IAEA Safety Standards

for protecting people and the environment

The Management System for the Disposal of Radioactive Waste

Safety Guide

No. GS-G-3.4

IAEA
International Atomic Energy Agency

THE MANAGEMENT SYSTEM FOR THE DISPOSAL OF RADIOACTIVE WASTE

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

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THE MANAGEMENT SYSTEM FOR THE DISPOSAL OF RADIOACTIVE WASTE

SAFETY GUIDE

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FOREWORD

by Mohamed ElBaradei
Director General

The IAEA's Statute authorizes the Agency to establish safety standards to protect health and minimize danger to life and property — standards which the IAEA must use in its own operations, and which a State can apply by means of its regulatory provisions for nuclear and radiation safety. A comprehensive body of safety standards under regular review, together with the IAEA's assistance in their application, has become a key element in a global safety regime.

In the mid-1990s, a major overhaul of the IAEA's safety standards programme was initiated, with a revised oversight committee structure and a systematic approach to updating the entire corpus of standards. The new standards that have resulted are of a high calibre and reflect best practices in Member States. With the assistance of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its safety standards.

Safety standards are only effective, however, if they are properly applied in practice. The IAEA's safety services — which range in scope from engineering safety, operational safety, and radiation, transport and waste safety to regulatory matters and safety culture in organizations — assist Member States in applying the standards and appraise their effectiveness. These safety services enable valuable insights to be shared and I continue to urge all Member States to make use of them.

Regulating nuclear and radiation safety is a national responsibility, and many Member States have decided to adopt the IAEA's safety standards for use in their national regulations. For the Contracting Parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment of obligations under the conventions. The standards are also applied by designers, manufacturers and operators around the world to enhance nuclear and radiation safety in power generation, medicine, industry, agriculture, research and education.

The IAEA takes seriously the enduring challenge for users and regulators everywhere: that of ensuring a high level of safety in the use of nuclear materials and radiation sources around the world. Their continuing utilization for the benefit of humankind must be managed in a safe manner, and the IAEA safety standards are designed to facilitate the achievement of that goal.

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1. INTRODUCTION

BACKGROUND

1.1. Radioactive waste (referred to in this Safety Guide as waste) must be managed in such a way as to avoid imposing an undue burden on future generations; that is, the generations that produce the waste have to seek and apply safe, practicable and environmentally acceptable solutions for its long term management (Ref. [1], para. 3.29). Management systems play an important role in applying such solutions, and should be implemented for all stages of waste management, from waste generation to waste disposal. Management systems for the disposal of radioactive waste are subject to the requirements established in Ref. [2]. Recommendations on meeting these requirements are presented in this Safety Guide and in Ref. [3].

1.2. This Safety Guide uses the term 'management system' instead of 'quality assurance'. The term management system reflects and includes the evolution in the approach from the initial concept of 'quality control' (controlling the quality of products) through 'quality assurance' (the system to ensure the quality of products) and 'quality management' (the system to manage quality). The management system is the set of interrelated or interacting elements that establishes policies and objectives and that enables those objectives to be achieved in a safe, efficient and effective way. The requirements for the management system established in Ref. [2] and the recommendations in the accompanying Safety Guide, Application of the Management System for Facilities and Activities [3], supersede the earlier code on quality assurance[1].

1.3. A management system should be used to ensure that adequate measures are in place to address technical issues relating to safety, protection of health, protection of the environment, security, quality and economics. Solutions to technical problems are provided by means of such processes as design and research and development, which are controlled by the management system. The management, in the management system:

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations, Code and Safety Guides Q1–Q14, Safety Series No. 50-C/SG-Q, IAEA, Vienna (1996).

(a) Should recognize the need to specify when activities in such processes are required to be conducted;
(b) Should require the scope of the activities to be carefully defined;
(c) Should require the activities to be carried out carefully;
(d) Should require the results to be evaluated and taken into account appropriately.

Technical issues may also have to be addressed so that managerial functions such as independent verification and checking may be carried out.

1.4. Disposal of radioactive waste involves a variety of technical and managerial activities, and may extend over a very long time (potentially hundreds of years). These characteristics present a series of challenges to the development and implementation of effective management systems for facilities and activities for waste disposal. The following aspects warrant particular consideration in developing a management system for programmes for waste disposal:

(a) By definition, waste is material for which no further use is foreseen. The provision of funds and the organizational arrangements to dispose of waste could be given inadequate attention if they were to become decoupled from the benefits drawn from the activity that generates the waste. The organization and funding of the necessary eventual waste disposal could be much more difficult to put into place later.
(b) Waste can be managed safely on an interim basis, in many cases for extended periods. As a consequence, the implementation of waste disposal may be postponed by a series of short term deferrals for additional assessment of the options.
(c) Under the 'polluter pays' principle, the organization that generates the waste is responsible for ensuring that the waste is managed properly. In some jurisdictions, ownership (and hence ultimate responsibility) for waste is transferred when the waste changes hands. In other jurisdictions, waste always remains the responsibility of the original generator. Care should be taken to keep the responsibility clear and fulfilled at all times.
(d) Public and political sensitivities to decisions about the disposal of radioactive waste can impose constraints on the waste disposal arrangements, timings and technical decisions that are feasible.
(e) Management systems for all waste management activities should encourage the adoption of unified approaches and solutions and international best practices because of the need to ensure continuity

between successive human generations, and the uncertainty in the long term of organizational, national and international structures.

(f) The organizations involved in waste management may be publicly or privately owned, or a combination of both. The respective interests, driving factors and responsibilities of different types of organization may present challenges in harmonizing them into a coherent overall management system for a waste management programme. Whatever the arrangements are, safety and environmental protection should always be paramount.

(g) The long term nature of waste disposal means that particular attention should be paid to:
  (i) Maintaining public confidence that management supervision will be continuous;
  (ii) Establishing confidence that the long term performance of the waste disposal facility will meet the requirements;
  (iii) Estimating costs and establishing the funding arrangements that will be necessary to continue to monitor and control the waste disposal system until active institutional control ceases;
  (iv) Ensuring continuity of understanding, attention and resourcing from one human generation to the next.

1.5. One particular aspect to consider when developing management systems for geological disposal facilities for radioactive waste is that, after the termination of active institutional control in the post-closure phase, safety and environmental protection will depend on a passive system, primarily the geosphere (i.e. intervention and maintenance are neither planned nor required). In addition to providing a protected, stable environment for the engineered barriers in the short term, the geosphere continues to provide isolation of the waste long after the engineered barriers degrade. This reliance on a geological system affects the development and implementation of the management system, in which the benefits of a stable geological system and the limited ability of humans to modify such a system must be recognized.

1.6. One aspect of the long term nature of all types of waste disposal is the unpredictability of the future behaviour of groups that may be affected by, or may have an impact on, the waste disposal facility; for example:

(a) Changes in lifestyle (e.g. the evolution from rural life to urban life, the extent of economic activity and exchanges of goods, and the resulting degree of self-sufficiency and reliance on local resources);

(b) The degree of technological development and the demand for resources, and hence the degree of interest in recovering buried or subterranean material and the ability to do so;
(c) The potential for the presence of subterranean material that should not be disturbed to be forgotten, leading to a potential for inadvertent intrusion into a waste repository.

