IAEA Nuclear Energy Series

No. NG-T-1.3

Development and Implementation of a Process Based Management System

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DEVELOPMENT AND IMPLEMENTATION OF A PROCESS BASED MANAGEMENT SYSTEM

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NUCLEAR ENERGY SERIES REPORT NG-T-1.3

DEVELOPMENT AND IMPLEMENTATION OF A PROCESS BASED MANAGEMENT SYSTEM

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2015

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FOREWORD

One of the IAEA's statutory objectives is to "seek to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world." One way this objective is achieved is through the publication of a range of technical series. Two of these are the IAEA Nuclear Energy Series and the IAEA Safety Standards Series.

According to Article III.A.6 of the IAEA Statute, the safety standards establish "standards of safety for protection of health and minimization of danger to life and property". The safety standards include the Safety Fundamentals, Safety Requirements and Safety Guides. These standards are written primarily in a regulatory style, and are binding on the IAEA for its own programmes. The principal users are the regulatory bodies in Member States and other national authorities.

The IAEA Nuclear Energy Series comprises reports designed to encourage and assist R&D on, and application of, nuclear energy for peaceful uses. This includes practical examples to be used by owners and operators of utilities in Member States, implementing organizations, academia, and government officials, among others. This information is presented in guides, reports on technology status and advances, and best practices for peaceful uses of nuclear energy based on inputs from international experts. The IAEA Nuclear Energy Series complements the IAEA Safety Standards Series.

The IAEA Safety Standards Series No. GS-R-3 defines requirements for establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security, quality and economic elements. The Safety Guides GS-G-3.1 to 3.5 provide guidance on how the requirements can be met for various installations and activities. This publication discusses practical ways to develop and implement a management system designed to fulfil the requirements of GS-R-3. Such a management system will be based on a set of processes that meet these integrated requirements. Information is provided to help both emerging nuclear organizations and mature organizations wishing to make the transition from a QA/QC based management system to one that meets the latest IAEA requirements for and guidance on management systems for nuclear facilities and activities.

The IAEA wishes to acknowledge the efforts and valuable assistance of the contributors listed at the end of this publication for their contribution to its development. The IAEA also wishes to thank the organizations of the contributors for permission to include the practical examples provided in this report. The Scientific Secretaries responsible for the preparation of this publication were J.P. Boogaard and P.T. Pyy of the Division of Nuclear Power.

EDITORIAL NOTE

Guidance provided here, describing good practices, represents expert opinion but does not constitute recommendations made on the basis of a consensus of Member States.

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1. INTRODUCTION

1.1. BACKGROUND

The IAEA has established, in IAEA Safety Standards Series No. GS-R-3 [1], requirements for "establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security, quality and economic elements." IAEA Safety Standards Series No. GS-G-3.1 [2], GS-G-3.5 [3] and similar IAEA Safety Guides specific to other technical areas provide guidance on how to fulfil the requirements specified in GS-R-3.

The requirements for a management system established in GS-R-3 are intended to ensure that safety is properly taken into account in all the activities of an organization. A management system that ensures this is often referred to as an integrated management system. The management system approach identified in the IAEA's safety standards publications also requires increased attention to organizational processes.

Establishing a process based management system involves a transition from programmes or systems based on a hierarchical management structure with dedicated quality assurance, quality control or quality management organizations based on historical standards. Consequently, users of the Quality Assurance Code[1] and of superseded IAEA safety publications on quality assurance, the International Organization for Standardization (ISO) 9001 standard [4], or ASME-NQA-1-2008 [5] and related addenda on quality management may at first find it challenging to implement the latest IAEA safety standards for management systems. In addition to the challenges associated with conceptual and scope shifts, organizations may be concerned that the adoption of a management system based on GS-R-3 may result in the loss of certifications or qualifications acquired under the ISO standards umbrella, for example. This concern will be lessened by an understanding of the latest IAEA requirements for management systems, and of what the transition to a process based management system and meeting the new requirements actually entails.

A process based management system enhances traditional quality programmes, and, when properly implemented, enables the organization to satisfy external agencies and registrars for certification of management systems such as ISO 9001 [4], ISO 14001 [6], OHSAS 18001 [7], and regulatory acceptance of security and safeguards programmes. It also ensures knowledge retention and the retention of all important aspects of existing programmes. As part of implementation, and to facilitate the same, organizations can develop maps, descriptions and other documents demonstrating how the certified quality assurance and quality management programmes have been addressed in the process based management system documents. Guidance comparing the requirements of GS-R-3 with ISO 9001 [8], or with ASME NQA-1 [9], may be used to help create such maps or documents.

A vendor provided management system delivered with a nuclear power plant to ensure safe operation is often a typical quality management system for operations and maintenance, which may, to a certain extent, integrate aspects related to safety and environmental protection. GS-R-3 [1], however, requires the organization to identify processes of the management system needed to achieve all its objectives in all life cycle phases (siting, design, construction, commissioning, and operation and decommissioning), meet all requirements and deliver the outcomes of the organization. Furthermore, such processes must be planned, implemented, assessed and continually improved. A management system complying with GS-R-3 [1] must be tailored to meet the objectives and requirements of the organization. As a consequence, a quality assurance or quality management system needs to undergo the kind of transition indicated earlier.

The guidance provided in this publication should be used in conjunction with IAEA guidance on continual improvement [10] and on Managing Organizational Change in Nuclear Organizations [11]. This publication contains information on how to make the transition from a quality management system to one aligned with IAEA requirements for management systems, thereby providing Member States and organizations wishing to adopt the new standards with guidance that facilitates such an undertaking. The guidance contained in this publication will enable Member States and organizations to introduce, apply and meet the new requirements in a planned and systematic manner, without negating any gains in safety performance or operational efficiency and effectiveness derived from their existing quality management system(s).

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[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Code on the Safety of Nuclear Power Plants: Quality Assurance, Safety Series No. 50-C-Q, IAEA, Vienna (1996).

The publication focuses on the steps an organization can take to make the transition from quality assurance, quality control (QA, QC) and quality management (QM) to a management system meeting IAEA GS-R-3 requirements, including:

— Developing an understanding of the major differences and similarities between QA/QC/QM systems and management systems integrating the objectives of an organization;
— Setting policies, goals and objectives and preparing the organization to implement a process based management system;
— Developing strategies and options, and engaging stakeholders;
— Developing detailed plans for implementation;
— Making the transition;
— Assessing the effectiveness of implementation, learning lessons, sustaining change and continually improving.

All these requirements will require senior management to establish and implement an effective integrated management system. 'Senior management' means the person or group who directs, controls and assesses the licensed organization at the highest level. The aim is to ensure that requirements for safety are not considered separately but put in the context of all the other requirements, for example those for security, safeguards, environment, personal safety and economy. It will also require that the management system reflect the processes established in the organization to ensure safety.

1.2. OBJECTIVE

The objective of this Nuclear Energy Series Report is to provide good practice, practical examples, and methods that can be used to help organizations implement a process based management system as defined by IAEA Safety Standard GS-R-3 [1].

Guidance provided here, describing good practices, represents expert opinion but does not constitute recommendations made on the basis of a consensus of Member States.

1.3. SCOPE

This publication provides guidance on implementing a process based management system to all life cycle stages of nuclear facilities and activities, including siting, design, construction, commissioning, and operation and decommissioning. As such, it can be applied to organizations implementing a management system for the first time, as well as to organizations wishing to make the transition from legacy management systems such as those based on QA and QM approaches.

1.4. USERS

This publication will be of interest to organizations wishing to develop process based management systems that comply with IAEA requirements and guidance on management systems, either on a voluntary basis, or as a requirement specified by a regulatory body. Thus, this publication is intended for:

— Operators of nuclear facilities and activities who are either legally obliged, or choose as best practice, to implement the requirements of IAEA GS-R-3;
— Suppliers of products or services that are required to be produced in accordance with the requirements of IAEA GS-R-3;
— Regulatory bodies that wish to use this document as guidance for their licensees;
— Regulatory bodies that wish to meet the requirements of IAEA GS-R-3 in their own management systems.

1.5. STRUCTURE

This publication first presents general characteristics of implementing a process based management system in Section 2. Section 3 discusses the general starting point of management system development: evaluating business needs and preparing an implementation strategy. In Section 4, developing and managing the implementation plan for the management system is discussed, and Section 4 also presents the manner in which detailed processes can be developed. Finally, monitoring and follow-up are discussed in Section 5.

Appendices I–III and Annexes I–X provide further information on concrete aspects of the implementation process, and various examples.

2. GENERAL CHARACTERISTICS OF IMPLEMENTING A PROCESS BASED MANAGEMENT SYSTEM

To implement a process based management system is to implement change, and this can be approached in various ways; however, experience has demonstrated that the adoption of a structured approach provides the best chance of success, efficiency and long term sustainability. Implementation of a process based management system may involve either the creation of a new system (in embarking countries or organizations) or transition from a mature QA/QC/QM system to a process based management system. In either case, the process to be followed is the same, even in the case of embarking countries where the detailed operating procedures (operation, maintenance, radiation protection, surveillance requirements, etc.) are delivered by the vendor as part of the installation.

The preferred approach is to manage the implementation effort as a project with a project manager and supporting staff (development team) as needed. The size and complexity of the effort to establish a process based management system or to transition an organization from its current management system, is proportional to:

— The identified gap between the current state of the management system and the intended outcome after implementation;
— The type, size and complexity of the organization.

An organization has to assess its individual situation and, using a graded approach, scale the requirements and activities to manage the development and implementation in accordance with its needs. Aspects of implementation to be considered are:

(a) A senior management decision to implement a process based management system, and allocate required resources for that effort, may be based on a documented implementation proposal (business case) weighing the resources (i.e. costs) versus expected benefits. However, there may be situations in which a decision has been imposed on an organization by a regulatory body, corporate body, client or stakeholder. This may eliminate the need to prepare an implementation proposal, or it may mean that only a simplified implementation proposal is needed.
(b) If an implementation proposal is prepared, the typical length of such a document is a few pages. The complexity of the content depends on the size of the organization and the decision making process used by senior management.
(c) Following approval of the implementation proposal, a project charter authorizing the execution of a project is often formally issued. This is usual in an organization with a structured project management process already in place. A project charter is a document issued by the project sponsor who formally authorizes the implementation, and provides the project manager with the authority to apply organizational resources to execute the project. It describes the initial requirements for the project and the expected outcome, and is prepared after senior management's decision to approve the implementation. In an organization that does not have a structured project management process, the function of the project charter may be carried out by a

memorandum or other communication vehicle, or may be included as an item in the organization's business plan and assigned to a responsible individual. A sample template of a project charter is presented in Annex I.

(d) The specific project implementation plan supporting the project charter should be documented. A project implementation plan is a detailed planning document that describes how the project will be executed and implemented. It defines project scope and deliverables, work breakdown, project organization and responsibilities, schedule, budget and other planning aspects. The plan forms a basis for measuring project progress and performance. The project plan is prepared by the project manager in collaboration with project team members and key stakeholders. The size and complexity of the project plan is proportional to the size of the project. Organizations that already have a defined project management process generally deploy that process and any available project plan templates. The project management process typically scales the plan to the size and complexity of the implementation. If an organization does not have a defined project management process, the project manager should scale the plan to the size and complexity of the implementation in consultation with the senior manager. Typically, for a smaller project, the project plan will be less elaborate than for a project with a large scope implemented by a large team, sometimes operating across multiple sites.

(e) Besides a graded approach to the transition project itself, the application of the management system requirements is also to be graded as required by GS-R-3 [1] to ensure an appropriate application of resources. Detailed guidance on grading the application of management system requirements is provided in Ref. [12]. The following considerations apply to grading the application of the management system requirements.

The implementation process can be, for example, broken down into four main stages and further into the ten steps depicted in Fig. 1. The main stages are:

(1) Evaluating the business needs and preparing an implementation strategy (Steps 1–4 in Fig. 1);
(2) Developing and managing the implementation plan (Steps 5–7 in Fig. 1);
(3) Developing and implementing the detailed processes (Step 8 in Fig. 1);
(4) Follow-up and continual improvement (Steps 9–10 in Fig. 1).

Figure 1 shows the implementation process identifying the key inputs, outputs and responsibilities at each stage. The person responsible for an action is printed in bold in the flow charts used in this document. For each step in the process, responsibilities have been identified.

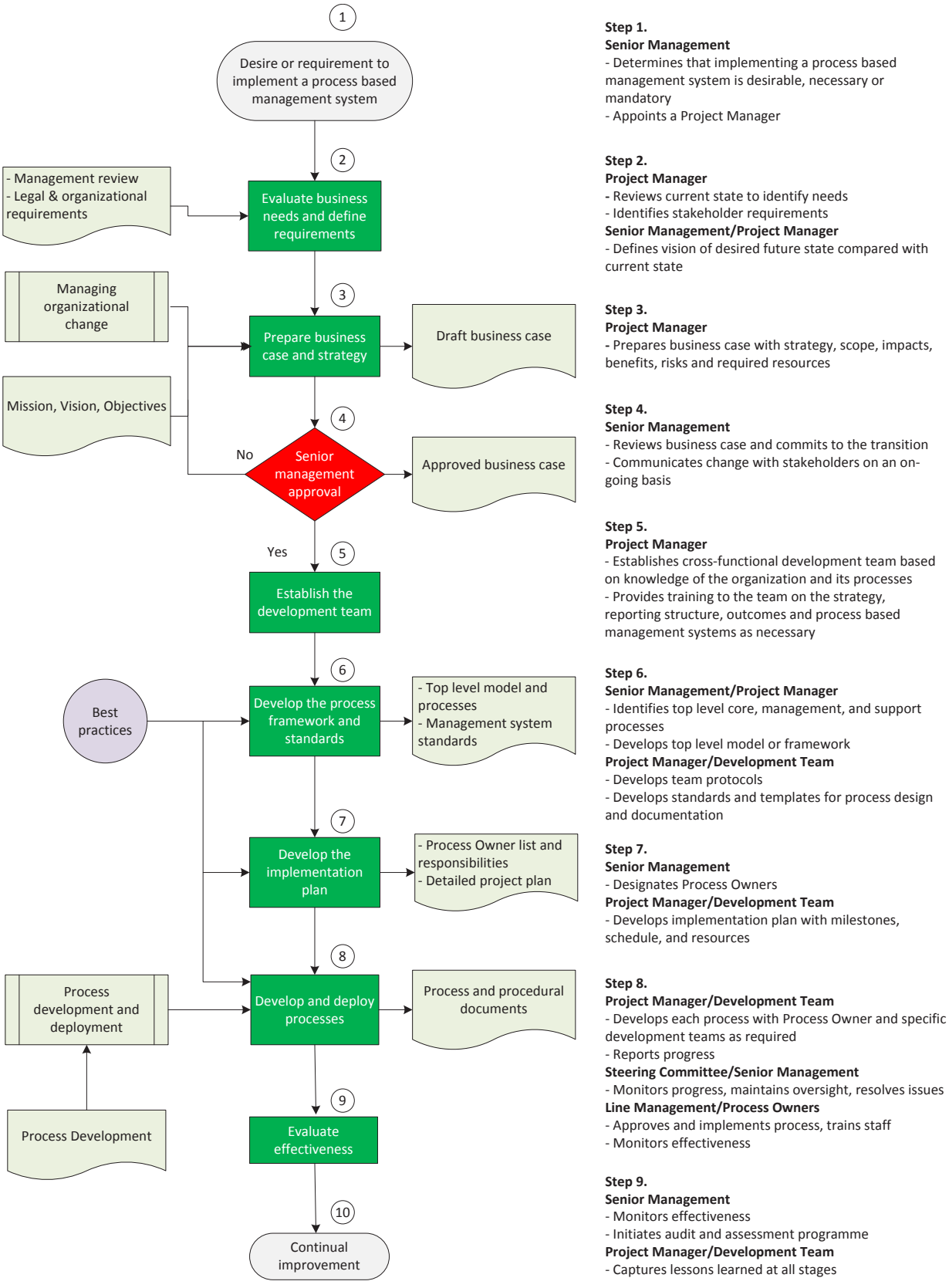
Although Fig. 1 and other flow charts in this publication are provided for guidance, the actual activities and sequence will depend on the specific circumstances of each organization.

3. EVALUATING BUSINESS NEEDS AND PREPARING AN IMPLEMENTATION STRATEGY

3.1. GENERAL

Before an organization begins the implementation of a process based management system, it needs to have a full understanding of the mission and objectives of the organization, its current management system status and a clear vision of what will be accomplished at the end of the implementation (Step 1 in Figure 1).

The implementation of a process based management system requires commitment by senior management and all levels of the organization. Since management and staff willingness and capacity to implement the system are important, it is good practice to assess organizational readiness for the proposed changes. First, the organization should consider its current management system status. It is recognized that most organizations that already have a QM system have also integrated into that system, to a certain extent, aspects related to safety, health, environment, security, quality and economics. The extent of integration should be evaluated to make a correct assessment for establishing the implementation scope, resources, timeline, and so on. Annex II shows a process



Step 1.
Senior Management
- Determines that implementing a process based management system is desirable, necessary or mandatory
- Appoints a Project Manager

Step 2.
Project Manager
- Reviews current state to identify needs
- Identifies stakeholder requirements
Senior Management/Project Manager
- Defines vision of desired future state compared with current state

Step 3.
Project Manager
- Prepares business case with strategy, scope, impacts, benefits, risks and required resources

Step 4.
Senior Management
- Reviews business case and commits to the transition
- Communicates change with stakeholders on an on-going basis

Step 5.
Project Manager
- Establishes cross-functional development team based on knowledge of the organization and its processes
- Provides training to the team on the strategy, reporting structure, outcomes and process based management systems as necessary

Step 6.
Senior Management/Project Manager
- Identifies top level core, management, and support processes
- Develops top level model or framework
Project Manager/Development Team
- Develops team protocols
- Develops standards and templates for process design and documentation

Step 7.
Senior Management
- Designates Process Owners
Project Manager/Development Team
- Develops implementation plan with milestones, schedule, and resources

Step 8.
Project Manager/Development Team
- Develops each process with Process Owner and specific development teams as required
- Reports progress
Steering Committee/Senior Management
- Monitors progress, maintains oversight, resolves issues
Line Management/Process Owners
- Approves and implements process, trains staff
- Monitors effectiveness

Step 9.
Senior Management
- Monitors effectiveness
- Initiates audit and assessment programme
Project Manager/Development Team
- Captures lessons learned at all stages

Step 10.
Line Management/Process Owners
- Continually improves the process

FIG. 1. Example of an implementation process flow chart. (The white oblongs show the initiator or terminator of a process or procedure; the green rectangles show actions or activities; the red diamonds show decisions; the light green symbols show documents; the grey circles show an undefined information source.)

maturity assessment table which may be used to assess the status of an organization's system, and facilitate the development of an implementation plan.

