

SAFETY GUIDES

*ON IMPLEMENTATION OF THE
LEGAL REQUIREMENTS*

SAFETY GUIDE

Management System for Facilities and Activities

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**SAFETY GUIDE
MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES**

TABLE OF CONTENTS

1.	GENERAL PROVISIONS.....	2
	OBJECTIVE.....	2
	SCOPE.....	2
	LEGAL BACKGROUND.....	2
2.	MANAGEMENT SYSTEM.....	2
	GENERAL PROVISIONS.....	2
	SAFETY CULTURE.....	3
	GRADING THE APPLICATION OF REQUIREMENTS.....	4
	DOCUMENTATION OF MANAGEMENT SYSTEM.....	4
3.	MANAGEMENT RESPONSIBILITY.....	6
	MANAGEMENT COMMITMENT.....	6
	SATISFACTION OF INTERESTED PARTIES.....	6
	ORGANIZATIONAL POLICIES.....	7
	PLANNING.....	7
	RESPONSIBILITY AND AUTHORITY FOR THE MANAGEMENT SYSTEM.....	8
4.	RESOURCE MANAGEMENT.....	8
	PROVISION OF RESOURCES.....	8
	HUMAN RESOURCES.....	9
	INFRASTRUCTURE AND THE WORKING ENVIRONMENT.....	9
	INFORMATION AND KNOWLEDGE.....	9
	FINANCIAL RESOURCES.....	10
5.	PROCESS IMPLEMENTATION.....	10
	DEVELOPING PROCESSES.....	10
	PROCESS MANAGEMENT.....	11
	GENERIC MANAGEMENT SYSTEM PROCESSES.....	11
	CONTROL OF DOCUMENTS.....	11
	CONTROL OF PRODUCTS.....	12
	CONTROL OF RECORDS.....	12
	PROCUREMENT.....	13
	COMMUNICATION.....	13
	MANAGING ORGANIZATIONAL CHANGE.....	14
6.	MEASUREMENT, ASSESSMENT AND IMPROVEMENT.....	15
	MONITORING AND MEASUREMENT.....	15
	SELF-ASSESSMENT.....	15
	INDEPENDENT ASSESSMENT.....	16
	MANAGEMENT SYSTEM REVIEW.....	16
	NON-CONFORMANCES.....	17
	IMPROVEMENT.....	18
7.	REFERENCES.....	20
8.	GLOSSARY.....	21



1. GENERAL PROVISIONS

OBJECTIVE

1.1 The objective of this document is to provide generic guidance and recommendations to the licensees for establishing, implementing, assessing and continually improving a management system which integrates all elements of managing the organization and ensures co-ordination in the fulfillment of the requirements towards safety, health, environment, security, quality and economics, and at the same time gives highest priority to safety.

SCOPE

1.2 The document is applicable throughout the lifetime of the nuclear facilities.

LEGAL BACKGROUND

1.3 The Act on the Safe Use of Nuclear Energy [1] and the Regulation for Providing the Safety of Nuclear Power Plants [2] establish requirements to the Quality Assurance Systems of the licensees.

1.4 The Management System incorporates and reflects the initial concept of quality control and its development thought quality assurance and quality management. It is a result of the recent development of public relations which leads to the acceptance of new community document and international safety standards.

1.5 Council Directive 2009/71/EURATOM [3] requires Member States to ensure that the national framework stipulates license holders to establish and implement management systems which give due priority to safety.

1.6 The main safety requirements and recommendations as established by the International Atomic Energy Agency (IAEA) in reference documents [4] – [8] are considered in this publication.

1.7 In addition the Western European Nuclear Regulators' Association (WENRA) reactor safety reference levels [9] are taken into consideration.

2. MANAGEMENT SYSTEM

GENERAL PROVISIONS

2.1 The management system should be established, implemented, assessed and continually improved. It should be aligned with the goals of the organization and contributes to their achievement. The main aim of the management system should be to achieve and enhance safety by:

- Bringing together in a coherent manner all the requirements for managing the organization;
- Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;



SAFETY GUIDE

MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

- Ensuring that health, environmental, security, quality and economic related requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.

