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

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**.

APPLICATION OF THE MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

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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

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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

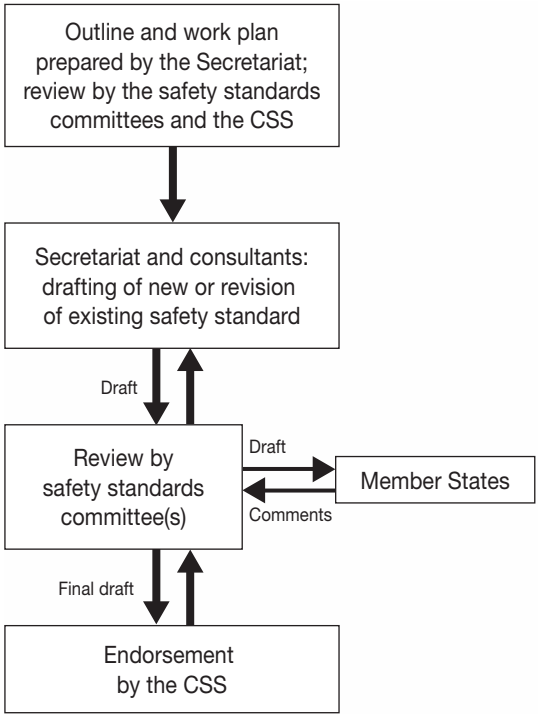
As well as by regulatory bodies and governmental departments, authorities and agencies, the standards are used by authorities and operating organizations in the nuclear industry; by organizations that design, manufacture for and apply nuclear and radiation related technologies, including operating organizations 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.

CONTENTS

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, security[1], 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 management[2] 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

improvements. If necessary, the individual should become involved in resolving any conflicts.

3.19. In some cases, the organization may appoint external organizations or individuals to develop all or part of the management system. However, the disadvantage of doing this is that there is no 'ownership' of the management system within the organization.

3.20. If the management system is developed by an external organization, care should be taken to ensure that the management system is relevant to the objectives of the organization and that it addresses the actual processes of the organization, and is not only a 'model' management system as used in other industries.

See Ref. [1], paras 3.12–3.14.

4. RESOURCE MANAGEMENT

PROVISION OF RESOURCES

4.1. Senior management should ensure that the resources[5] that are essential to the implementation of the strategy for the management system and the achievement of the organization's objectives are identified and made available.

4.2. To improve the performance of the organization, consideration should be given to the way resources are managed. This should include:

— Effective, efficient and timely provision of resources in the context of the opportunities and constraints;
— Management of tangible resources such as support facilities;
— Management of intangible resources such as intellectual capital;
— Inclusion of resources and mechanisms to encourage continual innovative improvement;
— Consideration of organizational structures, including needs for project and matrix management;

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

— Use of information management, knowledge management and the corresponding technology;
— Enhancement of competence by means of focused training, education and learning;
— Development of leadership skills and profiles for future managers of the organization;
— Use of natural resources and consideration of the impact of the use of resources on the environment;
— Planning for future resource needs, for example by analysing completed projects and by using such tools as predictive models for workloads.

Involvement of individuals

4.3. Senior management should improve both the effectiveness and the efficiency of the organization and its management system by involving and supporting all individuals. As an aid to achieving its objectives for performance improvement, the organization should encourage the involvement and development of its individuals by:

— Providing ongoing training and career succession planning;
— Defining individuals' responsibilities and authorities;
— Establishing individual and team objectives, and managing the performance of processes and the evaluation of results;
— Facilitating involvement in the setting of objectives and decision making;
— Recognizing and rewarding good performance;
— Facilitating the open, effective communication of information;
— Continually reviewing the needs of individuals;
— Creating conditions to encourage innovation;
— Ensuring effective teamwork;
— Communicating suggestions and opinions;
— Measuring individuals' satisfaction;
— Investigating the reasons why individuals join and leave the organization;
— Understanding and accommodating individual work styles and competences to gain the highest level of performance from each individual;
— Articulating instructions for achieving the expected quality of work;
— Obtaining feedback from individuals on a regular basis.

See Ref. [1], para. 4.1.

Managing information and knowledge

4.4. Data should be converted to information for the continual development of an organization's knowledge, and senior management should treat information as a fundamental resource that is essential for making factually based decisions and stimulating innovation. To manage information and knowledge, senior management:

— Should identify the organization's information needs;
— Should identify and access internal and external sources of information;
— Should convert information to knowledge of use to the organization;
— Should use the data, information and knowledge to set and meet the organization's strategies and objectives;
— Should ensure appropriate security and confidentiality;
— Should evaluate the benefits derived from the use of the information in order to improve the management of information and knowledge;
— Should ensure the preservation of organizational knowledge and capture tacit knowledge for appropriate conversion to explicit knowledge.

See Ref. [1], para. 4.2.

Financial resources

4.5. Resource management should include activities for determining the needs for, and sources of, financial resources. The control of financial resources should include activities for comparing actual usage against plans and for taking necessary action. Senior management should plan for, make available and control the financial resources necessary for: meeting safety standards; maintaining the safety culture; implementing and maintaining an effective and efficient management system; and achieving the organization's goals.

HUMAN RESOURCES

Competence, awareness and training

Competence

4.6. Senior management should ensure that the necessary individual competences are available for the effective and efficient operation of the organization. Senior management should evaluate both present and expected

needs for competences against the competences already available in the organization.

4.7. In the identification of the future needs for competence of the organization, the following should be taken into account:

— Future demands in relation to strategic and operational plans and objectives;
— Anticipated needs for succession for the management and the workforce;
— Demographic and economic conditions;
— Planned changes to the organization's processes, tools and equipment;
— The present competence of individuals to perform defined activities;
— Known changes to statutory and regulatory requirements and standards that may affect the organization and its interested parties;
— International experience in relevant businesses and industries.

Awareness and training

4.8. In planning for education and training needs, account should be taken of changes caused by the nature of the organization's processes, the competence levels of individuals and the culture of the organization. The objective should be to provide individuals with knowledge and skills that, together with attitudes and experience, will enhance their competence. In education and training, emphasis should be placed on the importance of safety, of meeting requirements and of the needs and expectations of interested parties. Training should also cover awareness of the consequences for the organization and individuals of failing to meet the requirements.

4.9. The organization's training plan[6] should include:

— The objectives of the organization's training plan;
— An analysis of any areas not covered and a needs assessment for the training;
— A description of the training programmes and methods to be employed;
— The resources necessary and responsibilities;
— Measurement of the transfer of knowledge (questionnaire, diploma, qualification, accreditation, assessment);

[6] In some Member States an annual training plan is prepared that reflects the schedule of planned training courses.

— Identification of the necessary internal support;
— An evaluation of the effectiveness of the training, including individual performance, the performance results of the organization carrying out the training, and the training process.

4.10. To support the achievement of the organization's objectives and the development of individuals, the following should be considered in planning for education and training:

— Safety and regulatory requirements;
— The experience of individuals;
— Tacit knowledge and explicit knowledge;
— Leadership and management skills;
— Planning and improvement tools;
— Team building;
— Adult learning styles and techniques;
— Decision making techniques;
— Problem solving techniques;
— Communication skills;
— Cultural diversity;
— The organizational culture;
— The needs and expectations of interested parties;
— Creativity and innovation.

4.11. To facilitate the involvement of individuals, education and training should address:

— The vision for the future of the organization;
— The organization's policies and objectives;
— How the actions of individuals affect the integration of safety, health, environmental, security, quality and economic objectives;
— Organizational change and development;
— The initiation and implementation of improvement processes;
— Individual benefits from creativity and innovation;
— The organization's impact on society;
— Introductory programmes for new individuals;
— Professional development programmes;
— Periodic refresher programmes for individuals who have already been trained;
— Programmes and results from other relevant businesses and industries.

4.12. To achieve quality and to maintain safety, individuals should be capable of performing their assigned tasks. Training should emphasize the correct performance of work and should provide an understanding of:

— The principles of the management system and the relevant management processes and procedures;
— Accountabilities and responsibilities in the organization;
— Individual and organizational values and behavioural standards;
— The relationship between the management system and the development of a strong safety culture;
— Key characteristics and attributes of safety culture;
— The importance of involving interested parties and how to best involve them.

4.13. Training should address the knowledge of concepts, including safety culture. It should also address the enhancement of skills and the reinforcement of good practices by applying lessons learned from experience.

4.14. Training should ensure that individuals understand the processes and tools that they are using and understand what constitutes acceptable quality for the products they produce and the processes they control. Training should focus attention on 'doing things right the first time' and on the safety consequences of inadequate or incorrect work.

4.15. Individual training plans for senior management should address and stimulate professional development and should include professional, managerial, communication and interpersonal skills. A process for the selection, training, assessment and development of all managers should be established.

4.16. Individual training plans should not be limited to initial qualification but should provide for maintaining proficiency and for progressive improvement. This should ensure that individuals are always aware of the state of the art in technology and best practices in relation to the work they perform.

4.17. Specific requirements for qualification should be established for critical or unique jobs if highly technical, specialized skills are necessary or if the job has a potential impact on safety and quality, and if it is necessary to ensure that the individual is competent prior to performing the task. Such jobs should be identified by the organization and the qualification requirements that are established should be satisfied.

4.18. Consideration should be given to the qualification and training of individuals performing work that needs special competence. In some cases this should involve individuals taking a practical and a written examination to demonstrate proficiency before they begin work.

4.19. Periodic requalification should be required, to demonstrate that individuals continue to be capable of performing their assigned tasks.

4.20. Training should be designed to ensure that the training content addresses the specific needs of individuals and the overall organization. This means that training should be planned and carried out using a systematic approach, with established measurable objectives and with a means of evaluating its effectiveness. Qualified instructors who are competent in the area of expertise and in the necessary instructional techniques should be involved in the analysis, design, development, implementation and evaluation of training. Training is crucial to the continuing development of personnel. Senior management should therefore also allocate technically competent experts in the subject matter to develop the training curricula necessary for the achievement of the organization's objectives and to enhance the development of personnel. Line managers should participate personally in the analysis of training needs, in the review and approval of training programmes and plans (as well as in the delivery of some parts of the training), and in the evaluation of the effectiveness of the training.

4.21. The training plans of the organization should be subject to ongoing review to determine their effectiveness. The training plans should be revised whenever necessary improvements or enhancements are identified on the basis of the results of the reviews.

4.22. The organization's overall objectives and their direct relation to the policies and the management system should be explained in the initial and continuing training of all individuals who are managing, performing and assessing work.

4.23. The success of the management system in bringing about continual improvement depends on acceptance of and confidence in the management system within the organization. All individuals, including those at the various management levels, should be informed about the importance of their respective roles.

4.24. Training in the application of procedures and instructions should be given to those individuals who have to apply the procedures to do their work. Additional training should be given when procedures or instructions undergo major revision. This training is an opportunity for senior management to explain the importance of complying with the requirements of the management system. Feedback of information on the application of the requirements should be sought and revisions should be made to correct any difficulties identified.

4.25. As a means of improving future training plans, all the education and training provided should be evaluated in terms of management expectations and the impact of the education and training on safety and on the effectiveness and efficiency of the organization. To improve processes and the quality of the products and training programmes and to enhance the organization's learning culture, competence in core subjects should be built up by means of engagement with academia and industry.

See Ref. [1], paras 4.3–4.4.

INFRASTRUCTURE AND THE WORKING ENVIRONMENT

Infrastructure

4.26. Senior management should define the infrastructure necessary for safety and for achieving the organization's objectives. The infrastructure includes resources such as workspace, equipment, support services, information and communication technology, and transport facilities.