The decision to start the implementation of a process based management system can be a result of:

— Organizational improvement initiatives resulting from the performance assessments and continual improvement activities illustrated in Fig. 2, which may include:
  • Benchmarking — where the organization has identified the opportunity for improving its performance to align with industry best practices. Brief guidance on organizational benchmarking is provided in Annex III.
  • Management review — where the organization's senior management has reviewed the effectiveness of the existing management system and identified a need to change to a process based management system.
  • Stakeholders' feedback — where feedback shows the need to increase the organization's performance and the transparency of its activities.
— A regulatory requirement — resulting from an alignment of national regulations to GS-R-3 [1]. In this case, the requirement is viewed as a licensing requirement to be respected by the organization.
— Corporate requirement — in order to align with corporate and legal requirements related to safety, health, environmental, security, quality, economic and other objectives.

For organizations with corporate stakeholders, especially those who build or operate nuclear plants with already established systems, it is important that the implementation aligns with corporate policies and strategic development and implementation plans. The development and implementation plan should include the training of staff with a focus on their role in the change and implementation process, and the application of the new management system to their duties. Corporate offices are a key stakeholder, as they normally determine resource allocation and provide policies that govern the organization. For a new owner or operator, it is important to first develop clear corporate policies, objectives, and a strategic development and implementation plan.

3.2. IDENTIFYING THE OBJECTIVES AND MANAGEMENT SYSTEM REQUIREMENTS

To implement an effective process based management system, the organization needs to have a clear understanding of what its main objectives are, and based on that understanding, determine the management system

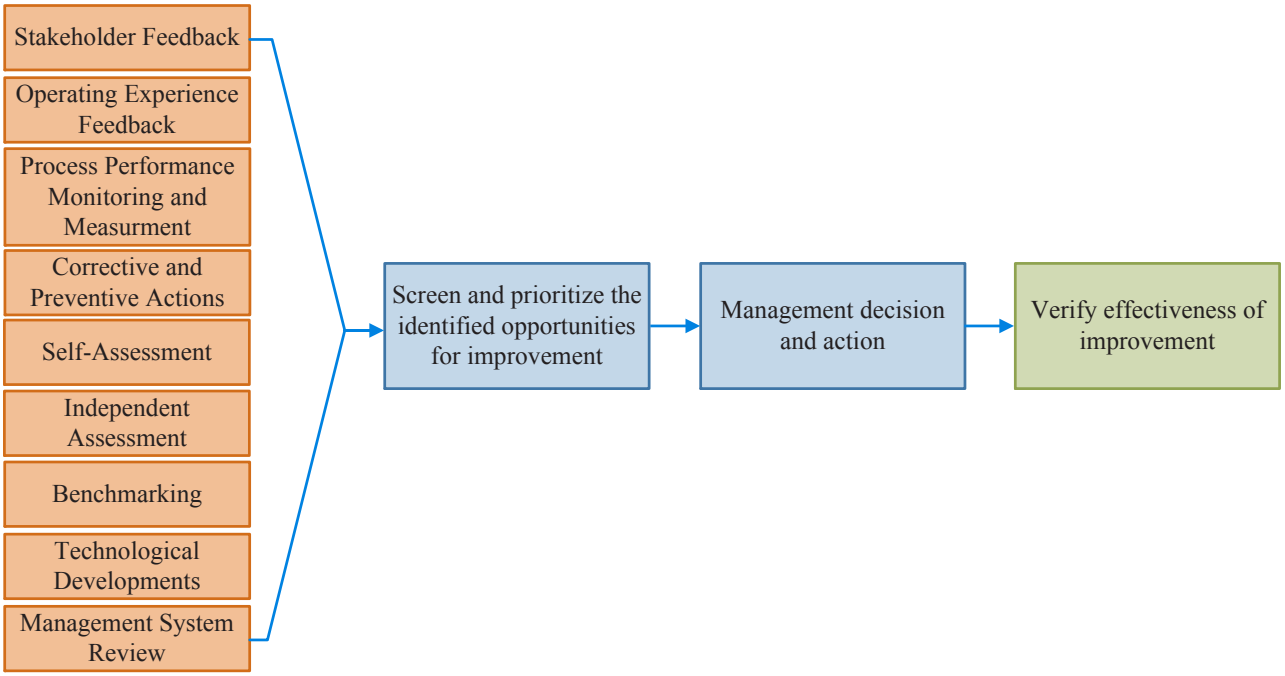


FIG. 2. Identifying and acting on opportunities for improvement.

processes, procedures and instructions. The objectives include safety, health, environment, security, quality, economics and various other requirements that an organization needs to take into account in order to conduct its business. Various types of requirements have to be taken into account for the development of a process based integrated management system; these can be divided into formal requirements, which have to be obeyed at all times, and additional requirements.

Figure 3 shows stakeholders as the source of requirements and their relationship and integration into the management system (depicted in the middle of the diagram). Requirements related to safety, health, environment, security, quality and economics take priority over other stakeholders' requirements.

Figure 4 presents another illustration of the integration of requirements in a coherent manner with an emphasis on safety. This illustrates that safety needs to be linked to all other requirements in decision making to achieve the ultimate goal of nuclear safety.

The organization should consider and understand the overall requirements that originate from various external and internal sources. These requirements may be applied in a graded approach. Detailed guidance on the application of a graded approach to meet requirements is given in Ref. [12].

Understanding management system requirements means not only understanding the language of a requirement, but also how the organization is expected to comply with it. Hence, the organization should consult relevant regulatory, corporate or organizational and other relevant authorities and stakeholders to seek clarification of the requirements and to determine or clarify expectations for satisfying these requirements.

Once a common understanding of the requirements and compliance criteria or expectations has been established, the organization should establish a common vocabulary or terminology for communicating requirements and compliance expectations internally and externally. A separate document presenting all the requirements in a

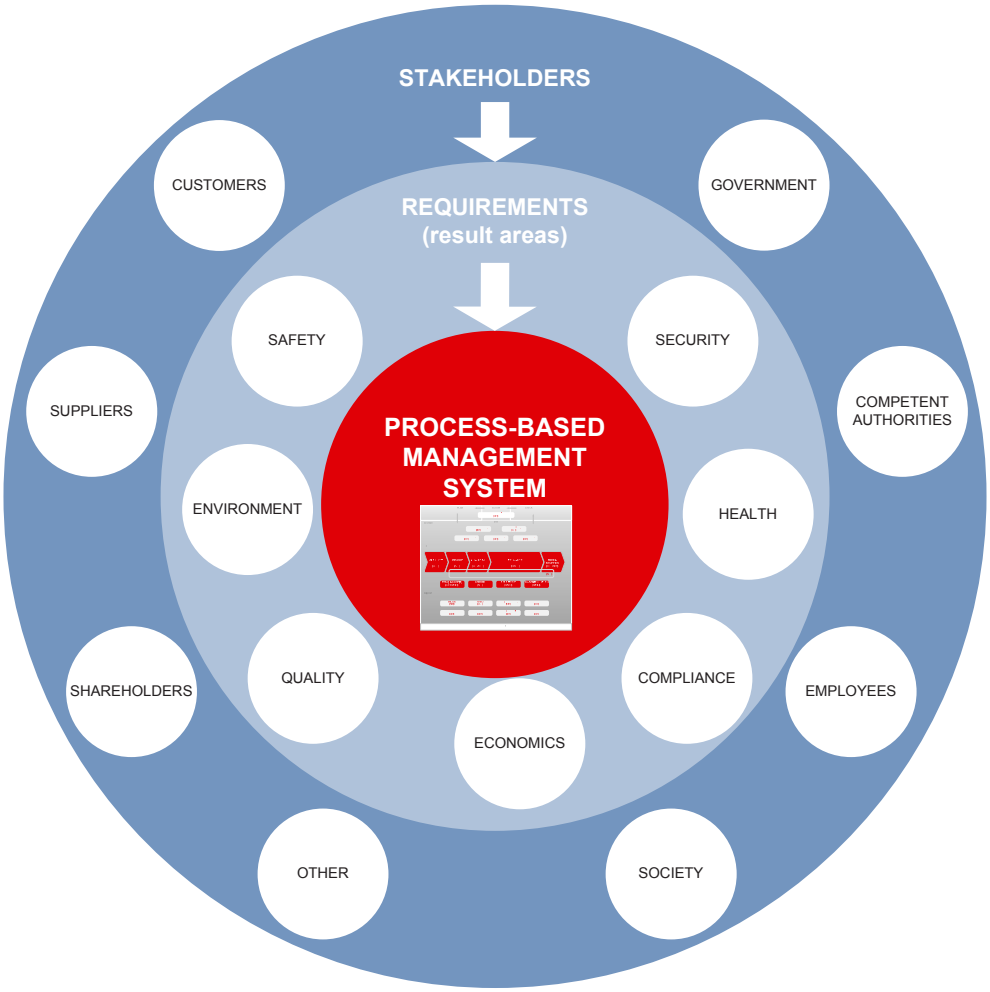


FIG. 3. Sources of requirements for a process based management system.

FIG. 4. Integration of requirements in a coherent manner in decision making with high priority given to safety is a prerequisite for a strong safety culture.

logical way, including the applicability of the requirements, is often beneficial, not only during the development of the process based management system, but also for staff, and for discussions with the regulatory body. The requirements relevant to the siting, design, manufacturing, construction, commissioning, operation including maintenance, and decommissioning of the NPP are to be sent to the regulatory body for review, and for approval where required.

Before an organization can develop an effective strategy for the implementation of a process based management system, it needs to have a realistic understanding of its business and goals, the starting point of the change and to foresee the potential impacts of the new management system on it. Such understanding is acquired only through detailed analysis and broad consultation.

3.3. DEVELOPING FUTURE OBJECTIVES AND AN ORGANIZATIONAL FRAMEWORK

Based on an understanding of the current state, the requirements of a process based management system and compliance expectations, senior management needs to paint a picture of what the organization might look like and how it will operate under the new management system. Appendix I provides some standard elements useful for the development of a management system. There needs to be a clear vision and high level understanding of what needs to be accomplished to achieve the desired end state (Step 2 in Fig. 1).

Senior management has to review the mission, vision, values, goals and policies of the organization as inputs to the management system. It is also important to consult with both internal and external (including future) stakeholders to identify, clarify and confirm their needs and understanding of the requirements and compliance expectations, and align all parties as necessary.

Once a common understanding of the requirements and compliance criteria or expectations has been established, the organization should establish a common vocabulary or terminology for communicating the requirements and compliance expectations internally and externally. The organization should also set a firm, commonly understood and agreed upon foundation for determining the direction and scope of the implementation and any related organizational changes.

Once the current state and desired future state are known, it is possible to analyse existing processes in terms of their potential for optimization, in order to enhance effectiveness and control. This can be achieved by performing a gap analysis to identify, for example:

— Missing, redundant, overlapping, orphan or obsolete processes;
— Processes that do not fully comply with requirements;
— Processes that are currently in use but have operational or regulatory compliance risks or are identified as ineffective or inefficient;
— The maturity of existing processes and supporting documentation;
— Differences in working styles of different organizational units or groups;
— Any need to develop or improve the process for managing organizational change.

After the gap analysis has been performed and detailed insights are available, the development team can determine what has to be developed or modified. Several approaches can be used. Normally, the top level processes and related supporting documents such as input requirements, checklists and templates for output documents are defined first, and a development and implementation plan is then defined and executed.

Although some organizations start to develop and implement the second level documents (specific procedures and instructions) once the top level documents have been implemented, most organizations develop the second level documents concurrently with the top level process. In this situation, the top level process, the related supporting documents and the related product specific documents are implemented at the same time. This approach has the advantage that each process can be implemented throughout the organization in a fully completed state.

Implementing changes in the management system always means managing organizational change. Introducing a new management system will not necessarily mean a complete reorganization, but will typically introduce new, more logical, and efficient working practices. It also aims to change responsibilities. If the implementation also requires a reorganization of departments, all aspects of managing organizational change should be applied. In this situation, the implementation may take longer and have a bigger impact on the organization as well as a greater potential for resistance to the change. In this situation, the scope should be expanded to engage or involve experts on organizational issues to help manage the implementation of the management system and the organizational change. Detailed guidance for this process is provided in Ref. [11].

Implementation of the organizational change should be planned, controlled, communicated, monitored, tracked and recorded. There are at least three key success factors that enable an effective and successful implementation as well as sustainable organizational change:

(1) The cultivation and maintenance of a strong organizational culture for safety throughout the implementation of the change;
(2) Flexibility to accommodate reporting relationships that will work within the context of the organization's culture during and after the implementation;
(3) Assertive, accurate and open communication before, throughout and after the implementation to proactively counter normal resistance towards changes.

The development team and senior management need to understand which factors may challenge successful implementation of the management system within their organization and take appropriate measures to avoid or mitigate them. Annex IV addresses some risk management aspects related to the implementation of process based management systems.

3.4. PREPARING AN IMPLEMENTATION STRATEGY AND PROPOSAL

Implementing a process based management system requires dedication and the deployment of resources (financial, human, time, etc.). Senior management should understand the benefits and the costs of the implementation when making decisions.

Senior management should appoint a project manager, sometimes also called a change agent, who can assess the situation, initiate the implementation efforts through preparation of an implementation strategy (or business case), and lead the development. The project manager also manages implementation and related organizational changes, and preferably has a broad understanding of the organization's business and skills in managing organizational change.

The implementation strategy needs to convince senior management of the benefits of a process based management system, i.e. the business case (Step 3 in Fig. 1). These benefits may include:

— Improved understanding of the goals, strategies, plans and objectives of the organization;
— Identification of the organization's core, management, and support processes, including sequence, interactions, ownership and accountability;
— Improvements in work culture;
— Better knowledge of how the organization does its work;
— Addressing needs and expectations of the staff;
— Transparency regarding the responsibilities of various organizational departments and interactions between departments;
— Better identification and management of risk;
— Improved standardization in performing work activities;
— Improved ability in monitoring and measuring organizational performance;
— Optimized use of resources, and reduced costs;
— Optimized management system documentation in a structure that avoids duplication, overlap and gaps and ensures that all supporting documentation can be identified and referenced from a process;
— Enhanced communication between employees, customers and stakeholders;
— Enhanced employee, customer and stakeholder satisfaction;
— Enhanced safety performance through planning, control and supervision.

Prior to starting the preparation of the implementation proposal, the project manager should assemble the required input information. The inputs to the implementation proposal are:

— The vision, mission, values and objectives of the organization;
— The critical success factors for the organization;
— Relevant laws, regulations, requirements, management system standards and technical codes/standards;
— Expectations of stakeholders and the internal members of the organization;
— General assessment of the current management system (or QA system) status;
— Assessment of available resources (e.g. human, financial and IT infrastructure);
— The organization's competency and knowledge related to process based management systems.

The project manager prepares a detailed implementation proposal based on these considerations. The purpose of the implementation proposal is to provide a basis for senior management to make knowledgeable decisions regarding the development and implementation of the management system.

The implementation proposal should be described in a concise document (typically a few pages in length), preceded by an executive summary. The executive summary should include a statement of what senior management is being asked to approve.

The document content should answer the key questions senior management may have when making the decisions on developing and implementing the management system and its changes:

— Why is this needed?
— What will the benefits be?
— What will the cost be?
— What risks to safety and organizational operations might the implementation reduce or cause?

To prepare the implementation proposal, the project manager should include the following considerations, knowing that an organizational change may require time to produce intended outcomes:

— The overall development and implementation strategy;
— The scope and realistic timeline of the implementation;
— A brief outline of what the implemented process based management system will be like, and a comparison with the current state;
— The overall benefits to the organization;
— A preliminary estimate of overall costs and resources needed;
— The identification of potential risks to safety and organizational functioning from failure to implement a process based management system;
— The identification of potential unintended risks to safety and organizational functioning resulting from implementation.

3.5. SENIOR MANAGEMENT APPROVAL

When senior management approves the implementation proposal (Step 4 in Fig. 1), it should appoint a sponsor, normally a member of the senior management team, who is responsible for overseeing and advising the project manager and resolving issues which lie beyond the responsibilities of the project manager. The project manager is responsible for planning and coordinating the development and implementation efforts. It is recommended that all development and implementation activities be managed as a project.

Senior management should communicate to the entire organization the need for the implementation in order to obtain everybody's support and commitment. Consistent messages and actions from senior management will have a positive impact on the implementation. When the implementation is in its early stages, communication should focus on 'what' and 'why' and not on 'how'. The best form of communication is face to face, as it allows for questions and concerns to be raised and discussed. For larger organizations, face to face communication can be undertaken by the project sponsor or project manager or both, but only after an initial announcement by senior management.

The implementation of a process based management system should be part of the organization's overall business plan. This will ensure that resources will be provided to support its implementation and also demonstrate that the implementation is a high priority for the organization.

The implementation will introduce a change to the organization. The following are the key conditions for effectively managing the change, as described in Ref. [11]:

— A clear understanding of why the change is necessary;
— A vision of what the organization should look like after the change, and a plan to achieve that vision;
— A clear definition of the end state (the desired outcome);
— Effective management of implementing organizational change;
— Effective use of technology;
— Good communication, delivering coherent and transparent information that encourages the involvement of staff members (see Annex V).