1.7. In comparison with nuclear power plants and other nuclear facilities, the state of development of, and the amount of experience with, waste disposal facilities is more varied between the States concerned, and not as extensive and mature. For example, while various types of near surface waste disposal facility are in operation at present, no geological disposal facility for spent fuel or high level radioactive waste is yet operating. Thus, management systems for the siting, design, construction, operation, closure and post-closure phases of waste disposal facilities will have to be developed and improved as knowledge of the development of these facilities is accumulated in States. The accumulation of management knowledge in the organization, in industry and in regulatory bodies and in and among States is very important. In this regard, peer review is considered an effective and useful evaluation method for all stages of development of a waste disposal facility, especially for new endeavours such as geological disposal facilities for radioactive waste.

1.8. The long term nature of waste disposal means that a waste disposal facility will be managed by successive generations and may be controlled under a series of different organizations and management systems; this could present challenges to the maintenance of continuous and consistent management oversight.

1.9. This Safety Guide is issued as one of several IAEA safety standards that deal with management systems for the safety of facilities and activities. It provides recommendations on how to meet the requirements in Ref. [2] for waste disposal, and is supplementary to the general recommendations provided in Ref. [3]. This Safety Guide has a companion standard [4] that provides recommendations on the development of management systems for the processing, handling and storage of radioactive waste prior to its disposal. Application of these requirements and recommendations relating to the management system for waste disposal will contribute to a high level of confidence that the waste disposal facility and its contents will be of sufficient quality and will continue to comply with existing limits, controls and conditions important to safety and environmental protection. The management systems will enable the parties involved to judge the level of safety and environmental

protection provided by the waste disposal facility as new information is obtained regarding disposal. In addition to the careful management of the activities that directly determine the level of safety and environmental protection, those activities that are involved in assessing and demonstrating safety and environmental protection should be managed (e.g. on-site evaluation, facility design, environmental impact assessment, authorization processes, establishment of waste acceptance criteria, planned and systematic methods for waste inspection and emplacement, collection of operational data, facility monitoring and the use of surveillance systems). All these activities should be reflected in a comprehensive safety case, which will provide reliable arguments that can be made about the continuing level of safety and environmental protection provided by the facility and reliable evidence to support them. However, it should be recognized that the prime responsibility for properly executing a particular task (e.g. in design, in construction or in the operation of a waste disposal facility) rests with those who are assigned the task.

1.10. The management systems applied to meet requirements for the siting, design, construction, operation, closure and post-closure phases of waste disposal facilities all contribute to applying the fundamental safety principles established in Ref. [1]. Requirements for legal and governmental infrastructure are established in Ref. [5]. Other technical requirements and recommendations relating to facilities and activities for the disposal of radioactive waste are established in other IAEA safety related publications [6–11]. The basic requirements for radiation protection are established in Ref. [12] and the requirements for emergency preparedness and response in Ref. [13].

1.11. The development and maintenance of a safety culture in an organization is central to the management systems described in this Safety Guide. A management system should help rather than impede a waste management organization in achieving its objectives, fostering positive attitudes towards the management system and the safety culture it supports. The importance of a strong safety culture has been recognized by IAEA Member States.

1.12. The precepts of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [14] should be considered in developing management systems for waste disposal activities, to give due recognition to the international aspects of the waste disposal activities.

1.13. The management systems discussed in this Safety Guide are intended also to apply to the period of active institutional control in the post-closure phase, but this Safety Guide is mainly concerned with management systems to be implemented and used over the next few decades. Although the recommendations are generally applicable to management systems that may be applied in the extended times of the post-closure phase (e.g. thousands of years and further in the future in the case of passive institutional control for geological disposal of radioactive waste), the recommendations are not intended to be unduly prescriptive for these time periods in the future. Understanding and knowledge will continue to grow and should be managed continuously in the organization, the industry and the regulatory body, and in and among States. This Safety Guide will be revised in the light of knowledge and experience gained on new processes, technological developments, and changes in the skills and tasks of personnel, as well as other, unforeseen, changes.

OBJECTIVE

1.14. The objective of this Safety Guide is to provide recommendations on developing and implementing management systems for all phases of facilities for the disposal of radioactive waste and related activities.

SCOPE

1.15. This Safety Guide covers the management systems for managing the different stages of waste disposal facilities, such as:

(a) Siting, design and construction;
(b) Operation (i.e. the activities, which can extend over several decades, involving receipt of the waste product in its final packaging (if it is to be disposed of in packaged form), waste emplacement in the waste disposal facility, backfilling and sealing, and any subsequent period prior to closure);
(c) Closure;
(d) The period of institutional control (i.e. either active control — monitoring, surveillance and remediation; or passive control — restricted land use).

The management systems apply to various types of disposal facility for different categories of radioactive waste, such as:

(i) Near surface (for low level waste);
(ii) Geological (for low, intermediate and/or high level waste);
(iii) Boreholes (for sealed sources);
(iv) Surface impoundment (for mining and milling waste);
(v) Landfill (for very low level waste).

1.16. This Safety Guide also covers management systems for related processes and activities, such as:

(a) Extended monitoring and surveillance during the period of active institutional control in the post-closure phase;
(b) Safety and performance assessments and development of the safety case for the waste disposal facility;
(c) Regulatory authorization (e.g. licensing).

1.17. This Safety Guide is intended to be used by organizations that are directly involved in, or that regulate, the facilities and activities described in paras 1.15 and 1.16, and by the suppliers of nuclear safety related products that are required to meet some or all of the requirements established in Ref. [2]. It will also be useful to legislators and to members of the public and other parties interested in the nuclear industry.

STRUCTURE

1.18. This Safety Guide follows the structure of Ref. [2]. The key points for establishing a management system, including general considerations, safety culture, graded application of requirements and documentation of the management system, are discussed in Section 2. The roles and responsibilities of the management of an organization for the development and implementation of an effective management system are discussed in Section 3. Resource management, including the provision of financial resources, human resources and an infrastructure and working environment, is discussed in Section 4. Planning and control of the processes used for the specific activities of the organization, the control of documents and control of records, and the management of organizational change are discussed in Section 5. Section 6 addresses the measurement, assessment and improvement of the management system itself.

1.19. To aid the user, the corresponding requirements of Ref. [2] are quoted at the beginning of each section.

1.20. Appendix I provides recommendations on issues relating to the management system that are specific to the operation, closure and active institutional control phases of waste disposal facilities. Appendix II provides recommendations on issues relating to the management system that are specific to the design, testing and application of, and change control processes for, computer modelling that will be used in all phases of activities relating to waste disposal.

2. THE MANAGEMENT SYSTEM

GENERAL RECOMMENDATIONS

2.1. Reference [2] requires in paras 2.1–2.4 that:

> "2.1. A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:
>
> — Bringing together in a coherent manner all the requirements for managing the organization;
> — Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;
> — Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.
>
> "2.2. Safety shall be paramount within the management system, overriding all other demands.

"2.3. The management system shall identify and integrate with the requirements contained within this publication:

— The statutory and regulatory requirements of the Member State;
— Any requirements formally agreed with interested parties (also known as 'stakeholders'[7]);
— All other relevant IAEA Safety Requirements publications, such as those on emergency preparedness and response [13] and safety assessment [15];
— Requirements from other relevant codes and standards adopted for use by the organization.

"2.4. The organization shall be able to demonstrate the effective fulfilment of its management system requirements."

"[7] Stakeholder: interested party; concerned party. 'Stakeholder' means an interested party — whether a person or a company, etc. — with an interest or concern in ensuring the success of an organization, business, system, etc. To 'have a stake in' something figuratively means to have something to gain or lose by, or to have an interest in, the turn of events. The term stakeholder is used in a broad sense to mean a person or group having an interest in the performance of an organization. Those who can influence events may effectively become interested parties — whether their 'interest' is regarded as 'genuine' or not — in the sense that their views need to be considered. Interested parties have typically included the following: customers, owners, operators, employees, suppliers, partners, trade unions, the regulated industry or professionals; scientific bodies; governmental agencies or regulators (local, regional and national) whose responsibilities may cover nuclear energy; the media; the public (individuals, community groups and interest groups); and other States, especially neighbouring States that have entered into agreements providing for an exchange of information concerning possible transboundary impacts, or States involved in the export or import of certain technologies or materials."