4.27. The process for defining the infrastructure necessary for achieving the organization's objectives effectively and efficiently should include the following:

- Consideration of the organization's plans and objectives; safety, health, environmental, security and quality policies; performance requirements; cost restrictions; and renewal needs;
- Evaluation of the infrastructure against the needs and expectations of interested parties;
- Consideration of environmental issues associated with the infrastructure, such as issues relating to conservation, pollution, waste and recycling.

4.28. Natural phenomena that cannot be controlled may affect the infrastructure. The plan for the infrastructure should address the identification and mitigation of the associated risks and should include strategies for protection to meet the needs and expectations of interested parties.

Working environment

4.29. Senior management should ensure that the working environment has a positive influence on the motivation, satisfaction and performance of individuals so as to enhance the performance of the organization. A suitable working environment depends on a combination of human and physical factors, and its creation should include the consideration of:

— Creative working methods and opportunities for greater involvement to realize the potential of individuals in the organization;
— Safety rules and guidance, including the use of protective equipment;
— Ergonomics;
— Location of the workplace;
— Diversity of skill in the workforce;
— Long term contracts;
— Possibilities to move from one site to another site of the same organization, from one unit to another unit, or from one department to another department;
— Career planning;
— The promotion system;
— Possibilities of access to knowledge or education programmes (i.e. external training);
— Social interaction;
— Facilities for individuals in the organization;
— Heat, humidity, light and airflow;
— Hygiene, housekeeping, noise, vibration and pollution.

See Ref. [1], para. 4.5.

5. PROCESS IMPLEMENTATION

DEVELOPING PROCESSES

5.1. There are always processes in place in an organization and the initial approach should be to identify, develop and manage them in the most appropriate way. No single 'process catalogue' — listing of processes that should be documented – can apply to every organization. Instead, each organization should determine which processes are to be documented, on the basis of applicable regulatory and statutory safety requirements, the nature of the organization's activities and its overall strategy. A common understanding should be developed of what a process is, how many processes are in place in the organization and how they interrelate.

5.2. A specific management process should, on an ongoing basis, provide a vehicle for establishing priorities, including priorities for new work, and excluding lower priority activities. This process should also integrate all review and oversight activities by management, to ensure that there is a structured approach to decision making that meets the needs of the business plan.

5.3. In determining to what extent a process should be documented, the organization should consider factors including the following:

— The effects of the process on safety, health, environmental, security, quality and economic elements;
— Statutory and regulatory requirements;
— The satisfaction of interested parties;
— Economic risk;
— Effectiveness and efficiency within the organization;
— The competence levels of individuals;
— The need to retain process knowledge;
— The complexity of processes.

5.4. Where it is necessary to document processes, appropriate methods should be used, such as graphical representations, written instructions, checklists, flow charts, methods using visual media and electronic methods.

5.5. Processes developed using a top-down approach should be hierarchically linked and should be more detailed the closer they are to the technical or task level. At the technical level the process may be better described in a procedure

or instruction. The operational framework within an organization is typically made up of a number of processes, most of which have interfaces across the organization. Some organizations have found it beneficial to structure their processes as follows:

— Core processes, the output of which is critical to the success of the facility or activity;
— Supporting processes, which provide the infrastructure necessary for the core processes (e.g. procurement training);
— Management processes, which ensure the operation of the entire management system.

5.6. To develop the processes necessary for the effective implementation of the management system (see para. 5.13), the organization should consider the following:

— The satisfaction of interested parties;
— Planning;
— Grading of the application of management system requirements;
— Process management;
— The approach to decision making;
— Communication;
— Knowledge management;
— Human resources;
— Infrastructure and the working environment;
— Control of products;
— Purchasing;
— Management of organizational change and resolution of conflicts;
— Documentation of the management system;
— Control of records;
— Measurement, assessment and improvement;
— Interactions between the processes;
— Documentation of the processes.

5.7. Analysis of the processes should be the driving force for defining the amount of documentation necessary for the management system; the documentation should not determine the processes.

5.8. The following approach should be used to develop the processes of an organization:

— Identifying the processes necessary for the management system and for its application throughout the organization:
  - What are the processes needed for the management system?
  - Who are the interested parties for each process (internal and/or external interested parties)?
  - What are the statutory and mandatory requirements?
  - What are the expectations of the interested parties?
  - What are the safety, health, environmental, security, quality and economic requirements affecting each process?
  - Who is the owner of the process (see para. 5.14)?
  - Are any of the processes outsourced?
  - What are the inputs and outputs for each process?
— Determining the sequence of and the interactions between these processes:
  - What is the overall flow of the processes?
  - How can the flow be described?
  - What are the interfaces between the processes?
  - What documentation is necessary?
— Determining the criteria and methods necessary to ensure that the operation and control of these processes are effective:
  - What are the characteristics of the intended and unintended results of each process?
  - What are the criteria for monitoring, measurement and analysis?
  - How can these criteria be incorporated into the planning of the management system and the product realization processes?
  - What are the economic issues (cost, time, waste, etc.)?
  - What methods are appropriate for data gathering?
— Ensuring the availability of the resources and information necessary to support the operation and monitoring of these processes:
  - What are the resources necessary for each process?
  - What are the communication channels?
  - How can external and internal information about each process be provided?
  - How is feedback of information to be obtained?
  - What data need to be collected?
  - What records need to be kept?
— Measuring, monitoring and analysing the processes:
  - How can process performance (process capability, satisfaction of interested parties) be monitored?
  - What measurements are necessary?
  - How can the data gathered best be analysed (statistical techniques)?

  - What information do the results of this analysis provide?
- Implementing the actions necessary to achieve the planned results and the continual improvement of these processes:
  - How can each process be improved?
  - What corrective and/or preventive actions are necessary?
  - Have these corrective/preventive actions been implemented?
  - Are they effective?

5.9. For each process, the following activities should be performed:

- Selecting a process team, made up of the team leader (normally the process owner (see para. 5.14)), the team itself (representatives from the departments that are affected) and a facilitator;
- Developing a description of the process;
- Identifying the major inputs and outputs and the interested parties;
- Determining the risks and hazards of the proposed process so as to identify its acceptability and the appropriate control measures necessary to ensure that risks and hazards are managed;
- Identifying additional expectations from the process so as to be able to control performance;
- Developing a flow chart for the process that incorporates the relevant expectations and identifies related documentation;
- Developing a process description that identifies:
  - Governing documents, definitions and key requirements;
  - Key process responsibilities and descriptions of activities;
  - Supporting documentation and requirements for records;
  - How the process is or has been validated where necessary;
  - Procedures for the approval and distribution of the process documents.

See Ref. [1], paras 5.1–5.5.

PROCESS MANAGEMENT

General

5.10. To manage the processes of the organization, an organization should determine the following:

- The processes that implement the vision, goals, strategy, policies and objectives of the organization;

— The requirements for the input to the processes and the output from the processes;
— How the processes interact to enable the organization's objectives to be achieved.

5.11. Managing the processes of the organization efficiently is critical to its success. Process management should incorporate mapping, planning, designing, building, operating, maintaining and improving the processes. Incorporating these elements into process management should lay the groundwork for achieving an organization's objectives for its long term success through effective process solutions that integrate individuals, processes and technology.

5.12. Process management should use information from the processes to evaluate them with the aim of optimizing performance. Where appropriate, statistical process control should be established and should be used to reduce product and process variability and to improve quality.

Identifying the organizational processes

5.13. The processes of the organization should be identified on the basis of a review of the working practices involved in achieving the objectives, satisfying the requirements and delivering the products and services. The key elements of this review should be:

— Identifying what work is done, who carries it out and how it is performed;
— Identifying the resource needs (in terms of individuals, financing and equipment);
— Clarifying the constraints or requirements that affect how a process operates;
— Creating a logical hierarchy of the processes.

Process responsibilities

5.14. The designated individual who has the authority and responsibility for each process is often referred to as the process owner. When designating the process owner for each process, the following considerations should be taken into account. A process owner:

— Should have the authority to assess the impact of the process on safety and on the plans and objectives of the organization;
— Should have the authority to monitor the effectiveness of the process;

— Should have a good understanding of the process;
— Should be concerned when the process does not work well;
— Should have the authority to propose and initiate changes in the process;
— Should have the authority to monitor and control the major resources used in the process;
— Should have the authority to effect changes to instructions.

5.15. Process ownership should not be regarded as a status issue. Process owners should not be selected on the basis of their position in the management structure. Ownership of processes should extend down to lower levels of management of the organization.

5.16. Senior managers should not feel they have to 'own' all the processes personally. However, they should use information about the processes from the process owners to help them direct and manage the organization.

5.17. The process owner:

— Should track indicators so that performance of the process is clear and any necessary immediate adjustment of the process is possible;
— Should use additional indicators to show the improvement of the process and to show whether the specified targets have been reached;
— Should conduct reviews of processes to identify preventive actions and improvements.

See Ref. [1], paras 5.6–5.9.

Processes contracted to other organizations

5.18. Processes contracted to other organizations (i.e. outsourced), such as processes in relation to security, safety assessment or the calibration of equipment, should be controlled to ensure that the process is performed according to the relevant requirements of the organization's management system. The nature of this control should depend on the importance of the outsourced process and the risks involved in outsourcing it.

5.19. Control may include a contractual agreement with the provider of the outsourced process that includes, for example, the following topics:

— Specification and validation requirements for the process;
— Any statutory or regulatory requirements to be met;

— Management system requirements, including requirements on process monitoring and methods of measurement, performance targets for processes and the reporting of results;
— Audits to be performed by the organization.

5.20. Where an organization has the competence to carry out a process but chooses to outsource that process for commercial or other reasons, the process control criteria should be defined within the organization and transferred into requirements for the provider of the outsourced process.

5.21. Where the organization chooses to outsource a process because it does not have the competence or resources to carry out the process in-house, the organization should ensure that the controls proposed by the provider of the outsourced process are adequate.

5.22. Outsourced processes sometimes interact with other processes within the organization's management system. These interactions should also be managed as part of the management system. These other processes may be carried out by the organization itself or may themselves be outsourced processes. Management of the interactions should include:

— Discussion of and agreement on the outputs from the organization that will serve as inputs to the outsourced process and the outputs from the outsourced process that will serve as inputs to the organization;
— Arrangements for the transfer of information between the organization and the provider of the outsourced process;
— Arrangements for monitoring and measurement of the outsourced process to be carried out by the organization;
— Possible interactions and communication channels between the provider of the outsourced process and the organization's interested parties.

5.23. In some situations, it may not be possible to verify the output from the outsourced process by means of subsequent monitoring or measurement. In such cases, the organization should ensure that the control over the outsourced process includes process validation.

See Ref. [1], para. 5.10.

Document control

5.24. A document control process should be established to provide for the preparation, review, approval, issuing, distribution, revision and validation (where appropriate) of documents essential to the management, performance and assessment of work. An electronic document management system can be used to aid in document control and management (see Annex I).

5.25. The responsibilities of each participating organization or individual should be defined in the document control process.

5.26. The types of document to be controlled should include, but should not be limited to: documents that define the management system; safety requirements; work instructions; assessment reports; drawings; data files; specifications; computer codes; purchase orders and related documents; and supplier documents.

5.27. Senior management (or an appointed individual, e.g. the process owner) should identify the need for documents and should provide guidance to the organizations and individuals preparing them so that they are prepared in a consistent manner. The guidance should cover the status, scope and content of the documents, and the policies, standards and codes that apply to them. It should also explain the need for the feedback of experience. Documents, and changes to documents, should be distributed to and should be made available at the location where the activities described in the documents are conducted.

