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**THE MANAGEMENT SYSTEM FOR THE
DEVELOPMENT OF DISPOSAL FACILITIES
FOR RADIOACTIVE WASTE**

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**THE MANAGEMENT SYSTEM FOR THE
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FOR RADIOACTIVE WASTE**

INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

The IAEA has undertaken a number of activities to assist Member States in the field of waste disposal, focusing on both the technology and safety aspects. In particular, over the past several years, a series of reports has been issued on the topic, for example on the scientific and technical basis of waste disposal, on the upgrading of near surface repositories, on disposal options for disused radioactive sources, and on safety guidance regarding borehole facilities for the disposal of radioactive waste.

The above mentioned reports provide Member States with guidance on a wide range of technical and safety issues that are important in developing and/or upgrading disposal facilities. However, as with other nuclear facilities and their operations, all activities associated with radioactive waste disposal need to be carefully planned and systematic actions undertaken in order to provide adequate confidence that a disposal system meets performance and safety requirements and objectives, and to enable future generations to re-evaluate a disposal system or its parts. In this regard, the 'management system' (a term currently used in the IAEA Safety Standards Series, replacing the previous terminologies 'quality assurance' or 'quality management' and integrating safety, protection of health and environment, security, quality and economics into one coherent system) plays an important role in realizing these objectives, and such a system needs to be implemented at every stage of the repository development process. This also applies to 'old' near surface repositories, which were planned, developed and operated without a formal management system in place. The application of an appropriate management system to such a repository may result in the identification of a series of deficiencies necessitating corrective action in line with compliance requirements for repository processes.

This report addresses management system requirements, planning, and establishment of management system procedures and methodologies relevant to three important stages of repository development: design, construction or upgrading, and operation. This basic information would be useful in the planning and implementation of a comprehensive management system for all activities and processes that take place during the life cycle of a repository. This document was initiated when the Safety Series Code 50-C/SG-Q (1996) on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations was still valid. In the meantime, the IAEA developed a new set of safety standards in 2006, which establishes requirements and provides guidance for the application of an integrated management system for facilities and activities. Recently, the IAEA published a Safety Guide entitled Management System for the Disposal of Radioactive Waste (2008), which makes recommendations to meet these requirements at all stages of a repository development process. This report takes these changes into consideration, and complements the recommendations of the Safety Guide, expanding on them for the design, construction, upgrading and operational stages, thus maintaining the timeliness and relevance of the material contained in it. This revision updates the information contained in the Safety Guide, thus keeping it current and useful.

The report was developed with the assistance of experts from many countries. The IAEA officers responsible for this report were: R. Dayal, B. Neerdael and S. Hossain of the Division of Nuclear Fuel Cycle and Waste Technology.

EDITORIAL NOTE

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SUMMARY

Currently, many Member States are safely operating near surface disposal facilities and some are in the initial or advanced stages of planning geological repositories. As for other nuclear facilities and their operational phase, all activities associated with the disposal of radioactive waste need to be carefully planned and systematic actions undertaken in order to maintain adequate confidence that disposal systems will meet performance as well as prescribed safety requirements and objectives. The effective development and application of a management system (integrating requirements for safety, protection of health and the environment, security, quality and economics into one coherent system) which addresses every stage of repository development is essential. It provides assurance that the objectives for repository performance and safety, as well as environmental and quality criteria, will be met. For near surface repositories, a management system also provides the opportunity to re-evaluate existing disposal systems with respect to new safety, environmental or societal requirements which could arise during the operational period of a facility.

The topic of waste management and disposal continues to generate public interest and scrutiny. Implementation of a formal management system provides documentation, transparency and accountability for the various activities and processes associated with radioactive waste disposal. This information can contribute to building public confidence and acceptance of disposal facilities.

The objective of this report is to provide Member States with practical guidance and relevant information on management system principles and expectations for management systems that can serve as a basis for developing and implementing a management system for three important stages; the design, construction/upgrading and operation of disposal facilities.

To facilitate the understanding of management system implementation at the different stages of a repository life cycle, a short overview of disposal systems is provided, including an integrated, stepwise approach, and associated activities relevant to the design, construction/upgrading and operational stages. Such a disposal system includes the near field and the surrounding geological media (far field). The near field consists of the waste, engineered barriers (including waste forms and containers) and the adjacent geological media disturbed by excavation and other operational activities. The natural barrier system consists of the geological media hosting the repository, and any other surrounding geological formations contributing to waste isolation. The biosphere is that part of the environment inhabited by living organisms. Radionuclides released from the repository or through geological barriers may be diluted, retarded or concentrated before causing any radiological impact on humans and other species. The purpose of a disposal facility is to limit radiological impacts to acceptable levels. The three main repository development phases are: pre-operational, operational and post-closure. The pre-operational phase includes development of the disposal system concept, siting and design, licensing, and construction. The operational phase is comprised of waste emplacement and subsequent repository closure. The post-closure phase covers maintenance and institutional control activities following repository closure.

All processes and activities associated with the disposal of radioactive waste need to be managed, performed, assessed and controlled in order to provide adequate confidence that safety, technical, environmental, quality and economic requirements and objectives are met. The management system includes controls for organization, design, procurement, procedures and processes, documentation, inventory, inspections, tests, validation and verification, equipment calibration, improvements in the event of non-conformance, audits, and continuous improvement. Effective implementation of the management system at each phase of the repository life cycle will contribute towards meeting current repository project requirements and objectives and enhance flexible implementation of changes in the future.

As mentioned in both the General Safety Requirements and the Safety Guide on waste disposal, a management system should support the development, implementation and continued enhancement of a pragmatic and strong safety culture, and should promote the adoption of best practices for all waste disposal activities.

The design and development of a repository is truly an interdisciplinary activity, involving a range of technical and management issues. The life cycle of a repository extends from hundreds of years for a near surface facility to hundreds of thousands of years for a geological repository. Unlike other nuclear facilities, there are many issues that are unique to disposal facilities and which require special consideration in the development and application of an effective management system that is applicable to a repository development project. The design

and development process starts with the compilation of design inputs and culminates with the production of design outputs, which are then transferred and used in subsequent stages of the repository development process. Both design input and output have to be verified, validated and approved before they can be used in subsequent stages of the design process.

A project on construction/upgrading of a repository may be divided into interrelated and interdependent processes as a way of planning and managing the project. It is necessary to clearly define and link the project processes, and to integrate them and manage them as a system. The same principles and practices of a management system can be applied as they are relevant to a project's management system. Project management processes include planning, organizing, controlling, reporting and corrective actions. One of the first requirements of a management system when initiating a project is the development of a project management plan. A project management plan is an important document which should be prepared and regularly reviewed to specify and control which activities and processes are necessary for the construction or upgrading of a repository.

It is necessary to apply management system requirements to repository operational processes. Few management system processes differ from what has been described for previous development stages.

1. INTRODUCTION

1.1. BACKGROUND

For appropriately conditioned and packaged radioactive waste, disposal in either a near surface or a geological repository is recognized as being the most viable option for protecting human health and the environment into the future without imposing an undue burden on future generations. The choice of repository for each waste type will primarily be determined by the quantities and characteristics of the radionuclides present in the waste [1, 2].

Near surface disposal is an option being practised in many Member States for low and intermediate level radioactive waste containing primarily short lived radionuclides and low concentrations of long lived radionuclides, and appropriate technologies for safely designing, constructing and operating such facilities are available [3–14]. According to IAEA terminology [15], the term ‘near surface disposal’ includes a wide range of disposal options, from engineered structures at ground level or earthen trenches a few metres deep to engineered concrete vaults and rock cavities a few tens of metres below the surface. Currently, many Member States are safely operating near surface disposal facilities [16, 17].

Concerning high level waste and spent fuel subject to direct disposal and other long lived waste requiring long term isolation and containment, the common and internationally accepted option offering the most safety and sustainability is geological disposal in a formation several hundred metres or more below the surface. Although research and development activities of the past several decades have adequately demonstrated the technical feasibility of geological disposal [18–22], only a few Member States will have operational geological disposal facilities within the next 10–15 years. Most Member States requiring such facilities are still in the initial or advanced planning stages.

As with other nuclear facilities and their operations, all activities associated with the disposal of radioactive waste need to be carefully planned and systematic actions undertaken in order to provide adequate confidence that a disposal system will meet performance and prescribed safety requirements and objectives. Some of these quality control/quality assurance issues related to disposal systems have been addressed in the past in separate IAEA documents [23–29]. However, the effective development and application of a management system (integrating the requirements of safety, protection of health and environment, security, quality and economics into one coherent system) at every stage of repository development is essential. It provides assurance that objectives for repository performance and safety, as well as environmental and quality criteria, will be met, and also provides the opportunity to re-evaluate existing disposal systems with respect to new safety, environmental or societal requirements which can arise during the operational period of a facility. This is particularly important when one considers that many existing near surface disposal facilities were initially planned, sited, designed, constructed, operated and closed (in some cases) without an effective management system. The application of management system requirements to such repositories may result in the identification of a series of deficiencies, requiring corrective action(s) as part of the repository compliance process [30].

The topic of waste management and disposal continues to generate public interest and scrutiny. Implementation of a formal management system provides documentation, transparency and accountability for the various activities and processes associated with radioactive waste disposal. This information can contribute to building public confidence and acceptance of disposal facilities. It is the responsibility of an organization (including designers, repository licensees or operators) to develop and implement a management system that is consistent with national and/or international standards/regulations and which provides assurance of the quality of activities and processes (including decision making) undertaken during the entire life cycle of a repository.

This report was initiated when Safety Series Code 50-C/SG-Q (1996) [31] on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations was still valid. In 2006, the IAEA issued a Safety Requirements publication, The Management System for Facilities and Activities [32]¹, and its accompanying

¹ These standards replace the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations [31], which was issued in 1996 to provide basic requirements for establishing quality management systems for the stages of siting, design, construction, commissioning, operation and decommissioning of nuclear power plants.

Safety Guide [33], which provides the means to address safety objectives and principles regarding management systems presented in the IAEA Safety Fundamentals [34]. IAEA Safety Requirements and Safety Guide given in Ref. [32, 33] and developments within the International Organization for Standardization (ISO) [35–38], along with the recently published IAEA Safety Guide on The Management System for the Disposal of Radioactive Waste (2008) [39], were taken into consideration during finalization of this report, thus maintaining the timeliness and relevance of the material contained in it. Member States' experience in developing and implementing quality management systems in national repository development projects was also taken into account [40–48]. Following current IAEA Safety Standards Series terminology, this report uses the term 'management system' instead of 'quality control', reflecting the evolution in approach from an initial concept of 'quality control' to 'quality assurance' and 'quality management'.