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

2.3 The management system should identify and integrate:

- The statutory and regulatory requirements to the activities performed;
- Any requirements formally agreed with interested parties;
- All other relevant IAEA Safety Requirements and Fundamentals;
- Requirements from other relevant codes and standards adopted for use by the organization.

SAFETY CULTURE

2.4 The management system should support the development and should promote a strong safety culture by:

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

2.5 Safety culture is that type of organizational culture where safety is of upmost priority, considered essential for the long term success of the organization.

2.6 Safety culture should be based on fundamental safety beliefs (assumptions) and a code of conduct that reflects the safety values that are commonly shared by all individuals. Ultimately the safety culture is revealed in the visible individual and collective behaviors of the organization.

2.7 Senior management should establish and promote a set of safety principles to serve as guidance to decisions and safety conscious behaviors, where safety has an overriding priority. Examples of such principles used in some organizations are as follows:

- Everyone has a role in nuclear safety;
- Leaders and managers demonstrate commitment to achievement and enhancement of safety;
- Trust and open communication permeate throughout the organization;
- Decision-making considers safety first;
- Nuclear is recognized as unique;
- A questioning attitude is cultivated;
- Organizational learning is embraced;
- A proactive approach to safety is adopted;
- Nuclear safety undergoes constant examination.



SAFETY GUIDE

MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

2.8 The following characteristics of safety culture can be used in order to achieve a common understanding of safety culture in the organization, so that everyone can seek strengths and weaknesses and thereby enhance the safety culture:

- Safety is a clearly recognized value;
- Leadership for safety is clear;
- Accountability for safety is clear;
- Safety is integrated into all activities;
- Safety is learning driven.

GRADING THE APPLICATION OF REQUIREMENTS

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

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

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

2.11 A grading process should be developed to determine the extent of the application of the requirements of the management system to the products and activities of the organization. A methodology for grading should be developed that ensures that all individuals in the organization apply this common sense approach in a uniform manner.

2.12 Grading of requirements allows to direct resources and attention to activities and products with high safety significance. This reduces the total costs in ensuring safety.

2.13 The following are examples of areas where grading could be applied:

- Type and content of training;
- Amount of detail and degree of review and approval of instructions;
- Need for and detail of inspection plans
- Degree of in-process reviews and controls;
- Requirements for material traceability;
- Type and level of detail in procurement documents;
- Type of assessment;
- Records to be generated and retained.

DOCUMENTATION OF MANAGEMENT SYSTEM

2.14 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.

2.15 The documentation for the management system should reflect:

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



SAFETY GUIDE

MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

2.16 The documentation of the Management System should be structured in three levels which 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.

2.17 The level one documents provide an overview of the policies and objectives of the organization and describe the management system that addresses the requirements that apply to the organization's work. The information at this level of the management system is 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.

2.18 The following information should be provided at level 1:

- Vision, mission and goals of the organization;
- Policy statements in different aspects managed by the system;
- 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;
- Arrangements for measuring and assessing the effectiveness of the management system.

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

2.20 The level two documents should describe the processes of the management system applied to achieve the policies and objectives and provide specific detail on activities to be performed and organizational units to carry them out. This information should include:

- process map of the management system, including the interactions between processes;
- description of 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;
- measurable objectives and activities to be carried out and controlled and who is responsible and accountable;
- identification and planning of activities to ensure that work is dealt with in a safe, systematic and expeditious manner.

2.21 The information at this level should provide administrative direction to managers in all positions; outline the actions that managers take to implement the management system. It should not be used to provide the details of how technical tasks are to be performed.

2.22 The documentation of level 3 should describe specific details for the performance of tasks by individuals, small groups of people or teams. The type and format of documents at this level can vary.

2.23 The documentation of the system should be written in a manner that makes it understandable to those who use it. The documents are current, legible, readable, readily identifiable and available at the point of use.