2.2. This Safety Guide provides specific recommendations for meeting the requirements of Ref. [2] on establishing management systems suitable for waste disposal facilities and related activities. The development of the management system for an organization will also be influenced by:

(a) Internationally recognized standards such as ISO 9001:2000 [16] for quality management systems and ISO 14001:2004 [17] for environmental management systems[2];
(b) Guidance associated with the defined regulatory and statutory requirements of States;
(c) Standard practices of the nuclear industry;
(d) The organization's own standard practices.

2.3. Whichever codes, standards and requirements are used in developing the management system, the design of the management system should incorporate systems and processes both to comply with all requirements and to demonstrate the compliance. Assessments of the management system (see Section 6) should demonstrate that the management system is under control, and that the procedures for executing the processes that are controlled under the management system are producing the specified results to satisfy the requirements, thus establishing that the processes are executed correctly.

2.4. The management system should be developed to cover all aspects of waste disposal facilities and the associated activities to be carried out, irrespective of whether they are individual or composite activities. This includes the safety assessments conducted to evaluate all aspects of a facility that are relevant to safety and environmental protection, and the structure and presentation of safety arguments and supporting evidence in the safety case for the waste disposal facility.

2.5. The management system should provide assurance that the waste disposal facilities and related activities will comply with all applicable requirements, respecting the principle of carrying out work correctly the first time. The management system should include measures to be taken in the event that requirements are not met, to the end of active institutional control.

[2] ISO 9001:2000 is relevant for organizations responsible for active and passive institutional control, but ISO 14001:2004 is not applicable for the passive institutional control (e.g. periods when only land use controls are imposed) of a waste disposal facility.

2.6. The management system should include plans and arrangements for the management system itself to continue for as long as is required to maintain continuous active institutional control over the waste disposal facility. The management system should be planned to take into account the extended periods of the waste disposal operations and of the active institutional control in the post-closure phases. These extended periods influence the long term planning that is necessary to maintain continuity of oversight of the waste disposal facility. Emergency response drills, exercises and planned reviews of the adequacy of measures for emergency preparedness and response should be continued during any extended pre-closure period after operations have ceased, when preparedness may decline in the seemingly static situation. The management system should also be designed to accommodate future technological advances and changes in waste acceptance criteria that could have implications for continued operation of the waste disposal facility.

SAFETY CULTURE

2.7. Reference [2] requires in para. 2.5 that:

> "The management system shall be used to promote and support a strong safety culture by:
>
> — Ensuring a common understanding of the key aspects of safety culture within the organization;
> — Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;
> — Reinforcing a learning and questioning attitude at all levels of the organization;
> — Providing the means by which the organization continually seeks to develop and improve its safety culture."

2.8. The management system should support the development, implementation and continued enhancement of a pragmatic and strong safety culture [18–20] and should promote the adoption of best practices, regardless of the type, scale, complexity, duration and evolution of the activities for waste disposal. The management system for activities for waste disposal should support the safety culture and environmental protection culture throughout all levels of the organizations involved, and for all stages in the lifetime of a waste

disposal facility. The management system should establish an environment in which staff can raise safety issues without fear of harassment, intimidation, retaliation or discrimination.

GRADING THE APPLICATION OF MANAGEMENT SYSTEM REQUIREMENTS

2.9. Reference [2] requires in paras 2.6 and 2.7 that:

> "2.6. The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:
>
> — The significance and complexity of each product or activity;
> — The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or activity;
> — The possible consequences if a product fails or an activity is carried out incorrectly.
>
> "2.7. Grading of the application of management system requirements shall be applied to the products and activities of each process."

2.10. Organizations involved in waste disposal should identify the relative importance of the various activities, facilities and equipment in meeting the overall safety, health, environmental, security, quality and economic requirements, with safety and environmental protection being of primary importance. Resources should then be selectively allocated and processes selectively designed to control the activities, facilities and equipment effectively and efficiently. Controls will vary for different facilities and activities for waste disposal.

2.11. Effective and efficient management of waste disposal involves the selective application of controls on the basis of fundamental factors important to meeting the safety, health, environmental, security, quality and economic requirements, such as:

(a) The quantities and potential hazards (radiological and non-radiological, for example chemical) of the waste, and the necessary degree of isolation;

(b) The dispersibility and mobility of the waste forms involved and the necessary degree of containment;
(c) Experience with, and maturity of, the waste disposal technology and the potential for future advances;
(d) The reliability of equipment and its function in relation to safety and environmental protection;
(e) The degree of uncertainty about future evolution of the geological environment and engineered barriers;
(f) Consideration of future human activities, as appropriate;
(g) The complexity and degree of standardization of the activities;
(h) The novelty and maturity of the activities;
(i) The size of the organization, the number and complexity of interfaces and the safety culture;
(j) Uncertainty about future public perception of radiation hazards and radioactive waste;
(k) Uncertainty about future government policy on the nuclear industry and radioactive waste management.

2.12. A graded approach may be adopted (e.g. on the basis of the findings of a hazard and operability studies (HAZOPS) assessment) in applying management system requirements to such aspects of waste disposal activities as the:

(a) Level of detail of work instructions and supporting documentation;
(b) Level of qualification and training of workers;
(c) Quantity, detail and retention times of records;
(d) Need for, and level of detail in, formal logbooks;
(e) Level of detail and frequency of testing, surveillance and inspection;
(f) Equipment to be included in status control for the facility;
(g) Key performance indicators to be measured;
(h) Equipment calibration requirements;
(i) Need to monitor the condition of equipment, emplaced waste and facility integrity;
(j) Traceability of items, including waste packages;
(k) Availability and conditions of storage of materials and control of the associated records;
(l) Level of reporting and authority to act on non-conformances and to implement corrective actions;
(m) Scope, frequency and detail of assessments;
(n) Scope, frequency and detail of facility audits to monitor operational processes and levels of safety and environmental protection;

(o) Need for, and detail of, environmental monitoring.

2.13. Grading is intended to guide the degree of control applied to an item in relation to the importance of its required function. Grading should not be used as a justification for not applying all of the necessary management system elements or required quality controls, or for performing less than adequate technical assessments of items that are less evidently important to meeting the safety, health, environmental, security, quality and economic requirements. Grading should not be used to sanction less than adequate practices. Grading does not mean excluding determination of the adequacy of any activity affecting quality or safety. Grading means making the stringency of the controls by which the adequacy of such activities is evaluated commensurate with the importance of the activities.

DOCUMENTATION OF THE MANAGEMENT SYSTEM

2.14. Reference [2] requires in paras 2.8–2.10 that:

> "2.8. The documentation of the management system shall include the following:
>
> — The policy statements of the organization;
> — A description of the management system;
> — A description of the structure of the organization;
> — A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;
> — A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.
>
> "2.9. The documentation of the management system shall be developed to be understandable to those who use it. Documents shall be readable, readily identifiable and available at the point of use.
>
> "2.10. The documentation of the management system shall reflect:
>
> — The characteristics of the organization and its activities;
> — The complexities of processes and their interactions."