1.2. OBJECTIVE

The objective of this report is to provide Member States with practical guidance and relevant information on management system principles and expectations for management systems that can serve as a basis for developing and implementing a management system for three important stages: design, construction/upgrading and operation of disposal facilities.

1.3. SCOPE

This report expands upon management systems for all activities associated with the above mentioned stages of disposal facilities, and complements a recently published Safety Guide [39], which covers general management systems for all the different stages of waste disposal facilities, including siting, closure and post-closure.

The report refers to requirements relevant to activities carried out during repository design, construction/upgrading and operation, but it does not address pre-disposal issues, such as waste conditioning, packaging, transportation, etc., which are covered by another Safety Guide publication [49].

In particular, the overall approach taken in this report is:

- To provide an overview of management system principles and requirements that are considered important in the design, development or upgrading of disposal facilities;
- To address how relevant management system requirements can be introduced in project management for the construction/upgrading of a disposal facility;
- To address how relevant management system requirements can be considered during the normal operation of a disposal facility.

1.4. STRUCTURE

Section 2 provides a brief overview of disposal systems and their development/improvement processes. In Section 3, a general description of a management system and most relevant management system requirements for the development of waste disposal facilities is provided. Section 4 discusses management principles and requirements as applied to the design and development/upgrading of a repository. The application of these management principles and requirements is discussed further in the case of construction/upgrading (Section 5), and during the normal operation of a disposal facility (Section 6).

2. OVERVIEW OF DISPOSAL SYSTEMS

To facilitate the understanding of management system implementation at different stages of a repository's life cycle, this section provides an overview of disposal systems as well as an integrated, stepwise approach along with associated activities that are relevant for the design, construction/upgrading and operation of a repository.

The focus will be put on existing disposal facilities that are essentially of the near surface type. Besides design and construction, the operation and upgrading stages of such repositories will provide an appropriate framework to better illustrate the added value of management system implementation.

2.1. CHARACTERISTICS OF NEAR SURFACE DISPOSAL SYSTEMS

A disposal system includes the near field and the surrounding geological media. The near field consists of the waste, engineered barriers (including waste forms and containers) as well as the adjacent geological media disturbed by excavation and other operational activities. The natural barrier system consists of the geological media hosting the repository, and any other geological formations contributing to waste isolation.

The biosphere is that part of the environment inhabited by living organisms. Radionuclides released from a repository or through geological barriers may be diluted, retarded or concentrated before causing any radiological impact on humans and other species. The purpose of a disposal facility is to limit radiological impacts to acceptable levels.

Experience with safety assessments of existing repositories shows that the radiological impact of repositories is generally linked to radionuclides that are long lived and/or highly mobile. However, radiological impacts involving short lived, high activity radionuclides may be a significant factor in both operational exposure and inadvertent human intrusion scenarios for such repositories.

2.1.1. The multiple barrier concept

The primary safety related objective of near surface disposal is to provide effective isolation of wastes from the surrounding environment. Achieving this objective generally requires that disposal facilities be sited, designed, constructed, operated, closed and maintained to prevent the release of radionuclides or hold released amounts to acceptable levels. In order to ensure that a disposal system is robust, a multiple barrier concept — which utilizes the properties of the waste form, engineered barriers and the site's natural barriers to prevent or restrict the release of the radionuclides from the facility [6, 13] — is generally selected. The relative contributions of various barriers to the overall safety of a disposal facility will depend upon the characteristics of the waste, site conditions and the disposal concept, and will be time dependent.

2.1.2. Disposal options

Selection of a particular repository design depends on many factors, including national radioactive waste management policies, waste characteristics and inventories, available site characteristics, climate conditions, technology and resource availability.

Two main options used for near surface disposal are: (i) shallow facilities close to the ground surface, and (ii) deeper facilities. Shallow facilities consist of disposal units located either above (such as mounds) or below (such as lined or unlined trenches, vaults, boreholes, bunkers, etc.) the ground surface. The thickness of the cover over the waste is typically several metres, and may consist of multiple layers engineered to limit moisture infiltration, control biotic intrusion and promote vegetation growth. Greater confinement facilities allow waste to be emplaced in rock cavities, including borehole type facilities of varying designs and depths, which are particularly suitable for the disposal of disused radioactive sources [50, 51]. The thickness of the soil and/or rock above the waste can be up to several tens of metres. These depths contrast with geological repositories for spent fuel and long lived radioactive waste, where waste is emplaced at depths of hundreds of metres.

Near surface facilities are generally located above the water table. However, local conditions may allow or require disposal modules to be constructed in the saturated zone. In both cases, the disposal units need to be designed and constructed to limit the flow of water into the repository and subsequent radionuclide migration. Major disposal system components generally include the following:

- Waste form;
- Waste container;
- Any additional engineered barriers or systems;
- Natural barrier system.

The waste form may involve a solid matrix in which radionuclides are immobilized through treatment and/or conditioning prior to packaging. Some wastes may not be conditioned, in which case the waste form will consist of the originally contaminated material (such as paper, glassware, plastic, wood, animal carcasses), possibly in a compacted form to reduce void space. Different types of materials can be used to stabilize waste, including cement, bitumen and polymers [2, 8, 12]. Combustible wastes, such as contaminated clothing, plastics, paper, wood and other organic matter may be incinerated and the ashes incorporated in a solid matrix [2].

The waste package, which consists of the waste form and container, may be designed to meet requirements for handling, transportation, storage, and disposal [2, 8, 12]. Alternatively, waste may be transferred to different containers prior to disposal. To limit the release of radionuclides and other contaminants, some packages include additional features such as absorbents and impermeable liners. Concrete, polymer coated concrete, carbon steel, high density polyethylene, and other engineered materials are also used for containers. Gas vents may be necessary if the disposal units incorporate impermeable barriers. The integrity of waste packages is important if: (i) they represent an engineered barrier or source of structural stability that is important to the safety casing, and/or (ii) the ability to retrieve the waste is considered.

Additional engineered systems may consist of structural walls, solid or free draining backfill materials placed around waste packages, chemical additives, low permeability soil or synthetic liners and covers. Depending on the disposal concept, these may be supplemented by other engineered components, including leachate collection and drainage systems, and impermeable subsurface cut-off walls. To ensure that an engineered barrier system is robust enough to perform as specified in a design, materials should be used that will maintain their function and integrity under anticipated repository conditions for the required period of time.

2.2. CHARACTERISTICS OF GEOLOGICAL DISPOSAL SYSTEMS

A disposal system also includes the near field and the surrounding geological media (far field) which have totally different features, dimensions, roles and safety functions. If a reference concept remains multi-barrier based, disposal options are defined according to waste inventory, design and safety requirements. The near field consists of the waste and engineered barriers (including waste forms/containers, as well as a bentonite buffer or concrete). The host geological media should have very specific properties in order to play in many cases a substantial role as a natural barrier. Direct under and overlying geological formations require detailed characterization with regard to their potential hydraulic and/or geochemical role in the performance assessment of the whole disposal system. The following paragraphs of this chapter specify, where appropriate, specific features related to geological disposal.

2.3. REPOSITORY DEVELOPMENT PROCESS

Figure 1 illustrates a generic repository development process, indicating the three life cycle phases of a repository, including key activities during each phase. Although shown as a linear sequential process for the sake of simplicity, it should be recognized that there could be iterative loops between the various activities among the three phases. For example, once a facility is operating, modifications can be made to its design and waste acceptance criteria in light of the results of an assessment of its performance, outcomes of monitoring activities and changes in the inventory to be disposed of. Furthermore, certain activities can run in parallel. For example, parts of a repository

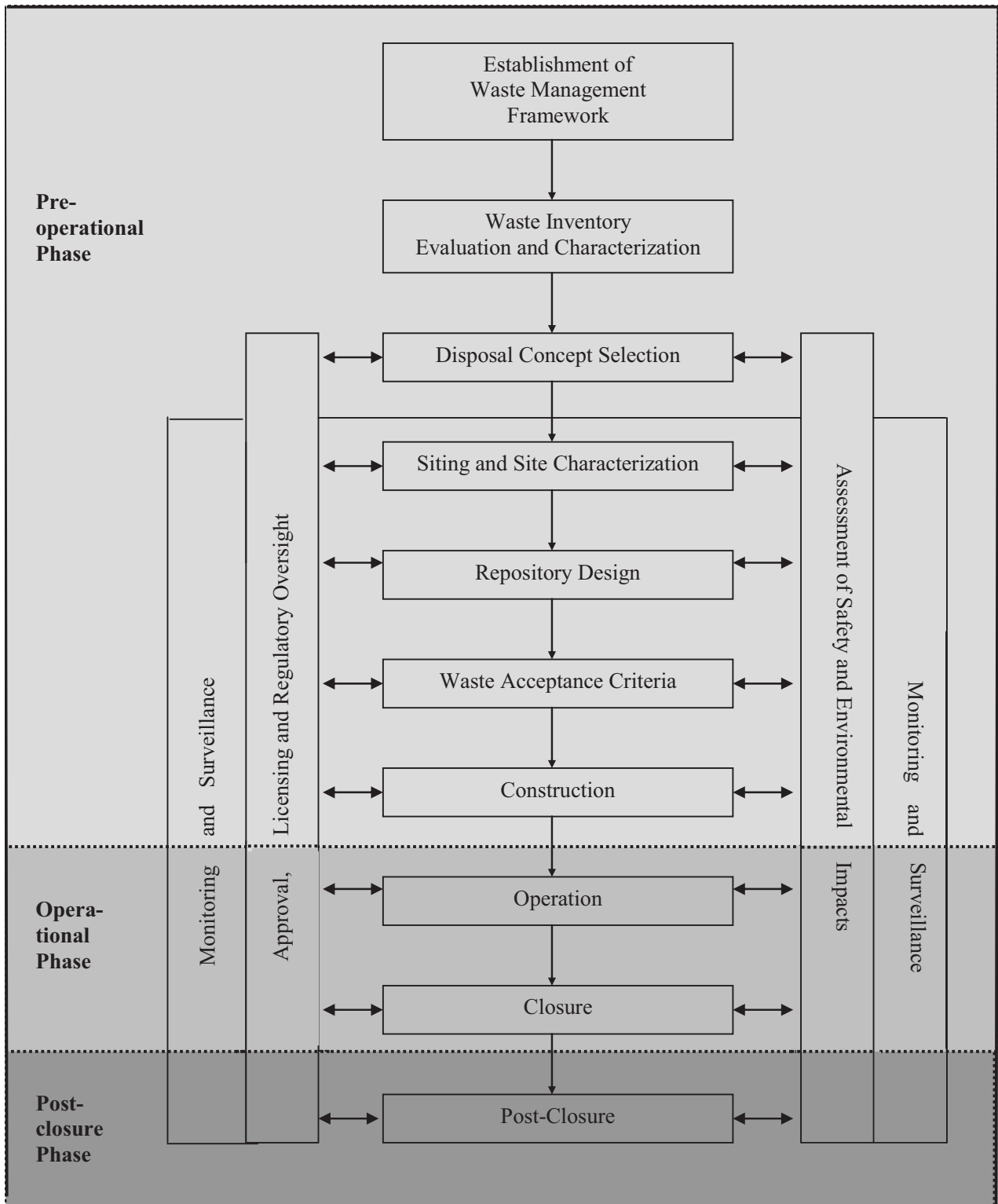


FIG. 1. A generic repository development process.