3. MANAGEMENT RESPONSIBILITY

MANAGEMENT COMMITMENT

- 3.1 The senior management should be responsible and accountable for:
- developing and implementation of a management system that is appropriate to the organization;
 - establishing and cultivating of principles that integrate all requirements into daily work;
 - providing the individuals performing the work with the necessary information, tools, support and encouragement to perform their assigned work properly.
- 3.2 Senior management should ensure that it is clear when, how and by whom decisions are to be made within the management system.
- 3.3 Visible support, leadership and commitment of senior management are fundamental to the success of the management system.
- 3.4 Senior management should develop individual values, institutional values and behavioral expectations for the organization to support the implementation of the management system and should act as role models in the visible promulgation of these values and expectations.
- 3.5 Managers at all levels should communicate to individuals the need of adopting these individual values, institutional values and behavioral expectations as well as to comply with the requirements of the management system.
- 3.6 Managers at all levels should demonstrate commitment to the establishment, implementation, assessment and continual improvement of the management system and allocate adequate resources to carry out these activities.
- 3.7 Managers at all levels should foster the involvement of all individuals in the implementation and continual improvement of the management system.
- 3.8 Managers at all levels should ensure the necessary training, resources and directions for the individuals under their supervision before any work begins.
- 3.9 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 also should 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.

SATISFACTION OF INTERESTED PARTIES

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



SAFETY GUIDE

MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

ORGANIZATIONAL POLICIES

3.11 Senior management should develop and disseminate throughout the organization a set of policies.

3.12 The policies should establish the philosophy, principles and main factors that govern the organization. On the basis of the policies the senior management should establish the management's plans, objectives and priorities with regard to safety, health, environmental, security, quality and economic considerations.

3.13 The policies should reflect the commitment of senior management to attaining their goals and objectives; their priorities; and the means by which continual improvement is implemented and measured.

3.14 The policies should:

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

3.15 Senior management should demonstrate its commitment to all the policies through its actions and provide firm and unambiguous support for the implementation of these policies.

3.16 The management actions should foster a corresponding commitment to high levels of performance by all individuals. All individuals are expected to demonstrate their commitment to the policies.

PLANNING

3.17 Senior management should establish goals, strategies, plans and objectives that are consistent with the policies of the organization.

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

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

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



SAFETY GUIDE MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

RESPONSIBILITY AND AUTHORITY FOR THE MANAGEMENT SYSTEM

3.21 Senior management in the organization is ultimately responsible for the management system and ensures that it is established, implemented, assessed and continually improved.

3.22 An individual reporting directly to senior management has specific responsibility and authority for:

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

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

4. RESOURCE MANAGEMENT

PROVISION OF RESOURCES

4.1 Senior management should determine the amount of resources necessary and provide the resources (people, infrastructure, the working environment, information and knowledge, suppliers, as well as material and financial resources) to carry out the activities of the organization and to establish, implement, assess and continually improve the management system.

4.2 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 support 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 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.



HUMAN RESOURCES

4.3 Senior management should ensure sufficient amount of resources with necessary qualifications on the basis of evaluation of the scope and complexity of the activities performed by the organization and in consistency with the organizational structure. Senior management should ensure selection and appointment of personnel with necessary competence.

4.4 Senior management should determine the competence and proficiency requirements for individuals at all levels and provide training or take other actions to achieve and maintain the required level of competence. An evaluation of the effectiveness and the efficiency of the actions taken should be conducted.

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

INFRASTRUCTURE AND THE WORKING ENVIRONMENT

4.6 Senior management should determine, provide, maintain and re-evaluate the infrastructure and the working environment necessary for work to be carried out in a safe manner, and for achieving the organization's objectives effectively and efficiently.

4.7 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.

INFORMATION AND KNOWLEDGE

4.8 The information and knowledge of the organization should be managed as resource. Senior management should treat information as a fundamental resource that is essential for making factually based decisions.

4.9 Data should be converted to information for the continual development of an organization's knowledge. To manage information and knowledge, senior management should take measures to:

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



FINANCIAL RESOURCES

4.10 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.

4.11 Senior management should plan for, make available and control the financial resources necessary for implementing and maintaining an effective and efficient management system; and achieving the organization's goals.

5. PROCESS IMPLEMENTATION

DEVELOPING PROCESSES

5.1. A major component of the management system is the process model that incorporates the hierarchy of the processes of the organization and formulates a standardized approach to describing and controlling processes. This should ensure that there is consistency and continuity between the various processes, including safety consideration in business decision making.

5.2. The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization should be identified. If the integration of some activities in a process is not possible the management system could include these activities as well.