5.28. The process for document control should explain the following:

— How to prepare documents;
— How to review documents and confirm their acceptability;
— How documents at different levels are to be subject to approval;
— How to issue and distribute documents;
— How to control any temporary documents;
— How documents are to be modified or changed;
— How to suspend or cancel documents;
— How to control documents from sources outside the organization;
— How to archive documents.

Appendix II provides more detailed guidance on these process activities. See Ref. [1], paras 5.12–5.13.

Control of products

5.29. Senior management (or an appointed individual, e.g. the process owner) should specify the types of work for which formal inspection, testing, verification and validation activities are needed and should state the acceptance criteria and the responsibilities for carrying out the work. A process should be established to specify what types of inspection, testing, verification and validation are to be performed, and when, for the types of work being carried out.

5.30. Each process should be subject to review, inspection, testing, self-assessment, verification and validation by either the organizational unit responsible for the work, another department or an independent outside agency.

5.31. Administrative controls and indicators should be incorporated into each process. These controls and indicators should be used to preclude inadvertent bypassing of the necessary inspection, testing, verification and validation requirements and to prevent inadvertent use of the product or operation of the process.

5.32. Performance indicators should be developed for each process to measure whether or not performance is satisfactory. Performance indicators should have particular emphasis on safety and should be monitored so that changes can be recorded and trends can be determined.

5.33. Trends in performance indicators should be analysed to identify both beneficial and adverse factors. Beneficial factors should be used to encourage improvement. The causes of adverse factors should be determined and eliminated.

See Ref. [1], paras 5.14–5.20.

Measuring and testing equipment

5.34. The selection, identification and means of use, calibration requirements and calibration intervals of all measuring and testing equipment used for determining the quality of the product or its operational status should be

specified. Responsibilities for controls for measuring and testing equipment should be defined. See Ref. [1], para. 5.15.

Control of records

Establishment of a records process

5.35. Records provide objective evidence of activities performed or results achieved. The processes or procedures of an organization generate an entire range of information, such as:

— Specifications;
— Assessment reports;
— Safety reports;
— Procurement documents;
— Non-conformance reports;
— Receipt and storage inspection reports;
— Test results;
— Calibration data of measuring and testing equipment.

5.36. The requirements for the management of records, such as statutory obligations, codes and standards, and customer expectations, should be identified and understood to ensure that they are addressed by the organization's management processes.

5.37. Responsibilities for maintaining and operating the records process and the facilities for the storage of records should be clearly defined and documented.

5.38. It should be ensured in the records process that records are specified, prepared, authenticated and maintained as required by the applicable codes, standards and specifications.

5.39. It should be ensured in the records process that records:

— Are categorized;
— Are registered upon receipt;
— Are readily retrievable;
— Are indexed and placed in their proper locations in the files of the record facility with the retention times clearly specified;
— Are stored in a controlled and safe environment;

— Are stored in appropriate storage media (see Annex I);
— Remain unchanged under normal circumstances.

If it becomes necessary to correct errors, any revisions of records should be adequately controlled and tracked.

5.40. Storage facilities for records should be maintained to prevent damage from causes such as fire, water, air, rodents, insects, earthquakes and the actions of visitors without admission rights.

5.41. Records that need special processing and control, such as computer codes and software and information stored on high density media or optical disks, should be maintained and controlled to ensure that they are readily retrievable and usable.

Categorization of records

5.42. Records should be categorized according to the needs of the organization and the necessary retention period of the records. Annex II provides guidance on retention periods for records.

Administration of records

5.43. All records should be readable, complete and identifiable with the product or process involved. They should be preserved to resist deterioration for the necessary retention times.

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

5.45. Records should be logged and listed in an index. The methods of logging and indexing to be used should be established before the receipt of records. The index should provide sufficient information to identify both the products and the relevant records.

Retrieval and accessibility

5.46. The senior management (or an appointed individual, e.g. the process owner) should ensure that records are indexed, filed, stored and maintained in facilities that allow their retrieval when necessary. The records should be accessible at all times during the specified retention periods. Access to locations where records are retained should be controlled. Consideration should be given to storing documents that may be necessary in emergency conditions at a location away from the facility.

Storage requirements

5.47. Senior management should establish expectations for the storage and the location for the maintenance, preservation and protection of records and associated test materials and specimens from the time of their receipt until the time of their disposal. Annex III provides supplementary guidance.

5.48. If the necessary storage conditions are unattainable, consideration should be given to the provision of a duplicate set of records to be stored in a separate facility. In such cases, the location and the construction features of both facilities should be such that the probability of the simultaneous destruction, loss or deterioration of both sites for records is sufficiently low.

Disposal

5.49. Senior management should identify who is responsible for the transfer or disposal of records. Records should be categorized and retained for the retention period specified by the organization. After the retention period specified for a record has elapsed, the record can be disposed of. This should be done by, or with the agreement of, the organization.

See Ref. [1], paras 5.21–5.22.

Purchasing

5.50. Individuals carrying out procurement activities:

— Should ensure that the information provided to suppliers is clear, concise and unambiguous, fully describes the products and services necessary, and includes technical and quality requirements;

— Should ensure, as a basis for selection, that the supplier is capable of supplying the products and services as specified;
— Should monitor suppliers to confirm that they continue to perform satisfactorily;
— Should ensure that the products and services conform to the requirements of procurement documents and perform as expected;
— Should specify the contact individual for all communications on procurement with the supplier;
— Should define, where necessary, the interfaces between the organization and suppliers and between different suppliers to ensure that key dates for supply are met.

Appendix III provides an example of a typical procurement process and includes additional guidance.

5.51. Senior management should establish relationships with suppliers so as to promote and facilitate communication, with the aim of improving the effectiveness and efficiency of processes on both sides. There are various opportunities for organizations to increase the quality of their products through working with their suppliers, such as:

— Optimizing the number of suppliers;
— Establishing two way communication at appropriate levels in both organizations to facilitate the rapid solution of problems and to avoid costly delays or disputes;
— Cooperating with suppliers in carrying out validation of the capabilities of their processes;
— Monitoring the abilities of suppliers to deliver conforming products with the aim of eliminating redundant verifications;
— Encouraging suppliers to implement programmes for continual improvement of performance and to participate in other joint initiatives for improvements;
— Involving suppliers in the organization's development activities to share knowledge and to improve the realization and delivery processes for conforming products effectively and efficiently;
— Involving suppliers in the identification of purchasing needs and the development of joint strategies;
— Evaluating, recognizing and rewarding the efforts and achievements of suppliers.

See Ref. [1], paras 5.23–5.25.

Communication

5.52. Communication in any organization should be recognized as very important when a specific process is being developed. The development of the process should involve individuals at all levels of the organization and, where appropriate, external interested parties, to ensure that the process addresses their needs.

5.53. Communication should be simple and to the point and should be designed to reach the widest audience. Communication should have the following purposes:

— To share relevant information;
— To involve all relevant organizations;
— To raise issues and resolve them.

5.54. Communication should be recognized as especially important when implementing changes. In such situations, the communication strategy:

— Should explain what is happening and why;
— Should address the effects on interested parties;
— Should describe what impact the activity or change will have on safety and on the organization's processes;
— Should include training for those who are involved in the communication of changes.

5.55. The communication process:

— Should be managed in such a way as to improve performance;
— Should make use of appropriate communication channels, such as letters, email and personal meetings;
— Should engage external interested parties to ensure that they understand the messages, especially when it is necessary to gain their acceptance;
— Should engage internal interested parties to improve their performance by making sure that they:
  • Know how their everyday actions relate to the organization's objectives and policies;
  • Know how they can influence business decisions;
  • Have the information they need to guide their actions;
  • Know they will share in success on the basis of their individual and team contributions;

— Should ensure that all external interested parties are kept up to date with relevant information;
— Should evaluate the effectiveness of the processes and the messages being communicated.

See Ref. [1], paras 5.26–5.27.

Managing organizational change

5.56. When organizational change is necessary, no reduction in the level of safety achieved should be acceptable, even for short periods of time, without appropriate justification and approval.

5.57. The drive to improve efficiency and reduce costs can result in organizational changes that can have significant safety implications. Examples of such changes are:

— Mergers of organizations, leading to a drive for harmonized standards and procedures;
— Changes in the arrangements for providing central support services;
— Reassignment of work activities, thereby increasing the likelihood that expertise in critical areas will be lost;
— Changes in the policies for recruitment, selection, induction and training of individuals;
— Reductions in the number of management levels and in the grades of individuals carrying out activities in the organization.

5.58. When major organizational changes are planned, they should be rigorously and independently scrutinized. Senior management should remain aware that it has the ultimate responsibility for safety and should ensure that safety considerations are given a priority commensurate with their significance during any process of major change.

5.59. Individuals should be made aware of how their responsibilities will change both during and after organizational changes. Consideration should be given to the possible need for temporary additional resources and for compensatory measures to manage the impacts during any transitional phase.

5.60. For changes for which it is judged that potentially significant effects on safety could arise, assessments should be carried out to ensure that the following factors are considered:

— The final organizational structure should be fully adequate in terms of safety. In particular, it should be ensured that adequate provision has been made to maintain a sufficient number of trained, competent individuals in all areas critical to safety. It should also be ensured that any new processes introduced are documented with clear and well understood roles, responsibilities and interfaces. All retraining needs should be identified by carrying out a training needs analysis of each of the new roles. The retraining of key individuals should be planned. These issues are especially important if individuals from outside the organization are to be used for work that was previously carried out internally, or if their roles are to be otherwise substantially extended.
— The transitional arrangements should be fully adequate in terms of safety. Sufficient personnel with knowledge and expertise that are critical to safety should be maintained until training programmes are complete. Organizational changes should be made in such a way as to maintain clarity about roles, responsibilities and interfaces. Any significant departures from preplanned transitional arrangements should be subject to further review.

5.61. Senior management should develop a specific process to manage and review organizational changes. The process should ensure that there is no degradation in the safety culture of the organization.

5.62. A safety assessment should be developed for any changes that have the potential to affect safety. For more significant changes, advice should be sought from internal and external experts.

5.63. Criteria for assessing the implications and controlling the impacts of organizational changes should include the following considerations:

— Changes should be classified against agreed criteria and in accordance with their safety significance.
— Changes may necessitate different levels of approval on the basis of their significance.
— The organization should explain how the planned changes will help in continuing to maintain acceptable levels of safety. This applies to both the final state of the organization and the arrangements during the transitional period from the old organizational arrangement to the new one.
— A review mechanism should be agreed on to ensure that the cumulative effects of small changes do not reduce safety.

— A method of monitoring progress in the planned introduction of significant changes should be developed and any shortfalls should be rapidly identified so that remedial action can be taken.

5.64. Communication with interested parties, including individuals, should be carried out honestly and openly, addressing the safety implications and other implications of the changes and explaining the steps being taken. The appropriate mechanisms for the feedback of information to monitor the effects of the changes that are implemented should be set up.

5.65. For each change, the project leader should apply a systematic and transparent project management process, the rigour of which should be commensurate with the significance of the change. In parallel, senior management should consider the overall integration of all changes, and should oversee very significant changes that are imposed and the cumulative effects of smaller changes that may interact with each other. Effects on ongoing activities during the implementation of changes should be studied well and given careful consideration.

5.66. For each project for change proposed, the risks to the objectives of the organization, including safety, health, environmental, security, quality and economic risks, should be identified and evaluated.