may be constructed at the same time that some parts are receiving waste and yet other parts are being closed. In addition, there are certain ‘cross-cutting’ activities, such as monitoring and surveillance, assessment of safety and environmental impacts, and approval, licensing and regulatory oversight, which need to be considered at all stages of a repository’s life cycle.

As shown in Fig. 1, the three main repository development phases are pre-operational, operational and post-closure [13]. The pre-operational phase includes development of a disposal system concept, siting and design, licensing, and construction. The operational phase comprises waste emplacement and subsequent repository closure. The post-closure phase covers maintenance and institutional control activities following repository closure. Activities related to each of these phases are described below.

The **pre-operational phase** begins with a conceptual design and siting considerations. It starts with the development of an initial disposal concept, based on the nature and estimated quantity of the waste requiring disposal, regulatory requirements, site availability and environmental constraints, availability of resources, waste transport routes, cost, and societal considerations. Construction of a repository may take place in a phased manner to provide additional disposal capacity for waste received over time at a facility.

The **operational phase** generally comprises commissioning, waste receipt and emplacement, backfilling, sealing/covering of disposal units, operational monitoring and surveillance, and closure.

Mainly in the case of near surface repositories, emplacement of waste comprises both physical placement in a repository and subsequent management until that part of the repository is covered or sealed. A repository may have a number of units progressively constructed and used for disposal. As soon as a particular part of a repository is filled to capacity, the voids around waste packages may be backfilled. It may also be necessary to protect that part of a repository with a temporary cover to limit infiltration of water and provide radiation shielding prior to closure. The repository operational period generally lasts up to some tens of years.

Closure begins after waste emplacement operations have been completed. Closure is generally conducted in accordance with an approved plan that includes an updated safety assessment and a description of the institutional controls intended for the post-closure phase. For a near surface disposal facility, typically a final cover system is emplaced to: (i) control erosion and ensure the physical integrity of a repository; (ii) minimize infiltration of water, and; (iii) to control plant, animal, or human intrusion. This is particularly important for shallow or above ground disposal units, since the waste is emplaced relatively close to the surface.

For geological repositories, the operational phase is more complicated when it involves highly active or long lived waste or spent nuclear fuel, together with access to a depth of several hundreds of metres. This has considerable implications for transport, handling and emplacement. Time scales are quite different for construction as well as for operation. A reference decision making process is mandatory when dealing with long term aspects for such types of waste. Finally, safeguards issues associated with spent fuels and some other nuclear materials have strong implications for operation and control [52]. Monitoring, surveillance and possibly provisions for retrievability need to be carefully defined in a totally different framework than that required for low level waste disposal, including specific requirements for repository closure.

The **post-closure phase** includes institutional controls as an integral part of an overall waste isolation system. These controls may include both active and passive measures. Maintenance, monitoring and surveillance of a disposal site constitute active institutional controls.

For near surface facilities, these generally include: (i) cover system inspections and any needed repairs; (ii) environmental monitoring, and; (iii) maintenance of fences and signs and other physical components. These active controls are conducted for periods ranging from several decades to a few hundred years. On-going monitoring and surveillance data can also be used to update safety assessments [6, 11, 13]. Passive measures may include disposal unit and site markers, land use and other legal restrictions, and archived records of waste inventories and their location within a repository. The purpose of passive controls is to preserve relevant operational records and reduce the likelihood of wastes being disturbed. It is also important to consider ensuring that funds will be available for the post-closure phase.

For geological repositories, the focus is more on passive safety, again with quite different time scales for monitoring and surveillance.

2.4. REPOSITORY UPGRADING (NEAR SURFACE TYPE FACILITY)

A repository may be upgraded based on different objectives, depending on the status of a disposal facility [30]. Specific actions may be undertaken to:

- Achieve regulatory compliance;
- Prevent an accident or incident;
- Provide corrective action for an accident or incident;
- Permit continuing operations;
- Improve current operational practices;
- Apply new technological developments;
- Comply to changes in regulations (not only radiation protection) or requirements (take into account dozens of years of operation);
- Expand disposal capacity;
- Restart disposal facility operations following a suspension;
- Prepare for final facility closure;
- Improve performance of a previously closed facility;
- Address public and other stakeholder concerns.

A systematic process, such as that illustrated in Fig. 2, may be followed to ensure that appropriate upgrading processes are identified and effectively implemented. The process illustrated is generic and may require modification to address each specific situation. The implementation process for each step may also vary. For many of the steps, the process may be iterative in nature. The corrective action process includes definition of initiating events, root cause analysis, potential corrective action identification and assessment, preferred action planning and implementation, and confirmation of the effectiveness of corrective action(s) implemented. Detailed information on repository upgrading can be found in an IAEA report [30], in which specific examples of initiating events that could necessitate corrective actions are also provided.

3. MANAGEMENT SYSTEM

All processes and activities associated with the disposal of radioactive waste need to be managed, performed, assessed and controlled in order to provide adequate confidence that safety, technical, environmental, quality and economic requirements and objectives are being met. In order to design and develop or upgrade a repository system, it is important to establish, implement, and maintain a management system. An effective management system provides a basis for developing and documenting reliable information for regulators and stakeholders. A management system includes controls for organization, design, procurement, procedures and processes, documentation, inventory, inspections, tests, validation and verification, equipment calibration, improvements in the event of non-conformance, audits, and continuous improvement. The effective implementation of a management system at each stage of a repository life cycle will contribute towards meeting current repository project requirements and objectives and enhance flexible implementation of changes in the future.

As mentioned in both the general Safety Requirements [32] and the Safety Guide on waste disposal [39], a management system should support the development, implementation and continued enhancement of a pragmatic and strong safety culture and should promote the adoption of best practices for all waste disposal activities.

A management system can be established for three major stages in the life cycle of a repository:

- Design and development of a new repository up to the construction stages and any upgrades to a repository during its life cycle;
- Construction of a new repository or upgrades to an existing repository by treating this stage as a project and applying a management system to it;
- Operation of a repository from waste emplacement up to its closure.

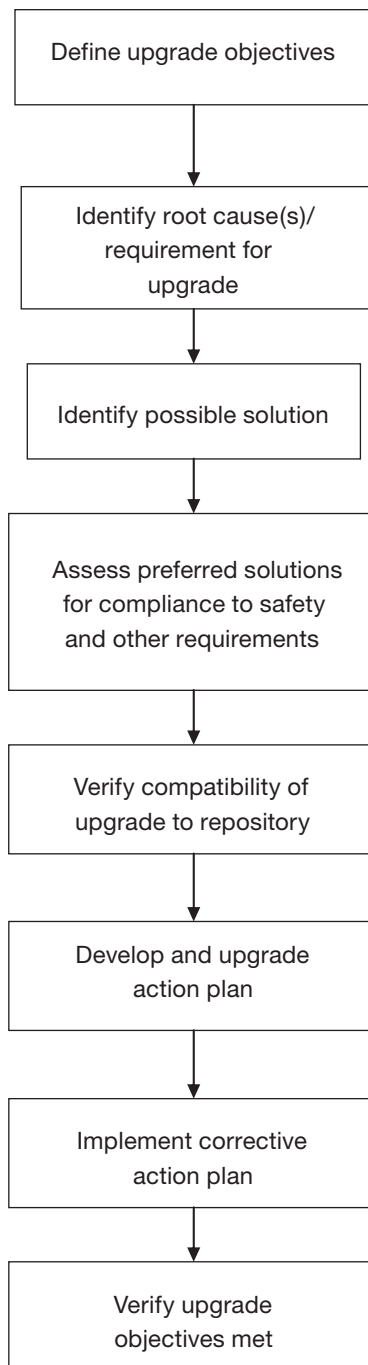


FIG. 2. Schematic illustration of the repository process.

3.1. MANAGEMENT STANDARDS, CODES AND GUIDELINES

To assist in the establishment of a management system, generally applicable principles and guidelines can be found in the following documentation:

- IAEA management system standards, codes and guidelines [32, 33, 39];
- Other relevant IAEA Safety Standards publications [such as 34, 53, 54];
- IAEA documents relating to management system issues in radioactive waste management and disposal [3, 4, 19, 23–29];

- International requirements on quality management systems: ISO 9001 and related guidance documents, including ISO 14001 and other ISO standards [35–38];
- National standards, codes, guidelines and documents [40–48].

3.2. MANAGEMENT RESPONSIBILITY

3.2.1. Management commitment

For a management system to be effective, plant managers need to demonstrate leadership, commitment and active involvement to develop, implement and improve systems, processes and activities in the design and development of a repository during its entire life cycle. An environment needs to be created to encourage the involvement and development of all responsible organizations and staff.

It is important that repository managers participate in management reviews, provide necessary resources, and facilitate the establishment and acceptance of management system policies and objectives.

If a responsible organization delegates the work of establishing and implementing all or part of an overall management system, it retains responsibility and accountability for the management system in all circumstances.