5.3. The processes of the organization should be structured as follows:

- Core processes - the output of which is critical to the success of the organization;
- Supporting processes - which provide the infrastructure necessary for the effectiveness of core and management processes;
- Management processes - which ensure the operation of the entire management system.

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

- Identifying the processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization. Their development is planned, implemented, assessed and continually improved;
- Determining the sequence of and the interactions between these processes;
- Determining the criteria and methods necessary to ensure that the implementation and control of these processes are effective;
- Ensuring the availability of the resources and information necessary to support the operation and monitoring of these processes;
- Measuring, monitoring and analyzing the processes;
- Implementing the actions necessary to achieve the planned results and the continual improvement of these processes.

5.5. The development of each process should ensure that the following are achieved:

- Process requirements, such as applicable regulatory, statutory, legal, safety, health, environmental, security, quality and economic related requirements, are specified and addressed;
- Hazards and risks are identified, together with any necessary mitigatory actions;
- Interactions with interfacing processes are identified;



SAFETY GUIDE

MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

- Process inputs are identified;
- The process flow is described;
- Process outputs (products) are identified;
- Process measurement criteria are established.

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

PROCESS MANAGEMENT

5.7. For each process a designated individual should be given the authority and responsibility for:

- Developing and documenting the process and maintaining the necessary supporting documentation;
- Ensuring that there is effective interaction between interfacing processes;
- Ensuring that process documentation is consistent with any existing documents;
- Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation;
- Monitoring, evaluation and reporting on the performance of the process;
- Promoting improvement in the process;
- Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the organization.

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

5.9. Each process should be evaluated to ensure that it remains effective.

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

5.11. The control of processes contracted to external organizations should be identified within the management system. The organization retains overall responsibility when contracting any processes.

GENERIC MANAGEMENT SYSTEM PROCESSES

CONTROL OF DOCUMENTS

5.12. Documents as policies; procedures; instructions; specifications and drawings; training materials; and any other documents which describe processes, specify requirements or establish product specifications should be controlled.

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

- How to prepare documents;



SAFETY GUIDE

MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

- 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.

5.14. The preparation, revision, review or approval of documents should be assigned to individuals who are competent to carry the work out and are given access to appropriate information to take decisions.

5.15. Changes to documents should be reviewed and recorded and should be subject to the same level of approval.

CONTROL OF PRODUCTS

5.16. The products of the organization should be controlled to meet the specified requirements and ensure that products perform satisfactory in service.

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

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

5.19. Products should be provided in such a form that it can be verified that they satisfy the requirements. Controls should be used to ensure that products do not bypass the required verification activities.

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

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

CONTROL OF RECORDS

5.22. Records provide objective evidence of activities performed or results achieved.

5.23. Records should be specified in the documentation of the management system. They should be completed during the process implementation and should be readable and clear.

5.24. It should be ensured in the records process that records are:

- categorized;
- registered upon receipt;
- readily retrievable;



SAFETY GUIDE MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

- indexed and placed in their proper locations in the files of the record facility with the retention times clearly specified;
- stored in a controlled and safe environment;
- stored in appropriate storage media.

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

5.26. The media used for records should be such as to ensure that the records are readable for the duration of the retention times specified for each record.

PROCUREMENT

5.27. The process of procurement should ensure that products and services meet the specified requirements.

5.28. The process should ensure:

- developing and specifying the purchasing requirements in procurement documents, including requirements for reporting and resolution of non-conformances;
- selection of suppliers of products on the basis of specified criteria and evaluation of their performance;
- making available evidence that products meet these requirements before the product is used by the organization.

COMMUNICATION

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

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

5.31. The communication process should:

- be managed in such a way as to improve performance;
- make use of appropriate communication channels, such as letters, email and personal meetings;
- engage external interested parties to ensure that they understand the messages, especially when it is necessary to gain their acceptance;
- 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; how they can influence business decisions; how their individual and team contributions influence the success of the organization;
- ensure that all interested parties are kept up to date with relevant information;
- evaluate the effectiveness of the processes and the messages being communicated.



SAFETY GUIDE

MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

MANAGING ORGANIZATIONAL CHANGE

5.32. When organizational change is necessary, no reduction in the level of safety achieved should be acceptable. Senior management should remain aware that it has the ultimate responsibility for safety of facility and activities, and should ensure that safety considerations related to changes are given a priority commensurate with their significance.

