may not be commonly understood? Such terms and any jargon that may cause confusion should be defined and clearly explained.
- References: Would other documents be of use to those who have to use the document? If so, the specifications, standards or other documents that are cited in the text and which may possibly provide additional information to users should be listed. If documents are referenced in part, the page and paragraph numbers should be stated.
- Details: How is the work that is the subject matter of the document conducted? This information may take the form of a flow chart or process map describing the sequence of actions necessary to accomplish the work. The text should be simple and direct. Approved numbering and nomenclature for job titles and documents should be used. The details

section of a document should describe what is to be done, typically by providing the following information:

- Planning and scheduling considerations, to ensure that work is dealt with safely, systematically and expeditiously;
 - Administrative and technical information;
 - Work steps and actions to be carried out;
 - Responsibilities and authorities;
 - Interfaces;
 - Lines of communication both within and outside the organization;
 - Any cross-references between the document and other documents, including working documents at level 3.
- Records: Which records are necessary to permit the work and which ones need to be retained after the work has been completed? The records that are necessary to demonstrate that the tasks specified in the document have been accomplished should be identified.
- Appendices (where applicable), if additional information is necessary.

2.59. To avoid unnecessary detail, cross-reference should be made to level 3 information such as supporting guidance or detailed working documents.

Level 3

Detailed working documents

2.60. Level 3 information consists of a wide range of documents to prescribe the specific details for the performance of tasks by individuals or by small functional groups or teams. The type and format of documents at this level can vary considerably, depending on the application involved. The primary consideration should be to ensure that the documents are suitable for use by the appropriate individuals and that the contents are clear, concise and unambiguous, whatever the format.

Job descriptions

2.61. Job descriptions should be developed for the different competences or types of work to define the total scope of each individual's job. Job descriptions should be used to establish baselines for identifying training and competence needs. While job descriptions are usually mandatory only at supervisory levels and above, they are an excellent way for senior management to communicate responsibilities, authority and interfaces to all individuals.

2.62. A typical job description should contain the following information:

- Job title;
- Purpose of the job;
- Name of the organization;
- Organizational structure;
- Position in the organization;
- Lines of reporting;
- Duties and authorities;
- Key tasks and responsibilities;
- Accountability;
- Necessary minimum training;
- Necessary qualifications;
- Necessary knowledge, skills and abilities;
- Necessary education;
- Necessary experience;
- Necessary medical fitness.

See Ref. [1], paras 2.8–2.10.

3. MANAGEMENT RESPONSIBILITY

MANAGEMENT COMMITMENT

3.1. The efficiency of a management system begins at the level of senior management. Responsibility for the effectiveness of the management system should not be delegated.

3.2. The senior management is responsible and accountable for the planning and implementation of a management system that is appropriate to the organization. It is the role of senior management to establish and cultivate principles that integrate all requirements into daily work. Senior managers should provide the individuals performing the work with the necessary information, tools, support and encouragement to perform their assigned work properly.

3.3. Visible and active support, strong leadership and the commitment of senior management are fundamental to the success of the management system. Senior managers should communicate the beliefs that underlie the organization's policies through their own behaviour and management practices. The whole organization should share the management's perception and beliefs about the importance of the management system and the need to achieve the policies and objectives of the organization.

3.4. Managers should be held responsible for ensuring that individuals working under their supervision have been provided with the necessary training, resources and direction. These elements should be provided before any work begins.

3.5. In assigning responsibilities and accountabilities, managers should ensure that the individuals concerned have the capabilities and the appropriate resources to discharge these responsibilities effectively. They should also ensure that individuals are aware of and accept their responsibilities, and that they know how their responsibilities relate to those of others in the organization.

3.6. Managers should examine samples of work practices and related information on a regular basis to identify areas needing improvement. They should also encourage each individual under their supervision to look for more efficient and effective ways of accomplishing assigned tasks.

3.7. The act of empowering individuals and making them accountable for their work should encourage individuals to take 'ownership' of their work and to seek improvement in their performance.

See Ref. [1], paras 3.1–3.5 and 3.12.

SATISFACTION OF INTERESTED PARTIES

General

3.8. Every organization has interested parties (also known as ‘stakeholders’⁴), all of whom have needs and expectations. In order to ensure that the formally agreed expectations of interested parties are determined and met and to enhance their satisfaction, senior management should identify all of the organization’s interested parties and should understand their ‘products’ or interests and their requirements, needs and expectations.

See Ref. [1], para. 3.6.

Statutory and regulatory compliance

3.9. Senior management should ensure that the organization has identified all applicable statutory and regulatory requirements that apply to its products, processes and activities, and it should include in the management system the methods of complying with these requirements.

ORGANIZATIONAL POLICIES

3.10. As part of the management system, senior management should develop and disseminate throughout the organization a documented set of policies that

⁴ 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.

establish the management's plans, objectives and priorities with regard to safety, health, environmental, security, quality and economic considerations. The policies should reflect the commitment of senior management to attaining their goals and objectives; their priorities; and the means by which continual improvement will be implemented and measured.

3.11. The policies:

- Should be appropriate to the purpose and the activities of the organization and should contain statements on safety, health, environmental, security, quality and economic considerations;
- Should include a commitment to comply with management system requirements and to seek continual improvement;
- Should be aligned with and should support the development of a strong safety culture;
- Should reflect relevant statutory requirements;
- Should provide an appropriate framework for action and for establishing and reviewing goals and objectives;
- Should be reviewed periodically for their continuing suitability and applicability;
- Should be effectively communicated, understood and followed within the organization;
- Should commit management to providing adequate financial, material and human resources.

3.12. Senior management should demonstrate its commitment to all the policies through its actions and should provide firm and unambiguous support for the implementation of these policies. Its actions should foster a corresponding commitment to high levels of performance by all individuals. All individuals should be expected to demonstrate their commitment to the policies. Adequate resources should be made available to implement all the policies. This includes provision of the necessary:

- Tools, equipment and material;
- Sufficiently competent individuals;
- Knowledge resources;
- Financial resources.

See Ref. [1], paras 3.7–3.8.

PLANNING

3.13. The establishment of goals, strategies, plans and objectives is a primary role of senior management. Senior management should provide the leading direction for the organization and should ensure a high level of safety. All levels within the organization should understand the direction set by senior management and should feel personally accountable for meeting the objectives. As a minimum, the priorities and objectives of the organization should be such as to ensure that regulatory requirements continue to be met.

3.14. To achieve a more highly developed safety culture and a well established business planning process, management should identify objectives that incorporate and effect continual improvement.

3.15. The objectives described in the plans should be widely communicated inside the organization. The entire organization should know and be fully committed to the objectives.

3.16. The organization's plans and objectives should represent an ambitious picture of the future of the organization, especially with regard to safety. For other areas of performance (availability of products, costs, industrial safety and communication with interested parties), the objectives should also reflect a strong willingness to undertake continual improvement. If a need for a strategic change is identified, senior management should integrate the necessary change into the corporate vision.

See Ref. [1], paras 3.8–3.11.

RESPONSIBILITY AND AUTHORITY FOR THE MANAGEMENT SYSTEM

3.17. Senior management should be fully committed to the management system and should regard it as a tool for use in managing the organization. The commitment of senior management should foster long term commitment and engagement on the part of the management and of all individuals of the organization, through a process of participation and consultation.

3.18. The individual who has responsibility for the management system should have the authority to raise issues relating to the management system at senior management meetings and to report on the status of corrective actions and