3.2.2. Stakeholder considerations

A number of stakeholders, both current and future, may be involved in repository design and development processes and merit consideration in the development and implementation of a management system. The nature and extent of involvement will vary in different Member States. Some examples include:

- Organization of assigned regulatory responsibility for ensuring that health, safety and environmental requirements and objectives are met, including potential quality requirements;
- Listing of requirements and expectations of waste generators to be fulfilled by a repository;
- Inclusion of local communities, organizations and members of the public interested in repository development, as well as related performance and safety;
- Hearing of public concerns regarding extended restrictions on land use and natural resources;
- Consideration of public attitudes, concerns, and expectations regarding the safety of disposal facilities in the long term;
- Creation of a detailed description of the interface between an existing system and its innovative aspects.

3.2.3. Planning

As a starting point, the responsible organization needs to establish, at the earliest practicable time consistent with a schedule, a documented management system plan based on national regulations and requirements for a given repository development project. A management system plan provides a basis for establishing and implementing a management system [32, 33, 39], including repository design, construction or upgrading, and operation consistent with applicable management system objectives and requirements. Improvements and changes to a management system are also planned and consistency and integrity are verified prior to implementation. Such a management system plan needs to address the following:

- Documentation required for a management system in compliance with the adopted management system standard;
- Responsibility for document generation, system implementation and operation;
- Resources required (such as personnel, inspection, equipment and training);
- Time schedule set for implementation of a new and modified qualified system, procedures;
- Control of activities to assess and verify a management system prior to implementation, and to assess the effectiveness of programme implementation (through audits, self-assessments and management reviews).

Further details are discussed in Section 5, which provides specific guidance on preparing a management system plan for the construction or upgrading of repositories.

In addition to the responsible organization's management system, a management system plan should identify management system policies, objectives, and responsibilities for equipment and service suppliers, contractors, and other organizations which interface with the design and development of repositories. Waste generators may also be required to implement related management systems when, for example, waste form or waste packaging requirements applicable to waste generators are integrated with design and related repository performance and safety.

For the establishment of a new repository or upgrading of existing disposal facilities, it may be useful to control design and development work in accordance with accepted principles of project management. Such requirements may be appropriately documented in procedures.

Individual management system requirements (such as document control, non-conformity control and training) are systematically converted into a comprehensive management system plan for a specific repository development project. The following considerations apply:

- The nature and extent of a management system plan will be dictated by the complexity and nature (particularly in terms of safety implications) of the proposed repository;
- All requirements for a management system need to be addressed, although the extent to which those requirements are applied will be a function of the activity or process;
- The manner in which each management system requirement will be applied to each major repository design, construction or upgrading and operation activity or process is documented. The culmination of this process provides the essence of the repository specific management system plan;
- The management system plan should also include a documented process for the transfer of repository structures, systems and components and related records from one phase to another, for example from construction to operation, etc.

The following steps need to be taken towards developing an effective management system plan:

- Appoint a manager competent in the application of management system principles and requirements;
- Determine the management system requirements to be included in the management system plan. In some cases, management system requirements will be prescribed by national or international standards;
- Prepare a comprehensive list of major activities that need to be carried out for the specific repository development or upgrading project (for typical examples of activities associated with a disposal facility see Figs 1–4);
- Develop a conceptual design for the repository in sufficient detail to help identify specific aspects (for example, safety related) of the repository that may require particular attention within the management system plan. For example, the important issue of inadvertent human intrusion may warrant an elevated level of design verification and validation;
- Establish a management system plan for each major activity or process, and address each of the management system requirements. In many cases, procedures will need to be prepared that provide details describing the required management system processes. Some procedures will be common to all activities. These can form the basis for a set of 'generic' procedures.

A typical management system plan structure for the development of a repository is comprised of the following aspects:

- References to national and international standards, regulatory requirements, procedures that are applied to management systems or for a specific activity;
- Objectives of the management system;
- A scope describing management system requirements, activities and processes and their level of grading for application;
- For the repository or development organization, definition of lines of authority, functions and interfaces of organizations that interact in development and disposal processes;
- The manner in which management system requirements are to be documented and implemented;

- Planning for assessment (including inspection, surveillance, quality audits and self-assessment);
- Identification and retention of records and maintenance;
- Provision of quality record generation and the treatment of those records.

Following the establishment of a management system plan, efforts should focus on implementing and reviewing the plan. This can be accomplished by using an iterative process whereby procedures are prepared, implemented through training, assessed, and if necessary, revised.

3.2.4. Management representative

Repository management is responsible for appointing a management representative who is responsible for ensuring that a management system is established, implemented and maintained by all participating organizations. A key responsibility is ensuring adequate coordination among the various involved parties and organizations that interface in the design and development processes. This position may have organizational, budgetary and scheduling independence from managers directly responsible for repository design and development tasks.

The management representative may also be responsible for promoting health, safety and environmental awareness of repository design and development organizations and other involved parties.

3.3. DOCUMENTATION REQUIREMENTS

Specifically, a management system requires the establishment of [24]:

- A document control system for the preparation, review, approval, issuing and revision of documents (such as procedures, instructions, specifications, drawings or other media that describe processes, specify requirements or establish design) and data management, performance and assessment of work undertaken. This includes the identification of authorized individuals or organizations responsible for preparing, reviewing, approving, issuing and revising documents and data related to activities;
- A record management system for the identification, collection, indexing, filing, storing, maintenance, retrieval and disposal of records. The system shall ensure that all records are legible, complete and identifiable with the item or activity involved, and are stored and maintained in such a manner that they are readily retrievable from facilities that provide an appropriate environment to prevent damage, deterioration, or loss. Provisions need to be made for the transfer of information between managing organizations during the entire repository life cycle.

Some aspects specific to the repository should be taken into account, for example:

- The long term nature of the disposal system (which may extend for hundreds or thousands of years). These things need to be considered:
 - Archiving methods and procedures should be prescribed as soon as a document management system becomes operational (for example, during first design operations before site selection) and continue throughout the different stages of design, development, construction project and life cycle of the disposal facility;
 - Criteria for preparation and archiving of documents that need to be taken into account include safety (in relation to potential incidents or risks), traceability (in relation to past events) and history (in order to satisfy any inquiry by future generations about present activities);
 - Classification of records and archiving of long term records on a periodic basis without waiting for the end of operational activities;
 - Storage of records in two archives held in physically separate locations. To ensure long term archiving of records, consideration could be given to depositing a set of records into a national archive organization.
- Preparation, transfer, archiving and maintaining records in appropriate conditions over the entire repository life cycle, including the post-closure period (for example, the use of low maintenance media which at the same time ensure readability, such as special permanent paper);

- Technological advances in data storage, management practices and operating procedures may evolve significantly during the life cycle of a repository.

Particular attention needs to be paid to ensuring that documents used to control work processes remain relevant, current, understandable and readily available in the situation in which they will be used. They need to be periodically reviewed, and kept up-to-date as equipment, information technology, industrial practices, language, educational levels, and regulatory requirements evolve over time.

3.4. RESOURCE MANAGEMENT

Personnel with relevant qualifications, training, skills and experience are required to perform activities affecting a management system to ensure competence in the application of relevant regulatory, technical, safety, environmental, quality, and economic requirements. Records must be kept to document that staff members possess the necessary skills, training, qualification and experience.

As a starting point, a management representative should ensure that funding arrangements for the repository development project are in place, and that responsibilities, mechanisms and schedules for collecting funds are established before a specific work activity is undertaken. For example, funds should be available at the end of a repository operation for repository closure.

A management representative should be adequately trained, experienced and possess the necessary skills to interpret and apply management system principles and requirements. Training in management system principles, the management system plan, and procedures applicable to specific repository development, or upgrading of a project is typically conducted to ensure that all involved organizations understand and are prepared to perform activities affecting the management system.

A design team may require a large variety of professional skills, which shall be identified in the management system plan.

Personnel who perform assessments in the design and development process need to be experienced, trained and qualified.

In addition to human resources, the management system shall ensure that tangible resources, such as sites, facilities, equipment, information and communication technology and software, and intangible resources, such as intellectual property, are made available.

It is important that the interdisciplinary nature of and different groups involved in design and development processes are properly defined. This includes identifying organizational structures to manage interdependencies in a documented, controlled and effective manner. Communication plans need to be prepared that explicitly identify:

- The nature of the interfaces;
- Required lines of communication;
- Responsibilities of the stakeholders;
- Expected performance and safety of the repository.

3.5. MONITORING AND MEASUREMENT

In the context of repository development/upgrading, monitoring and measurement include obtaining the necessary input data for design and development processes, as well as the ongoing monitoring data necessary for validation activities. This may include, for example:

- Waste characteristics (including radionuclide activity and inventory, waste quantities, physical dimensions and mass of waste packages, content and properties of waste packages);
- Site characteristics (including seismic, hydrogeological, meteorological, biological, geochemical and geomorphologic data);
- Repository conformity to safety requirements and performance (including radionuclide release, environmental impact and repository structural integrity);

- Conformity of a management system to requirements and its effectiveness;
- Continual improvement of management system effectiveness.

The selection of monitoring and measurement methodology requires confirmation of the achievability of desired results (such as the location of sampling points at a repository for radiological measurements, sampling frequency, range and detection limits of radiological measurements).

3.6. ASSESSMENT OF REPOSITORY DEVELOPMENT

Assessment is an essential component of a management system for repository development or upgrading. Periodic assessment should verify compliance with, and provide ongoing continual improvement of, the design and development process. Assessments are performed by competent individuals and/or organizations, and scheduled on the basis of the status and relative importance of an activity.

This section identifies basic assessment principles and controls that, when adopted and effectively implemented, can provide assurance that design processes are adequate and effective, that a process for continual improvement exists, and that project design performance objectives will be met.

There are a number of assessment methodologies that may be used:

- Self-assessment and internal audits;
- Management system review;
- External audits and peer review.

Each of these methods, subdivided into internal and external assessment, is discussed below:

3.6.1. Internal assessment

3.6.1.1. *Self-assessment and internal audit*

Self-assessment and surveillance internal auditing provides an evaluation of the effectiveness and efficiency of the design and development organization and of the maturity of the management system. In self-assessment management, the people responsible for the work perform an assessment, but during the internal audit, auditors do not audit their own work. The intent of self-assessment and internal audit, which may involve management, is:

- Continuous improvement of the design and development process;
- Measuring of progress against objectives;
- Prioritization of opportunities for improvement;
- Guidance in the prioritization and commitment of resources for improvements.