5.33. When major organizational changes are planned, they should be rigorously and independently scrutinized.

5.34. 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.
- It is ensured that adequate provision has been made to maintain a sufficient number of trained, competent individuals in all areas critical to safety.
- Any new processes introduced are documented with clear and well understood roles, responsibilities and interfaces.
- All retraining needs are identified by carrying out a training needs analysis of each of the new roles. The retraining of key individuals is planned.
- The transitional arrangements are fully adequate in terms of safety. Sufficient personnel with knowledge and expertise that are critical to safety are maintained until training programs are complete. Organizational changes are made in such a way as to maintain clarity about roles, responsibilities and interfaces.

5.35. A process should be established to ensure that changes are reviewed and assessed, planned, controlled, communicated, monitored, tracked and recorded and to ensure that safety is not compromised.

5.36. A safety assessment should be developed for any changes that have the potential to affect safety. Criteria for assessing the implications and controlling the impacts of organizational changes should include the following considerations:

- Changes are 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 explains 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.
- A review mechanism is agreed on to ensure that the cumulative effects of small changes do not reduce safety.
- The total workload imposed on the organization to implement the changes in parallel with continued operational activities is given careful consideration.
- A method of monitoring progress in the planned introduction of significant changes is developed and any shortfalls should be rapidly identified so that remedial action can be taken.

5.37. Communication with interested parties, including individuals, should be carried out addressing the safety implications of the changes and explaining the steps being taken. Individuals should be made aware of how their responsibilities will change both during and after organizational changes.



5.38. 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.

5.39. Changes should be endorsed by those individuals whose areas of responsibility are affected. An endorsement should be sought from the organization's safety unit.

6. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

6.1. Measurement, assessment and improvement should be part of the establishment of a learning culture in the organization.

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 to reduce the risk of complacency.

6.3. In addition to the early detection of any deterioration, an assessment of weaknesses in the management system should also be used to identify potential enhancements of performance and safety and to learn from both internal and external experience.

MONITORING AND MEASUREMENT

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

6.5. During the development of the processes measures should be established to monitor the performance. Standards and criteria of performance should be established that are directly related to the product provided by the organization and based on the objectives set by senior management.

6.6. Performance should be measured against these standards and criteria. 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.

SELF-ASSESSMENT

6.7. Senior management should perform self-assessment to identify, correct and prevent management problems that hinder the achievement of the organization's objectives.

6.8. Self-assessment 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?



SAFETY GUIDE

MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

- 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?

6.9. Effective self-assessment 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.

6.10. 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.

6.11. The results and decisions of the self-assessment should be recorded and related actions resulting from the recommendations should be taken promptly. The effectiveness of these actions should be evaluated. The results of self-assessment should be used as input to the organization's continual improvement process. The improvement process should lead to enhanced levels of safety and performance.

INDEPENDENT ASSESSMENT

6.12. Independent assessments should be conducted regularly on behalf of senior management:

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

6.13. Independent assessment could include reviewing, checking, inspecting, testing, internal audits, audits performed by external organizations and surveillance.

6.14. Independent assessment should be focused on safety aspects and areas where problems have been found. Results should be verified in accordance with written criteria and, where possible, evaluated objectively against specified standards and/or requirements.

6.15. Independent assessment could be conducted by an organizational unit established with the responsibility for conducting independent assessment; by a working group formed especially for the purpose, composed of members of personnel or by external organization. The team should have sufficient authority to discharge its responsibilities. Individuals conducting independent assessments should not assess their own work.

MANAGEMENT SYSTEM REVIEW

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



SAFETY GUIDE MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

- 6.17. The review could cover but should not be limited to:
- Outputs from all forms of assessment;
 - Results delivered and objectives achieved by the organization and its processes;
 - Non-conformances and corrective and preventive actions;
 - Lessons learned from other organizations;
 - Feedback on the satisfaction of interested parties;
 - The performance of suppliers;
 - Opportunities for improvement;
 - Relevant statutory and regulatory changes.
- 6.18. The outputs of the management system review should be used as inputs to the improvement process.
- 6.19. The schedule of reviews should facilitate the timely provision of data for strategic planning for the organization.
- 6.20. The review should identify whether there is a need to make changes to or improvements in policies, goals, strategies, plans, objectives and the processes.
- 6.21. The outputs of the review should be communicated to the individuals in the organization to demonstrate how the process of management system review leads to new objectives that will benefit the organization.