The role of senior management in the implementation is critical. The full support and visible participation of senior management will positively impact the success of the project and its ability to achieve its goals. It is vital that management at all levels supports the vision and engages in the activities necessary to implement a new management system or to improve the existing system.

3.6. ADDITIONAL CONSIDERATIONS FOR EMBARKING COUNTRIES

Appendix II addresses the needs of embarking and newcomer nuclear countries. References [2, 3] provide guidance on documenting management systems. In addition, IAEA TECDOC 1058 [13] provides more detailed

and valid guidance on good practices related to preparing procedures within the nuclear industry. IAEA Safety Report Series No. 74 [14] provides specific guidance to embarking countries on implementing a strong safety culture, starting with the pre-operational phases.

4. DEVELOPING AND MANAGING THE IMPLEMENTATION PLAN

4.1. ESTABLISHING THE MANAGEMENT SYSTEM DEVELOPMENT TEAM

The appointed project manager should establish the development team (Step 5 in Fig. 1) as early as possible. As a minimum, the following roles are normally considered. Figure 5 gives an example of a project organization structure.

Management system owner: Designated by senior management as the overall architect of the management system, this individual coordinates the development of the top level processes, provides standards for top level process development (e.g. templates for flow diagrams and process descriptions) and monitors the interfaces between top level processes during development to ensure proper integration. Provides overall coordination and liaises with the designated process owners (the process owner is the individual designated by management to be accountable for the implementation, effectiveness and continual improvement of the assigned process).

Management system specialist / Quality Assurance specialist: Provides expert knowledge on management systems standards and QA/QC standards.

Departmental representative: Represents a department on behalf of the department head, and provides knowledge regarding the activities in a department. Coordinates the development activities within a department.

Requirements specialist: Provides expert knowledge of the standards, regulations, codes, requirements and so on for all process and procedural documents. Together with the project manager, consults the relevant regulatory, corporate, organizational and other relevant authorities and stakeholders to seek clarification of the requirements and determine or clarify their expectations for satisfying the requirements. These expectations should form the criteria for assessing the management system to judge whether or not it meets the requirements. Standards specialists can also be involved in the review of the documented processes to ensure the requirements are met, and can prepare matrices providing a documented record of compliance against requirements.

Process development specialist: Develops processes in accordance with guidelines established for management system documents. Supports the Process Owner and process specific development teams in developing processes.

Steering committee: Provides oversight of the project, including progress monitoring and issue resolution.

Communications specialist: Develops, implements and reviews communication throughout the development and implementation of the management system. This individual should be appointed in the early stages of the project to facilitate the understanding and engagement of stakeholders.

It must be noted that some functions can be combined. Especially when the management system specialist has good project management skills, this person is often appointed as project manager.

Depending on the specific process, support from individuals in many areas is generally required. These areas include, but may not be limited to, nuclear safety, operations, maintenance, environment, all the engineering disciplines, health and safety (including radiation protection), physical security, safeguards, finance, information technology, human resources and change management. The supporting individuals may be the (future) process owners for the related processes.

The need for external resources should be considered during the initial development phase of the management system; however, the focus should be on rapid knowledge transfer to enable in-house development and sustainability. Consultants are unlikely to provide an off the shelf solution and cannot implement sustainable change without in-house ownership and support.

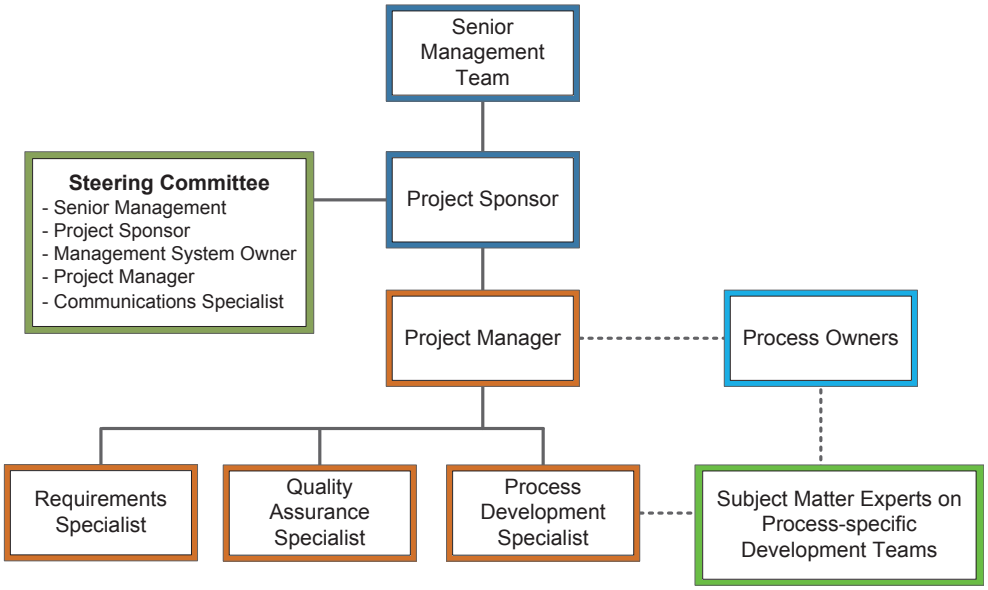


FIG. 5. Example management system development project structure.

The appointed project manager should consult with stakeholders to identify appropriate individuals for the development team based on their understanding of the organization's structure, activities, requirements, compliance expectations, and the impact of the management system on safety.

If a standards specialist is available, this specialist will be involved in consulting stakeholders with respect to the requirements. Requirements include legal obligations, requirements that management (corporate and local) has chosen to adopt based on organizational policies and standards adopted for business reasons or contractual obligations. The requirements will include:

— The values and objectives of the organization itself;
— National and local legal and regulatory requirements regarding (nuclear) safety, radiation protection, occupational health, environment, security, quality and emergency preparedness;
— IAEA requirements, including nuclear safety, radiation protection, security, waste management, management systems, training and emergency preparedness;
— Requirements based on guidance from industry organizations such as the World Association of Nuclear Operators and the Institute of Nuclear Power Operators;
— Requirements based on guidance from financial and accounting standards bodies, voluntary private sector organizations, and committees such as the Basel Committee on Banking Supervision, the Committee of Sponsoring Organizations of the Treadway Commission, or the Criteria of Control Board, which provide guidance to management on governance, business ethics, internal control, enterprise risk management, fraud, and financial reporting;
— Standards set by national or international organizations, such as ISO, the European Foundation for Quality Management, the National Institute of Standards and Technology, and the National Quality Institute.

Training and orientation should be provided as required to ensure the development team understands the organization, requirements and compliance expectations.

Once the development team has been assembled and prepared, it can assist with preparing the implementation plan.

4.2. DEVELOPING THE PROCESS FRAMEWORK AND STANDARDS

The senior management team, with the support of the development team, should identify the top level processes (Step 6, Fig. 1) that are needed to achieve the organizational goals, provide the means to meet all

requirements and deliver the products of the organization under the new set of management system requirements. This involves identifying the:

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

Appendix III provides more detailed guidance on how to identify core, support and management processes. It also provides examples of typical core, support and management processes in different nuclear facilities during their entire lifespan. See also Refs [2, 3].

4.2.1. Developing a top level process model

The senior management and development team have to consult with the various stakeholders inside and outside the organization to develop a top level process model or framework depicting what the organization and its operations would look like under the new set of management system requirements. Senior management engagement and involvement is essential to securing their ongoing ownership of the top level process model. Annex VI provides examples of a top level process model, and Annex VII provides an example of a template for a top level process description.

The establishment of a top level process model is a critical step for successful implementation. It signals a concrete commitment by senior management and the organization to the adoption of a process based management system. Senior management is responsible for determining the level to which the process based approach, and all it entails, will be applied in an organization, but shall retain the ultimate responsibility for company business and safety. The measures or indicators that senior management has decided will be used to judge performance under the process based approach should be clearly communicated and understood by all staff in relation to their duties. Senior management is also responsible for:

— Deciding and assigning authority and responsibility (i.e. accountability — e.g. through the definition of process owners) for the function or performance of the processes;
— Deciding how power and control, including control of budgets, will be shared, if at all, between process owners and functional managers;
— Establishing the conflict resolution mechanism to be used once the process approach has been implemented.

During the initial stages of process development, the organization should focus on the processes, their inputs, activities and outputs, and not on who is involved in the process.

4.2.2. Defining responsibilities and process ownership

There should be clearly defined roles and responsibilities during and after the implementation. Functional managers should be kept involved and engaged at all times. Effort should be made to show functional managers how process owners can help them. Functional managers should understand the implementation project and the desired end state to ensure a positive working relationship with process owners. Functional managers may also be considered potential process owners, although delegation of this role to someone actively involved in the day to day functioning of the process may be desirable to enable the management to maintain an oversight and resolve potential problems.

Once the processes have been defined, process owners for top level processes can be identified. Process owner responsibilities are outlined in GS-G-3.5 [3]. Depending on the process, the process owner may be a fulltime position within the organization, or a process role. If it is a process role, it is important that adequate time and resources be made available to effectively fulfil this role. Process ownership should be assigned to the appropriate

level of the organization to allow for the effective implementation of processes. When selecting individuals to perform the process owner function or role, the following qualities of the individual should be considered:

— Ability to work effectively in a team environment;
— Managerial and communications skills;
— Ability and interest to understand the need for the process, the process activities and the process requirements;
— Motivation to continually monitor the effectiveness and efficiency of the process and to make changes with the authority provided by the senior manager and defined in the management system when performance degrades or when opportunities to improve performance are identified (proactive approach);
— Understanding of where the process fits in the organization, its interfacing processes, and stakeholder needs, i.e. the individual should be a systemic and systematic thinker;
— Ability to monitor industry best practices and make changes to processes to take advantage of any lessons learned;
— Ability to keep process documentation up to date.

4.2.3. Establishing the process framework and document hierarchy

Typically, the management system is described in a series of documents structured in a hierarchical pyramid. IAEA safety guides (e.g. GS-G-3.1 [2] and GS-G-3.5 [3]) on the implementation of requirements specified in IAEA GS-R-3 [1] describe an example of such a document hierarchy consisting of a three level structure of information.

The number of levels in the hierarchical structure is established by the organization. There is no one way of depicting the document structure, and each organization should define one that is appropriate to its context. Many organizations have structured their documentation using three or four levels.

The organization needs to clearly identify those documents that describe or implement the management system and those that are outputs of the processes. Each type of document should be assigned to an appropriate level of the hierarchical structure. The following paragraphs provide information on a typical structure.

Level 1, the top level of the pyramid, is made up of the highest level document(s) and presents an overview of how the organization and its management system are designed to meet the policies and objectives of the organization. Often, these are included in the so called management system manual and contain:

— The mission, vision, goals and policy of the organization and the main governing requirements for the management system;
— A brief description of the management system and its key processes;
— The hierarchical structure of the organization’s documents;
— A high level organizational structure with a brief description of key responsibilities and authorities of senior managers, organizational units and key committees, as applicable;
— Responsibilities of process owners;
— Arrangements for measuring and assessing the effectiveness of the management system.

Level 2 documents consist of the processes to be implemented to achieve the objectives of the organization and the responsibilities, including, for example, the designated process owner, position or organizational unit responsible, to carry them out.

Level 2 documents consist of:

— Process maps, and processes including the interfaces between related processes;
— Responsibilities, authorities, interface arrangements, measurable objectives and activities to be carried out.

The information at level 2 provides administrative direction to managers in all positions and describes the actions that managers have to take or implement. The level 2 documents may also briefly describe how technical tasks are to be performed.

Level 3 documents consist of detailed procedures, instructions and guidance that enable the processes to be carried out, and specify the position or unit that is to perform the work, including:

— Documents that prescribe 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 may vary considerably, depending on the application. The primary consideration should be to ensure that the documents are suitable for use by the appropriate individuals and that their contents are clear, concise, unambiguous, and produced in accordance with a template or structure suitable for that type of document.
— Procedures and work instructions defining the steps for performing work activities to achieve a specific analytical, functional or operational objective: for example, maintenance procedures, operating procedures, laboratory procedures, but also procedures for safety analyses, core management or reporting non-conformances.
— Documents that contain data or information, such as design documentation and drawings, or information reports.
— Job or position descriptions that define the different competencies or types of work encompassing the total scope of an individual's job. Job descriptions should be used to establish baselines for identifying training and competence needs.

If a fourth level is defined, it typically consists of records and reports providing evidence of the activities which have been carried out. Otherwise, these documents also belong to level 3.

Figure 6 illustrates a 3 level documentation system in a pyramidal structure. It creates a consistent structure for the documents. Also, quick identification of the position of a document within the hierarchy and the assigned process will become possible. Although the structure and the details may evolve, carefully thinking through the initial management system design to include all document types will minimize subsequent change.

In some cases, documents may be shared by more than one process. One may have on the top level of the management system the processes with titles such as 'Perform Planning Process' and 'Perform Maintenance Process'. These two processes may, for example, share a single supporting document for the planning and implementation of 'Control of Foreign Material'. This practice should be considered when referencing one shared document. This would avoid duplication and ensure consistent understanding.

Figure 7 provides an example of a regulatory body management system document hierarchy illustrating the relationship between regulatory framework documents and the internal processes of a regulatory body.

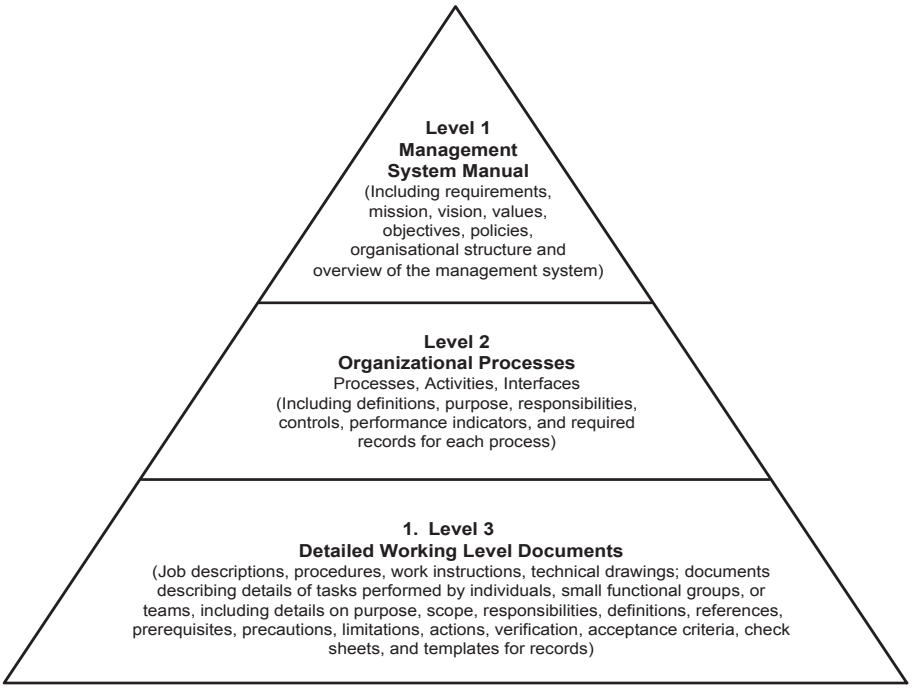


FIG. 6. An example hierarchy of documents in a process based management system.

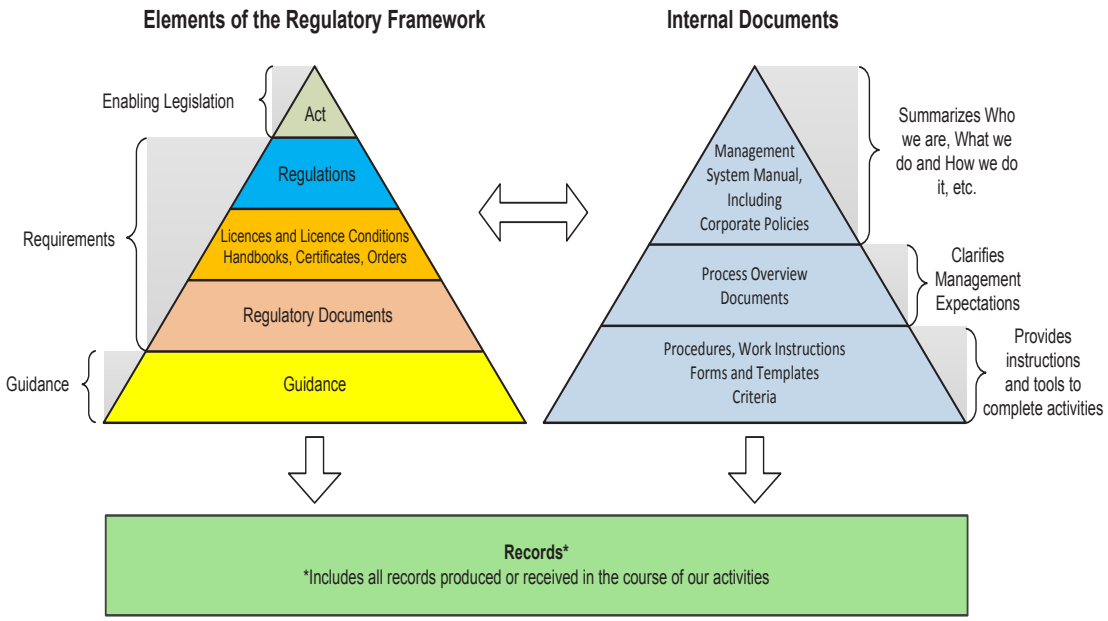


FIG. 7. Example hierarchy of MS documents (example for a nuclear regulatory body).

Annex VIII provides examples of a hierarchy of documents associated with one of the processes in a process model, before and after the implementation.