Examples of criteria used to assess the performance of a design and development organization and a management system include leadership, policy and strategic definition, planning, human resource development and management, process management, information systems, and analysis measuring results and external influences.

3.6.1.2. *Management system review*

Management review is a periodic appraisal of the effectiveness of management systems put in place to direct that part of an organization responsible for repository development.

The purpose of such reviews is to provide a basis for improvement of existing management systems and their processes, taking into account experience gained from previous application of the systems.

Management review typically includes appraisal of any assessments (including internal and external audits and feedback from suppliers or other interested parties) carried out since the last review, and attainment of objectives and performance criteria, followed by critical evaluation of procedures put in place to manage the design

process. The review process will identify, for example, any unworkable or onerous management procedures and suggested improvements.

Reviews are normally carried out by management, including top management, and appropriate management system technical staff.

3.6.2. External assessment

3.6.2.1. External audit

An organization external to the design and development of a repository organization normally performs external audits which contribute to the following:

- Added assurance of the effectiveness of a management system by an independent body;
- Compliance to management system certification;
- Additional value through benchmarking and highlighting best practices in a management system.

3.6.2.2. Peer review

Peer review is a documented review of work that is often conducted when the material (such as design output) being reviewed is subject to standard review methods, or when there is a high degree of uncertainty or uniqueness associated with the concept being evaluated.

The purpose of peer review in the design control process is to assure that an in-depth assessment of assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific design input are technically adequate, competently performed, properly documented, and satisfy established technical and management system requirements.

The peer review process may encompass all design basis stages of a planned repository, including conceptual, basic and detailed design stages. Peer review may also be applied to verification activities associated with repository design, operation, and maintenance, monitoring of performance, improvement and closure.

Peer reviews can provide an evaluation of a subject for which quantitative methods of analysis or measures of success are unavailable or undefined.

They are normally conducted by competent individuals and/or organizations independent of those which performed the work, and which are collectively as competent (for example, peers) as those who performed the original work.

3.7. CONTROL OF NON-CONFORMITY

Non-conformities may occur and be detected at any stage of any process in the design and development of disposal facilities. Control of non-conformance, for example in design output, may involve one or more of the following actions:

- Recording of the non-conformity with reference to the document (standard, code, procedure, safety case, etc.), prescribing the requirements, preferably detailing all sections in the document applicable to the non-conformity;
- Identifying, segregating or withdrawing a non-conforming design element or document;
- Precluding intended original use of a non-conforming design element or document;
- Correcting or eliminating the non-conformity, or authorizing its use, or accepting it as an exception or concession.

3.8. ANALYSIS OF DATA

Data is collected and analysed to determine performance against repository safety case and management system objectives. This data can also be used to demonstrate the suitability and effectiveness of a management system and to identify areas of improvement. A specific feature of radioactive waste repositories is their long life cycle. During this period, data should enable future generation to re-evaluate a disposal system and its design if necessary. This is quite straightforward for near surface disposal facilities or pilot/test phases sometimes proposed in the case of underground disposal. Relevant data are obtained from the following:

- Results of monitoring and measurement;
- Results from assessments;
- Refinements in inputs to processes;
- New statutory and regulatory requirements;
- Technological advances;
- International experience at other repositories;
- Material advances in containment barriers;
- Developments in waste encapsulation processes.

For geological repositories involving much longer time scales, information and knowledge preservation and transfer are also activities which need to be carefully defined and implemented over time. However, there is no practical experience available at this stage.

3.9. CONTINUAL IMPROVEMENT

A repository organization continually seeks to improve processes, output from processes (such as design output and repository performance) and the effectiveness of a management system. Continual improvement may originate from any of the following:

- Analysis of data;
- Management system policy and objectives;
- Corrective and preventive actions, audit results and management review;
- Regulatory authority communications.

3.10. CORRECTIVE ACTION

Corrective actions are taken to eliminate the cause of non-conformances in order to prevent recurrences and to serve as a tool for improvement. The following are examples of controls that may be implemented:

- Review of a non-conforming design element;
- Determination of the cause of a non-conformity;
- Determination and implementation of actions required to prevent recurrence of a non-conformity;
- Recording of the results of actions taken;
- Review of the results of actions taken to close out a corrective action.

3.11. PREVENTIVE ACTION

Preventive actions are taken to address root causes of potential non-conformances and to prevent recurrences. The 'doing the job right the first time' philosophy is a goal, since failure to prevent non-conformances generally results in corrective actions that are expensive or difficult to implement. Sources of information that can be of use in developing preventive actions may include, for example:

- Results of audits and assessments;
- Output from data analysis;
- Results of monitoring (environmental, structural, etc.), particularly with respect to the gradual development of trends;
- Changes in the nature or characteristics of radioactive waste and/or containment material properties;
- Observations concerning, for example, changes in the frequency, magnitude, etc. of parameters and characteristics used in safety assessments or repository design and development processes (such as the corrosion rate of repository metallic components).

A written procedure is typically prepared, addressing potential non-conformities and their causes, including an evaluation of what should be done to prevent the recurrence of potential non-conformities, determination and implementation of actions needed, documentation of the results of action taken, and review of actions taken for closing out.

4. APPLICATION OF A MANAGEMENT SYSTEM TO REPOSITORY DESIGN AND DEVELOPMENT

The design and development of any repository is truly an interdisciplinary activity, comprising a range of technical and management issues. The life cycle of a near surface repository can already extend over hundreds of years and that of a geological repository over hundreds of thousands of years. Unlike other nuclear facilities, there are many issues unique to disposal facilities which require special consideration in the development and application of an effective management system that is applicable to a repository development project. These include the following:

- Containment of radioactive waste is required for an extended period of time (from 300 years for near surface disposal, and up to ten times longer for the direct disposal of spent fuel);
- The design lifetime, as well as performance and safety objectives of a repository, are far larger than those of a nuclear reactor;
- The long term nature of disposal means that a disposal facility will likely be controlled through a series of different organizational and management systems. This requires proper planning and maintenance of continuous and consistent management oversight;
- Ownership of waste and the transfer of responsibility for waste to disposal organizations and the attendant costs need to be well defined and established;
- Resources, including funds and organizational arrangements for waste disposal, need to be put in place during the initial planning stages and maintained, without interruption, over the entire repository life cycle;
- Given public sensitivity regarding the long term nature and radiological content of disposal operations, particular attention needs to be given to: (a) maintaining public confidence in the sustainability of continuous management supervision; (b) establishing confidence in the technical viability of a disposal system's long term performance, and; (c) establishing funding arrangements and assuring continuous monitoring and control of disposed wastes;
- Given the long term nature of disposal operations, particular attention needs to be paid to preserving records during the entire repository life cycle and established mechanisms for the transfer of records to other organizations are required;
- The potential for inadvertent human intrusion into disposal facilities during the life cycle of a facility needs to be considered;
- Repository development may rely on an iterative process between operation, design, and research and development (R&D) to optimize performance and safety of a disposal concept. In addition, uncertainties may affect some parameters used in design input;

- Authenticity, assumptions and the measurement uncertainty of data must be assessed prior to design process input;
- A closed repository must stay under long term institutional control, rather than being subject to decommissioning with the release of property for other uses;
- The evolution of long term events and processes (such as population growth, degradation of repository components, etc.) with the potential of affecting repository performance and safety needs to be taken into consideration;
- The performance and safety of a repository may rely on passive monitoring systems;
- Large uncertainties in design and safety assessment input parameters (such as the durability and lifetime of engineered barrier materials and concentrations of difficult to measure radionuclides) need to be taken into account;
- Since provisions need to be made to monitor the performance of a repository into the post-closure phase, special controls are typically required for information management systems, record preservation and retrievability, as well as for the transfer of a repository to future organizations or management structures;
- Advances in radioactive waste treatment and disposal technologies may indicate that design changes need to be considered carefully with time which, in the case of near surface facilities, may lead to repository upgrading during the operational phase;
- Changes in legislative, regulatory and statutory requirements may directly impact on design and development processes during a repository life cycle;
- Transparency and availability of information to various stakeholders, as well as public involvement (including open door events and meetings with the public or public representatives) during the life cycle of the repository and in the post-closure phase, may need to be accommodated in the design and development process, depending on the experience of individual Member States.

4.1. REPOSITORY DESIGN AND DEVELOPMENT

The design and development process starts with the compilation of design inputs and culminates with the production of design outputs (such as products), which are then transferred and used in subsequent stages of the repository development process. All stages of the design process are subject to design control to ensure the quality of design input, design process and design output. Both design input and output have to be verified, validated and approved before use in subsequent stages of the design process.

A schematic view of the repository development process is presented in Fig. 3 (numbers in boxes indicate various activities) and an example of the design process, applied to a near surface repository in the vadose zone, is presented in Fig. 4.

The development process starts with provisions by various organizations/stakeholders (1) of input information (Fig. 3). The input information (2) is used to sequentially develop conceptual designs (3), basic engineering designs (4), and detailed engineering designs (5). Throughout this process, the outputs (8) are reviewed from a safety and related management system perspective (7). These reviews examine the designs to ascertain the likelihood of release of radionuclides from a repository. If a design does not meet safety objectives, it may have to be modified (for example, additional or enhanced engineered barriers built and/or a reduction in waste loading) to be compliant.

A design is complete when the output (6) has been verified and validated (including expert judgment and, if appropriate, peer review) (8) and approved before use; the drawings and specifications (5) are meant to be provided to the relevant people and organizations (9) for use. After construction and operation (10), the monitoring and measurements taken during operation and after closure provide information (11) which can be used to modify aspects of the design.

Close coordination between those involved in the design process is ensured through a communication plan. This plan could detail what input, output and general information is transmitted to whom for information, action or participation. In certain cases, the inclusion of this plan in a management system plan may be sufficient to meet a Member State's requirements.

The management and support processes shown in Fig. 3 support the design and development process in the remainder of this section.