2.15. Operation of a waste disposal facility may continue over an extended period of time, possibly several decades. Closure and post-closure activities at the facility may not commence for many decades thereafter. Both management practices and operating processes may evolve significantly. Particular attention should be paid to ensuring that documents used to control work processes remain relevant, current, understandable and available to the diverse organizations and in the situations in which they are and will be used.

3. MANAGEMENT RESPONSIBILITY

GENERAL

3.1. The processes for fulfilling the responsibilities of senior management in relation to the disposal of radioactive waste are subject to the requirements established in Ref. [2], and the recommendations presented in this Safety Guide and provided in Ref. [3] should be considered.

MANAGEMENT COMMITMENT

3.2. Reference [2] requires in paras 3.1–3.5 that:

> "3.1. Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities.
>
> "3.2. Senior management shall develop individual values, institutional values and behavioural expectations for the organization to support the implementation of the management system and shall act as role models in the promulgation of these values and expectations.
>
> "3.3. Management at all levels shall communicate to individuals the need to adopt these individual values, institutional values and behavioural expectations as well as to comply with the requirements of the management system.

"3.4. Management at all levels shall foster the involvement of all individuals in the implementation and continual improvement of the management system.

"3.5. Senior management shall ensure that it is clear when, how and by whom decisions are to be made within the management system."

3.3. The management responsible should recognize that waste disposal concerns the entire lifetime of a facility built in the natural environment, and that the facility will need to perform as anticipated over a long period. National and international policies and principles for waste disposal and industry norms and industry standards that currently constitute an accepted management system will evolve over an extended period of time and may affect any aspect of waste disposal. Policy decisions (e.g. regarding fuel reprocessing) and technological innovations and advances (e.g. in partitioning and transmutation) may lead to fundamental changes in the overall waste management strategy. However, management will retain its responsibility for all activities at all times, and continuous commitment by management will remain a prerequisite to ensuring safety and the protection of human health and the environment.

SATISFACTION OF THE EXPECTATIONS OF INTERESTED PARTIES

3.4. Reference [2] requires in para. 3.6 that:

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

3.5. Several broad considerations relating to satisfying the expectations of the many present and future interested parties involved (e.g. the operator, the regulatory body, suppliers, national and local governments, the public) should be taken into account in developing the management system for facilities and activities for waste disposal. The requirements of some interested parties (e.g. the regulatory body) must be complied with, while the expectations and preferences of other interested parties may never be complied with entirely. Many issues may be sufficiently important to warrant consideration when developing the management system for waste disposal, such as:

(a) Legal aspects of waste disposal (such as state or provincial laws and regulations, occupational health regulations, hazardous material regulations, mining regulations);
(b) Physical protection and security provisions that may be required, as appropriate, for nuclear and other radioactive material;
(c) Operational limitations including those derived from agreements with local authorities or organizations or operating logistics;
(d) The adequacy of the activities performed by the organizations that carried out the steps in waste management prior to waste disposal;
(e) Public attitudes, concerns and expectations about safety and environmental protection in relation to waste disposal activities in the long term (for aspects such as the selection process and site evaluation, the adequacy and reliability of organizational and financial arrangements, the degree of confidence in the protection of public health and the environment in relation to waste disposal facilities, the ability to respond to problems that may arise during the period of active institutional control, and safety and environmental protection during the closure and post-closure phases);
(f) Public concerns about extended restrictions on the use of land and geological resources;
(g) Other concerns of interested parties (e.g. cultural expectations about working hours and the composition of the workforce, social expectations about distributing risks and benefits, economic constraints if nuclear activities have a broad scope but are on a small scale, political choices about activities for sustainable development).

ORGANIZATIONAL POLICIES

3.6. Reference [2] requires in para. 3.7 that:

> "Senior management shall develop the policies of the organization. The policies shall be appropriate to the activities and facilities of the organization."

3.7. The management system for waste disposal should specify the requirement to create and periodically review the policies of the organizations involved and the associated arrangements to do so. Organizational policies for waste disposal facilities and activities should cover not only the safety, health, environmental, security, quality and economic aspects but also the items listed in para. 3.5.

3.8. Reviews of the policies for waste disposal facilities and activities should take into account:

(a) Changes in legislation on waste management and environmental matters.
(b) Changes in regulations or in the regulatory body responsible for waste management and the environment.
(c) Changes in national policies for waste or for the environment.
(d) Any changes in national resource policy (e.g. considering spent fuel as a resource or, alternatively, as waste; changes in the relative costs of obtaining new uranium stocks versus reprocessing spent fuel).
(e) International developments (e.g. standards, conventions, agreements on information exchange).
(f) Technological advances (e.g. more efficient fuel reprocessing, more effective waste packaging).
(g) Lessons learned from experience, including experience gained from other waste disposal operations.
(h) Non-conformances, corrective and preventive actions and results of assessments.
(i) Results of domestic and international assessments.

PLANNING

3.9. Reference [2] requires in paras 3.8–3.11 that:

> "3.8. Senior management shall establish goals, strategies, plans and objectives that are consistent with the policies of the organization.
>
> "3.9. Senior management shall develop the goals, strategies, plans and objectives of the organization in an integrated manner so that their collective impact on safety is understood and managed.
>
> "3.10. Senior management shall ensure that measurable objectives for implementing the goals, strategies and plans are established through appropriate processes at various levels in the organization.
>
> "3.11. Senior management shall ensure that the implementation of the plans is regularly reviewed against these objectives and that actions are taken to address deviations from the plans where necessary."

3.10. For the plans, goals and objectives that define the strategy for achieving the integrated safety, health, environmental, security, quality and economic objectives for the waste disposal facilities and activities, long term aspects should be considered, such as:

(a) Providing adequate resources for future maintenance (the adequacy of resources for maintenance may need to be periodically reviewed over operational periods that may extend over decades);
(b) Preserving technology and knowledge and transferring it to people joining the activities in the future;
(c) Retaining or transferring ownership of waste disposal facilities;
(d) Succession planning for the technical and managerial human resources;
(e) Continuing arrangements for interacting with interested parties.

RESPONSIBILITY AND AUTHORITY FOR THE MANAGEMENT SYSTEM

3.11. Reference [2] requires in paras 3.12–3.14 that:

> "3.12. Senior management shall be ultimately responsible for the management system and shall ensure that it is established, implemented, assessed and continually improved.
>
> "3.13. An individual reporting directly to senior management shall have specific responsibility and authority for:
>
> — Coordinating the development and implementation of the management system, and its assessment and continual improvement;
> — Reporting on the performance of the management system, including its influence on safety and safety culture, and any need for improvement;
> — Resolving any potential conflicts between requirements and within the processes of the management system.
>
> "3.14. The organization shall retain overall responsibility for the management system when an external organization is involved in the work of developing all or part of the management system."

3.12. In deciding on the manager to be responsible for the management system for facilities and activities for waste disposal, senior management should ensure when defining duties that all activities and phases are covered in a

comprehensive and coherent manner, and that they are covered continuously over the period that the associated safety, health, environmental, security, quality and economic concerns continue.

4. RESOURCE MANAGEMENT

GENERAL

4.1. Resource management necessary for disposing of radioactive waste is subject to the requirements established in Ref. [2], and the recommendations presented in this Safety Guide and provided in Ref. [3] should be considered.

4.2. Reference [2] requires in paras 4.1–4.5 that:

> "4.1. Senior management shall determine the amount of resources necessary and shall provide the resources[9] to carry out the activities of the organization and to establish, implement, assess and continually improve the management system.
>
> "4.2. The information and knowledge of the organization shall be managed as a resource.
>
> "4.3. Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained.
>
> "4.4. Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that

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

individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organization's objectives.