The development team, in consultation with relevant parts of the organization, has the task of establishing documentation templates for describing processes, procedures, forms and other routinely produced documents in the management system. These templates facilitate the development of documents. Consistency ensures a uniform style, reduces error at the time of use and facilitates inter-departmental training.

The templates for the different types of documents describing the management system (process descriptions, working level procedures, etc.) are normally described in the document control process procedures in order to ensure that a standard format is used for each category of document. The responsibility for developing the different templates should be defined in the top level process. The templates for the corporate processes and the control mechanism for all documents should be defined at the corporate level to ensure a standard to control all documents, since different activities may require different templates.

Each document requires a unique identifier. It is advisable to define a document identification system related to the document structure and level of the documents in the management system. Some organizations indicate the process and level of the document in the cover sheet. For example, an illustration showing a structure can be used, in which the shading on the diagram indicates the level of the specific document.

The number of management system documents should be kept as low as possible to permit easier control of the system and to ensure its user friendliness. Also, the documents themselves should be designed with the end user in mind in order to increase the chances of the tasks being performed correctly. The use of flow charts in the documentation is encouraged. When using flow charts, flow charting standards (e.g. those of the Institute of Nuclear Power Operators, or examples provided in this publication) should be identified and used to support uniform application and understanding.

4.3. DEVELOPMENT OF A DETAILED IMPLEMENTATION PLAN

An implementation plan (Step 7 in Fig. 1) should be prepared by the development team to describe the activities required for successful implementation. The implementation plan should align with the project charter and the implementation strategy. The implementation plan governs only project activities and therefore should reference and direct the user to the use of existing processes such as document control and project management. If those processes are not yet available, they should be developed as early activities in the implementation plan.

The detailed implementation plan for process development and related organizational changes normally includes:

- The purpose and scope of the implementation.
- The project charter and implementation strategy.
- An implementation project organizational chart.
- Structure, tasks and responsibilities, and authorities of the project team members, steering committee, specialists and other key positions.
- Tasks and responsibilities of the organizational divisions, departments, units, groups and other specialists or staff involved in the development and implementation of the management system.
- Planning, including schedule, timelines and milestones (an example of a schedule with milestones is given in Annex X).
- A detailed breakdown of the project resource requirements, including project team resources, external resources, if required, and anticipated management and departmental resources required to support oversight, development and initial implementation.
- Identification and prioritization of the risks associated with the project (e.g. implementation delays, resource constraints, implementation issues) and a risk reporting strategy, including the future impact of the implementation or change considering the:
  - Safety impact of the proposed change (additional measures might be necessary to ensure that the change does not have a negative impact on safety);
  - Change readiness and commitment of the organization;
  - Impact on organizational culture and behaviour;
  - Impact on organizational responsibilities and structure;
  - Impact on performance effectiveness;
  - Potential impacts on organizational planning, performance monitoring and performance indicators;
  - Impact on stakeholders and interfaces (both internal and external).
- Training requirements (e.g. process owners, internal auditors and other stakeholders).
- Implementation activities including:
  - Schedule, timelines and milestone controls;
  - Preparation of the process development and implementation plans for each specific process, including priority, sequence of development and addressing the issues identified during the gap analysis;
  - Project reporting (milestones, progress and budget);
  - Process implementation, rollout and training;
  - Implementation monitoring and oversight including:
    - Oversight meetings, lessons learned and issue resolution;
    - Evaluation of implementation effectiveness through stakeholder feedback, self-assessments, audits, management review, etc.
  - Project close-out.
- Architecture for supporting documentation, including:
  - Development of the level 1 management system document, as required;
  - Management system development standards (e.g. process design, flow charting and documentation standards and templates, and software to be used).
- Organizational project management methodologies.
- Communication plan.
- Change management methodology appropriate for the type and scope of the change. If change management expertise is required but not available within the development team, it should be obtained either internally (from within the organization or by training a member of the development team) or externally. Reference [11] gives detailed guidance on managing change in nuclear organizations, and much additional literature is available, for example Refs [15, 16].
- Significance of the identified gaps and a strategy to address the gaps.

In most cases, the existing management system includes processes, although they may not be called by this name. Such processes may be bureaucratic, ineffective and without clear outputs, poorly defined and without

defined responsibilities, lacking important steps or interfaces, and may be rather inefficient. As processes are frequently dependent on input from one other, there may be a need to develop certain processes before others. This is particularly important when developing processes for a new organization. For example, processes to ensure consistent development and management of process and procedural documents are an early requisite, as are the processes most in need of improvement to support ongoing work. Prioritization should take into account the organizational needs and stakeholder requirements. However, as processes are developed, individual interactions and changes in the internal and external environments may require processes to be developed in parallel or in a different order.

The definition of the management system framework, structure and document format should be given priority as it enables the consistent development and description of processes. The processes for preparation, review and approval of management system documentation are be the first ones to be developed and approved. Annex IX provides an example of such a process.

A communications specialist should be involved in preparing a communications plan that considers stakeholders directly involved in the accomplishment of the organization's mission and goals, establishes lines of communication, and consults with stakeholders when making decisions which may affect them. This can be achieved only through open communication and understanding the stakeholders' needs. It will be beneficial to involve some stakeholders who are indirectly involved in the accomplishment of the mission and goals in the preparation and implementation of the communication plan.

The detailed implementation plan is most often to be submitted to senior management for final approval. Once the implementation plan has been approved, the project charter may require revision to update key areas such as resources, milestones, timelines and budget. Revisions to the project charter typically require the approval of the steering committee.

4.4. COMMUNICATING A DETAILED IMPLEMENTATION PLAN

Communication to foster understanding, engage stakeholders and solicit feedback should begin at the conceptual stage of the project and continue at every stage to ensure there are no surprises for participants or stakeholders. Once the implementation plan has been approved, the plan should be communicated to internal and external stakeholders, as appropriate. The importance of timely and patient communication cannot be overstated, since missing or incorrect information leads to rumours and resistance.

To foster acceptance for the plan and its implementation, including organizational change, the strategy and plan should be packaged and communicated to all levels of the organization as a positive undertaking that highlights the tangible benefits for all management and staff.

The development team, other project teams and all levels of management should use appropriate communication channels or modalities available to them to periodically inform the organization and its stakeholders about the implementation of the management system, including the progress being made and any significant issues that have arisen. The communication channels should focus on face to face interactions, supported by leaflets, memos, email and an intranet. Frequently asked questions and answers should be posted on the organization's intranet.

The organization may use individuals who will promote the implementation within their organizational units (i.e. project managers). These individuals, the development team and senior management should be aided by the communications specialist and the communication tools developed to deliver effective messages to the organization and its stakeholders. Management at all levels needs to foster the involvement of all individuals in the implementation and continual improvement of the management system in order to succeed.

5. PROCESS DEVELOPMENT AND DEPLOYMENT

Previous sections have indicated that a top level model or framework typically identifies the main processes for the organization. Each process requires the development of individual subprocesses or procedures to support

each main process and its subsequent implementation across the organization. The objective is to apply a consistent methodology to develop processes that meet all requirements, standards and organizational objectives while minimizing duplication.

In order to ensure consistency in the description of processes, a specific process describing the preparation, review and approval of management system documents should be established. This process should clearly describe the responsibility for the development of documents of each type and level. An example of the administration of management system documents is presented in Annex IX. The owner of this process could be the owner of the document control process, or alternatively this role could be assigned to the management system owner.

The process owner coordinates the development and implementation of the process with support from the development team as needed. Depending on the complexity, development may make use of a support team and specific plans to manage the development and implementation of the process.

Identifying and understanding the requirements in terms of inputs, outputs and constraints is a key element for producing an effective process. The steps for development of a specific process are shown in Fig. 8, and later in the text, the steps in the figure are referred to.

The implementation plan identifies the order and priority of each process to be developed (Step 1). For each process, the remaining steps in Fig. 8 provide an approach for developing, documenting and implementing the process.

The process owner is typically responsible for forming the team (Step 2 in Fig. 8) that will develop a specific process, and may require other individuals from the organization to help develop the process. The size and skills of the team will depend on the type of process being developed, and on the experience of the process owner. The team typically includes subject matter experts, process users and customers of the outputs, supported by individuals familiar with process development and standards. However, while a team may not always be required, it is important that stakeholders and those involved in carrying out the process or receiving the results of the process are involved at each stage.

To ensure competency, it is important that the process owner arranges training for those involved where necessary, particularly with regard to process development, integration of management system requirements and document structure.

For a particular process, the objective is to identify all requirements that may influence the process and outcomes of the process (Step 3 in Fig. 8). Formal requirements represent legislation, standards and licences, which have to be obeyed at all times, and additional requirements defined by the organization or by stakeholders.

Other requirements originate in the business strategy, come from the stakeholders, represent industry standards or good practices or may also include other linked processes and their requirements.

Consideration of the above items typically results in a large number of requirements that need to be analysed. These analyses will result in more or less detailed requirements, guidelines, criteria and standards which have to be taken into account for the processes. The requirements, criteria and guidelines should be documented and are typically captured in a matrix or database that groups common requirements and indicates those requirements applicable to each process. It is advisable to also indicate whether a requirement belongs to the group of formal requirements or to the group of additional requirements. This facilitates knowledge management and makes the revision of processes easier. It is advisable to develop a specific process to identify the requirements and their revisions, and to specify how revised requirements should be evaluated to incorporate the new requirements in the processes. Many of these requirements may be similar, and for integration, they may be consolidated into a number of common requirements.

In some cases, the requirements may conflict, such as free evacuation routes and access for emergency response forces and security requirements for access restrictions. Another example would be decontamination requirements for floors and anti-slip requirements as part of occupational health requirements, or the free ventilation requirements for chemical storage provisions and the ventilation regime requirements in radiological zones. In case of conflicting requirements, it should be noted that safety should have the overriding priority. Which requirement is chosen as the overarching requirement should be clearly justified and documented. If formal requirements conflict, the justification for the overarching requirement should be presented to the involved regulatory authorities for review and approval. It is important that the approval of these deviations is clearly documented.

Depending on the maturity of the organization, existing knowledge may be applicable to the process being developed. It is important to capture and collate this information (Step 4 in Fig. 8) so it may be considered and used in the development of the final process.

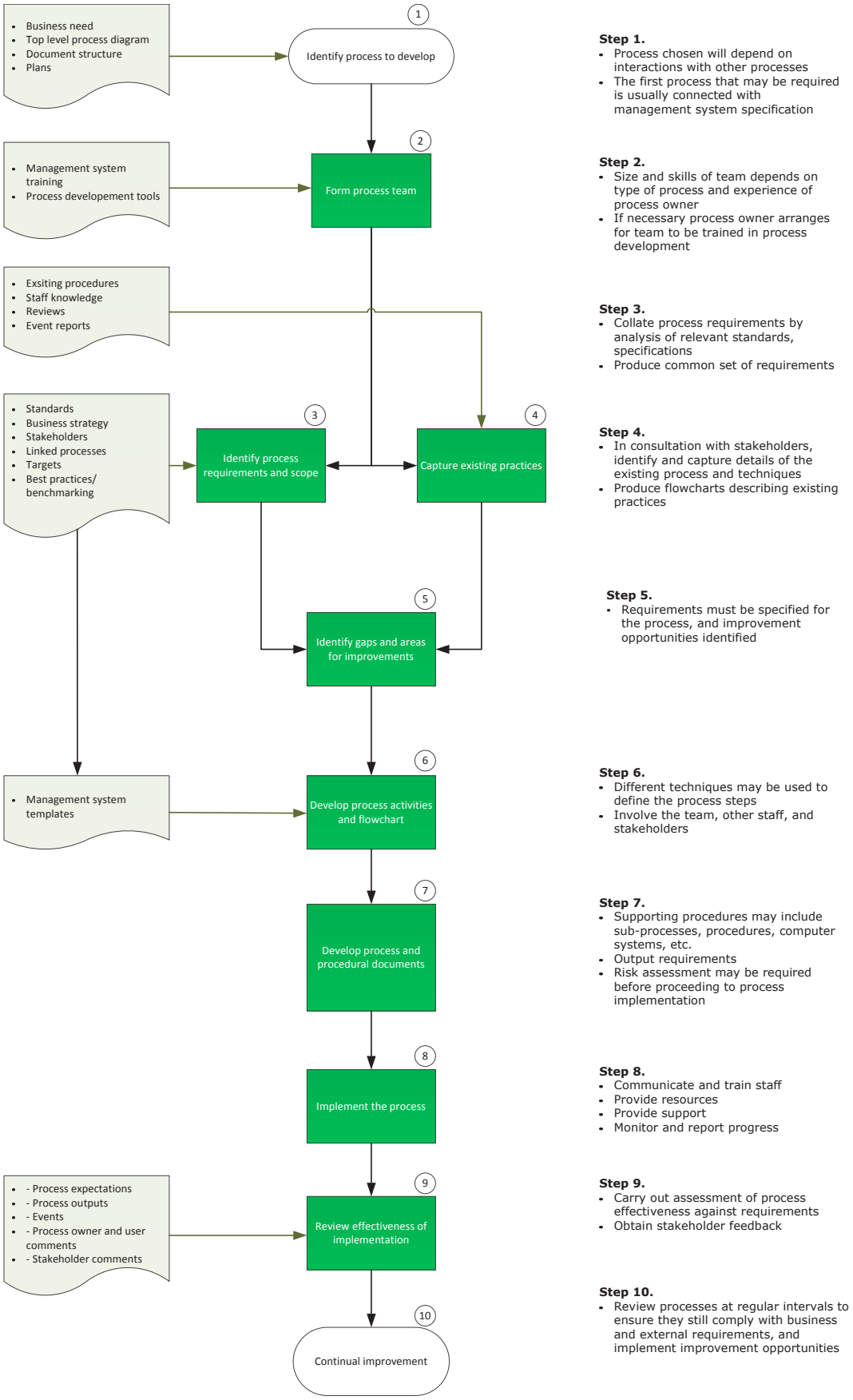


FIG. 8. Process development and implementation. (The white oblongs show the initiator or terminator of a process or procedure; the green rectangles show actions or activities and the light green symbols show documents.)

Existing knowledge consists of such aspects as:

— *Documented arrangements:* These may be procedures, process descriptions, and data on applicable requirements and their relation to a process.
— *Undocumented arrangements:* These often exist in an organization and should be captured and incorporated in processes, procedures and instructions. This information (staff knowledge) should be collected by consulting with staff either through interviews, staff involvement in the team, or through assessments.
— *Other information:* The output from activities such as production reports, formal audits, regulatory and management reviews, and event reports should also be reviewed to provide input. These and other information on risks provide valuable information on areas for improvement.

The above information should be collated into an information package to identify the existing status and any potential areas for improvement.

The objective of the gap analysis (Step 5 in Fig. 8) is to compare the identified requirements for the processes with existing arrangements and information gathered in the previous steps. Areas for improvement can then be identified and a strategy devised for developing the process and its supporting documentation.

The process team, supported as required by subject matter experts, should systematically analyse the information and identify any gaps. This can be done by reviewing each requirement and identifying its status as follows:

— Covered — the requirement is addressed in existing documentation;
— Partially covered — some aspect of the requirement is not covered;
— Not covered — the requirement is not addressed.

Figure 9 illustrates one example of how a gap analysis can be documented.

A second step in the analysis is the identification of which processes are available to address the gap, whether they are still appropriate, and whether additional processes or procedures will need to be developed.

Once the gap analysis is complete, a strategy to address any gaps should be generated. This strategy should be produced in consultation with the team and relevant stakeholders and may include the production of a new or modified process or documents or both. Agreement by senior management may be required before moving to the next stage of process and document development.

When the gap analysis for the processes has been completed and the processes that should be developed or modified are known, a similar action should be carried out for related procedures and instructions, to determine whether each is acceptable as is, or whether any need to be revised, replaced or removed from service.

The gap analysis matrix should be updated during process and document development and used as a final check that requirements have been addressed. The matrices from all processes can be combined and used to produce an organizational compliance matrix, which can provide confidence to regulatory agencies and certification bodies that all requirements have been addressed.

The process owner develops the process using the gap analysis matrix, and existing information in accordance with the requirements of the management system. Generally, the process owner will involve a development team and other stakeholders to produce the process documentation.

Gap analysis matrix				
Requirements for the future state process	Existing process situation	How the requirements are covered, including reference to any documents.	Requirement status • Covered • Partially • Not covered	Description of gaps identified

FIG. 9. Example of a gap analysis framework in table format.

The first step of the development involves defining the key activities and producing a flow chart (Step 6 in Fig. 8). This involves the identification of:

— The key activities to be included in the process;
— The optimal order in which to complete the activities;
— Resources needed for drafting and review;
— Potential risks and issues related to the process and its interfaces;

Development of the process activities and flow diagram should engage staff involved in the process, and other stakeholders as appropriate. Those involved may need to be trained in:

— Process mapping techniques (the way in which a process can be visualized);
— Understanding process, scope and (stakeholder) requirements identified during the gap analysis (acts, regulations, standards, codes, licences, management and industry expectations);
— Identifying process activities and related inputs, outputs and constraints;
— Placing the activities in a logical order;
— Identifying process responsibilities;
— Defining process performance indicators.

During the process development, those involved should initially focus on optimizing the process activities, and flow, inputs and outputs, rather than focusing attention on who is currently involved in the process. This avoids sub-optimization and retention of steps that do not add value arising from historic ownership of certain aspects of the process. Following such optimization, appropriate decisions can be made as to who in the organization should perform each activity. The process flow chart should clearly indicate who is responsible for each action or decision.

The process flow chart should be used to establish the scope and alignment of the lower level supporting documents.

Once the main activities and flow chart for the process are developed, the next step is to develop or update all documents (e.g. process documents, procedures, templates and forms) required for implementing the process (Step 7 in Fig. 8). Some of these documents may require the production of additional flow charts. Developing the documentation is the responsibility of the process owner. Existing arrangements that are still valid should be assigned to process steps to ensure compliance, help in optimization and reduce duplication. Depending on the scope and complexity of the process, subprocesses may be required. The definition of subprocesses should be controlled and coordinated by the main process owner, but may require the appointment of subprocess owners to develop and maintain them.