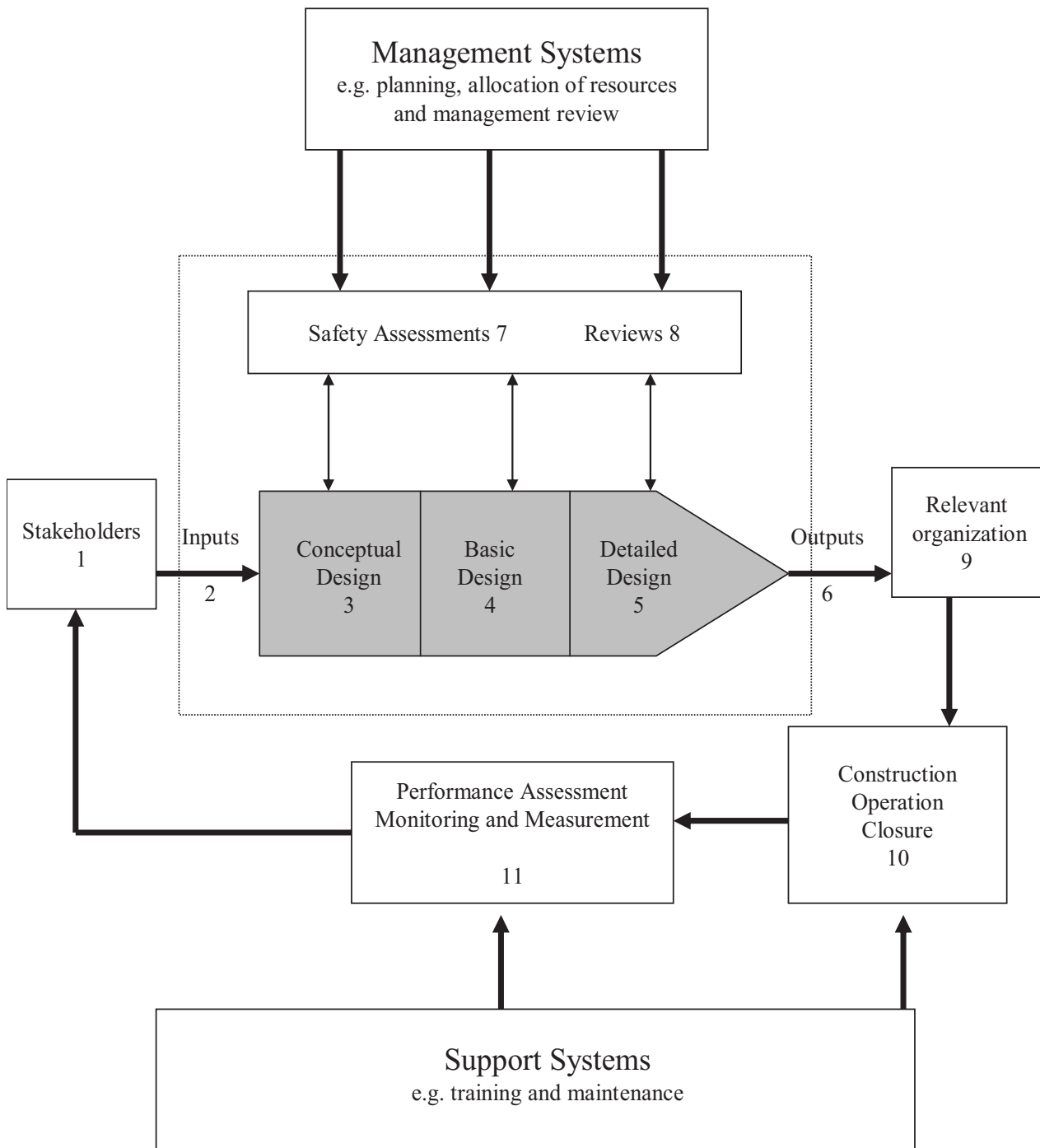


FIG. 3. The repository design and development process.

The design control process addresses all factors that can affect the quality of design processes. The elements of the process can be contained in a design control programme, which:

- Describes measures taken to ensure the adequacy of verification or checking of design, such as design review, use of alternative calculation methods, or of qualification and testing performance;
- Prescribes communication channels and identifies the positions or organizations responsible for design verification or checking;
- Describes measures ensuring that independent verification/checking is performed by individuals/groups other than those originally responsible for the design.

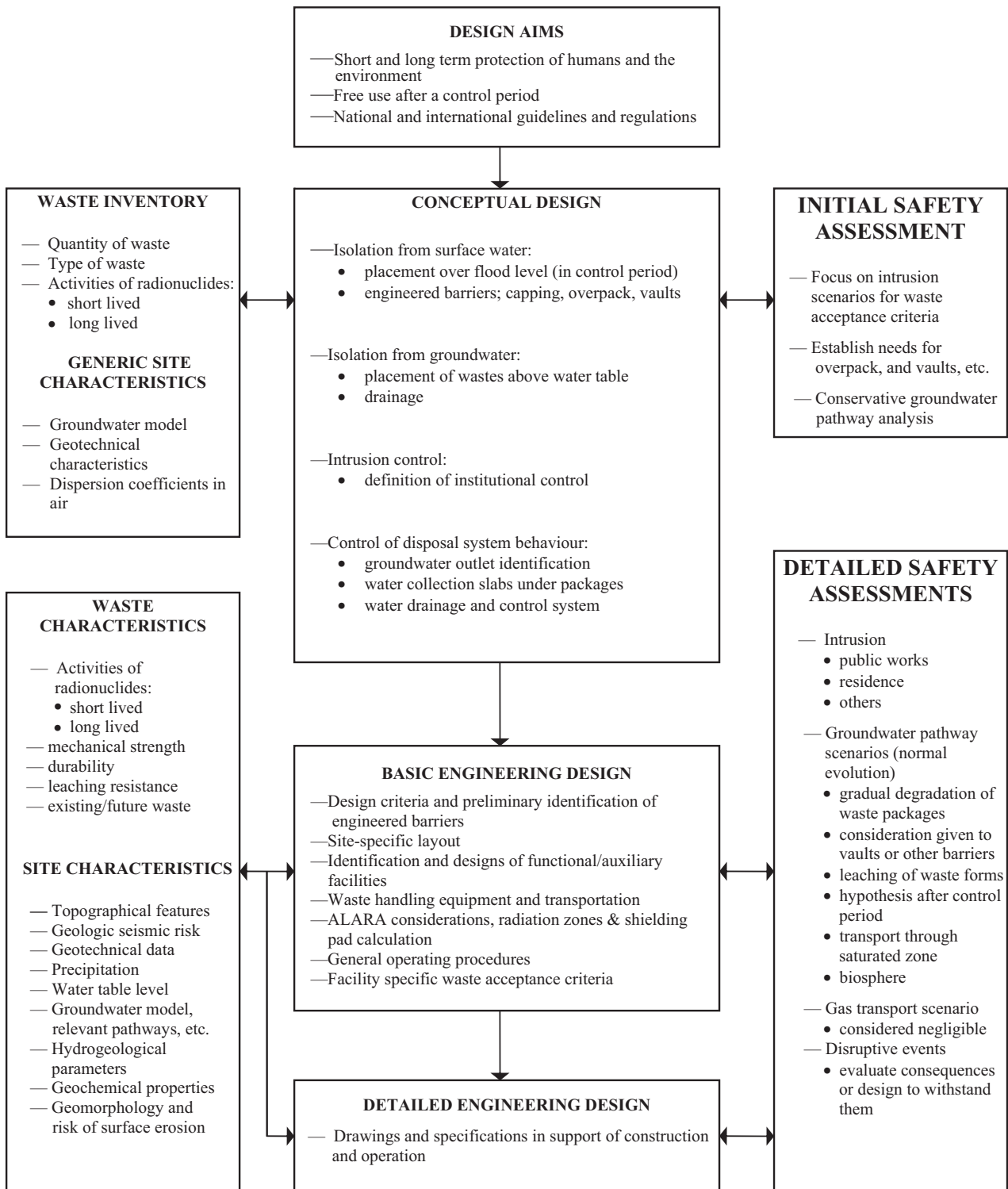


FIG. 4. Example of the design process applied to a near surface disposal facility in the unsaturated zone.

Design control documentation is implemented before design work starts. This includes measures to ensure that requirements contained in governing documents are correctly translated into design documents (such as drawings, procedures or instructions).

A graded approach in the application of design control is more effective and can provide confidence in the quality of a design (or its part) commensurate with the item's importance to meeting pre-defined performance objectives.

Computer software, used to calculate or develop data in support of a design process, needs to be adequate for the purpose or validated. Changes to computer software are systematically evaluated, coordinated, and approved to ensure that the impact of a change is assessed before updating a baseline.

Software design verification includes confirming the numerical accuracy of computations and the accuracy of data input to computer codes and confirming that the correct computer codes have been used as part of design validation. Software design verification is performed by an independent individual/group with the same (or greater) level of competence than those originally involved.

4.2. GRADING

The responsible organization needs to identify the relative importance of the various activities, facilities and equipment to meeting overall safety, health, environmental, security, quality and socio-economic requirements. Resources can then be selectively allocated and processes selectively designed to control activities, facilities and equipment adequately, effectively and efficiently. Controls will vary for different disposal facilities and activities.

Grading the application of management system requirements [32, 33] reflects the relative importance of meeting the performance objectives and technical requirements of each component, service and/or process associated with a repository development project. For example, if a component or activity is identified as critical to the performance and safety of a repository in a safety assessment (for example, one which ensures the prevention of accidents or mitigation of accident consequences, resulting in the protection of workers, the public and the environment from undue radiation hazards), then extensive management system controls are applied. Conversely, components or activities with minor safety implications require only limited management system controls.

A management system procedure is used to prescribe how and which items and activities need to be graded and the levels of control required. This grading provides important input into the design process.

The main objective during the life cycle of a repository is to reach safety objectives and therefore safety features of activities, processes, facilities and equipment are directed at reaching the highest level in the grading process. Considerations regarding equipment failure or non-conforming activities which pose a health and safety risk to repository personnel and the public are important in a grading process driven by repository safety. Another consideration is identification of critical aspects of activities, processes, facilities and equipment.

As an example, in the case of near surface disposal facilities a higher grading level is typically granted for the following:

- Engineered barriers for the retention of radionuclides and/or prevention of human intrusion, which are required to perform through to the planned post-closure phase;
- Treatment and characterization of radioactive waste prior to the storage. This treatment can be undertaken by the waste producers or by the disposal facilities through activities related to waste acceptance (classification and characterization of materials and radioactive waste);
- Dose control and shielding requirements in place during the operational phase.