"4.5. Senior management shall determine, provide, maintain and re-evaluate the infrastructure and the working environment necessary for work to be carried out in a safe manner and for requirements to be met."

PROVISION OF RESOURCES

4.3. Facilities and activities for waste disposal will require resources in the areas of finance, human resources, and infrastructure and the working environment. Senior management should be responsible for making arrangements to provide adequate resources for facilities and activities for waste disposal, to satisfy the demands imposed by the safety, health, environmental, security, quality and economic aspects associated with the full range of activities involved and the long duration of the activities.

FINANCIAL RESOURCES

4.4. Funding arrangements for waste disposal activities should be specified, and responsibilities, mechanisms and schedules for providing the funds should be established before the funds are needed. In particular, the funds that will be necessary should be ensured before the termination of the practice that generates the waste. According to the 'polluter pays' principle, the generator of the waste would fund its management.

4.5. Management systems for facilities and activities for waste disposal should include provisions to deal with several funding challenges:

(a) For various reasons (e.g. bankruptcy, cessation of business), it may not be feasible to obtain the necessary funds from the waste generator, especially if funds were not set aside at the time the benefits were received from the activity that generated the waste, or if ownership of the waste (e.g. ownership of spent imported radioactive sources) has been transferred to other parties. The need to apply the 'polluter pays' principle and the appropriate means of applying the principle through a tax mechanism could be considered in such cases.

(b) If funds are to come from public sources, this will compete with other demands for public funding, and it may be difficult to gain access to adequate funds on a timely basis.
(c) It may be difficult to make realistic estimates of costs for facilities and activities for waste disposal that are still in the planning stage and for which no experience has been accumulated.
(d) It may be difficult to estimate anticipated costs for activities that will only begin in the long term, because they will depend strongly on assumptions made about future inflation rates, bank interest rates and technological developments.
(e) It may be difficult to set appropriate risk and contingency factors to be built into estimates of future costs, owing to the uncertainty associated with unforeseeable future changes in societal demands, political imperatives, public opinion and the nature of unplanned events that may require resources for dealing with them.
(f) Costs tend to rise, particularly in the absence of commercial competition.

Consideration should be given for each waste stream to whether commercial arrangements are in place, and, if so, what they are and how long they will be in force. This will enable the operator to tailor financial arrangements appropriately, taking into account the other funding challenges listed above.

HUMAN RESOURCES AND INDIVIDUAL COMPETENCE

4.6. The reliability and the effectiveness of facilities and activities for waste disposal will depend on all personnel in all the organizations involved. At all times, they should carry out their assigned work competently and with a clear understanding of the consequences for safety and environmental protection of their tasks.

4.7. Human resource planning for waste disposal activities of long duration should incorporate measures to ensure the continuing availability of a sufficient number of competent personnel. This includes any extended pre-closure phase after operations have ceased but prior to closure, and the period of active institutional control during the post-closure phase, when the seemingly static situation may lead to an unnoticed degradation of the intended level of human resources. This may influence decisions about required staffing levels and educational qualifications, skills and experience of new personnel. Additionally, in some States, personnel performing work in defined positions

important to safety and environmental protection should be authorized (e.g. licensed) as required by the appropriate regulatory body.

4.8. Training programmes, procedures and succession plans should be established to ensure that suitable proficiency is achieved and maintained and to avoid the potential loss of knowledge, practical experience and technical expertise over time.

4.9. Training and retraining should include familiarization with the management system for the facilities and activities for waste disposal.

4.10. Training and retraining needs should be reviewed on a planned basis and updated as required to respond to changes in technologies for waste management, legislative and regulatory requirements, and any other factors associated with waste disposal activities.

4.11. Retraining should be arranged to ensure that personnel adequately understand the implications of changes such as:

(a) Modifications to materials (e.g. change of the supplier of concrete, steel or buffer clay) and to equipment;
(b) The installation of new equipment (e.g. hoisting gear, ventilation systems);
(c) Changes in procedures (e.g. waste emplacement and backfilling);
(d) Any tightening or relaxation of controls (e.g. on the number of waste packages that may be moved at any given time);
(e) The introduction of additional control points (e.g. supplementary testing of material from new sources);
(f) Changes in regulatory requirements.

4.12. Throughout the lifetime of a waste disposal facility or the duration of waste disposal activities, accumulated experience, including lessons learned from incidents and events, should be reviewed periodically and used in revising training programmes and in future decision making.

INFRASTRUCTURE AND WORKING ENVIRONMENT

4.13. In designing waste disposal facilities, consideration should be given to incorporating measures for ease of long term operation, maintenance of equipment, closure of the facility and post-closure activities.

4.14. For long term waste disposal activities, future infrastructural requirements should be specified and plans should be made to ensure that these will be met. In such planning, consideration should be given to the continuing need for assured supplies of suitable materials, support services and spare parts for equipment that may eventually no longer be manufactured, for equipment upgrades to meet new regulations and make operational improvements, and for the evolution and inevitable obsolescence of software.

4.15. Consideration should also be given to the need to develop, initiate and sustain the monitoring programme for the post-closure period of the waste disposal facility.

5. PROCESS IMPLEMENTATION

GENERAL

5.1. The processes for disposing of radioactive waste are subject to the requirements established in Ref. [2], and the recommendations presented in this Safety Guide and provided in Ref. [3] should be considered.

DEVELOPING PROCESSES

5.2. Reference [2] requires in paras 5.1–5.5 that:

> "5.1. The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved.
>
> "5.2. The sequence and interactions of the processes shall be determined.
>
> "5.3. The methods necessary to ensure the effectiveness of both the implementation and the control of the processes shall be determined and implemented.

"5.4. The development of each process shall ensure that the following are achieved:

— Process requirements, such as applicable regulatory, statutory, legal, safety, health, environmental, security, quality and economic requirements, are specified and addressed.
— Hazards and risks are identified, together with any necessary mitigatory actions.
— Interactions with interfacing processes are identified.
— Process inputs are identified.
— The process flow is described.
— Process outputs (products) are identified.
— Process measurement criteria are established.

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

5.3. All the management and work processes necessary to satisfy the safety, health, environmental, security, quality and economic requirements associated with the disposal of radioactive waste should be identified, developed, implemented, maintained and appropriately improved in a controlled fashion. They should produce the necessary evidence to demonstrate that objectives for safety and for environmental protection will be met throughout the long lifetime of a waste disposal facility.

Strategy for developing integrated management and work processes

5.4. In developing management system processes and work processes for facilities and activities for waste disposal, the operator should integrate them with the overall strategy of the waste management programme and the criteria for waste products and waste packaging that were set for, and achieved by, the activities that generated the waste products to be disposed of. Requirements are established on the siting and development of waste disposal facilities, and recommendations are provided in Refs [6–11]. Basic requirements for radiation protection are established in Ref. [12] and requirements for emergency preparedness and response are established in Ref. [13].

5.5. As the best approach to developing a waste management strategy, the entire process by which waste is generated should be considered, as well as the

subsequent treatment, storage and disposal of the waste. By this means an integrated overall process will be developed. The development of detailed processes for waste management should be associated with the safety assessment process, and the design–assessment coupling of processes should be iterative; for example:

(a) Tentative waste product specifications should be developed when the entire sequence of waste management activities is first conceived;
(b) The level of safety and environmental protection provided by various combinations of processes, waste products and facility characteristics that are assumed to be possible should be assessed;
(c) The feasibility of implementing the various designs should be evaluated;
(d) A revised set of assumptions should be input into a new safety assessment.