The effort required to develop the supporting documentation is dependent on the scope of the project, the extent of the identified gaps and the overall alignment of documentation to the process. Changes to existing documentation may be categorized as minor revisions, major revision, or new documents. Plans may need to be established for each category of change, and an overall schedule for document development is advisable if not already defined in the implementation plan. In this step, all existing procedures and instructions must be linked to the newly developed processes and should be updated or made obsolete where necessary. Annex IX gives an example of a process for the development, review and approval of management system documents.

The process structure and format of supporting documents will depend on the requirements of the organization. However, it is recommended that each process contain the process flow diagram, compliance requirements, key inputs and objectives of the process, key outputs, and that they define the process owner. Each document should have a unique identification number and revision status.

It is essential that each process document be well defined with clear interfaces, that ownership is anchored in the organization and that process effectiveness is measured. To ensure this for every process, the designated process owner is normally the owner of related documents and is responsible for ensuring:

— Completeness and consistency;
— Simplicity and ease of use;
— The appropriateness of a document to the relevant process;

— Alignment with other processes;
— The assignment of document authors and reviewers.

There may be a need to describe how specific processes interact to meet a regulatory requirement or a technical standard. Some organizations prepare special documents for this purpose (e.g. maintenance programme, fire protection programme, dosimetry programme or conventional safety programme). Such a document should not direct work, but should describe the programme and where the various elements are covered within the processes of the management system. The use of multiple programme documents should be discouraged, since producing them requires resources and detracts from a process based approach. Examples of where programme description documents might be beneficial include:

— When there is a need to demonstrate to external agencies where requirements are covered within the management system processes, and an implementation reference table or database will fulfill that objective;
— When there is an internal requirement to ensure elements are covered;
— When such documents are required for knowledge retention within the organization.

The strategy and effort required to implement each process (Step 8 in Fig. 8) will depend on the degree of the change. For example, if the future state requires organizational changes and significant changes to the way work is performed, then a comprehensive process implementation strategy should be prepared including the reappraisal of any risks. If the future state involves minor changes and requires minimal change in the organizational structure, the implementation strategy can be simple. Although the strategy should focus on the impact of the changes on individuals and departments, the implementation of a process based management system should be clearly communicated to all stakeholders. Implementation strategies may include one or more of the following: formal training, process and document orientation sessions, workshops and on-the-job training.

The change should be managed in accordance with the process for managing organizational change, especially when implementation involves changes to management responsibilities.

If the process changes are significant or the process is complex, or both, a validation of the process should be considered prior to full implementation. Validation confirms that the process not only meets the requirements but also works under real or simulated conditions. The simplest form of validation is a table top review with process participants. Process review is Step 9 in Fig. 8.

More complex forms such as targeted pilots and exercises may be required, especially for processes that are not part of day to day practice, such as emergency preparedness procedures. During the change process, roles and responsibilities should be clearly defined — nobody should be unsure of their roles and responsibilities, especially when they are related to safety. The organization should consider a gradual implementation of the new management system — this staged approach should be an integral part of change management and control, and should be applied to all activities within the project (training, communication, process development and roll-out, etc.).

The project plans should include contingencies for additional resources, staff and financing for unforeseeable situations such as a need for additional training and for making the situation and plans clear to the personnel by taking time and providing more information internally to improve implementation. Typically, 10% or 15% of the estimated budget is allocated to such contingencies.

For successful implementation, it is important to communicate the reasons for and benefits of the implementation. Staff involved should be informed of the anticipated benefits of the implementation of the new process and its potential to enhance safety and performance before the development starts. They should be kept informed of progress, challenges and achievements. Experience shows that communication has to be assertive, timely, repetitive and factually correct so that good outcomes may be expected from the development.

Staff involved in the process will need training; however, the extent of training will depend on the significance of any change and the involvement of the staff concerned. For a major process change or implementation of a new process, a training plan may be required. Participation by process staff in implementation assessments/audits has proven to be a very effective tool to deepen process staff's understanding of the process and its performance issues. It should however, be clearly communicated that such individuals are participating in the assessment as part of their development *and* training.

6. FOLLOW-UP AND CONTINUAL IMPROVEMENT

To ensure successful implementation and prompt response to any issues that arise, it is important to monitor and evaluate the processes during implementation and after it (Steps 9–10 in Fig. 1). Consequently, both the process owners and the project manager are, on their corresponding levels, responsible for:

— Monitoring the implementation and addressing any issues that may arise;
— Providing a summary indicating the overall implementation performance, e.g.
  • Status against process implementation milestones;
  • Status of key performance indicators;
  • Project issues and risk status.

Actions should be identified, assigned and completed to address and mitigate identified performance issues. Throughout the implementation, the development team and senior management should monitor and collect feedback on the progress of the implementation and take concrete, visible actions based on this feedback.

The following are normally used to monitor and obtain feedback on an implementation:

— Internal audits;
— External audits;
— Self-assessments;
— Improvement proposals;
— Non-conformance reporting;
— Management reviews.

Once the implementation of the new process is considered complete and a suitable ‘burn-in’ or familiarization period has elapsed (typically 2–6 months), a review should be conducted to assess the overall effectiveness and ability to meet requirements. The implementation review comprises the following activities:

— Review of the results against requirements and expectations;
— Assessment of the implementation;
— Identification of lessons learned.

Self-assessments should be carried out by individuals, process owners and management (other than senior management) at all levels in the organization. Each unit within the organization should routinely conduct its own self-assessments of processes and performance. The self-assessments should periodically compare present performance with management expectations, worldwide industry standards of excellence and regulatory requirements to identify areas needing improvement and initiate corrective actions. The need for improvement should be recognized as a normal part of routine work.

The independent assessments by the organization itself may include reviewing, checking, inspecting, testing, internal audits 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, requirements or both. One of the independent assessment types, also called independent oversight, is a safety review which can consider several aspects such as an independent safety analysis of outage programmes, of day to day operation activities or maintenance. Another type of independent assessment which should be planned and conducted on behalf of senior management is internal audits. These audits are normally planned and carried out by or on behalf of the management system department. Besides the internal independent assessments, independent assessments by external organizations could also be carried out. Normally, these are requested by senior management.

Additionally, stakeholder feedback sessions, for example to assess the process outcomes against process requirements, often provide valuable information for further improvement of the processes. Finally, the effectiveness

of the implementation and processes will be reviewed in the formal management system review carried out by the senior management of the organization. Any actions should be identified, prioritized and implemented for further improvement of the process itself or of the implementation practices.

The organization's audit plan should reflect the status of the implementation, and related changes to the management system. This enables future audits to provide information related to the effectiveness of the newly implemented processes. The results of the audits should be used for further improvement of the processes and the associated implementation practices. GS-G-3.1 [2] provides detailed guidance on self-assessment, independent assessment and the management system review.

The outcome from the above review should be collated, summarized and lessons learned identified. These lessons learned may be categorized as follows:

— Process lessons learned;
— Implementation lessons learned;
— Management system lessons learned;
— Key success factors for sustainability;
— Recommendations for future improvements.

This information should be communicated to improve the implementation of other processes and changes. Where the process change is part of a major implementation of process management, it should be fed back to the core project team for use in the final project closeout report.

Reference [2] gives specific guidance related to measurement, monitoring and improvement processes. The implementation plan should be revised, if required, and the new revision should be approved at the appropriate level.

On a regular basis, progress reports should be prepared by the project manager and submitted to the project sponsor, steering committee and senior management. The following aspects are normally included in a progress report:

— A summary of the process development, roll-out, training and effectiveness review process;
— Summary of human and financial resources used;
— Progress in relation to project milestones;
— Challenges, potential solutions and the issue resolution process to be used;
— Updates on the risk identification and mitigation process.

If there is a change in scope, budget, resources, or timeline, the implementation plan should be changed accordingly, and approved at the appropriate level.

In addition to the implementation plan, terms of reference (authorities, responsibilities, membership, frequency of meeting, etc.) should be developed for the steering committee and for the development team. The terms of reference may be included in the implementation plan.

International practice requires organizations to continually improve performance (Step 10 in Fig. 8). The management system is one area where organizations may look for continual improvement opportunities. Regular reviews are required to reflect changes in or findings from:

— Corporate requirements;
— Audits and inspections;
— Management system reviews;
— Self-assessments;
— Non-conformities, and corrective and preventive actions;
— Benchmarking;
— Stakeholder feedback;
— Government and regulatory requirements.

Guidance on these improvement processes can be found in Ref. [2].

Appendix I

ELEMENTS OF A MANAGEMENT SYSTEM

This appendix lists the elements frequently used in the introduction of a management system.

I.1. MANAGEMENT SYSTEM MANUAL

The management system manual is not an essential requirement but it is a typical good practice. It should be a short roadmap aimed at helping employees and other stakeholders understand the essence of how the organization operates, and should offer a high level, typically pictorial view of the relationship between major elements and processes. Usually, the management system manual includes the following, described in more detail below. The requirements in GS-R-3 have to be taken into account. Also, the main structure shall follow, as in this example, the structure 'plan, do, check, act'. Only the basic aspects should be described, since the tasks and responsibilities have to be clearly defined in the processes.

— Management statement of commitment [1];
— Safety culture considerations [1].
— Plan:
  • Vision, mission, values;
  • Goals and objectives;
  • Policy statements;
  • Organizational structure.
— Do:
  • Requirements;
  • Grading;
  • Processes.
— Check:
  • Management controls and management review;
  • Measurement;
  • Self-assessment;
  • Independent assessment.
— Act:
  • (Self-) evaluation;
  • Problem identification and resolution;
  • Corrective action programme;
  • Continual improvement.

These topics may be broken down, as described in the following subsections.

I.1.1. Management statement of commitment

The management statement of commitment is given by the CEO or leader of the organization. The statement commits the organization to a process based management system and sets the expectation that all leaders and staff will follow the requirements of the management system. This statement can also include a high level policy statement integrating safety, health, the environment, and so on.

I.1.2. Safety culture

It is a good practice to include safety culture in the statement of commitment, the safety culture values, leadership and expectations for role modelling for managers and staff at all levels.

In this section, an organization may describe how processes in the management system contribute to safety culture, and the expectation that each process includes a consideration of how it can contribute to safety culture and safety performance. This section may point to a document that describes how safety culture is established, monitored and assessed. Additional guidance on safety culture can be found in Refs [14, 17–19].

I.1.3. Vision, mission and values

Typically, the mission, vision and values are high level aspirational statements that drive the organization. A workshop-type meeting with senior management is often held as part of the strategic planning process to define and document the mission and vision. Some organizations use the opportunity of creating value statements to engage employees.

I.1.4. Goals and objectives

Goals and objectives describe the high level goals of the organization. This section usually points to the business planning process (the process that periodically considers all the activities and resources necessary to achieve organizational goals over some future period, typically between 1–5 years).

I.1.5. Policy statements

It is a good practice to have a single policy statement at a high level, and if necessary, more specific policy type guidance may be included within the process specific documents.

I.1.6. Organizational structure

The organizational structure describes the main structure of the organization. A high level organization chart is often included in the management system manual. The detailed organizational structure is typically documented elsewhere electronically, on the organization's intranet or both.

The structure includes a high level description of authorities, responsibilities and accountabilities for the CEO or president, board, board subcommittees, leaders and officers of the company and management committees. (Details do not need to be included in the management system manual, and are often documented separately.)

The structure also describes who has responsibility for the effectiveness of the management system and the independence of the audit and independent assessment functions.

I.1.7. Requirements

The requirements identify broad requirements and point to where specific requirements are maintained. These include:

— Legal and statutory requirements;
— Regulatory requirements;
— Business requirements;
— Standards and code requirements;
— Management requirements;
— Stakeholder requirements.

I.1.8. Grading

A graded approach is to be used within all processes of the management system. The grading methodology may be briefly described in the manual, and is typically described in detail in a separate document. Guidance on grading is provided in Ref. [12]. If specific grading requirements for an individual process are needed, these may be described in the process itself or in a document used as an input to that process.

I.1.9. Processes

The manual should provide a pictorial representation of the key processes of the organization. All processes, both business and operational, may be grouped into core, support and management processes, but other groupings may be used. Some examples of process models are presented in Annex VII.

Benchmarking similar organizations for process descriptions and models using documents such as the NEI/EUCG Standard Nuclear Industry Model for guidance [20] may be considered.

I.1.10. Example processes

The following processes are often defined for the various stages of a nuclear power plant life cycle. The abbreviations used are G:General; S: Siting; DE: Design; C: Construction; CO:Commissioning; O: Operation; D: Decommissioning.

— Control of documents [1] (G);
— Control of products [1] (G);
— Control of records [1] (G);
— Communications [1] (G);
— Managing organizational change [1] (G);
— Procurement and purchasing management (control of non-conforming items) and supply chain oversight (G);
— Vendor field oversight (S, C, CO);
— Licensing and permits (G);
— Strategic, business and initiative planning (G);
— Risk management (technical, financial, etc.) (G);
— Financial management (tax, payroll, accounts payable) (G);
— Human resource management (G);
— Training and qualification (G);
— Design management (DE, C, CO, O, D);
— Configuration management (DE, C, CO, O, D);
— Project management (G);
— Monitoring and measurement (G);
— Assessment (independent assessment, self-assessment, assessment of the management system, etc.) (G);
— Site selection (includes environmental assessment) (S);
— Construction management (C);
— Commissioning management (CO);
— Operations management (O);
— Work management and maintenance (O);
— Equipment reliability (CO, O);
— Waste management (conventional and radioactive) (S, C, CO, O, D);
— Fuel management (procurement, fuelling, IAEA interface, high level waste disposal) (C, CO, O, D);
— Industrial health and safety management (G);
— Radiation protection management (could include radioactive waste) (CO, O, D);
— Outage management (O);
— Security management (G);
— Emergency preparedness and fire protection management (C, CO, O, D);
— Decommissioning management (D);
— Licence management, including management of requirements.

Appendix II

ADDITIONAL CONSIDERATIONS FOR EMBARKING COUNTRIES

This Appendix addresses the needs of embarking nuclear nations and especially the licence holders and operators (industry) who are involved in introducing a nuclear power programme to their country or region. To ensure timely development of the nuclear power project, and to ensure safe operation, all the aspects of safety, health, environment, security, quality and economics have to be integrated in the management system as established in the IAEA Safety Requirements, The Management System for Nuclear Facilities and Activities [1]. The integration of all these elements from the start of the project is essential during siting, construction and commissioning, to ensure that all activities will be carried out safely and in compliance with national and international requirements. In the case of embarking nuclear countries, as part of establishing a process based management system, some consideration may first have to be given to establishing the overall framework or management system infrastructure in which to incorporate a process based approach. This section addresses some of these additional considerations.

The lead organization, a NEPIO — (Nuclear Energy Programme Implementing Organization), in a particular country that has decided to embark on a nuclear power programme, which has engaged third parties to support this activity, may already have given consideration to the QA requirements necessary to ensure confidence that structures, systems and components will perform satisfactorily in service. More likely, the owner and operator organization that has been formed has to do this, and may, to some extent, use the vendor experience and still sometimes require modification to the laws and regulations of the country. This can form the basis of an effective process based management system. The perception that implementing a process based management system may be at the expense of good QA is a misunderstanding that should be addressed by the leadership of nuclear organizations, their suppliers and regulators as part of the implementation process. The development of a process based management system is an evolution from a QA system as described earlier, and any investment already made in defining quality requirements will be preserved and will benefit the development of a process based management system. A process based management system framework enhances confidence in achieving all required results by considering and managing aspects such as safety, health, environment, security, economics and safety culture, in addition to quality.

(a) Language and translation

Since the market of nuclear power plants involves only a small number of vendors and main contractors, the language of the embarking nation is in most cases different from the language of the vendor/contractor. This can cause misunderstandings and introduce risk and confusion during the life cycle of the project. Although regulatory requirements are typically written in one of the official languages of the embarking nation, many requirements, standards, and codes are in English, which is also the case when assistance is requested from the IAEA or the World Association of Nuclear Operators.

Translation of the requirements of codes and standards into a language familiar to both the embarking country and the contractor should be considered for the contract.

It has been shown that all safety, health, environment, security, quality and economic requirements have to be considered in an integral way to avoid a negative impact on safety. In addition, integration of requirements already incorporated in design, manufacturing and construction will bring economic benefits and increase the efficiency of the operation. Furthermore, operational experience has shown that process based management systems have clearly defined responsibilities, accountabilities and interfaces, which foster safety culture and well defined safe working practices. These aspects will be especially beneficial when both the main contractor and the future owner or operator develop a management system that will clearly define the responsibilities of both organizations, and the interfaces between them.

The language of the management system should be one of the official languages of the embarking country, and English where appropriate and where the law permits. It must be clearly stated which language version should prevail in the event of inconsistencies.

One of the challenges of using the official language of an embarking nuclear nation is that in some cases the technical vocabulary related to requirements of the nuclear industry may be lacking. In such cases, English may

be preferred. Additional training focused on the vocabulary used in foreign language documents may be required to ensure clear understanding by key staff, particularly if a foreign language is used in contracts, tenders and standards. A good practice is to use an official language of the contracting nation as the binding language of the contract, putting the onus on the tenderer to ensure the requirements are translated and understood.

(b) Documents (instructions and manuals)

References [2, 3] provide guidance on documenting management systems. In addition, IAEA TECDOC 1058 [13] provides more good practices related to preparing procedures within the nuclear industry. Although many good practices and examples of well designed procedures are available through operating experience exchange and benchmarking, a key factor is to ensure that procedures are designed using modern human factors practice, i.e. that the procedure is easy to use and designed in a manner that minimizes the chances of human error. Some organizations use technical writers trained in procedural design to assist and guide technical subject matter experts in the preparation of procedures.