Grading can also be applied in following areas:

- Activities undertaken during concept development, design, development and preparation of specifications of new processes, facilities and equipment modifications thereto with a nuclear safety or radiological protection function;
- Activities related to the performance of radioactive products or waste processes at the site;
- Activities related to radiological and environmental monitoring;
- Activities related to the management of releases (including radioactive liquids or gases and non-radioactive waste);

- Activities related to radiological, operational and occupational health and safety (such as decontamination, cleanliness, disassembly, dismantlement of active parts and systems that assure the confinement of radioactive pollution by limiting its dispersion);
- Activities related to the design, maintenance and reconstruction of buildings and other repository structures;
- Regulatory and licensing requirements;
- Stakeholder requirements;
- Level of technological development of a component or activity;
- Difficulty in repairing or replacing of components;
- Stage of element design (conceptual, basic or detailed);
- Level of complexity, uncertainty, operational importance and demonstrated performance.

After a grading classification has been made, the level of controls and requirements to be applied to each classification level is defined. Generally, several graduations will be established in connection with a greater or lesser relationship to safety and the expected efficiency of the storage system. Once established, a regulation to be fulfilled is assigned to each level and a level of control is assigned to each activity or component.

Examples of design activities that could be graded include:

- Verification and validation of input data;
- Design analysis;
- Design review and approval;
- Controls applied to design change;
- Records control;
- Interface control.

4.3. DESIGN AND DEVELOPMENT PLANNING

The design process is managed by establishing a design plan. This plan lists and describes major activities throughout the design process, for example:

- Definition of planned design activities;
- Design stages (including conceptual, basic, detailed);
- Schedule, critical paths and milestones for planned activities;
- Responsibilities for design activities;
- Interfaces between organizations and activities;
- Identification of expected outputs and their intended use;
- Resources required (for example, the number of engineers and draftsmen);
- Verification and validation procedures and methods;
- Assessment processes.

A design plan should be documented, approved and revised, as necessary.

4.4. DESIGN AND DEVELOPMENT INPUT

The types of inputs typically utilized in the design and development of a repository are provided in Figs 3 and 4. It is important that the input used in a design and development process be subjected to rigorous management system controls through verification, validation and review of input data on site and waste characteristics.

In addition to the inputs provided in Fig. 4, the following may also be considered as inputs:

- Regulatory requirements, standards and codes;
- Information from other repositories of a similar type (regarding monitoring, safety assessment, operational performance and construction);

- Requirements for the institutional control period;
- Risk levels and factors;
- Operational performance (including containment integrity, radionuclide releases and doses);
- Socioeconomic factors;
- Long term disposal options.

4.5. DESIGN AND DEVELOPMENT OUTPUT

Design output needs to be documented. Output is prepared to allow for verification in comparison for specified requirements in design inputs, and validated for use in meeting design objectives (see also the sections which follow).

Design output documentation includes, where applicable:

- Identification of design elements (including facilities for waste receipt, assay, transport, decontamination, conditioning, packaging and emplacement);
- Definition of design analysis objectives (including ensuring the safety of workers and the public);
- Definition of design analysis results (for example, those relating to groundwater transport, gaseous transport, human intrusion and natural events);
- Input information traceable to the source of information (such as waste characteristics including volumes and activity, and waste acceptance criteria);
- Records demonstrating traceability to the data, material and calculations used in the design process (waste generator information);
- Identification of the assumptions (including risk factors) used in the design, and confirmation that these were verified in subsequent design stages;
- Information on all computer calculations, including the identification, validation/verification of software, outputs and results;
- Criteria established for the acceptance of design elements;
- Approvals and revision history of design documentation;
- Identification of critical repository safety components and activities for use in establishing priorities in other project stages.

Procedures are established to define and describe the content and format of design output documents. One approach to addressing this requirement involves establishing standard types of design output documents, for example:

- Drawing, specification, instruction and component lists;
- Specific design reports;
- Functional descriptions of each phase in a repository's life cycle;
- Design assessment reports;
- Environmental impact assessments;
- Preliminary safety analysis reports;
- Final safety analysis reports;
- Waste acceptance criteria;
- Land use restrictions.

To ensure that design outputs can be utilized, they need to be:

- Understandable; for example, a design organization may select documentation styles and formats to accommodate potential users of such documents;
- Archived in such a manner that documentation supporting design outputs is readily accessible throughout a repository's life cycle, including the post-closure institutional control period;
- Formally distributed to necessary users and relevant interested parties.

All of these aspects can be incorporated in a procedural document for design and development control, which covers other documentation generated throughout the design process.

4.6. SAFETY ASSESSMENT

Safety assessment is part of a larger iterative process which also involves waste inventory, design and site characterization. Safety assessment covers the whole life cycle of a repository, including the post-closure phase. Site knowledge, facility design and safety arguments should be refined iteratively to establish a robust safety case and well founded technical specifications.

In managing the development of a design (or changes in a design) for a disposal facility, it should be recognized that this will be associated with the concurrent development of a safety assessment, and that the processes involving design and safety assessment will be iterative. An appropriate safety assessment is a basic part of a design and development review, verification and validation. A specific role is granted to safety assessments in justification of upgrading activities.

The design safety assessment cycle is usually repeated several times until a coherent set of overall facility design specifications and an associated safety assessment are obtained to guide the detailed design development of a facility.

Accordingly, within the IAEA organized coordinated research project (CRP) on Improvement of Safety Assessment Methodologies for Near Surface Disposal Facilities: A Harmonized Iterative Methodology (ISAM methodology [55]) was developed to carry out post-closure safety assessments. The ISAM methodology gained widespread acceptance. Over the life cycle of a disposal facility (not only in the pre-operational phases), a safety assessment should be periodically reviewed in a systematic and planned manner in connection with the accumulation and analyses of data coming from design processes and later from regular monitoring and other sources.

4.7. DESIGN AND DEVELOPMENT REVIEWS

The objective of design reviews is to provide assurance that design output results are able to meet requirements, or uncover whether changes or improvements need to be made.

Documents may be reviewed by members of the design team, the end user (repository operator) and/or by those managing the overall project, as well as national or international experts (peers) if appropriate, to ensure that the context of the work has been correctly interpreted and that results are presented in a usable form.

The results of design reviews are reported to the designer for action or as design input.

4.8. DESIGN AND DEVELOPMENT VERIFICATION

Design verification is a process intended to provide assurance that all design input requirements have been met by the design output. This verification is completed before a design output is used. Design verification needs to be independently performed by persons other than those involved in the design process based on access to all required design information.

Once a design is verified, it is not necessary to repeat the verification process for identical designs. Design modifications are verified and their impacts on the original design determined.

Results of a verification, and any necessary actions, are recorded.

4.9. DESIGN AND DEVELOPMENT VALIDATION

Validation is performed to ensure that a design output is capable of meeting requirements for its intended use.

Experimental tests to provide confidence in demonstrating the capability of a design output to meet performance objectives may be conducted.

Some examples of validation are:

- Demonstrating that concrete can survive a seismic event of a specified magnitude;
- Conducting accelerated testing (such as weathering) of concrete;
- Independent performance assessment modelling;
- Creating natural and anthropogenic analogues;
- Conducting prototype demonstrations;
- Undertaking field demonstrations.

After repository construction, and during the commissioning stage, a final design validation may be performed.

When theoretical models are used to predict repository behaviour, the results are typically validated to confirm the applicability of the models used.

4.10. DESIGN CHANGE CONTROL

Design change is an essential part of the design process to be controlled.

Procedures are established, assigning responsibilities for reviewing, approving, and controlling the implementation of design changes.

Consideration is given to the impact of design changes and their consequences or influences on other areas of design. Design changes need to be effectively communicated to all involved organizational units.

When design changes are made, reasons for the changes must be clearly established and documented.

Design changes are typically reviewed and approved by:

- The organization responsible for the original design;
- Other organizations with proven competence in the specific design area with access to the original design requirements;
- The governing regulatory body.

5. APPLICATION OF MANAGEMENT SYSTEMS TO A REPOSITORY PROJECT

Guidelines for the application of management system principles and requirements to projects are provided in ISO 10006: 2003 [37]. A project for the construction or upgrading of a repository may be divided into interrelated and interdependent processes as part of its planning and management. It is necessary to clearly define and link project processes, so they can be integrated and managed as a system. The same management system principles and practices as outlined in Section 3 can be applied, as they are relevant to the project's management system.

Some specific applications of a management system to a repository project (construction) are presented below.

5.1. MANAGEMENT RESPONSIBILITY FOR PROJECT ORGANIZATION

A project organization may be a separate from or part of a repository's organization. Project organizational structure will be appropriately designed to ensure effective and efficient communication and cooperation between all participants of a project. Management commitment on behalf of a project organization, stakeholder and participant involvement in a project, and development of a management system plan for establishing and implementing management system requirements for project management processes will be drawn up along the same management system practices as provided in Section 3.2.

5.2. PROJECT DOCUMENTATION

The project organization should establish its own document and record management system or use those established by the repository organization. Specific requirements for a document and record management system (see Section 3.3) need to be incorporated in the document and record procedures of a project organization.

5.3. PROJECT RESOURCE MANAGEMENT

Resources needed for a project should be identified and, when they would be required, constraints on resources such as radiological safety considerations should be documented in a resource plan. Resources should be managed (see Section 3.4) and controlled to ensure that enough are available and that deviations are identified and acted upon.

For effective project management, project team members should participate in team development activities and be provided with the background specifications of radiological safety and repository operation.

5.4. PROJECT MANAGEMENT REVIEWS AND PROGRESS EVALUATIONS

A project organization's management should review the project's management system at planned intervals to ensure continuing effectiveness (see Section 3.6.1.2). The project's management system should be periodically subject to self-assessment and a management system audit in accordance with the management system practices provided in Section 3.6.1.1.

Progress evaluations should cover all project processes and will provide information on the attainment of milestones and objectives during construction or upgrading of a project. Progress evaluations can provide valuable information on project performance and should cover:

- An assessment of the project management plan's adequacy and how work performed complies with it;
- Identification and evaluation of how well project processes are interlinked;
- Identification and evaluation of activities and results that would adversely impact on the construction or upgrading of the project.

Progress evaluations should also be used to determine inputs for the remainder of a project's work, to facilitate effective communication and to drive process improvements in the project.

5.5. PROJECT MANAGEMENT PROCESSES

The construction of a new repository or upgrading of an existing repository should be managed as a project. Management of such a project will be achieved by considering all processes involved. Project management processes include planning, organizing, controlling, reporting and corrective actions.