The design–assessment cycle should be repeated, usually several times, which will result in a set of processes, waste products, facility specifications and associated safety assessments that will guide the development of the entire set of waste management activities.

5.6. Consideration should be given to which data are needed and to what variability and uncertainty in data are acceptable for the following:

(a) To characterize waste sufficiently at each step (if possible) in the overall waste management programme;
(b) To be valid over any extended period of storage of waste products;
(c) Before, during and after operations, to dispose of waste.

It should be borne in mind that previously unrecognized variations (e.g. in the composition of waste streams or in the properties of absorbing backfill materials and host geological media) could necessitate adjustment of the facility design or in the specifications of the materials to be used for waste products, seals and backfill.

PROCESS MANAGEMENT AND CONTROL OF PRODUCTS

5.7. Reference [2] requires in paras 5.6–5.10 and 5.14–5.20 that:

> "5.6. For each process a designated individual shall be given the authority and responsibility for:

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

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

"5.8. Each process shall be evaluated to ensure that it remains effective.

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

"5.10. The control of processes contracted to external organizations shall be identified within the management system. The organization shall retain overall responsibility when contracting any processes.

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

"5.15. Activities for inspection, testing, verification and validation shall be completed before the acceptance, implementation or operational use

of products. The tools and equipment used for these activities shall be of the proper range, type, accuracy and precision.

"5.16. The organization shall confirm that products meet the specified requirements and shall ensure that products perform satisfactorily in service.

"5.17. Products shall be provided in such a form that it can be verified that they satisfy the requirements.

"5.18. Controls shall be used to ensure that products do not bypass the required verification activities.

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

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

5.8. In the management system for waste disposal, care should be taken to ensure the continuity of control of the waste and waste disposal activities, and to ensure that the linkages and relationships between all the organizations involved are maintained. The use of a waste disposal facility will have long term safety, health, environmental, security, quality and economic implications. People in future generations who were not originally interested parties will inherit responsibility for managing the facility and associated activities. The management system should be sustainable and should include provision for its own review in a planned manner to maintain confidence that it will evolve to accommodate changes in management philosophies and strategies to meet the needs of future interested parties.

5.9. This section provides guidance on planning and control of the processes used in many of the activities of waste disposal organizations. Appendix I provides more extensive guidance on dealing with issues for management systems specific to the operation, closure and active institutional control period of the post-closure phases of waste disposal facilities. Appendix II provides extended guidance on the design, testing, application and change control processes for computer modelling that will be used in all phases of activities relating to waste disposal.

Control of work processes

5.10. Work processes affecting the safety, health, environmental, security, quality and economic requirements of facilities and activities for waste disposal should be controlled so that:

(a) The applicable prerequisites, including environmental conditions, physical parameters, equipment characteristics and personnel competences, are satisfied;
(b) All process variables are kept within specified acceptance criteria.

In the control of work processes used up to the closure phase, allowance should be made for the occurrence of natural events (e.g. earthquakes) and natural processes (e.g. groundwater movement) throughout the entire lifetime of the facility. This includes the phase after closure when the protection of people and the environment should be ensured for the sealed facility by means of passive engineered barriers and natural processes, rather than continuous human supervision and possible intervention. Control of work processes may be achieved through the design of the work process, validation, the use of operating procedures and work instructions, process surveillance and monitoring, and product inspection and testing. Paragraphs 5.11–5.44 provide recommendations on applying several of these approaches to the control of specific processes used in activities for waste disposal.

Design of work processes

5.11. In the design of work processes, the detailed sequence of steps in the activities for waste disposal and issues relating to the specific work processes should be considered; for example:

(a) Careful planning of exploratory geological investigations to maximize the amount of information collected and to minimize disruption to the integrity of the geological medium;
(b) Precise excavation of underground cavities to minimize damage to the surrounding geology;
(c) Protection of waste packages and containers from degradation before the facility is closed, particularly during periods before emplacement;
(d) Use of special handling tools and techniques, protective clothing or facilities for radiation protection;
(e) Emplacement of packages in waste disposal facilities and use of the associated handling devices;

(f) Requirements for in situ monitoring and retrievability;
(g) Testing and assay requirements (e.g. equipment, methods or materials).

5.12. In experiments and pilot scale tests that are carried out prior to the full scale development of a waste disposal facility, the aim should be:

(a) To identify, as feasible, where direct measurements or extrapolation of measurements can be used to quantify important characteristics of the facility after closure;
(b) To identify those variables that are critical to achieving acceptable long term behaviour of the facility and its contents.

Validation of work processes

5.13. Validation of work processes, as feasible, should include:

(a) Determining the process variables that should be controlled to ensure the adequacy of the waste disposal facility as well as of the waste packages emplaced in the waste disposal facility;
(b) Establishing the limits or tolerances for the process variables;
(c) Determining adequate control methods for the process variables, including the frequency of required sampling and testing of the waste disposal facility and its contents.

5.14. Process validation should be performed in accordance with documented and approved procedures, and the results should be reported. Appropriate reports and records should be made available to all subsequent managements responsible for the waste disposal facility.

5.15. Where, historically, a waste disposal facility has been closed, but the work processes and facilities used prior to closure were not validated, the management of the waste disposal facility should use all available information and take all feasible steps to verify that the processes were adequately characterized, evaluated and controlled by the organization that was responsible for obtaining the authorization to close the facility.

Special processes

5.16. Special processes are processes for which:

(a) The output from the process depends strongly on the control of the process or the skill of operators, or both (e.g. inspection results from radioassay);
(b) It is not possible fully to confirm the conformity of the output with the specified acceptance criteria by inspection or testing after the process has been conducted and the output is still under control (e.g. the backfilling of a waste disposal facility).

Special processes associated with waste disposal include:

(i) Non-destructive examination and testing of waste packages (e.g. radiography in real time or otherwise, gamma and neutron radioassay techniques);
(ii) Corrective action (e.g. closure welding of lids on overpacks) for waste containers that do not comply with specified requirements;
(iii) Remote analytical methods including sampling methods (e.g. for controlled emplacement of backfill materials in the high radiation fields around emplaced waste packages).

5.17. All special processes used should be validated (i.e. demonstrated to be effective using methods and conditions that are representative of the intended application, as witnessed by an expert in the discipline), and any limitations should be documented.

5.18. In validating non-destructive gamma or neutron radioassay techniques:

(a) Algorithms for validating radionuclide content should be validated with empirical data;
(b) Objects to be measured (e.g. waste packages) should exhibit attenuation properties and moderating properties according to the standards used in developing the method or calibrating the equipment;
(c) Assay errors should be quantified for each material to be measured.

5.19. Special processes should be performed by qualified personnel and should be authorized in accordance with approved procedures. The results should be recorded. Where industry standards apply for special processes, the requirements of such standards should be complied with. When any changes are made in environmental samples and conditions, methods, equipment and qualification of personnel, the special processes should be revalidated.

Inspection and testing

5.20. Inspection and testing are important elements for controlling work processes. They should be planned, documented, executed and recorded to ensure that important parameters of waste disposal are controlled, and that the facility conditions at closure meet the design specifications. Acceptance criteria should be specified for each inspection step in the work processes used in all stages of the lifetime of a waste disposal facility and in the associated activities.

5.21. If it would be difficult or impossible to verify work processes on completion, or if this would be too late, the design of the workflow should include 'hold points' at which the acceptability of important results should be verified before work proceeds. Procedures should specify that work should not proceed beyond hold points until designated inspection personnel have confirmed its acceptability. The degree of independence of inspection personnel should be commensurate with the significance for safety and environmental protection of the parameters being inspected. Hold points may be waived if full justification on grounds of safety and environmental protection or quality is documented and approved.