5.67. The interactions between different changes should be given careful consideration. Changes that on their own may have only a limited effect on safety may combine and interact to produce much more significant effects. Where possible, different initiatives for changes that are pursued at any one time and that may affect safety should be minimized. In addition, the total workload imposed on the organization to implement the changes in parallel with continued operational activities should be given careful consideration.

5.68. The individual who has the authority to approve changes to be implemented should be clearly designated. For each change, and on the basis of the significance of the change, controls should be applied to ensure that it is possible to identify the individual in the organization who is authorized to approve the change.

5.69. Preferably, one individual should approve each change, and the change should be endorsed by those individuals whose areas of responsibility are most affected. This should be given particular importance when the activities that will permit the change to be made are the responsibility of different parts of the

organization. Evidence that the change satisfies safety requirements should be made available and an endorsement should be sought from the organization's safety unit. The approval should indicate whether an independent review has been carried out and how the recommendations from the review, if any, have been addressed.

5.70. If changes may affect any third party approvals, licences, accreditations or certifications, then these parties should be consulted.

5.71. Adequate monitoring should be carried out to provide early warning of any effects on performance, thereby ensuring that there is sufficient time to take remedial action before acceptable safety levels are challenged. Wherever possible, such remedial action should be planned in advance. Care should be taken in choosing the measures to be monitored and in assessing their effectiveness in providing early warning of any trend towards deterioration. Changes with the potential for major effects on safety levels should be subject to more extensive monitoring to detect adverse trends earlier. The likely effectiveness of changes should also be considered and the speed with which a situation that may be critical to safety can be rectified should be assessed.

See Ref. [1], paras 5.28–5.29.

6. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

GENERAL

6.1. Measurement, assessment and improvement should be part of the establishment of a learning culture in the organization. Individuals at all levels should review their work critically on a routine basis to identify areas needing improvement and the means of achieving it.

6.2. To avoid any decline in safety performance, senior management should remain vigilant and objectively self-critical. As a key to this, objective assessment activities should be established. The nature and types of assessment activity should be adjusted to suit the size and product of the organization, should reduce the dangers of complacency and should act as a counter to any tendency towards denial. In addition to the early detection of any

deterioration, an assessment of weaknesses in the management system could also be used to identify potential enhancements of performance and safety and to learn from both internal and external experience.

6.3. The relationships between the activities of measurement, assessment and improvement are shown graphically in Fig. 1. Independent assessment includes internal audits, external audits, surveillance and reviews, checks, inspections and tests. Self-assessment should be conducted at all levels in the organization to assess performance and safety culture. At the organizational level it can be carried out by senior management. At the unit or work group level other managers and individuals can carry it out. The management system review is carried out for senior management to determine the suitability, adequacy, effectiveness and efficiency of the management system in achieving objectives and improving performance. Senior management should use the information yielded by all these activities to improve safety and performance; small improvements can always be implemented as they are found.

MONITORING AND MEASUREMENT

6.4. The management system should ensure that standards of performance are established. These standards should be directly related to the product provided by the organization and based on the objectives set by senior management. Once the standards have been established, performance should

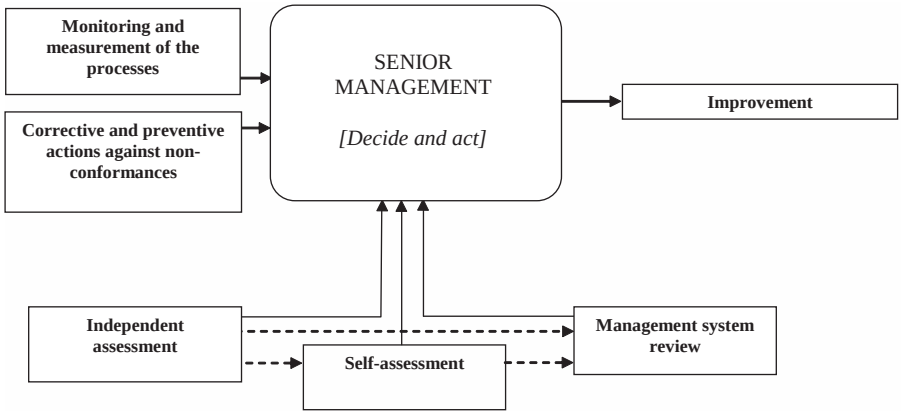


FIG. 1. Relationships between the activities of measurement, assessment and improvement. The broken lines show where one activity is used as an input to focus the activities of another assessment.

be measured against them. These measurements should be monitored at regular intervals to ascertain whether or not improvements in the quality of the product or process are necessary. Performance indicators should be used and other appropriate methods of measurement should be developed.

6.5. Senior management should bear in mind that problems often have their origins in the management system and that individuals have little or no control over eliminating these problems or improving performance. When the need to change management processes is identified, such changes should be formally proposed, agreed and introduced. It may be necessary to refer recommendations for change to senior management.

See Ref. [1], para. 6.1.

SELF-ASSESSMENT

Self-assessment by senior management

6.6. The purpose of self-assessment by senior management should be to identify, correct and prevent management problems that hinder the achievement of the organization's objectives. Self-assessment by senior management should go beyond such matters as conformance to regulations, product standards or established procedures. Self-assessment by senior management should evaluate issues such as:

— Are the plans and goals of the organization still appropriate and valid?
— Are managers regularly monitoring the plans and goals and the achievement of these goals?
— Do individuals understand the plans, goals and objectives?
— Is the overall performance focused effectively on meeting objectives?
— What is expected of the organization?
— What is expected of individuals in the organization?
— Are the expectations being met?
— What opportunities are there for enhancing safety and improving quality?
— Are there any declining trends in effective and safe performance?
— How could the organization make better use of its human resources?

6.7. Effective self-assessment by senior management should evaluate such conditions as: the state of the knowledge, motivation and morale of individuals;

safety culture; the amount of mutual trust and communication among individuals; the existence of an atmosphere of creativity and improvement; and the adequacy of human and material resources.

6.8. The results and decisions of the self-assessment by senior management should be recorded and related actions resulting from the recommendations should be taken promptly. Senior management should evaluate the effectiveness of these actions.

6.9. Reports from managers, summary results of self-assessment, and independent assessment and feedback are useful sources of information on the overall performance of the organization and should all be used to assist senior management in targeting improvement actions.

6.10. Senior management should retain overall responsibility for carrying out self-assessment for management. Direct participation by senior management is essential to the success of the process since it is in a position to have an overview of the organization as a whole.

6.11. The results of self-assessment by senior management should be used as input to the organization's continual improvement process. The improvement process should lead to enhanced levels of safety and performance.

Self-assessment by managers and individuals

6.12. Individuals and management (other than senior management) at all levels in the organization should periodically compare present performance with management expectations, worldwide industry standards of excellence and regulatory requirements to identify areas needing improvement.

6.13. Each unit within the organization should routinely conduct its own self-assessments of processes and performance.

6.14. Managers and individuals should seek continual improvement by identifying areas needing improvement and then taking corrective actions. The need for improvement should be recognized as a normal part of routine work.

6.15. Senior management should reinforce a questioning attitude in individuals and should encourage the discovery and reporting of all areas needing improvement. Managers should avoid punishing or intimidating individuals for

unintentional errors and should not react defensively to suggestions for improvement.

6.16. Managers at every level should periodically assess the performance of their respective units to determine the quality of the leadership being provided, to enable the organization to meet requirements and expectations. This self-assessment should place emphasis on the use of human and material resources to achieve the organization's objectives.

6.17. Self-assessment should actively identify opportunities for improvement. To prevent significant performance problems, self-assessment should seek to identify weaknesses that could cause more serious errors or events.

6.18. Self-assessment should rely on certain organizational characteristics that provide support and enhance the effectiveness of self-assessment. These characteristics, which are common in highly effective organizations, are as follows:

— The organization has an environment or organizational culture that encourages individuals (and workers temporarily assigned to the facility) to participate actively in the self-assessment processes.
— Senior management encourages this environment by communicating to individuals the importance of self-assessment and the teamwork necessary for it to be successful in improving performance.
— Self-critical behaviour occurs in this environment.
— Senior management demonstrates ownership of the self-assessment process by directing, prioritizing and providing sufficient resources.
— Individuals recognize that minor problems may often lead to more significant events, and they identify undesirable work practices and behaviour and weaknesses in processes from these minor problems.

6.19. Various methods of self-assessment may be used. Examples of self-assessment techniques include the following:

— Workspace inspections or observations and routine communications with individuals, including informal interviews, to determine whether expectations are understood;
— Coaching or observation programmes in which weaknesses in performance are documented for further action;
— Review, analysis and trending of important performance and safety data;
— Reviews of new corrective action reports by senior management;

— Reviews of important data on process performance;
— Benchmarking to identify opportunities for improvements in performance;
— Periodic reviews of performance by senior management, such as management review meetings in which managers provide a summary of key performance weaknesses or strengths in areas for which they are responsible.

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

— Adverse trends in performance data or problems tracked in the corrective action programme;
— Indications of process inefficiencies;
— Input from ongoing self-assessment activities or information provided by independent or external assessment groups;
— Significant changes for which an early progress check is necessary;
— Implementation of new programmes or revisions to existing programmes or processes;
— New or recent issues or problems.

6.21. Information used in preparing for and conducting self-assessments typically includes:

— Historical information, such as open actions (actions not yet completed) and completed actions from the corrective action programme, performance trends, lessons learned, critiques, operating experience and regulatory or other commitments;
— Current performance information, such as the results of observation programmes or measurements of performance;
— Information that may indicate that more significant problems could result if the error is not corrected, such as problems identified from the results of observation programmes;
— Reports from previous self-assessments or inspections.

See Ref. [1], para. 6.2.

INDEPENDENT ASSESSMENT

Types of independent assessment

6.22. Independent assessment may include reviewing, checking, inspecting, testing, internal audits, audits performed by external organizations and surveillance. Independent assessment should be focused on safety aspects and areas where problems have been found. Assessment plans should be reviewed and adjusted to reflect new or emergent management concerns and performance problems. Appropriate combinations of various types of assessment should be used to provide a balanced evaluation of performance. Results should be verified in accordance with written criteria and, where possible, evaluated objectively against specified standards and/or requirements. Appendix IV provides detailed guidance on how to perform independent assessments.

Internal audits

6.23. A schedule of internal audits should be established by the assessment unit and endorsed by the senior management of the organization.

6.24. Internal audits should not be conducted for the sole purpose of determining compliance with requirements. They should be conducted to evaluate the need for corrective actions, with the emphasis on seeking opportunities for improvement and enhancing performance.

6.25. Internal audits should also be prompted by significant changes in the management system or the associated processes, or by weaknesses in performance or in safety.

Surveillance

6.26. Surveillance of work performance is considered to be the best technique for assessing and reporting on a specific area or an ongoing activity. It is flexible and less formal than audits and can be performed in a relatively short period of time with limited preparation. However, advance notice should usually be given.

6.27. Surveillance should be carried out:

— To provide information and data in a specific performance area;

— To provide information and data on an individual activity;
— To provide immediate feedback of results;
— To follow up on observations in previous assessments.

6.28. Surveillance should be applied where:

— Flexibility in timing, methods, individuals and reporting is desirable.
— Additional information is necessary to develop conclusions regarding previous assessments.
— There is a need to respond to opportunities that arise at short notice.

6.29. For work or tasks that occur frequently, several surveillance visits should be carried out over a period of time to determine whether any adverse trends exist.

6.30. A single instance of surveillance should not be considered sufficient to assess fully the overall effectiveness of the management system. In addition to monitoring and observing work that is being done, reviews of documentation and interviews should also be carried out.