(c) Cultural aspects

IAEA Safety Report Series No. 74 [14] provides specific guidance to embarking countries on implementing a strong safety culture starting in the pre-operational phases. In particular, it addresses the importance of the management system in enabling safety culture and discusses various challenges that typically face embarking countries, including:

— Understanding the significance of nuclear safety and safety culture;
— Managing the complexities arising from multicultural and multinational elements;
— Developing leadership competencies for safety;
— Developing management system processes to support safety culture;
— Promoting learning and feedback;
— Performing cultural assessments and encouraging continuous improvement;
— Strengthening communication and interfaces.

Management systems require individuals at all levels of the organization to comply with established processes and procedures. A healthy work culture striving for safety is not only based on compliance with rules or authorities, but encourages open communication, a questioning attitude, mutual respect, and high levels of team and interdisciplinary engagement.

Aspects of culture and intercultural communication are important in the actual implementation of an integrated management system. This means that the exact manifestations of the principles discussed in this publication and its references may look slightly different in different cultures. The increasingly multinational and multicultural nature of the nuclear industry means that all countries are encouraged to develop a common understanding, terminology and language for safety culture.

(d) Regulations of the contractor country

Requirements may be different in the contractor country compared with the embarking country (e.g. requirements for environmental assessments). In cases where the embarking country has not yet established an equivalent system of requirements, it may have to rely on the requirements of the contractor country, or specify internationally accepted standards in contracts. In such cases, it is desirable to translate such requirements into an official language of the embarking country or, where this is impractical, to ensure that a sufficient number of staff within the embarking country are fluent in the source language of the requirements.

Appendix III

IDENTIFYING PROCESSES

(a) Identifying core processes

The following questions may be helpful in identifying core processes:

— Which processes have the greatest impact on performance (safety, health, environment, quality, cost, business and innovation)?
— What are the critical outputs of the organization, and which processes deliver these?
— Which processes reflect the unique competencies of the organization and are mission critical?
— Which processes are the value creating activities of the organization and are the processes that are seen and experienced by external stakeholders (e.g. customers)?
— Which processes have the greatest impact?
— Which processes are so important to the organization's competitive position that it would never outsource them?

(b) Identifying management and executive processes

These provide direction and governance for an organization. They are generally implemented by senior management to:

— Set organizational goals;
— Direct and manage the organization;
— Manage external relationships and interfaces;
— Manage and improve processes;
— Assess and improve the performance of work.

Management processes also shape and manage the core and support processes used by an organization.

(c) Identifying support processes

Support processes exist to sustain the organization. Since the support needs of many organizations are similar, these processes tend to be fairly standard and some aspects may be candidates for outsourcing. The customers of support processes are internal customers and processes within the organization. Examples of support processes are:

— Financial services;
— Human resources services;
— Ensure optimal plant condition;
— Radiation protection;
— Emergency preparedness;
— Security and safeguards;
— Environmental monitoring;
— Information technology support;
— Materials and procurement support;
— Documentation and records;
— Purchasing.

Annex VI gives examples of processes developed in different organizations.

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Annex I

EXAMPLE OUTLINE OF A PROJECT CHARTER

[Project Name] Project charter
Project manager: [Name]
Sponsor: [Name]
Date: [dd/mm/yyyy]

This charter serves to announce the initiation of the [project name] project. We are undertaking this project to [describe project purpose], as summarized below.

[Senior management/the project management board or committee/the sponsor] has selected [project manager name] to lead this project.

This charter formally initiates this project and authorizes the project manager to act in that capacity on behalf of [senior management/the project management board or committee/the sponsor.]

Please provide your complete cooperation to the project and to [Project manager name].

Thank you.

[Signed by the sponsor (or senior management or the chairperson of the project management board or committee)]

PROJECT OVERVIEW

(1) Project purpose or justification:

— Problem statement;
— Business need and benefits.

(2) Project objectives:

— Project goals and objectives (i.e. specific, measurable, achievable, realistic, timely (SMART) objectives).

(3) Project requirements:

— High level requirements, including applicable legal, corporate and other requirements;
— Alignment to the organization's vision, mission and objectives.

(4) Project description and overall deliverables:

— High level project description, including high level project activities and product(s) or service(s) to be delivered;
— Project organization and roles, responsibilities and accountabilities, including project manager responsibilities and authorities.

(5) Project risks:

— High level description of project risks, barriers and mitigation measures.

(6) Project milestones:

— Estimated schedule and project milestones.

(7) Project budget:

— Summary of the estimated costs and estimated internal and external resource requirements (number, person-hours and from which departments or organizations).

Annex II

PROCESS MATURITY ASSESSMENT

This Annex provides guidance on assessing process maturity levels to assist in identifying gaps in the management system.

Process maturity		Process maturity levels				
Result areas		1: Not present	2: Ad hoc level	3: Activity level	4: Process level	5: System level
A	Responsible person / process owner	No responsible person or process owner appointed.	Responsibilities are vague or assigned ad hoc.	A person responsible for the activities is in place who is aware of his or her responsibilities and acts responsibly with regard to his or her own activities.	Process owner is in place who feels and acts responsibly for the process results. The focus is on control but improvement is an ad hoc activity.	Process owner is in place who feels and acts responsibly for the process results. There is cooperation between process owners, and the focus is on continual improvement.
B	Required performance and reporting	No standards or objectives identified.	Required performance is vague or defined ad hoc. Results are reported ad hoc.	Required performance standards are implicitly or partially known and defined at the activity level. Results are reported but not always in relation to the required results.	Process performance standards are defined, documented and communicated. Results are measured and reported against the standards.	Performance standards and targets are defined, documented and communicated for processes and the system as a whole. Process and system results are measured and reported against standards and targets.
C	Compliance requirements	Compliance requirements are unknown.	Compliance requirements are not well known. Compliance cannot be demonstrated.	Compliance requirements are implicitly or partially known. Compliance cannot be demonstrated.	Process compliance requirements are systematically identified, documented and communicated. Compliance is demonstrated, but improvement is an ad hoc activity.	Compliance requirements are systematically identified, documented and communicated for the whole system. Compliance is demonstrated. Continual improvement is demonstrated.

Process maturity		Process maturity levels				
Result areas		1: Not present	2: Ad hoc level	3: Activity level	4: Process level	5: System level
D	Risk control	Risks are unknown.	Ad hoc reaction to risks and incidents.	Operational risks are implicitly or partially known. There is some control of the operational risks.	Operational process risks are systematically identified, documented and communicated. Control is demonstrated. Improvement is an ad hoc activity.	Operational, tactical and strategic risks are systematically identified, documented and communicated. Control is demonstrated. Continual improvement is demonstrated.
E	Structure	No structure.	Ad hoc organization of activities.	Responsibilities are documented, e.g. job descriptions. Activities are organized by department.	Activities and responsibilities are structured on process lines. Processes are documented, up to date and communicated. Response to deviations is part of a process.	Processes are linked and form an integral structure. The system is documented, up to date and communicated. Response to deviations and continual improvement are integral parts of the system.
F	Execution	No or ineffective execution of activities.	Ad hoc execution of activities.	Planned execution of activities. Reactive response to deviations.	Execution of the process as planned. Adequate response on deviations. Improvement is an ad hoc activity.	Execution of the process as planned. Proactive and integral response to deviations. Proactive, integral and continual improvement.

Annex III

BENCHMARKING ORGANIZATIONAL CHANGE

Benchmarking is a tool that organizations may use to develop an effective strategy for implementing a process based management system. Benchmarking a given activity involves examining, understanding and comparing an organization's plans, practices and performance against those of organizations that have done an exemplary job of carrying out that activity. Benchmarking can foster a successful outcome or support innovation and continual improvement. The concept can be applied to the changes that an organization needs to make when implementing a process based management system.

To successfully undertake benchmarking, an organization needs management commitment and a sound knowledge of its own corporate objectives, processes and operating environment. The benchmarking exercise will require resources. It is the responsibility of senior management to allocate sufficient resources to undertake the exercise.

In addition, an organization needs to:

— Identify and fully understand the area(s) to be benchmarked;
— Understand possible benchmarking partners well enough to make a knowledgeable selection;
— Plan and prepare well for the benchmarking exercise;
— Agree and adhere to a code of conduct to minimize misunderstanding during the benchmarking (for example, there can be both planned and inadvertent exchanges of information that turn out to be operationally or organizationally sensitive);
— Judiciously collect and analyse information;
— Document benchmarking results, incorporate them into the implementation and organizational change plans and processes and implement them.

When identifying areas to benchmark, the organization should focus on areas or processes that are significant to safety, that are strategically important or that need significant improvement. The organization should conduct an analysis of these areas or processes in order to determine if benchmarking would contribute to increased assurance of:

— A successful implementation;
— Successful organizational change;
— Significant benefits such as enhanced safety, process improvement, increased productivity, efficiency and effectiveness.

The organization should evaluate the cost effectiveness of benchmarking, the availability of performance indicators and the probability of success of the benchmarking exercise before deciding to choose a given area for benchmarking.

Once the area to benchmark has been chosen, the organization should identify and choose potential benchmarking partners. The choice of benchmarking partner will depend on a number of factors and, depending on the type of benchmarking method chosen and the completeness and quality of information provided, visits to the chosen organizations may or may not be needed.

For the implementation of a process based management system, consider benchmarking against organizations that have already implemented the IAEA GS-R-3 requirements to learn from the experience they have accumulated. The organization may also consider organizations that have implemented a process approach using other management system standards (e.g. based on ISO standards, and national or international business excellence models).

The structure of the processes and the manner of their description will vary from organization to organization. The structure and description depend on the standards adopted by the organization, its experience, primary activities and organizational culture. All these aspects should be taken into consideration when choosing a partner for benchmarking.

When selecting a benchmarking partner for the implementation of a management system that conforms to the GS-R-3 requirements, the following aspects should be considered:

— Primary activities — it is preferable to select an organization with similar types of facilities and activities. Other high reliability organizations outside the nuclear industry (e.g. airline industry, oil and gas, pharmaceutical or chemical) may also provide useful benchmarking opportunities.
— Organizational type and structure — the benchmarking partner's organization should be similar and the organizational level at which the benchmarking is done should be equivalent: e.g. corporate, subsidiary or private company.
— Location — considering the cost of benchmarking, selecting a partner from the same area or region is normally more cost effective.
— Performance of the organization — the benchmarking partner should be an organization with high performance. However, it is also important not to neglect organizations that have had difficulties in implementation, in order to learn from them and to avoid repeating the same types of mistakes.

Figure III–1 illustrates other factors to consider when choosing organizations against which to benchmark and conducting the benchmarking. A publication of the Canadian Nuclear Safety Commission[1] gives additional guidance for benchmarking.

The data collected during the benchmarking exercise should be analysed using various methods to identify best practices and methods and factors that enable the organization to be a top performer in the benchmarked area. Differences in practices, including organizational culture, between the organization doing the benchmarking and those of its benchmarking partner should be well understood to enable the organization contemplating the implementation or organizational change to make the necessary adjustments in its own facilities.

The organization should use the results of the benchmarking to develop strategies to address performance gaps, taking into account the size of the gap; the potential safety, productivity, efficiency and effectiveness improvement that will result from addressing the gap; the cost effectiveness of implementing the strategies to close the gap and the success factors for closing the gap. This should be done as part of the overall gap analysis for implementation of the new management system so that results of the benchmarking are integrated into the overall implementation plan. The organization conducting the benchmarking should communicate the results of the benchmarking internally to all relevant stakeholders, and externally to the benchmarking partner.

[1] CANADIAN NUCLEAR SAFETY COMMISSION, A Guide to Benchmarking at the CNSC, Final Report of the Benchmarking Working Group, CNSC, Ottawa (2002).

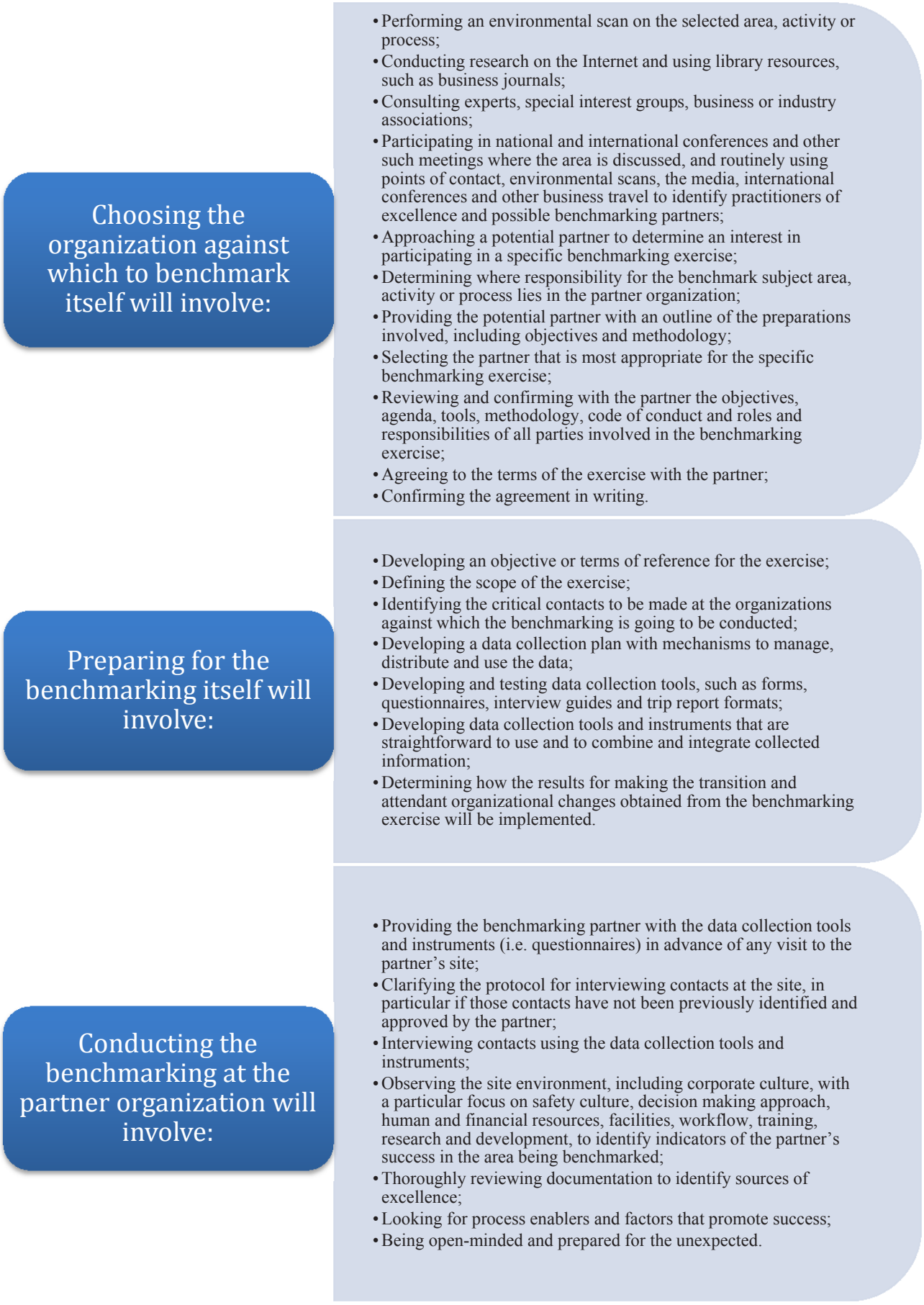


FIG. III–1. Example of a benchmarking approach.

Annex IV

RISK MANAGEMENT

Implementation of a process based management system is not a trivial undertaking. The organization should conduct a thorough project risk analysis, evaluate various measures to avoid or mitigate the identified risks and factor these into the project planning for the implementation or organizational change.

The identified risks may stem from a number of sources and may be of many types, including those relating to health, safety, environment, security, safeguards, quality, economics, operational performance, legal and/or licence condition compliance, economic or commercial performance, technical capability, stakeholder satisfaction, public or stakeholder perception and confidence, and social and political considerations. IAEA TECDOC 1209[1] provides examples of risk management.

For risk management, a systematic approach to identifying potential risks, looking specifically at the area in which the risk is identified, but also looking at the intersection with the other areas, is the best way to avoid or overcome risks. The idea is to try to identify all of the possible consequences and the probability of occurrence, in order to find an optimal decision set to minimize adverse effects and maximize social and organizational objectives in a cost efficient manner. A risk management framework providing this systematic approach is shown in Fig. IV–1.

FIG. IV–1. Risk management framework for any proposed action.

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Risk Management: A Tool for Improving Nuclear Power Plant Performance, IAEA-TECDOC-1209, IAEA, Vienna (2001).

The development team and senior management should be aware of the attendant risks and maintain a prioritized risk register specifying the risks, their likelihood, their impact on the project and the measures the organization will take to mitigate the risks.

Many of the risks or challenges will stem from the cultural issues associated with any organizational change. Implementation of a process based management system requires a shift in thinking and organizational culture. Focus shifts to process ownership, process performance, and the satisfaction of process requirements and needs of the customers of the process, as well as greater emphasis on matrix management approaches. Training should be provided to management and staff to raise their awareness and sensitivity to these shifts.

In addition to maintaining a strong safety culture and flexibility, the development team and senior management should:

— Understand the potential consequences of ineffective implementation.
— Understand and appreciate that the implementation or organizational changes will not be achieved overnight — a transition period is required, along with long term commitment to the change. Experience shows that the overall implementation time is often 18–24 months. The organization should think through what transition structures, activities and contingencies or interventions it will need to put in place during the implementation period to ensure success. Management should use effective intervention, participation, facilitation and firm leadership strategies to manage project risks and cultural or other implementation issues.
— Understand that implementation requires consistent leadership by senior management and involvement of all staff. There will be uncertainties that can lead to project challenges, including cost overruns, which may stall or challenge the progress of the implementation. Senior management should be prepared to provide the necessary resources and leadership to overcome these challenges.
— Understand the importance of leading by example, and the need to encourage all levels of the organization to support the implementation project. Senior management and the core project team should challenge the organization to be the best it can be. The organization should be challenged to be at the forefront in terms of international best practice.
— Understand the importance of communicating the benefits and successes but also the challenges associated with implementation. Stakeholders should be continually informed of progress, anticipated benefits of the new management system, and its potential to enhance safety and performance.