One of the first requirements of a management system when initiating a project is development of a project management plan. A project management plan is an important document which should be prepared and regularly reviewed to specify and control which activities and processes are necessary for construction or upgrading of repository projects and should include:

- Reference to stakeholder requirements and a definition of project objectives;
- Identification of project processes;
- Identification of organizational interfaces;
- Integration of various plans from project processes, including a management system plan, work breakdown structure, project schedule, project budget, communication plan (with regulators, the local community and authorities, repository management, relevant government departments, subcontractors and experts), risk management plan (including lack of resources and social risks), and purchasing or subcontracting plans;

- Identification of repository characteristics and milestones and how attainment of these should be measured and assessed;
- Provision of a baseline for progress measurement;
- Definition of performance indicators for measurement;
- Provision of a progress review regarding repository construction or upgrading;
- Provision of regular reviews for the project management plan.

More specifically, the following processes can be identified:

- *Interface management between various stakeholders, the regulator, the repository organization and the project organization:* Interface management can be accomplished by establishing procedures for its implementation through holding project meetings and by identifying interface problems during progress evaluations. Changes to be introduced to the project scope or during construction or upgrading of a repository should be identified, evaluated, documented and implemented. All such changes should be controlled by, for example, a configuration management system.
- *Determining the scope of the construction or upgrading project based on the design and development phase of a repository:* Output from repository design and development (see Section 4.5) should be systematically structured into manageable activities, for example, through a documented work breakdown structure. Activities taking place during construction and upgrading should be clearly defined so that results are measurable. During project execution, activities are controlled by a project management plan, which should include reviews and evaluations to identify potential deficiencies and opportunities for improvement.
- *Planning of activities, estimation of duration, schedule development and schedule control:* The project organization should carry out regular scheduling reviews at intervals, as defined in the project management plan. The repository organization should be informed of variances from the schedule and any remedial action taken.
- Cost estimation, budgeting and cost control.
- *Communication planning, information management and communication control:* A documented communication plan should be established to ensure effective and appropriate communication. The communication plan should reference and define document and record management systems. Recorded information should indicate conditions prevailing at the time the activity was performed. All external and internal information relevant to construction or upgrading which may be of use during the long life span of a repository and in the post-closure period should be retained.
- *Risk identification, assessment, treatment and control:* Risks are identified at the initiation of a project, at progress evaluations and when variances or deviations are found which require significant decisions to be made. Risks impacting on the long term performance of a repository and on radiological health and safety should be documented, and a responsible person assigned to manage the risk. Solutions to eliminate or mitigate risks should be determined and verified for appropriateness. Throughout the construction or upgrading of a repository, a risk management plan and relevant risk reports (these could also form part of progress evaluation reports) should be prepared, in particular using the graded approach to repository equipment, facilities and processes (see Section 4.2).
- *Purchase planning, control and establishment of documentation requirements, supplier evaluation and contract control:* Suppliers should be selected and evaluated depending on the assigned management system level of a product. Purchasing should be controlled through the conducting of regular progress reviews, as well as through product quality assessments and product compliance to requirements. Thus, it is necessary that purchase documentation adequately describe a product, its characteristics and other applicable requirements which have to be met, and specify appropriate management system requirements which should be applied.
- *Improvement through measurement and analysis, corrective action, preventive action and loss prevention:* Measurement results and data analysis from project management processes should be used by a project and the repository organization to implement corrective action, preventive action and loss prevention. It should be ensured that measurement, collection and validation of data are effective in order to optimally contribute to improvements during the construction or upgrading of a repository. Data and the results of measurements can be obtained from an evaluation of individual activities and processes, auditing, product evaluation, supplier performance and project progress review and evaluations. The management system practices provided in Sections 3.9–3.11 can be applied to implement improvements during the construction and upgrading of a project.

6. APPLICATION OF A MANAGEMENT SYSTEM TO A REPOSITORY OPERATION

In all repository processes it is necessary to apply management system requirements to repository operational processes. Few management system processes differ from what has been described for previous development stages. Specific requirements for repository operation are mainly related to:

- Repository organization;
- Implementation and control of processes;
- Control of products;
- Control of purchasing.

For geological repositories, more requirements need to be fulfilled, namely those in connection with radiation protection and safeguards but which can be considered to belong to the repository organization and/or the implementation and control of processes.

6.1. REPOSITORY ORGANIZATION

Personnel performing operations should be adequately trained, appropriately qualified (see Section 3.4) and meet all regulatory requirements prior to performing tasks. The people or organization in charge of management systems should be independent of those who have direct responsibility for the work. During the operational phase of a repository, the responsible organization should remain as stable as possible and the responsibilities, authorities, lines of communication and organizational structure should be described and documented (for example, in an organizational manual). In the event that a repository operation is — even partially — subcontracted, the overall responsibility for compliance to requirements will remain with the repository organization.

6.2. IMPLEMENTATION AND CONTROL OF PROCESSES

Processes required for repository operations, including management system processes, key processes (such as processes for the maintenance and monitoring of barriers and for radiological protection) should be identified, and an interaction sequence determined. For each process, applicable regulatory requirements for safety and environmental control and process operations need to be established according to the chosen grading level, which should be documented and approved for use in the process.

6.3. CONTROL OF PRODUCTS

Prior to use, product compliance to requirements should be established via inspection, testing, or verification. The control level to be applied to each process, activity or item should be analysed based on a graded approach for process activities or items, taking into account regulatory requirements, methods and documented instruction. Analysis results will determine the type of control needed, its frequency and which organization is responsible for carrying it out. This information should be documented in a process control plan. Products from repository processes should be verified in relation to compliance with requirements prior to use (additional engineered barriers should be checked regarding compliance to specification requirements prior to use). If the result of a process cannot subsequently be fully verified, then the process should be validated. For some validated processes, operators should be qualified to ensure consistency and compliance with process requirements.

6.4. CONTROL OF PURCHASING

Suppliers will be selected depending on the assigned management system level according to the graded approach (see Section 4.2):

- Products with the highest grading level will require an audit of the supplier to establish the effectiveness of the supplier's management system in order to provide added assurance of compliance to product requirements;
- For other products requiring the assurance of a management system level, suppliers with approved or certified management systems, or calibration and approved or accredited test laboratories should be selected;
- For off-shelf or commercial grade items it is not necessary to perform a supply evaluation;
- If a sole supplier of a product does not have a documented management system, increased surveillance activities should be performed by the repository organization during the product provision process.

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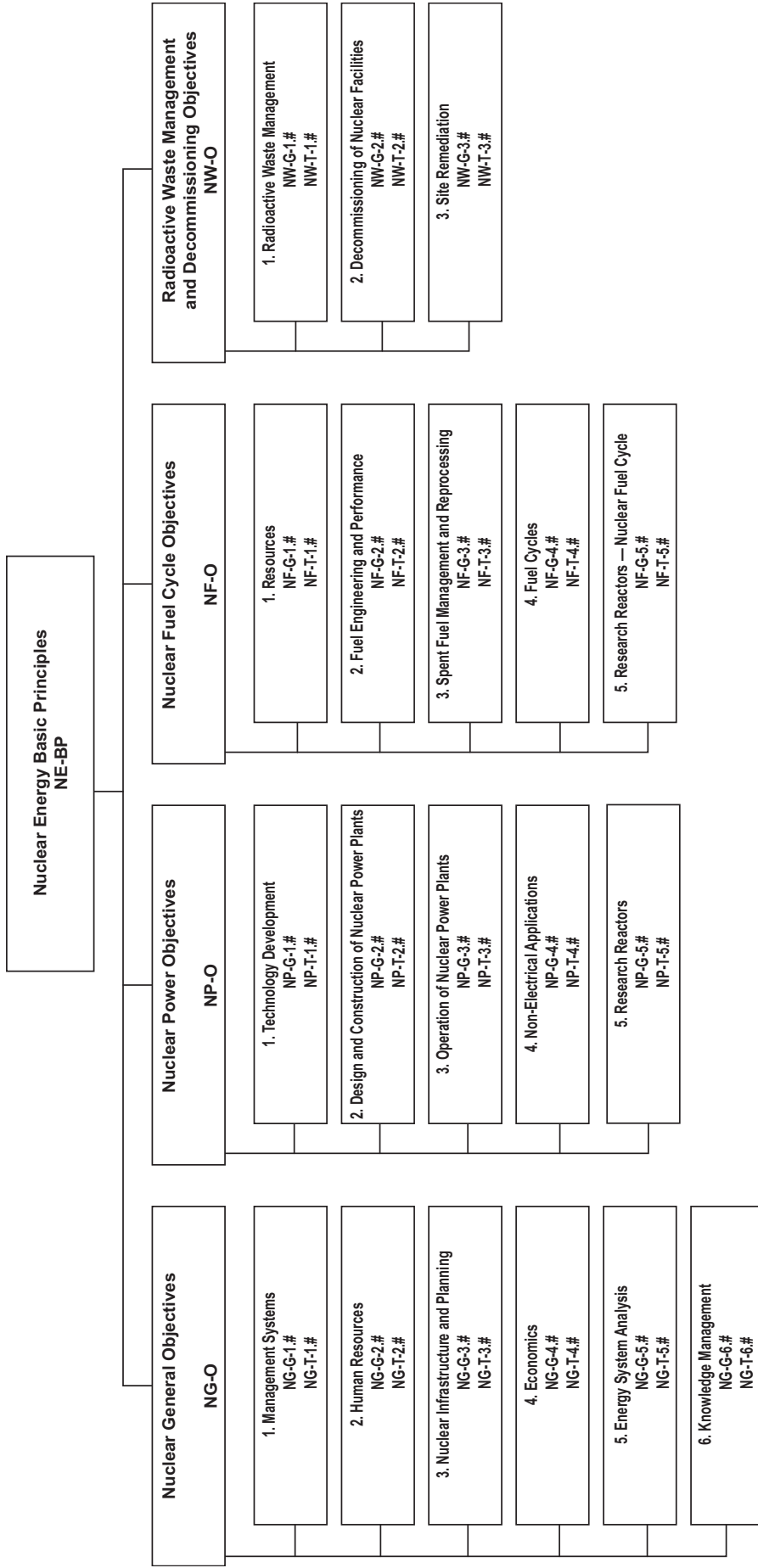
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