Responsibilities of the assessment unit

6.31. The assessment unit should be responsible for assessing, as a minimum, whether activities are being performed in accordance with specified requirements. The unit should, where possible, identify opportunities for improvement. In some organizations, an outside agency is assigned the task of conducting independent assessments on behalf of management. The following material is also relevant to such an outside agency, particularly if the agency uses individuals from the organization as part of the assessment team.

6.32. The assessment unit, in conjunction with senior management:

— Should define the assessment techniques;
— Should identify the resources necessary to achieve an effective assessment;
— Should obtain access by assessment teams to levels of senior management having the responsibility and authority to ensure corrective actions;
— Should make arrangements for the temporary assignment of specialists to assessment teams;
— Should define the scope, methods and schedules for initiating, conducting and reporting assessments;

— Should determine the distribution lists for assessment reports;
— Should make provisions for follow-up activities.

6.33. The assessment unit should operate as an arm of and an advisor to senior management. The assessments should focus on evaluating the performance of work and actions and should include the review and evaluation of management system documents.

6.34. Individuals carrying out assessments should view the organization being assessed as if they were interested parties of the organization, so as to produce meaningful feedback on the organization's performance.

6.35. Peers who are technically competent to review and evaluate the work and processes being assessed could also conduct assessments. These peers should not be individuals who have direct responsibilities in the areas being assessed.

6.36. Independent assessments do not necessarily always need to be carried out by the assessment unit. Independent assessments could also be carried out by other individuals who have been brought together for a specific assessment or by a joint team that includes members of the assessment unit and other individuals in the organization.

6.37. Individuals from other departments on short term secondments could supplement the assessment unit or could participate in assessments conducted by any external organizations for the duration of the independent assessment. Such individuals should have an understanding of the work area being assessed and should be conversant with the type of assessment being used.

6.38. Individuals within the organization that is conducting independent assessments should not have responsibility for the work performance being assessed. Individuals carrying out assessments should exercise objectivity in examining evidence and in forming conclusions.

6.39. A team leader should be appointed to manage all phases of each assessment. The team leader should be responsible for:

— Selecting the team members;
— Planning;
— Representing the team;
— Managing the team during the assessment;
— Interacting with the managers of work that is being assessed;

— Preparing and submitting the report;
— Checking the effectiveness of any corrective actions.

6.40. Team members should abide by the leadership, direction and guidance of the team leader.

6.41. Inexperienced members of the team should be adequately monitored and supervised until they are considered proficient in the type of assessment being carried out.

6.42. Assessors should be capable of looking for opportunities for improvement and providing recommendations to senior management. Problems and good practices should be reported in a way that will help senior management to understand what actions are necessary.

6.43. Individuals performing assessment activities should be trained in and familiar with:

— The principles of the management system;
— Methods of assessment;
— Observation and interview techniques;
— Evaluation and objective reporting;
— Communication and leadership skills.

6.44. Individuals could be assigned to the assessment unit teams on a rotational basis as part of career development.

See Ref. [1], paras 6.3–6.6.

MANAGEMENT SYSTEM REVIEW

6.45. Senior management should develop activities for management system review into a process that extends to the whole organization. Management system reviews should be platforms for the exchange of new ideas, with open discussion and evaluation of the inputs, and should be stimulated by the leadership of senior management.

6.46. The frequency of review should be determined by the needs of the organization. Inputs to the review process should result in outputs that provide

data for use in planning for improvements in the performance of the organization.

Review inputs

6.47. Inputs that will allow the evaluation of the efficiency and effectiveness of the management system in the review should cover:

— The status and the organization's objectives and the results of improvement activities;
— The status of actions from past management system reviews;
— The performance of the organization in achieving its objectives, plans and goals;
— The results of assessments of all types;
— Feedback on the satisfaction of interested parties;
— Advances in technology, research and development;
— Results from benchmarking activities;
— The performance of suppliers;
— New opportunities for improvement;
— The control of process and product non-conformances;
— The status of activities in strategic partnerships;
— Other factors that may impact the organization, such as financial, social or environmental conditions;
— Relevant statutory and regulatory changes.

Review outputs

6.48. Senior management should use the outputs from the management system review as inputs to the improvement process. Senior management should use this review as a powerful tool in the identification of opportunities for improvement in the performance of the organization. The schedule of reviews should facilitate the timely provision of data for strategic planning for the organization. Selected outputs should be communicated to the individuals in the organization to demonstrate how the process of management system review conducted by senior management leads to new objectives that will benefit the organization.

6.49. Additional outputs to enhance efficiency should include:

— Performance objectives for safety, products and processes;

— Objectives of improvements in performance and safety for the organization;
— Appraisals of the suitability of the organization's structure and resources;
— Strategies and initiatives for satisfying interested parties;
— Loss prevention and mitigation plans for identified risks;
— Information for strategic planning for meeting the future needs of the organization.

See Ref. [1], paras 6.7–6.10.

NON-CONFORMANCES AND CORRECTIVE AND PREVENTIVE ACTIONS

6.50. In many organizations there are several processes to control non-conforming products or processes, for example product inspections. The process or processes should include provisions to prevent the inadvertent use or installation of products or processes that do not conform and to ensure that effective corrective action is taken.

6.51. Non-conformances should be regarded as opportunities for improvement and as such should be used as an input to the management system improvement process.

6.52. Senior management should foster a 'no blame' culture to encourage individuals to identify non-conforming products and processes. Senior management should also be involved in the resolution of difficult issues and should provide a process for resolving professional differences of opinion.

6.53. Senior management should ensure that those performing work are aware of and use the process for prompt notification and reporting of non-conformances.

6.54. All individuals should have the opportunity to identify, and should be encouraged to identify, non-conforming products and processes, and should have the opportunity to identify improvements and suggest them via the management system.

6.55. Senior management should allocate responsibilities so that non-conformances are monitored and followed up until it has been verified that the

agreed corrective actions have been completed, including the provision of feedback to the individuals who identified the non-conformances.

6.56. Individuals responsible for classifying and analysing non-conformances should have an adequate understanding of the area in which they are working and should have access to pertinent background information concerning the non-conformances. Safety considerations should have priority over cost and schedule considerations in the classification and analysis of non-conformances.

6.57. Determination of the cause of a non-conformance may require a thorough investigation by technically qualified and experienced individuals. The investigation may need to include the participation of the individuals involved and those who identified the non-conformance, to gain a complete understanding of the problem. The managers responsible for the determination of the cause of the non-conformance should assign sufficient resources to the task.

6.58. Non-conforming products should be properly identified, segregated, controlled, recorded and reported The impact of the non-conformance should then be evaluated and reviewed and the non-conforming product should be (a) accepted; or (b) reworked or corrected within a specified time period; or (c) rejected and discarded or destroyed to prevent its inadvertent use.

Non-conformance control

Identification of non-conformances

6.59. Any individual who finds products or processes that do not meet specified requirements, or who observes abnormal behaviour, should be obliged to report the matter formally using the appropriate process.

6.60. Conditions and events to be handled by the non-conformance control process should include:

— Deviations from approved process parameters or procedures;
— Delivery or procurement of items or services that do not meet requirements;
— Failures of individuals to implement work instructions;
— Inadequate documentation containing incorrect or incomplete information;

— Inadequate training of individuals to perform the safety related tasks for which they have been given responsibility.

Reporting

6.61. A formal report of a non-conformance:

— Should identify who is reporting the non-conformance, when it was found and to whom it was initially reported;
— Should identify the non-conforming product or process and state its location and the method used to physically mark, label, segregate or otherwise control the product or process to prevent its inadvertent use;
— Should include a description of the non-conformance;
— Should describe the immediate action taken by the individual reporting the non-conformance, or by others, to minimize the adverse effects of the non-conformance.

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

Initial actions

6.63. Promptly on being advised of a non-conformance, managers:

— Should ensure that a report has been drawn up, verify the details contained in it and acknowledge notification;
— Should initiate any necessary immediate action to minimize the effect of the non-conformance;
— Should confirm that the product or process has been identified (i.e. physically marked, labelled, segregated or otherwise controlled) as non-conforming;
— Should determine what restrictions on further use of the product, service or process should be put in place;
— Should arrange for a more detailed review of the non-conformance;
— Should review other related non-conformances.

6.64. Non-conformances should be reviewed as soon as practicable by appropriate individuals. The review should determine:

— The cause of the identified non-conformance;

— Any safety implications of the non-conformance;
— The actions to correct the non-conformance and to prevent the repetition of similar non-conformances; these corrective actions should be agreed upon and should be subject to approval.

6.65. Information about the non-conformance and its implications for safety should then be used to determine the impact on affected activities until the agreed and approved corrective action is verified as having been satisfactorily completed.

Corrective actions

6.66. The objective of a corrective action process should be to identify, document, evaluate and trend non-conformances and to take actions to correct non-conformances.

6.67. Senior management should support the corrective action process by encouraging the effective identification and correction of non-conformances.

6.68. The degree of evaluation used for non-conformances that have been reported and are subject to the corrective action process can vary widely. Because of the time and effort involved in the evaluation of non-conformances, a graded approach should be applied to ensure that the most intensive evaluation is reserved for the problems of highest significance.

6.69. The following criteria should typically be considered for a successful corrective action process:

— Senior management encourages individuals at all levels in the organization to identify and report all types of problem.
— Problems include issues needing more evaluation before corrective action, as well as those that are easily corrected and are documented for trending purposes only.
— Individuals have a thorough understanding of the problem reporting process.
— Individuals have easy access to methods of reporting problems.
— An individual discovering a problem takes immediate actions that include:
  • Reporting the problem to supervisors as necessary;
  • Ensuring that a document reporting the problem is initiated;

- If immediate actions are considered sufficient to correct a problem, closing the document that drew attention to the problem without further evaluation. In this instance, the problem report remains in the corrective action database for trending purposes. Minor problems may be symptoms or indicators of more significant issues, and trending can provide early indications of such issues.

6.70. New non-conformances that are reported in the corrective action process should be reviewed promptly for their effect on safety.

6.71. Senior management should ensure that corrective actions are subject to approval, prioritized and completed in a timely manner, on the basis of their significance. Managers should be held accountable for meeting due dates for corrective actions. Extensions or exceptions to due dates for completing corrective actions should be controlled and should be made only in response to new issues of higher priority.

6.72. Non-conformances and associated causes should be trended to identify repeat occurrences, generic (common) issues and weaknesses while the weaknesses are still at a level at which they do not pose a significant hazard.

6.73. Trend analysis data should be reviewed and summarized periodically. Senior management should review a report of the results.

6.74. Corrective actions designed to prevent any recurrence of significant non-conformances should be reviewed for effectiveness. These reviews help to determine whether corrective actions are also effective in preventing recurrence.

6.75. Senior management should monitor the status of corrective actions frequently and should consider:

— Whether the time delay is reasonable for corrective actions that are still open (not completed);
— Whether the necessary resources are available to complete open corrective actions;
— Whether managers are being held accountable for completing corrective actions.

Preventive actions

6.76. The purpose of preventive actions is to prevent the potential causes of non-conformances from occurring and to maintain safety and performance. A process for preventive actions:

— Should take proactive steps to ensure that a potential non-conformance does not occur;
— Should use process analysis to determine how to build in process changes.

6.77. Preventive actions should include, but should not be limited to, the following:

— Changing processes or the organizational structure;
— Retraining and requalifying individuals;
— Improving safety culture;
— Changing or modifying documents;
— Improving the management system;
— Enforcing requirements for documents;
— Issuing new documents.

See Ref. [1], paras 6.11–6.16.