Annex V

COMMUNICATION

Good communication is vital for a successful organizational change, such as implementing a process based management system. It is important to present the intentions of the organization, to explain the reason for the change, how it affects stakeholder interests and activities, and how everyone involved will be kept informed.

The transition to, or the development and implementation of, a process based management system needs to be well communicated both within and outside the organization. As soon as the scope and time lines are clearly defined, and the commitment of senior management has been obtained, the plans, timelines, benefits and transition team structure should be communicated. During the transition, or development and implementation process, regular communication to the staff is necessary in order to engage them and reduce uncertainty and resistance.

During these communication stages, the successes, challenges, and evolution of the project and staff involvement in the next phase should be explained. It is also important for the project to communicate successes as part of the communication strategy. Communication needs be continuous and repetitive, and staff members on all levels have to bring the message further. Inefficient communication is often involved in poor project outcomes.

For organizations with corporate stakeholders, especially those who build or operate nuclear plants, it is important that the new approach aligns with the corporate policies and strategic development plans (if any). Corporate offices are key stakeholders, since they provide policies that govern the organization. The level of consultation and involvement of other stakeholders depends on their importance to the organization. This implies a graded approach to involvement and consultation, as follows:

— Obtaining agreement — when required by law or regulations, e.g. from regulatory bodies;
— Direct involvement in development of the management system — if the stakeholders are part of the organization, e.g. corporate/headquarters or staff;
— Informing — when changes in the management system affect interfaces with other organizations, e.g. government agencies or suppliers.

Communication vehicles could be, but are not limited to:

— Intranet for actual status, updated e.g. on a weekly basis;
— Bulletin boards for highlights, successes and benefits, e.g. monthly updates;
— Leaflets or newsletters for introduction of the change plan, introduction of team members, main milestone planning, successes, challenges and staff involvement;
— Email, as appropriate, but is not to be used as the only tool.

Annex VI

EXAMPLES OF PROCESS MODELS

The main objective of a process model implemented in a nuclear power plant is to produce energy in a safe, economic and reliable manner following the division into core, management/executive and support processes. In Fig. VI–1, the core process is further divided into four areas: operate, maintain, equipment reliability and design configuration, underlining not only operation, but also proactive needs to manage design configuration (design authority) and plan maintenance.

The main objective of a process model implemented in a regulatory body is to assure nuclear safety through providing nuclear safety oversight following the division into core, management and support/enabling processes. As shown in Fig. VI–2, the core processes are further divided into managing the regulatory framework, managing licensing and certification and assuring compliance.

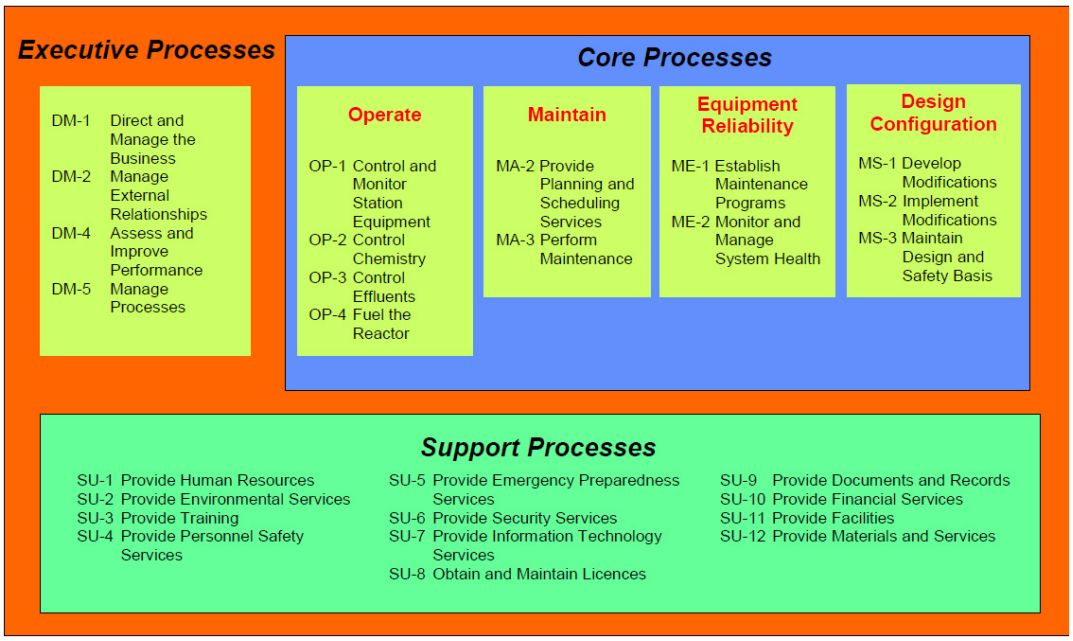


FIG. VI–1. Example of a process model from a nuclear power plant.

A–VI.1. EXAMPLE OF PROCESSES BASED ON ISO 9001

(1) Management responsibility

— Management reporting;
— Management system administration;
— Organizational structure;
— Management review;
— Licences, occupational health and safety assessment;
— Safety related organizational changes.

(2) Management of personnel and resources

— Recruitment, selection and appointment;
— Performance, assessment and training;

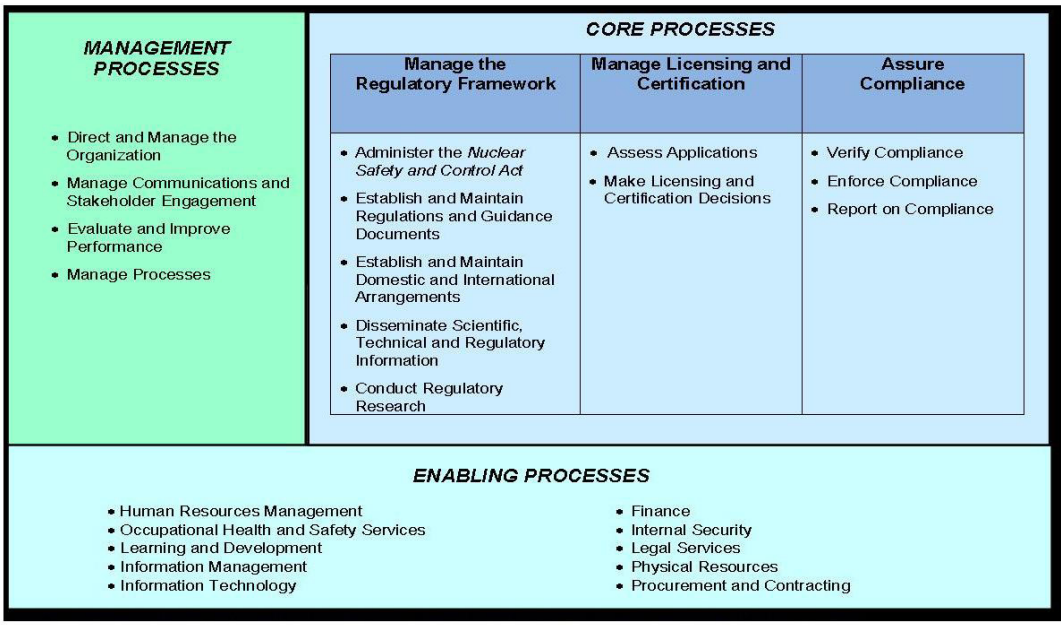


FIG. VI–2. Example of a process model from a regulatory body.

— Software and code administration;
— Operation of installations and laboratories;
— Health, safety and environmental aspects for projects;
— Health, safety and environmental aspects of operations;
— Waste management;
— Reporting and handling (potentially) unsafe situation;
— Handling and reporting accidents and/or emergencies;
— Reactor safety committee assessments of safety relevant operations;
— Employing temporary workers / outsourcing;
— Administration and maintenance of equipment and installations.

(3) Implementation

— Quotation management;
— Project management;
— Numerical calculations;
— Purchasing and receipt of goods;
— Preparation of reports;
— Calibration of measuring devices;
— Incoming and outgoing correspondence;
— Archiving.

(4) Improvement cycle

— Internal audits;
— Complaints and product non-conformances;
— Improvement proposals;
— Feed back of operational experiences.

Annex VII

EXAMPLE OF A TOP LEVEL PROCESS DESCRIPTION TEMPLATE

TABLE VII–1: PM-00660-DM-4 ASSESS AND IMPROVE PERFORMANCE

Process identifier and name:	***Process reference:***	***Process category:***
DM-4 Assess and Improve Performance	PRR-00660-DM-4 Assess and Improve Performance	Executive

This process applies to:
All processes and activities at the facility. The process includes assessments, cause investigations, the application of operating experience and corrective action management.

The business need for this process is to:
Measure performance against management, regulatory, and industry standards and expectations in order to correct problems and identify areas for improvement.

The process includes the following key activities:
- The performance of ongoing monitoring;
- The performance of focused self-assessments;
- The performance of independent assessments;
- The application and sharing of operating experience;
- The documenting of performance problems;
- The screening of performance problems;
- The identification and review of trends from condition reports;
- The determination of causes and proposal of actions;
- The tracking of actions to completion.

The following key groups carry out the process and will have input to changes to the process:
Station management team

Major inputs (supplied by):
Performance standards and expectations for each process

• Performance objectives and indicators;	(Management)
• Management, corporate or regulatory requirements;	(Management, Process owners, regulators)
• Industry operating experience.	(Industry)

Major outputs (customers):

• Event investigation reports;	(Management, regulators, industry and Process
• Assessment reports;	owners, Management)
• Proposed improvement or corrective actions;	(Process owners, Management)
• Station operating experience.	(Industry, management and personnel at site)

Key performance indicators:
- To be determined

Key interacting processes:
- All processes

Process owner (job title):	***Responsible manager (title):***
Performance improvement manager	Station manager

The flow chart in Fig. VII–1 describes the *Assess and Improve Performance* process as defined in the template of Table VII–1. The numbers (e.g. SI-A62) in the activity blocks refer to lower level documents that support detailed implementation.

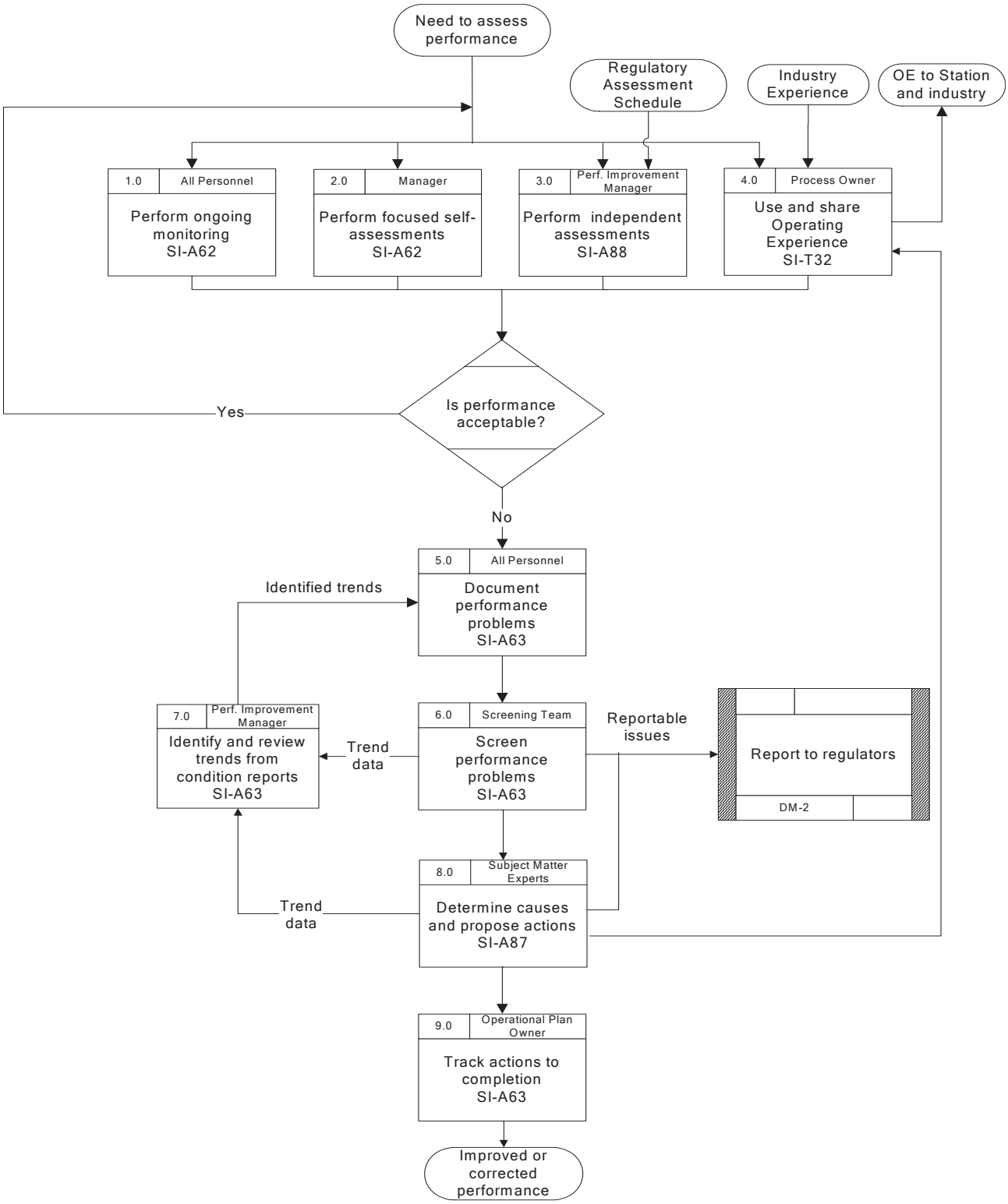


FIG. VII–1. Sample process flow chart (DM-4, Assess and improve performance).

Annex VIII

EXAMPLE OF A PROCESS DOCUMENT HIERARCHY

This annex shows current and future state diagrams of a document hierarchy for the process Assess and Improve Performance identified in Fig. VI–1 of Annex VI and described in Annex VII. Figure VIII–1 identifies what needs to happen with each document. Figure VIII–2 shows the future-state hierarchy for the same process. During development, the list of documents on Fig. VIII–2 is subject to change as new information arises from the development of this and related processes. Such figures are updated as needed.

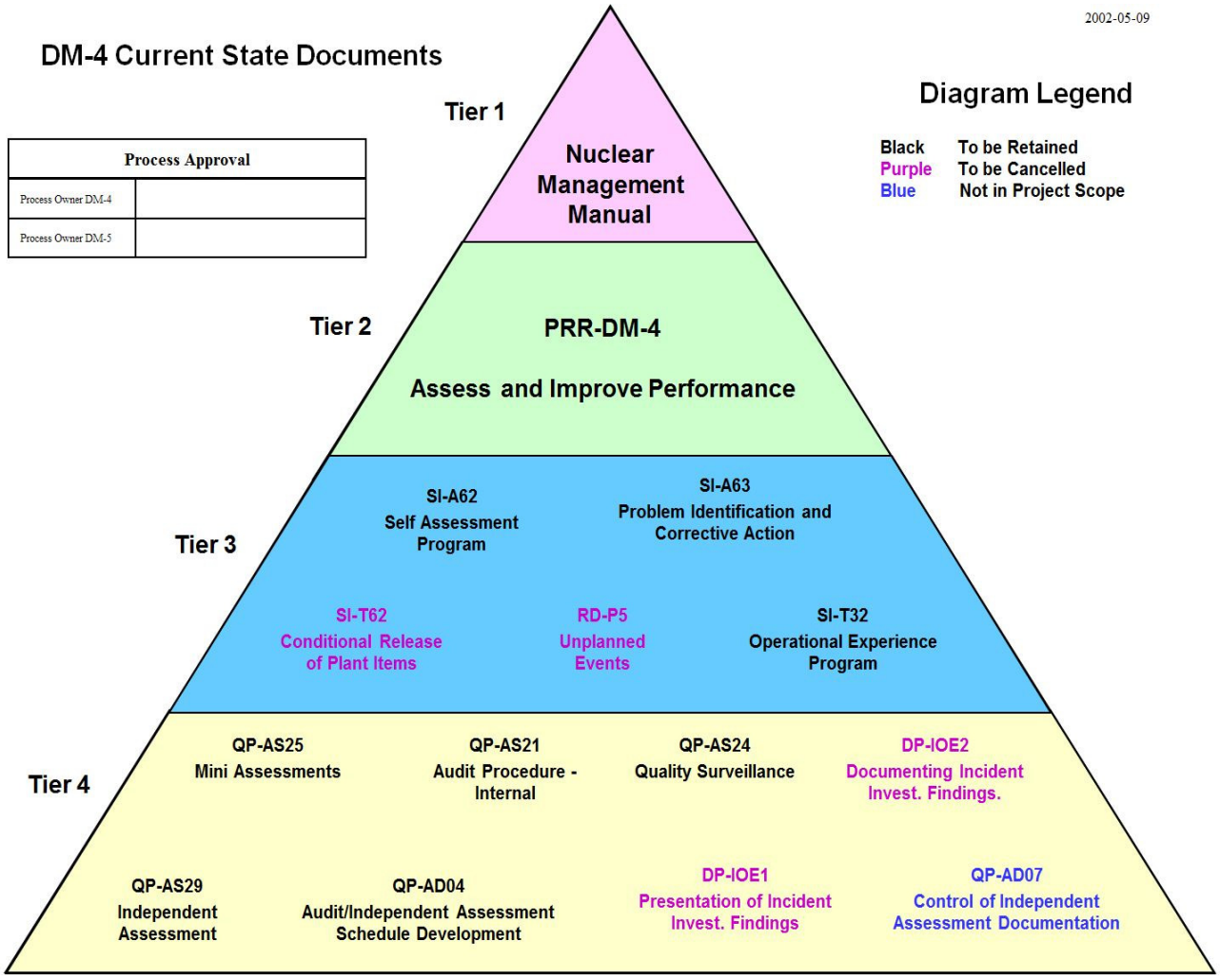


FIG. VIII–1. Example of a document hierarchy for a Level 1 process before implementation.