5.22. Inspections carried out as part of waste disposal activities should include:

(a) In-process inspection of the waste disposal facility during construction;
(b) Final inspection of the facility before waste packages are accepted;
(c) Inspection at source of items important to safety and environmental protection for which the quality is difficult to verify upon receipt;
(d) Inspection on receipt of items important to safety and environmental protection, including verification of related certification and documentation;
(e) Inspection, and testing on receipt, of characteristics of commercial grade items that are important to safety and environmental protection;
(f) Inspection of installed items that are important to safety, environmental protection or waste isolation, including witnessing of equipment and/or system operational tests;
(g) Post-installation acceptance inspection for structures, systems and components being accepted in this fashion;
(h) In-process inspection of waste emplacement and backfilling processes;
(i) Inspection (e.g. by non-destructive assay or real time radiography) of waste packages destined for disposal (e.g. on receipt at the waste disposal facility, during storage awaiting disposal or after repackaging, if

required), including either comprehensive inspection or random sampling inspection;
(j) In-process inspection of waste repackaging processes;
(k) Regular inspection to verify the operability of equipment or systems used for the prevention, detection or mitigation of accidents.

The operating organization for waste management may itself carry out internal inspections in the course of controlling and improving its processes. Other bodies (such as the regulatory body or independent organizations or experts) may independently carry out external inspections to maintain confidence that the operating organization is conducting its operations in an acceptable manner.

Site evaluation

5.23. While political aspects are important throughout the lifetime of a waste disposal facility, and before a waste disposal project is commenced, the initiation of technical activities relating to site evaluation may heighten the political aspects, especially when field surveys begin. The management system should allow for this.

5.24. All data used should always be traceable to their origin and should be developed into a coherent, well documented description of site characteristics. It should be recognized that data may not readily satisfy the required level of confidence if they are derived from, for example:

(a) Estimated values;
(b) Extrapolated values;
(c) Existing information from local studies that were conducted for other purposes.

Lack of confidence in the quality of the data (i.e. in their accuracy, applicability, completeness or quantity) may preclude their use. In such cases a pragmatic approach should be taken, on the basis of expert judgement. The use of such data should be declared, justified, authorized and recorded.

5.25. When statistical data derived on a national, continental or worldwide basis are used, the values obtained should be examined to determine whether they need to be adjusted to compensate for unusual characteristics of the site and its surroundings. The availability, precision, nature and scope of the data to

be collected should be compatible with the methods and models in which they will be used.

5.26. Typically, the sources of siting data include:

(a) Current and historical data or information relevant to the current census, postulated population movements, meteorological and seismological surveys and records;
(b) Data or information from indirect exploration (i.e. inferred or calculated from indirect tests and data or mock-up investigations, but collected for other purposes);
(c) Data or information from direct exploration (i.e. obtained from samples, from direct observations or from in situ tests);
(d) Laboratory testing data or information obtained from tests conducted on samples obtained from direct exploration.

5.27. The format of information and data should, as far as practicable, be consistent, should facilitate the comparison of results between waste disposal sites and should allow for the prompt identification of gaps in information.

Design of a waste disposal facility

5.28. The design process always requires effective input and output controls and records. In addition, the design process for a waste disposal facility should be part of a larger iterative process that also involves site characterization and development of the safety case for the facility. Site knowledge, facility design and arguments concerning safety and environmental protection should be refined iteratively to establish a robust safety case and well founded technical specifications.

5.29. A documented process should be developed to acquire, review, track, quantify and qualify all design data and to demonstrate their suitability before they are used as input data into any system, computer program or computer model. This includes data generated as a result of literature searches, laboratory tests, field tests and observations, seismic analyses, monitoring and measuring, and test results from other relevant sources.

5.30. Data relating to natural geological systems may incorporate uncertainties or may be based on estimated values deduced from similar situations. The uncertainties and the basis for the estimated values should be clearly documented so that they will be recognized during the design process.

5.31. Before and during the process of designing the waste disposal facility, advantage should be taken of lessons learned and of knowledge and experience from comparable existing facilities and current projects.

5.32. Computer software programs and models will be used during all phases of waste disposal activities, particularly during the design phase. Appropriate means should be provided for verifying and validating such applications. Appendix II provides guidance in this area.

5.33. Information about the design parameters that were considered important to the safety, health, environmental, quality, security and economic aspects of the facility should be retained and controlled for as long as any concerns about the facility persist.

Safety case

5.34. As noted in paras 5.28–5.33, in managing the development of a design for a waste disposal facility, it should be recognized that this will be associated with the concurrent development of the safety case, and the processes involving the design and the safety case will be iterative. Typically this proceeds as follows:

(a) Development of a tentative design and set of technical characteristics of the waste disposal facility;
(b) Assessment of the level of safety and environmental protection that will be provided by the assumed facility design and the associated combinations of waste products, facility characteristics and natural processes (e.g. behaviour of natural geological systems);
(c) Development of supporting evidence and reasoning on the robustness and reliability of the safety assessment;
(d) Modification of the facility design on the basis of variations in the design characteristics that will improve safety, environmental protection and feasibility;
(e) Revision of the safety case using the revised design.

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

5.35. Over the lifetime of the waste disposal facility, the safety case should be periodically reviewed in a systematic, planned manner in the light of

accumulating data and updated as necessary. The documented safety cases in some States are embodied in reports that are prepared to demonstrate compliance with regulatory requirements.

Research and development

5.36. The research and development activities involved in developing and assessing a proposed waste disposal facility can be conducted both in the laboratory and in the field. There is always a residual uncertainty in the conclusions that may be drawn from these activities about the behaviour to be expected for the waste disposal facility. This residual uncertainty should be recognized in the management system for such activities, as follows:

(a) The study of natural systems has the potential to compromise their original characteristics. In particular, physical intrusions into geological formations (i.e. exploratory boreholes and shafts) create new pathways for potential groundwater movement. The existence of these new pathways may shorten the time before any contaminants leached from the waste in the eventual waste disposal facility can return to the accessible environment. The more information is sought from additional exploratory probing, the greater is the risk of compromising the setting to host the waste disposal facility.

(b) The transport of contaminants from the eventual waste disposal facility will normally be expected to occur very slowly. In developing supporting evidence for the safety assessment, it is challenging to extrapolate from experiments in short term groundwater movement over the very long time periods involved for the later waste disposal facility. To develop a basis for the safety case, arguments concerning safety and environmental protection may have to be based, at least in part, on natural analogues of the various material properties and the phenomena expected to occur.

(c) The natural geological setting of a waste disposal facility is normally subject to slow and possibly variable processes. This may lead to substantial irreducible uncertainties in modelling the long term evolution of the system quantitatively, and substantial uncertainty may remain in the best possible assessment. The safety case should be developed in recognition that such uncertainties will remain but that the range of possible behaviour has been evaluated and considered for time periods appropriate for the nature of the waste.

Construction

5.37. For underground waste disposal facilities, consideration should be given to particular demands on the facility and the equipment that will be used in it under special conditions:

(a) The facility and equipment are expected to function for an extended period of time, possibly several decades;
(b) Some equipment will normally be expected to remain permanently in the underground environment (except possibly when removed for repair);
(c) Civil works may be difficult to access unless the means of access to them is carefully planned and maintained;
(d) Equipment, once in place, may be difficult to access, recover or return to the surface.