NON-CONFORMANCES

- 6.22. Products and processes that do not conform to the specified requirements should be identified, segregated, controlled, recorded and reported to an appropriate level of management within the organization. The impact of non-conformances should be evaluated and non-conforming products or processes should either be:
- Accepted for use;
 - Reworked or corrected within a specified time period;
 - Rejected and discarded or destroyed to prevent their inadvertent use.
- 6.23. The use of non-conforming product or process should be subject to authorization by the management. When non-conforming products or processes are reworked or corrected, they should be subject to inspection to demonstrate their conformity with requirements or expected results.
- 6.24. Conditions and events that should be handled by the non-conformance control process are for example:
- 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.
- 6.25. Individuals responsible for classifying and analyzing non-conformances should have an adequate understanding of the area in which they are working and have access to pertinent



SAFETY GUIDE MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

background information concerning the non-conformances.

6.26. Safety considerations should have priority over cost and schedule considerations in the classification and analysis of non-conformances.

6.27. Determination of the cause of a non-conformance could require a thorough investigation by technically qualified and experienced individuals. The investigation could need to include the participation of the individuals who identified the non-conformance, to gain a complete understanding of the problem.

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

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

6.30. Potential non-conformances that could aggravate the organization's performance should be identified. This could be done: by using feedback from other organizations; through the use of technical advances and research; through sharing of knowledge and experience; and through the use of techniques that identify best practices.

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

6.32. All individuals should have the opportunity to identify, and be encouraged to identify, non-conforming products and processes.

6.33. All individuals should have the opportunity to identify improvements and suggest them via the management system.

6.34. Feedback should be provided to the individuals who have identified and reported non-conformances.

IMPROVEMENT

6.35. Opportunities for the improvement of the management system should be identified and actions to improve the processes should be selected, planned and recorded. The decisions made and the reasons for the actions undertaken should be communicated to the individuals in the organization.

6.36. Opportunities for improvement should be identified from the following:

- Feedback from use;
- The performance of the management system in meeting goals and plans;
- 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.



SAFETY GUIDE
MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES

- 6.37. Continual improvement should be achieved:
- At the working level, by introducing small 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 which lead either to the revision and improvement of existing processes or to the implementation of new processes.
- 6.38. Continual improvement should be made by means of a process.
- 6.39. The process could be effective if the following elements are included:
- Reason for improvement;
 - Current situation;
 - Analysis of the causes of the problem;
 - Identification of possible solutions;
 - Evaluation of effects;
 - Implementation and standardization of the new solution;
 - Evaluation of the effectiveness and efficiency of the new process.
- 6.40. Improvement plans should include plans for the provision of adequate resources. Actions for improvement should be monitored through to their completion and the effectiveness of the improvement should be checked.



7. REFERENCES

- [1] Act on the Safe Use of Nuclear Energy, promulgated in the State Gazette No. 63 of 28 June 2002, amended in the State Gazette No.80 of 12 October 2010.
- [2] Regulation for Providing the Safety of Nuclear Power Plants, promulgated in the State Gazette, No. 66 of 30 July 2004.
- [3] The Council of the European Union, Council Directive 2009/71/EURATOM of 25 June 2009 establishing the Community framework for the nuclear safety of nuclear installations, Official Journal of the European Union L 172/18 of 2 July 2009.
- [4] INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-R-3, IAEA, Vienna, (2006).
- [5] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Management System for Facilities and Activities, IAEA Safety Standards No. GS-G-3.1, IAEA, Vienna (2006).
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- [8] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Oversight of Management System, IAEA-TECDOC-DD 1035, Draft, IAEA, Vienna (2010).
- [9] Western European Nuclear Regulators' Association, Reactor Harmonization Working Group, WENRA Reactor Safety Reference Levels, Issue C, Management System, January 2008, (www.wenra.org-Publications).



8. GLOSSARY

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.

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 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.

Stakeholders: 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 neighboring 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.