IMPROVEMENT

6.78. A strategic objective of an organization should be the continual improvement of processes in order to enhance the organization's performance. Opportunities for improvement should be identified from the following:

— The performance of the management system in meeting goals and plans;
— Feedback from use;
— Experience from outside organizations;
— Technological developments in the field;
— Improvements identified by individuals;
— Improvements identified from reviews of the characteristics of products and processes, such as their reliability;
— The results of assessments, corrective and preventive actions, and management system reviews.

6.79. Continual improvement can be achieved:

— At the working level, by introducing small incremental improvement activities conducted within existing processes by those directly involved from day to day;
— At the process level, where each individual process owner is in charge of improvement;
— At the organizational level, through significant improvement projects throughout the organization (at the level of the management system) which lead either to the revision and improvement of existing processes or to the implementation of new processes. These projects are usually carried out by cross-functional teams and are distinct from routine operations.

6.80. Significant improvement projects often involve a major redesign of existing processes and should include:

— Definition of the objectives and an outline of the improvement project;
— Analysis of the existing process (the 'as is' process) and investigation of opportunities for change;
— Specification and planning of the improvement to the process;
— Implementation of the improvement;
— Verification and validation of the process improvement;
— Evaluation of the improvement achieved, including lessons learned.

6.81. Significant improvements should be made in an effective and efficient way using project management methods.

6.82. Individuals in the organization should be considered the best source of ideas for improvements. Even small improvements should be controlled in order to understand their cumulative effects.

6.83. Those individuals in the organization who are involved in implementing an improvement should be provided with the authority, technical support and resources necessary for the changes associated with the improvement.

6.84. Continual improvement should be made by means of a process that contains the following elements:

— Reason for improvement: A process problem should be identified and an area for improvement selected, noting the reason for working on it.
— Current situation: The effectiveness and efficiency of the existing process should be evaluated. Data should be collected and analysed to determine

what types of problem occur most often. A specific problem should be selected and an objective for the improvement process should be set.

— Analysis: The causes of the problem should be identified and verified.
— Identification of possible solutions: Alternative solutions should be explored. The process with the best solution should be selected and implemented. The best solution is one that will eliminate the causes of the problem and prevent the problem from recurring.
— Evaluation of effects: It should then be confirmed that the problem and its causes have been eliminated or their effects reduced, that the solution has been effective and that the objective for the improvement process has been met.
— Implementation and standardization of the new solution: The old process should be replaced with the improved process, thereby preventing the problem and its causes from recurring.
— Evaluation of the effectiveness and efficiency of the new process: The effectiveness and efficiency of the improvement project should be evaluated and consideration should be given to using its solution elsewhere in the organization.

See Ref. [1], paras 6.17–6.18.

Appendix I

TRANSITION TO AN INTEGRATED MANAGEMENT SYSTEM

I.1. Having an integrated management system that is focused on satisfying all requirements is essential to an organization if it is to compete and survive in the global environment, while also maintaining and enhancing safety. An integrated management system can provide a number of benefits, together with enhanced safety and business performance. An integrated management system can lead to considerable savings in developing and maintaining organizational activities such as individual training, and reviews and approvals by interested parties, particularly when the costs and efforts of maintaining a number of separate activities and their review and upkeep are considered. Senior management should evaluate its needs and existing management systems, including its quality assurance systems, against the guidance provided in this Safety Guide and should take steps to develop and implement an effective transition plan to move to an integrated management system.

I.2. The following key steps will assist organizations with different types of management system in any stage of development and will aid in achieving an integrated management system:

— Organizations with existing management systems that are not integrated:

  Those organizations that have separate management systems for the safety, health, environmental, security, quality and economic areas should examine the commonalities between various programmes such as documentation control, records and assessments. They should then address the generic approaches and processes to manage their activities on the basis of the requirements and guidance provided in their national requirements and in IAEA publications. A detailed transition plan and a team of experts from the different areas should be established to develop the overall framework and processes for the integrated system.

  Organizations that at present have a quality assurance programme that meets the requirements of Ref. [2] should already have defined most of their activities in its processes. Many of the concepts in this Safety Guide may already have been introduced. The objective of the new guidance on management systems is to bring together all the requirements in an integrated way rather than having separate systems for safety

management, health management, environmental management, security management, quality management and business management.

— Organizations with a management system that does not use processes to manage activities:

If the organization has a quality assurance system that does not use a process approach, it should consider the benefits of an integrated approach, should identify all requirements and define its processes and their sequences and interactions, and should develop an integrated management system following the guidance in this Safety Guide.

— Organizations with no management system:

Those organizations that are just starting to establish their management system should seriously consider the advantages and benefits of taking a holistic view of their business and should consider investing the efforts and resources necessary to move in the direction of an integrated management system. This Safety Guide and the related Safety Guides provide the relevant guidance for establishing, implementing, assessing and continually improving a management system.

Appendix II

ACTIVITIES IN THE DOCUMENT CONTROL PROCESS

PREPARATION OF DOCUMENTS

II.1. Individuals preparing, revising, reviewing or approving documents should have access to the appropriate information.

II.2. When documents are in their preparatory phase, they should be marked and controlled so that their draft status clearly distinguishes them from documents that have already been issued.

II.3. An appropriate document identification system should be established. Each document should be uniquely identified.

II.4. Standard forms should be identified and controlled, whether the document is to be taken alone or as part of another document.

II.5. The need for traceability of a document to related hardware or software should be determined.

II.6. During preparation, the activities described by the documents should be assessed using the grading process, so that the appropriate controls are chosen and included.

REVIEW OF DOCUMENTS AND CONFIRMATION OF ACCEPTABILITY

II.7. Documents should be reviewed before issue. The review should comprise a critical examination of the need for and the adequacy of the document, with respect to prescribed requirements, guidelines and relevant modifications. Account should be taken of the safety significance of the document.

II.8. The document review process should identify the organizations and individuals involved in the review process and the levels of independence necessary for reviewing the documents.

II.9. The reviewing organization or individuals should have access to the relevant information upon which to base an effective review, to ensure that safety considerations are adequately addressed.

II.10. The reviewing organization or individuals should be competent in the specific topic that they are being asked to review.

II.11. A record of the review should be prepared showing the date of the review and the name of the reviewer and including the reviewer's comments and their resolution.

II.12. One aspect of review can involve validating the implementation of the document through simulation, a mock-up of the proposed product, a walk-through of the proposed procedure or a similar activity. This validating process is usually applied to significant working level instructions and procedures.

APPROVAL OF DOCUMENTS

II.13. Documents should be approved according to a prescribed method before they are issued for use. The responsibilities for approval should be clearly defined by senior management. Acceptance by, or the approval of, the regulatory body should be obtained where this is required.

ISSUE AND DISTRIBUTION OF DOCUMENTS

II.14. An issue and distribution process for documents that uses up to date distribution lists should be established. Those individuals who participate in an activity should be aware of, should have access to and should use the documents that have been approved for performing the activity. The process should ensure that changes to documents are relayed to all affected individuals and organizations. Copies subject to revision updating (controlled copies) should be identifiable.

II.15. The documents issued should be marked so that the nature of their use is made clear, especially if their use is restricted to a certain purpose. Examples of marking include 'approved for use' or 'for test purposes only'.

II.16. Controlled documents should be distributed to and used by the individual performing the activity. Obsolete documents should be removed from circulation to prevent their inadvertent use.

II.17. To preclude the use of inapplicable documents and to ensure the control of current documents, the distributor should employ a written acknowledgement system. The recipient should indicate receipt of the document and should return or dispose of the previous issue.

II.18. Master copies of documents should be retained until they are superseded or withdrawn. The need for archiving master copies of documents should be considered.

II.19. Uncontrolled copies of documents may be supplied, provided that they clearly indicate that they will not be automatically updated and are valid on the day of issue only. In these circumstances it is the responsibility of those using the information contained in the documents to check before use that the documents are still current.

TEMPORARY DOCUMENTS

II.20. Under certain circumstances, a temporary document may be necessary to cover an activity for a limited period. This will be necessary when an immediate amendment to an existing document cannot be justified. Temporary documents should be subject to the same controls as permanent documents.

II.21. Temporary documents should have a defined period of validity. When this period expires, the document should be withdrawn or its contents should be integrated into an appropriate document, or the temporary period of validity should be renewed.

CONTROL OF MODIFICATIONS TO DOCUMENTS

II.22. Modifications to documents should be subject to the same level of review and approval as the original documents. A modification to one document may affect other documents and affected documents should be revised accordingly. Where practicable, modifications to documents should be highlighted in the documents by the use of sidelining (marking clearly in the margin any text that should be modified or deleted) or other suitable means.

SUSPENSION OR CANCELLATION OF A DOCUMENT

II.23. When a document is to be suspended or cancelled, it should be removed from use. Suspension and cancellation notices should identify uniquely the reference and issue numbers of the document to which they apply and should give the document's effective date of application and the reasons for its suspension or cancellation. In the case of suspension notices, the duration of suspension should also be provided.

II.24. Suspension and cancellation notices should be subject to approval at the same level as the original document, and should be distributed to all controlled copy holders, to preclude the use of suspended or cancelled documents.

DOCUMENTS EXTERNAL TO THE ORGANIZATION

II.25. A registration system should be established and maintained to record and control the receipt and amendment of documents that are generated and controlled externally. The registration system should, as a minimum, register the receipt date of the document, its reference number, title, date of issue and/or issue status, and the individual or individuals to whom it was passed for distribution or, if appropriate, review.

II.26. Documents from external sources should be reviewed to ensure their suitability before acceptance and use.

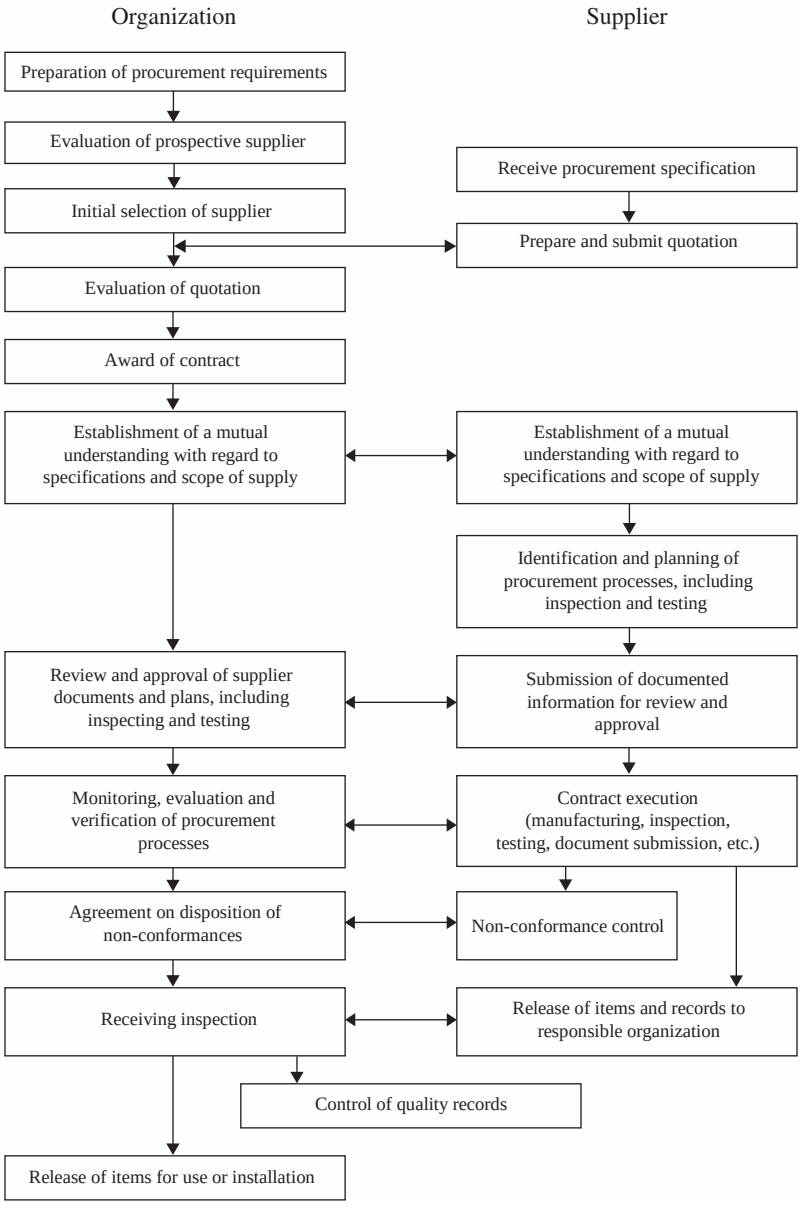
DOCUMENT ARCHIVES

II.27. When documents such as procedures and drawings that were subjected to the formal issue process are withdrawn from use, the master copies should be archived as records, following the guidance in this Safety Guide.