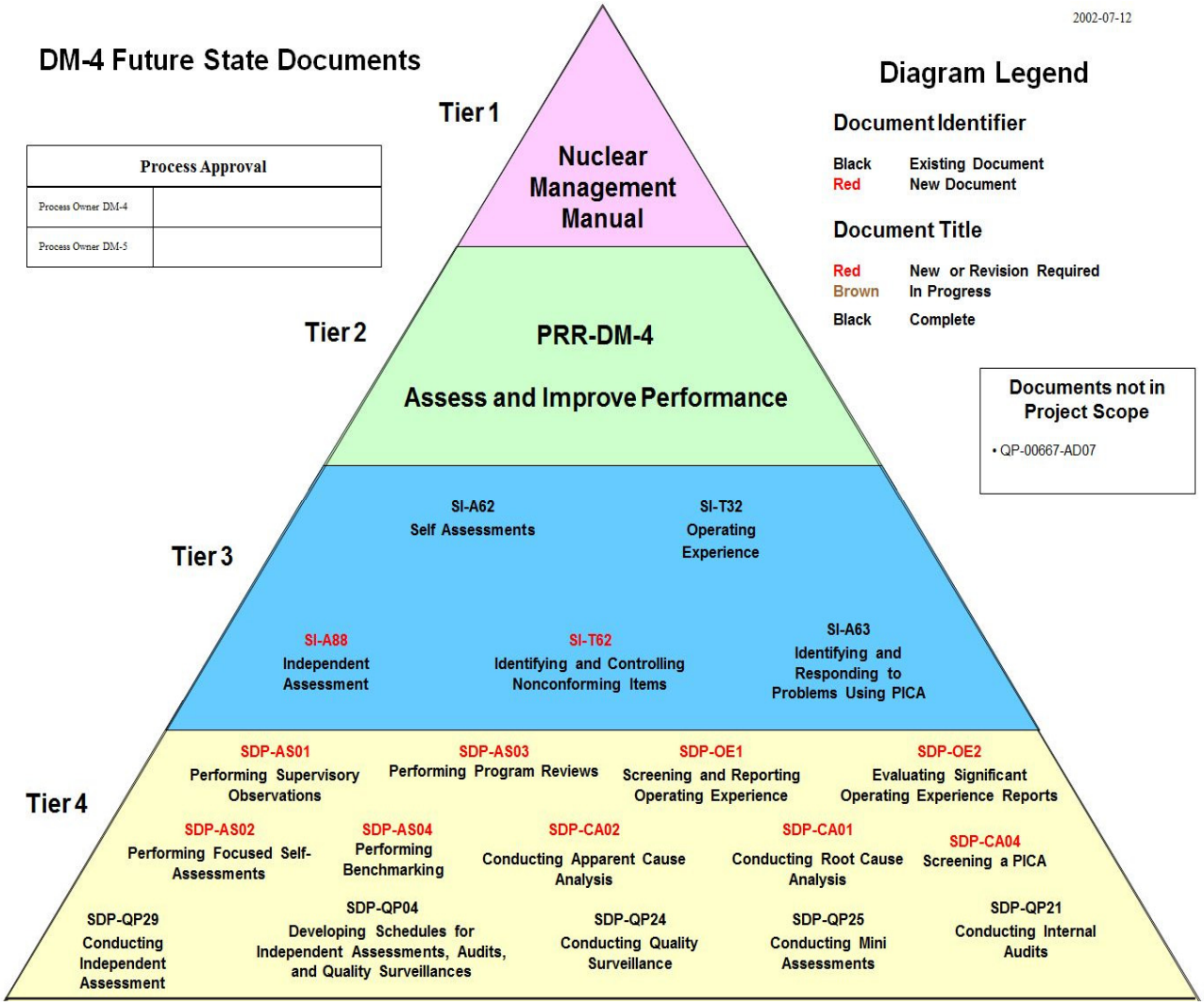
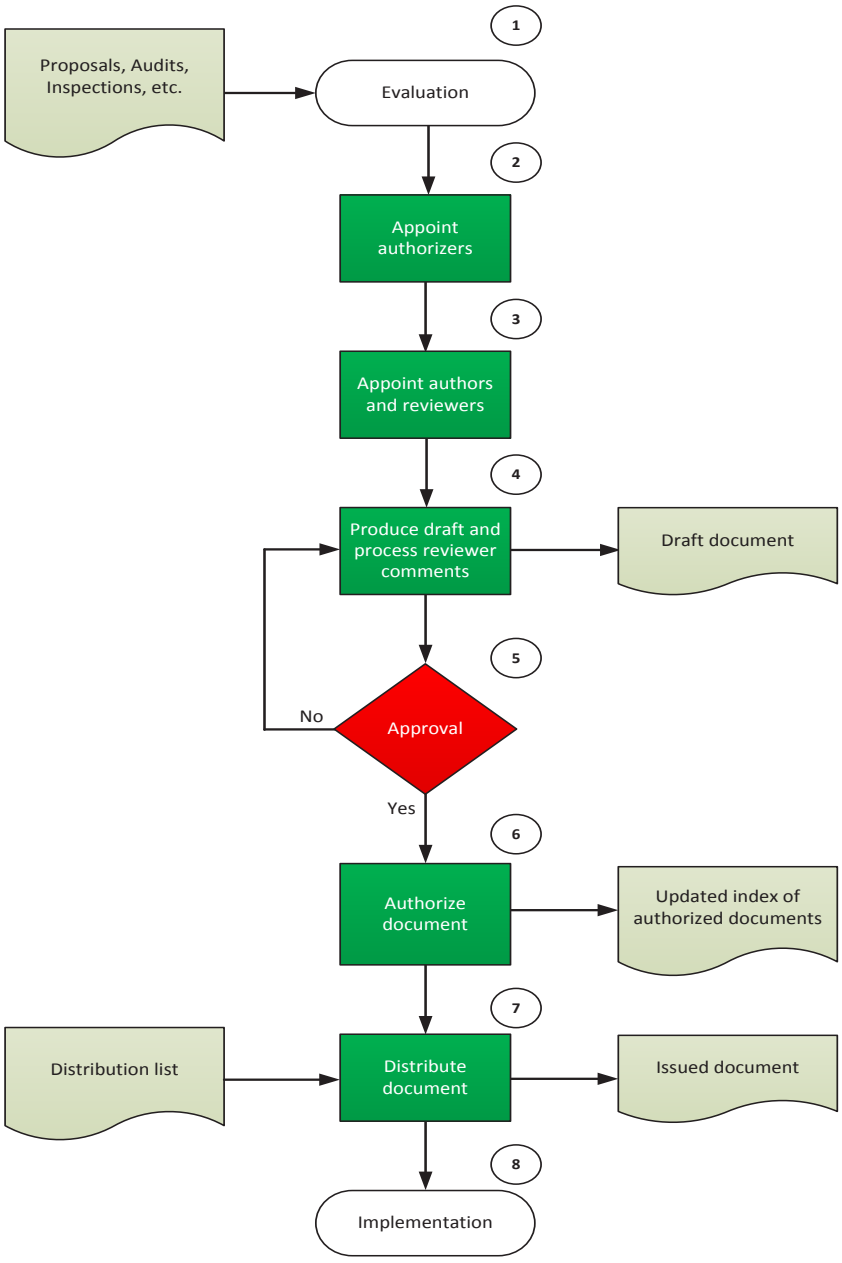


FIG. VIII–2. Example of a document hierarchy for a Level 1 process after implementation.

Annex IX

EXAMPLE OF A DOCUMENT ADMINISTRATION PROCESS

This Annex provides an example of a process for controlling management system documents. IAEA Safety Series Report 75[1] provides examples of processes applicable to research reactors.



Step 1.
Management system representative
- Evaluates the need for revision at least once every 3 years
- Evaluates proposals for new documents

Step 2.
Management system representative
- Decides in consultation with Process Owner whether a document needs to be drafted or withdrawn at corporate or local level
- Appoints authorizer in consultation with corporate or local Process Owner

Step 3.
Authorizer/Process Owner
- Appoints author(s) and reviewer(s)

Step 4.
Author
- Prepares draft
- Processes comments from reviewers

Reviewer(s)
- Reviews draft documents

Authorizer
- Monitors progress and resolves issues

Management system representative
- Confirms correct templates and layout
- Monitors progress and consults Process Owner regarding implementation

Step 5.
Authorizer
- Resolves issues as required
- Approves final document and obtains any higher level approvals if required

Step 6.
Management system representative
- Updates index of authorized documents

Process Owner/Document Owner
- Initiates agreed arrangements for implementation, including training if required

Step 7.
Management system representative
- Distributes document

Process Owner/Document Owner
- Completes agreed arrangements for implementation

Step 8. Management
- Confirms effectiveness of implementation

FIG. IX–1. Management system administration. (The white oblongs show the initiator or terminator of a process or procedure; the green rectangles show actions or activities; the red diamonds show decisions; and the light green symbols show documents.)

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Implementation of a Management System for Operating Organizations of Research Reactors, Safety Reports Series No. 75, IAEA, Vienna (2013).

Annex X

EXAMPLE OF AN IMPLEMENTATION SCHEDULE

Table X–1 provides an example of a two year implementation schedule where:

— PL is the project leader responsible for the preparation of corporate documents;
— DM is the department manager responsible for the preparation of departmental procedures and documents in this example;
— PS is the project sponsor appointed by senior management;
— SG is a steering group appointed by senior management;
— SM is senior management;
— M1 signifies month 1, etc;
— EoP stands for the end of the project.

The project plan associated with the schedule included a series of audits at the various stages of implementation. A section on certification is also included in the schedule.

TABLE X–1. EXAMPLE OF AN IMPLEMENTATION SCHEDULE

Action	Person responsible	Completion Date	Approval	
			By	Date
Appointment of project leader (PL)	SM			
Preparation of project charter	PL	M1	SM	M1+1
Proposal of project team members	PL	M2	SM	M2+1
Appointment of project team members	DM	M3		
Installation of project sponsor (PS) and steering group (SG)	SM	M4		
Preparation of overall time schedule	PL			
Description of tasks and responsibilities of project team and tasks and responsibilities of department heads in the implementation project	PL		SM	
Preparation of communication plan	PL		SM	
Implementation of communication plan	PL	EoP	PS/SG	
Overview of requirements (e.g. nuclear / environmental / non-nuclear-related health and safety / ISO)	PL		PS/SG	
Review of requirements	PL		PS/SG	
Proposal for layout of procedures / documents / checklist items / form sheets	PL		PS/SG	
Preparation of distribution list and distribution method for corporate and local documents	PL		PS/SG	

TABLE X–1. EXAMPLE OF AN IMPLEMENTATION SCHEDULE (cont.)

Action	Person responsible	Completion Date	Approval	
			By	Date
Proposed selection of the certification body, if required	PL		SM	
Completion of the project plan	PL			
Review and approval of project plan	PS/SG		SM	
Kick-off meeting with senior management team, departmental heads with presentation of action plan and required resources	SM			
Tasks and responsibilities of all involved managers to obtain full commitment	SM		SM	
Identification of corporate procedures to be developed	PL		PS/SG	M5
Identification of supporting documents to be developed	PL		PS/SG	M6
Preparation of procedures for drafting/ review/approval/control of MS documentation	PL	M6+xx	PS/SG	M7
Identification of corporate procedures/documents already available	PL	M7+xx		M8
Review and adaptation of available procedures	PL	M8+xx	PS/SG	M9
Preparation and review of new corporate procedures	PL	M9+xx	PS/SG	M10
Preparation and review of management system manual	PL	M10++	SM	M11
Training of employees on corporate documents	PL	M11+xx		
Appointment of internal auditors	PL	M5+	PS/SG	M12
Internal auditor training	PL	M12+xx		M13
First internal audit campaign on corporate procedures	PL	M13	PS/SG	M14
Identification of local procedures/instructions for checklist items/form sheets already available	DM*	M5+xx		M15
Identification of local procedures/documents to be prepared	DM	M15+xx		M16
Review and adaptation of available local procedures/documents	DM	M16+xx		M17
Preparation and review of new departmental procedures	DM	M17+		M18
First internal audit campaign on departmental procedures/ documents	PL	M18+xx	PS/SG	M19
External review by IAEA or certification body could be considered	PS/SG		SM	
Adaptation/review and approval of corporate documents	PL			

TABLE X–1. EXAMPLE OF AN IMPLEMENTATION SCHEDULE (cont.)

Action	Person responsible	Completion Date	Approval	
			By	Date
Second internal audit campaign on corporate procedures/ documents	PL	M20+xx	PS/SG	M21
Adaptation/review and approval of local documents	DM	M19+xx		M22
Second internal audit campaign on local procedures/documents	PL	M22+xx	PS/SG	M23
Certification steps				
Definition of certification scope	PL	M5+	SM	
Document review by external certification body	PL	M24+xx		M25
Adaptation of corporate procedures after second audit campaign and after document review by certification body	PL	M25+xx		M26
Third internal audit campaign on corporate procedures/ documents	Pl	M22+xx	SG	M27
Adaptation of local procedures after document review by certification body	DM	M25+xx		M28
Third internal audit campaign on local procedures/documents	PL	M25+xx	PS/SG	M29
External review by IAEA could be considered	PS/SG		SM	
Pre-certification audit if applicable	Certification body	M29+xx		M30
Adaptation/review and approval of corporate documents	PL	M30+xx		M31
Adaptation/review and approval of departmental documents	DM	M30+xx		M32
Certification audit if applicable	Certification body	M32+xx		M33

* Department Manager who is responsible for preparation of departmental procedures and documents in this example.

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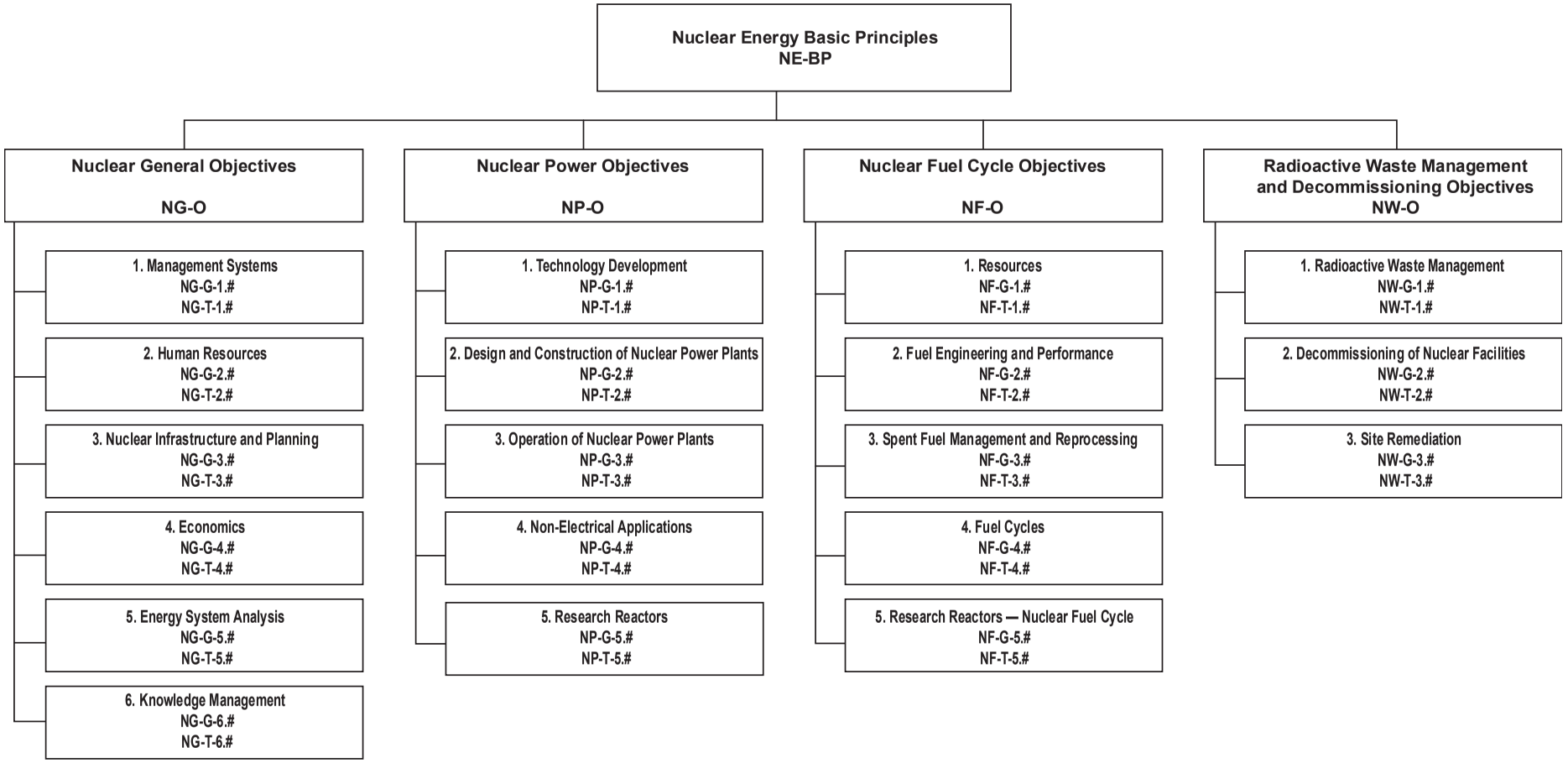

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