Appendix III

ACTIVITIES IN THE PROCUREMENT PROCESS

III.1. The following flow chart depicts a typical procurement process. The text that follows provides guidance on some of the steps in the process.



PREPARATION OF PROCUREMENT DOCUMENTS

III.2. Procurement documents should generally cover the points below. The associated responsibilities should also be identified.

- Scope of the work: A full description of the work to be undertaken by a supplier, including interfaces with other work, so that the intent is clearly understood and prospective suppliers can deliver the products or services as specified.
- Technical requirements: The technical requirements for products or services should be specified with reference to technical documents such as: codes, specifications, regulatory requirements, standards, design basis documents and drawings, process requirements and requirements for the approval or qualification of the products, procedures or processes. Each specified requirement should be achievable and its achievement should be verifiable. It should be ensured that, when the requirement is met, the product or service is rendered fit for its intended purpose.
- Training requirements: Needs and requirements should be identified and the necessary resources should be provided, for example the need for nuclear facility induction training to enable individuals to work on the site and move around the site unescorted.
- Inspection and testing requirements: When inspection or testing of products is necessary, this should be specified. Acceptance criteria for the requirements should also be specified.
- Access to the supplier's facilities: Conditions of access to the supplier's premises to carry out activities such as inspections, audits and surveillance should be defined. These activities may be performed by the organization or by other authorized parties acting on its behalf.
- Identification of the standards applicable to the management system: The management system standards to be complied with must be clearly defined. If the organization wishes to quote national or international management system standards, an evaluation should be performed to determine whether additional requirements other than those established in Ref. [1] are necessary. When international standards other than those of the IAEA are quoted, care should be taken to ensure that the additional requirements are adequately addressed by the management system.
- Document requirements: The documents that the supplier is required to submit to the organization for approval or comment should be clearly identified in the procurement documents.

— Record requirements: Requirements on records and on material samples should be made clear to the supplier prior to concluding the contract. This could best be achieved by providing or requiring a record schedule that details all record requirements to be submitted by the supplier. Instructions for the retention by or transfer of records from the supplier and/or subsidiary suppliers should be specified. These should include the records that are requested by the organization to ensure that the products or services have met or will meet the requirements. Retention periods and responsibilities for the maintenance of records by the supplier should also be specified.
— Timing of submissions: Clear instructions should be given to suppliers regarding the times when the necessary documents and records should be submitted.
— Non-conformance reporting: The supplier should have a clear understanding of the non-conformance control process. It should be made clear which party may sanction which type of non-conformance.
— Subsidiary supplier controls: Unless otherwise specified by the organization, the supplier should be responsible for the control of subsidiary suppliers. Therefore, if a subcontract is placed, the supplier should be requested to secure from the subsidiary supplier all rights of access as a contractual requirement. The supplier should be required to impose management system requirements on the subsidiary supplier consistent with the importance of the subcontracted product. This would include, for example, the responsibility to monitor and evaluate the performance of the subsidiary supplier.

REVIEW AND APPROVAL OF PROCUREMENT DOCUMENTS AND CHANGES TO THEM

III.3. The responsibilities for review and approval of procurement documents within the organization should be defined.

III.4. Procurement documents should be reviewed and approved before issue to ensure that all requirements have been included and are in accordance with the specified procedures of the purchasing organization and regulatory requirements. Changes to procurement documents should be undertaken in a controlled manner. Changes to procurement documents should be subject to the same level of control as the original documents.

SELECTION OF SUPPLIERS

III.5. The selection of suppliers should be based on an evaluation of their capability to provide products or services in accordance with the requirements of the procurement documents.

III.6. Senior management should use specified criteria to evaluate and select suppliers. Responsibilities for determining suppliers' capabilities should be identified.

III.7. Methods to be used in evaluating prospective suppliers should include, for example:

— Evaluating the prospective supplier's history of providing a product that performs satisfactorily in actual use, such as:
  • The experience of users of identical or similar products and services provided by the prospective supplier;
  • Review of records that have been accumulated in connection with previous procurement actions and operating experience with the product;
  • Review of historical data relevant to the products or services being procured that are representative of the prospective supplier's current capability. If there has been no recent experience, the prospective supplier should be requested to submit information on an equivalent product or service for evidence of current capabilities.
— Evaluating the prospective supplier's management system:
  • Assessing the capability of the prospective supplier by evaluating the supplier's facilities and evaluating individuals and the implementation by the supplier of the management system;
  • Objectively evaluating the prospective supplier's current records supported by documented qualitative or quantitative information such as statistical records or other records attesting to the prospective supplier's performance.
— Evaluating the capability of the prospective supplier by investigating samples of current production.

III.8. After the initial selection of prospective suppliers, procurement documents should be forwarded to them indicating the date for submitting tenders (quotations), and the procedures for resolving questions and seeking clarification (for example by meetings, presentations and/or assessments).

EVALUATION OF QUOTATIONS AND AWARD OF CONTRACT

III.9. Submitted quotations (bids or tenders) from prospective suppliers should be evaluated in a logical manner to ensure that they conform to the requirements of the procurement documents.

III.10. The evaluation of quotations carried out by the organization should be a team effort involving the organizational units responsible for the technical and procurement activities. The size of the team undertaking the evaluation should be determined by the size and complexity of the product to be purchased.

III.11. The award of the contract should be based on the capability of the supplier to meet the requirements of the procurement documents. All actions arising from the evaluation of quotations should be fully documented and resolved, including the grounds for awarding the contract.

EVALUATION OF SUPPLIER PERFORMANCE

III.12. Senior management should monitor, evaluate and verify how the supplier performs against the procurement requirements. The organization, its designated representative or other parties authorized by the organization may do this. These activities should provide for:

— Establishing a mutual understanding, between the organization and the supplier, of the specifications and intent of the procurement documents;
— Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement requirements;
— Reviewing documents that are generated or processed in activities that fulfil procurement requirements;
— Coordinating feedback of experience between the organization and suppliers;
— Identifying and processing changes to information;
— Establishing a method for the exchange of documents between the organization and the supplier.

III.13. Depending on the complexity and scope of the products, senior management should initiate activities prior to and following the award of a contract. These activities may take the form of meetings, or other means of

communication, to establish a mutual understanding between the organization and the supplier regarding:

— Procurement document requirements;
— The intent of the organization in monitoring and evaluating the supplier's performance;
— Financial arrangements, schedules, safety impacts and regulatory impacts;
— Training of individuals, if necessary, by the organization or suppliers to ensure the proper usage of supplied products;
— The planning and processes to be employed by the supplier to meet procurement requirements.

III.14. Senior management should identify notification points for evaluation as early as practicable in the procurement process. These should be documented and agreed between the organization and the supplier.

III.15. The necessity and extent of communication prior to and following the award of a contract depend on the uniqueness of the product, its complexity, the frequency of procurement from the supplier in the past and the supplier's past performance in supplying similar products.

NON-CONFORMANCES IN PROCUREMENT

III.16. Non-conformances identified during the procurement process should be handled in accordance with the guidance in Section 6 of this Safety Guide. The identity of the individual responsible for sanctioning each level of non-conformance should be made clear to the supplier. Non-conformances identified by the organization should be reported to the supplier immediately for processing through the supplier's non-conformance control process.

ACCEPTANCE OF PRODUCTS

III.17. Products and associated documents should be inspected immediately upon receipt in order to verify that they meet specified requirements.

RELEASE OF PRODUCTS

III.18. Products should not be released for use or installation until all inspections have been satisfactorily concluded and all specified documents have been received and checked.

SUPPLIER ASSESSMENTS

III.19. The assessment unit of the organization should develop a schedule of supplier assessments. The frequency of assessments should be determined by factors such as the importance of products and the performance of the supplier.

III.20. Supplier assessments should be carried out when:

— It is necessary to determine the capability of a supplier and the adequacy of its management system before awarding a contract or placing a purchase order;
— After the award of a contract, it is necessary to determine whether the supplier is appropriately performing the functions as defined in the management system, applicable codes and standards, and other contract documents;
— Significant changes are made in the supplier's management system, such as significant reorganization or significant revisions of procedures;
— It is suspected that the quality of a product or service is in jeopardy owing to a deficiency either in the regulatory requirements or in the management system.

Appendix IV

PERFORMANCE OF INDEPENDENT ASSESSMENTS

PLANNING AND SCHEDULING

IV.1. A schedule of independent assessments should be established, with account taken of those activities of the organization that affect safety. The schedule should include assessments of all major processes over a defined period.

IV.2. The schedule should be flexible and should allow for changes on the basis of:

— The frequency and results of previous assessments;
— Any significant changes to requirements resulting from new regulations;
— Changes in the organization or boundaries of responsibility for organizational units;
— Any significant findings from external or third party assessments;
— Feedback from non-conformances and from processes for preventive and corrective actions;
— External events that may potentially affect assessment results;
— The possibility of placing contracts with organizations that have previously not been used by the organization.

The schedule should also be updated after agreeing any new contracts.

IV.3. The assessment schedule should allow adequate time for preparation, the conduct of the assessment, the evaluation of identified concerns and the reporting of results.

IV.4. For each assessment, a plan should be established to select areas, processes or activities and requirements to be assessed.

CONDUCT

IV.5. Assessments should concentrate on the observation of how activities are actually being performed. Assessors should also interview individuals and examine completed work activities.

IV.6. Information on the qualification and training of individuals should be examined. The assessor may need to ask individuals specific questions to determine, for example, their experience or knowledge of procedures. The assessor may also check the conformance with, and the adequacy of, the procedures.

IV.7. The planning and conduct of an assessment should follow an organized plan. Nonetheless, circumstances may arise that require flexibility. The assessor should pursue any questionable area after consultation with the team leader. This consultation should ensure that the investigation is necessary.

IV.8. When suspected non-conformances are encountered, the assessor should check to determine whether senior management has already identified them and whether actions are being implemented to correct them. Conditions found during the assessment that need prompt attention should immediately be brought to the attention of senior management.

IV.9. Assessors should be alert for conditions that reflect good practices from which the organization might transfer lessons learned. This could include areas where objectives are consistently achieved or exceeded.

IV.10. When suspected non-conformances are detected, they should be discussed with the responsible individuals to avoid misunderstandings.

EVALUATION

IV.11. The assessor should analyse and consider the cause of non-conformances in order to evaluate and identify the proposed corrective actions. The findings should describe the non-conformance and identify any areas where improvement could be made. Similarly, when good practices are recognized, they too should be analysed to determine those factors that contributed to their success.

REPORTING

IV.12. Assessment results should be reported clearly and promptly. The assessment report should communicate the findings in a way that makes their significance readily apparent. For reports to be effective, they should be

submitted in their final form as quickly as possible, emphasizing particular products if necessary. The report should include:

— A list of positive and negative findings;
— A list of individuals contacted, procedures reviewed and areas visited;
— A description of assessment methods adopted by the assessors;
— References to the assessment plan that indicate which areas were assessed and why they are important;
— A summary statement on whether the activities assessed were satisfactory or not;
— Opportunities for improvement and good practices.

FOLLOW-UP ACTIVITIES

IV.13. Senior management should evaluate and investigate the assessment findings and should ensure that managers determine, schedule and approve corrective actions. For corrective actions, the implementation time frame should be such that the impact on safety is taken into account.

IV.14. The organization that has been assessed should report to the assessment unit and senior management the progress achieved in completing corrective actions.

IV.15. The implementation of the corrective actions should be subject to verification by the assessment unit.

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Annex I

ELECTRONIC DOCUMENT MANAGEMENT SYSTEM

I–1. An effective electronic document management system (EDMS) will build on and utilize the controls applied for and the experience gained with the paper document management system.

I–2. An EDMS consists of the computer hardware, software and databases that allow for the integrated preparation, input, distribution, storage, location and retrieval of electronic documents, whether initially created electronically or produced from paper documents.

I–3. An EDMS employs a number of technologies that were developed specifically to manage document based information. These include:

— Document capture tools such as scanning, optical character recognition, electronic data interchange, electronic forms and bar coding;
— Work flow management and electronic forms that support an orderly flow of documents through an organized production system and flexible collaboration across teams and departments;
— Archival and document management tools that support organized electronic storage, indexing, version control, archiving, search, retrieval and distribution of documents.

I–4. An EDMS permits the rapid retrieval and distribution of documents. Documents can be used without regard to their actual storage location. Documents received from any source (scanning, fax, electronic data interchange or the Internet) can be routed to individuals according to content, priority or workload. Various offices can share documents and data across networks in a manner that is transparent to the user.

I–5. The incorporation of EDMS related technology into day to day operations enables several users to have access to a single document simultaneously. In addition, documents do not need to be physically in one place to be processed as a whole. Storing documents in the EDMS permits them to be viewed by any user with the proper security clearance.

I–6. In organizations where an EDMS is used to aid in managing work flow, the status of all work can be known at any time, as managers and supervisors

can electronically view any work queues and move or reallocate work as appropriate.

I–7. Documents stored in the EDMS will need to be protected by online security.

I–8. The master copies of documents stored electronically will need to be archived so that the organization is able to restore even the oldest of documents.

I–9. The EDMS will need to support version and revision control of documents such as contracts, guides, documentation or publications.

I–10. Modifications and comments will need to be stored electronically with the original and used to produce revisions to the document on-line. Modifications of documents carried out under the EDMS will need to be done under specific authorization.

I–11. An EDMS will need to manage the whole document lifetime. This includes:

— Identifying the originator of the document;
— Identifying the owner or manager of the document;
— Keeping track of when the document was created and last modified, for each version of the document;
— Distinguishing whether the document is present in a draft version or its final version;
— Keeping track of any form template that is associated with the document;
— Identifying the elements of the document that are saved and managed as separate documents and the relationship between those elements.

I–12. An EDMS will further need to be able to do the following:

— Manage document security with access provisions for documents of various types to ensure that documents are stored correctly and can be exchanged (sent, processed and distributed) using acceptable standards and formats appropriate to the documents.
— Secure documents, especially valuable documents, by maintaining their availability and confidentiality. The confidentiality of the intellectual content of documents may be compromised by unauthorized access. Documents can also be lost owing to unauthorized access or deliberate

interference causing corruption. The proposed software will need to have extensive security features built into it.

— Provide appropriate access to documents. Documents will need to be available to all individuals who need access to the information they contain and who are able to gain the appropriate level of authorization for access. Individuals will need to be able to identify readily what documents are available. Appropriate standards will need to be in place to ensure that access is possible across different technological environments and that documents are accessible over time as technology develops.

EDMS DOCUMENT CAPTURE

I–13. Some organizations capture digitally their paper based document vaults. Many benefits accrue to users who expend the resources necessary to capture documents digitally. In simple terms, digitally capturing paper documents is accomplished by scanning the paper documents (imaging) and indexing the scanned files in an EDMS. Records stored electronically will need to be stored in such a way that they are compliant with applicable standards for legally admissible evidence.

I–14. Although some organizations adopt a 'from this day forward' approach, using the EDMS to manage newly created documents, many organizations stress the ability to convert existing data warehouses into electronic repositories. Organizations that need to convert hard copy information to electronic files quickly will need to analyse the demands on the entire imaging subsystem carefully. In a paper based environment, significant amounts of time are spent in simply managing the paper files rather than actually using the information stored on the paper. Once the digital image is created, it will need to be indexed in order to be accessible to the user community.

I–15. The methods used to capture document specific information will need to facilitate future document retrieval.

EDMS DOCUMENT RETRIEVAL

I–16. Viewer software is used to allow users to have 'read only' access to documents. Document users will need to be given access to read documents only, without the capability to modify them.

I–17. The EDMS stores documents in the proper locations on the appropriate devices. Proper logical storage allows the retrieval of documents for other activities. Storage and subsequent retrieval will need to be accomplished automatically. For example, when a user makes a request to modify an engineering design document, it will not be necessary for the user to know where the original document resides within the EDMS. Rather, the EDMS will need to retrieve the document transparently and to execute automatically the appropriate application, focusing on the retrieved document.

I–18. The EDMS will need to be able to manage archived documents as well as documents under preparation, amendment or approval. The EDMS will need to control access to the archived documents so that they cannot be modified.

I–19. Documents can also be lost owing to unauthorized access or deliberate interference causing corruption. Most breaches come from within an organization. Standard system security packages will need to be designed to counteract this threat with several means of security built into them, such as:

— Enforcing sign-on disciplines (e.g. unique sign-on identifiers for each authorized user, no group accounts, suspending unused identifiers, lockouts after three unsuccessful attempts to sign on, password protected screen savers and timeouts for inactive sessions on critical systems);
— Enforcing password disciplines (e.g. passwords to be mandatory, changed frequently and stored in encrypted format, and their immediate reuse prevented);
— Establishing formalized procedures for granting access to information systems, including a declaration that the user will comply with the organization's policy on information technology security;
— Limiting access to sensitive information to those who need it and preventing access for others. Saving sensitive information on a personal computer that has no access restrictions is a breach of security. In such a case, either access restrictions on the computer are necessary or, alternatively, the storage of sensitive material on the computer needs to be forbidden;
— Classifying documents according to their content. Electronic access can be granted on a need to know basis and by the use of classification levels;
— Making all authorized users aware of their responsibility to maintain the confidentiality of documents, to protect their passwords, to abide by the organization's security policy and to report any breaches of which they become aware;

— Employing encryption for both the storage and the transmission of confidential information;
— Educating individuals about the vulnerability of non-encrypted information held on networked computers.

Annex II

MEDIA FOR RECORD STORAGE

II–1. Examples of media that may be used to store records are:

— Paper with a pH (acidity level) of between 6 and 9;
— Film, 35 mm roll;
— Silver–gelatine type microfilm or X ray film;
— Microfiche;
— Magnetic tape or disk;
— Optical laser disk;
— Hardware such as graphite samples, weld samples or other materials that have been or are able to be subjected to qualification testing;
— Electronic firmware (computer or component) such as thermal luminescent dosimeters (for short term use only);
— Media for records that need special processing and control, such as computer codes and software, and information stored on high density media or optical disks, which will need to be maintained and controlled to ensure that the records are readily retrievable and usable.

II–2. The following media are considered to be acceptable for records with retention periods of up to 30 years:

— Paper copy retained in a controlled environment with an indexing system to allow retrieval within a reasonable time (e.g. one working day).
— Microfilm or other microforms prepared appropriately and stored in adequate conditions.
— Punched paper tape or cards where the information is stored as physical artefacts on a paper/card medium. Such media will need to be stored in equivalent environmental conditions to hard paper copy.
— Magnetic media stored and maintained appropriately, such as disk packs, storage modules or disk cartridges.

II–3. The following media are considered to be acceptable for records with retention times of up to five years:

— Any of those media considered acceptable for retention periods of up to 30 years, plus optical disks. Records using optical disk media may be held for periods beyond five years provided that periodic checks are made for any deterioration in image quality. The record will need to be copied onto

a new optical disk if any deterioration in image quality is found. This may be before the manufacturer's certified lifetime of the original disk is exceeded.

II–4. The following media are considered to be acceptable for records with retention times of up to three years:

— Any of those media with retention times of five years or 30 years, plus flexible disk cartridges (floppy disks) and magnetic tape cartridges stored and maintained appropriately.

II–5. The preparation and storage requirements for the different media should reflect the manufacturer's guidance for the media.

Annex III

RECORD RETENTION AND STORAGE

III–1. Records that might be considered for long term storage include:

— Approved specifications of products;
— Records of the condition of products;
— Records demonstrating that individuals are competent to perform their work;
— Records demonstrating compliance with statutory and regulatory requirements;
— Configuration management records;
— Records of the investigation of an accident, malfunction or non-conformance.

III–2. Records such as management system documentation, procedures and assessment reports might also be considered for long term storage.

III–3. It is recognized that the nomenclature and type of records may vary from organization to organization, and alternative categories may be chosen at the discretion of the organization. Retention times could be standardized to the following:

— Greater than 30 years;
— 30 years;
— Five years;
— Three years.

III–4. Senior management will need to establish storage and location requirements for the maintenance, preservation and protection of records and associated test materials and specimens from the time of their receipt until their disposal. A record storage process will need to include the following:

— A description of the document or record storage facility;
— A description of the filing system to be used;
— A method for verifying that the records received are in agreement with the transmittal document and that the records are in good condition;
— A method for verifying that the records agree with the records index;
— Rules governing access to and control of the files;

— A method for maintaining control of and accountability for records removed from the storage facility;
— A method for filing corrected or supplemental information and disposing of records that have been superseded;
— Periodic checking to ensure that the records are not damaged, deteriorating or missing.

III–5. Continued ability to read the data will need to be ensured, with account taken of any technological changes that occur. Any changes in reading equipment and technology should only be made after consideration of how the capability to access and read existing recorded data will be maintained. This may necessitate transferring data to new media. In such cases checks will need to be carried out to ensure that the data are readable and accessible and that they are an exact copy of the original.

III–6. Paper records will need to be firmly attached in binders or placed in folders or envelopes for storage on shelves or in containers. Steel file cabinets or safes are preferred.

III–7. Records that are processed by special methods will need to be packaged and stored as recommended in the manufacturer's instructions, in line with applicable standards. Examples are: radiographs, photographs, microfilm, magnetic tapes, microdiskettes, laser disks and those records that might be sensitive to light, pressure, humidity, magnetic fields, dust and temperature.

III–8. Record storage facilities will need to protect the contents from possible damage or destruction by such causes as fire, flooding, insects and rodents, and from possible deterioration under adverse environmental conditions of light, temperature and humidity.

III–9. The following factors among others will need to be considered in the construction of a storage facility:

— Location and security;
— Type of construction, including structural features and internal surface treatment;
— Pipework layout and drainage;
— Control of ventilation, temperature and humidity;
— Prevention, detection and fighting of fires;
— Protection against electromagnetic radiation.

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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