5.38. In managing the construction of a waste disposal facility, the maximum possible amount of information should be gathered about:

(a) The nature of the geological formations that will be encountered before they are reached or breached;
(b) The response of the geological formations to, and the effect on geochemical and geohydrological conditions of, the perturbations induced by the construction activities.

5.39. Lines of communication between the organizations involved and arrangements for the issue of design information should be established. Prior to starting construction, the construction organization should ensure that the information deriving from the design process reflects the present site conditions as well as expected future conditions.

5.40. To ensure that the requisite quality of the item being constructed or installed is preserved, and because the site area may be very large, measures for performing housekeeping operations should be established and implemented in accordance with specified requirements.

Status of waste packages and materials

5.41. Procedures should be established to ensure that only intended and accepted waste packages are emplaced in the facility, and that only those materials and items (e.g. concrete, backfill, seals) are used that have the required properties to tolerate the conditions that will prevail in the facility in

the post-closure phase. Durable identification should be maintained on waste packages and on documentation traceable to the packages. The procedures should include transfer of the identification if waste is repackaged.

Emplacement of waste packages in the waste disposal facility

5.42. After waste packages have been received at the waste disposal facility and before they are emplaced, measures should be taken to ensure that:

(a) The waste packages meet the waste acceptance criteria for the facility (e.g. specific and total activity in the packages, surface contamination, radiation field at the package surface, package weight, limited amount of mobilizing agents in the waste form, limited amount of liquid);
(b) The waste packages are properly identified;
(c) The waste packages do not show signs of unacceptable deterioration;
(d) The required documentation and records (e.g. the inventory of radionuclides, relevant properties of emplaced waste forms) are available and acceptable so that the future stability of the waste, the radiological properties and the internal pressures in waste packages can be estimated or determined;
(e) All prerequisite processes have been accomplished satisfactorily;
(f) Surface contamination and surface dose rates meet requirements;
(g) Criticality control measures for fissile material are in place, are effective and are maintained;
(h) Intended movements of waste packages within the waste disposal facility can be performed safely, inadvertent criticality is precluded and occupational exposures are minimized.

5.43. Procedures governing the management of emplaced waste prior to closure should, as necessary, provide for monitoring of the package integrity, the operational status of any required thermal cooling and monitoring and alarm equipment, the operational status of other equipment for the detection and mitigation of accidents, and the legibility of the identification of the waste packages.

Retrievability before or after closure

5.44. Waste packages may have to be retrieved and relocated if problems arise after they have been emplaced (e.g. due to threats to package integrity and/or due to extraordinary deviations from the estimated conditions in the safety assessment). Procedures should be established to ensure that waste packages

can be identified, located and accessed after they have been emplaced, if the waste disposal concept includes measures to facilitate retrievability before or after closure.

CONTROL OF DOCUMENTS

5.45. Reference [2] requires in paras 5.12 and 5.13 that:

> "5.12. Documents[10] shall be controlled. All individuals involved in preparing, revising, reviewing or approving documents shall be specifically assigned this work, shall be competent to carry it out and shall be given access to appropriate information on which to base their input or decisions. It shall be ensured that document users are aware of and use appropriate and correct documents.
>
> "5.13. Changes to documents shall be reviewed and recorded and shall be subject to the same level of approval as the documents themselves."

5.46. Documents should be periodically reviewed and kept up to date as equipment, information technology, industrial practices and regulatory requirements evolve. For the very long term control of documents, the possible evolution of language and educational levels between generations should also be taken into account.

CONTROL OF RECORDS

5.47. Reference [2] requires in paras 5.21 and 5.22 that:

> "5.21. Records shall be specified in the process documentation and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable.
>
> "5.22. Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory

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"[10] Documents may include: policies; procedures; instructions; specifications and drawings (or representations in other media); training materials; and any other texts that describe processes, specify requirements or establish product specifications."

requirements and knowledge management obligations of the organization. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record."

Content of records

5.48. Records describing the waste products that are being disposed of that will be needed to implement the planned waste disposal option and for other foreseeable needs should be created before the waste is disposed of. The information should be managed to preserve knowledge of the results of the prior waste processing, handling and storage steps. These records should include information on:

(a) The origin of the waste and the processes that generated it;
(b) The physical and chemical forms and properties of the waste;
(c) The type of package;
(d) The specific and total activity of radionuclides (within the acceptance criteria for waste disposal);
(e) The dose equivalent rate at the package surface;
(f) The level of surface contamination on the package;
(g) The leachability coefficient of the treated radioactive waste;
(h) The total weight of the waste packaging;
(i) The package filling date or period.

Records should also be created and retained to describe the history of the waste disposal facility and related activities. Such records typically include:

(i) Facility authorizations (e.g. licences) issued by the regulatory body;
(ii) Commissioning certificates;
(iii) System descriptions;
(iv) The safety case and/or safety assessment (in some States, these are included in reports that are prepared to demonstrate compliance with regulatory requirements);
(v) The environmental impact study;
(vi) The design of the waste disposal facility;
(vii) Technical specifications and amendments;
(viii) Design calculations and drawings;
(ix) Approved design changes;
(x) Design and peer review reports;
(xi) Verification and validation reports for the facility design;

(xii) Technical analysis, evaluations and reports;
(xiii) As-built records;
(xiv) Procurement records for systems, structures and components;
(xv) Operating procedures;
(xvi) Emergency procedures;
(xvii) Emplacement plans;
(xviii) Transfer records from previous waste management steps, including waste processing, handling and storage;
(xix) Records generated during the operation, closure and post-closure phases, including records on emplaced waste packages;
(xx) Assessment, inspection and verifications relating to all processes and phases;
(xxi) Non-conformances and corrective actions relating to all processes and phases;
(xxii) Training and qualification of personnel relating to all processes and phases.

Management should decide whether the waste package records and waste disposal facility records are to be stored together at the waste disposal facility or separately at different locations.

Retention of records

5.49. Arrangements should be made to ensure that records are maintained for the period of time for which the waste that has been disposed of is considered to remain an issue for safety, the protection of human health and the environment, and security. Retention periods may vary depending on the nature of the facilities and activities in which the waste was generated and on the half-lives of the radionuclides involved (e.g. for waste from a nuclear medicine laboratory rather than high level waste resulting from the reprocessing of spent nuclear fuel), and they should be approved as required by the appropriate national authorities or regulatory body.

5.50. The records for a waste disposal facility that need to be retained for an extended period should be subject to a regular systematic review to examine the implications of any changes that have occurred in regulatory requirements and in legislative, organizational, technical and scientific circumstances.

5.51. Records for a waste disposal facility that need to be retained for an extended period should be stored in a manner that minimizes the likelihood and consequences of loss, damage or deterioration due to unpredictable events

such as fire, flood or other natural or human initiated occurrences. Storage arrangements for records should meet the requirements prescribed by the national authorities or the regulatory body. This retention status should be periodically reassessed. When unpredictable events lead to the inadvertent destruction of records, the status of surviving records should be examined and the importance of their retention and their necessary retention period should be re-evaluated.

Recording media and record keeping

5.52. The quality of the recording media and the conditions of storage of records relating to waste disposal facilities should be such that the information will be preserved throughout the required retention period. Records of enduring value should be stored on materials of the highest available archival quality. Where records are preserved electronically, the records should be retrievable and readable for the entire retention period required. This may require periodic updates of software, or the use of a controlled non-proprietary form and/or system. Irrespective of the storage media used, consideration should be given to the storage of multiple copies in several diverse locations with independent protection systems.

Transfer of information between organizations and to future generations

5.53. When responsibility for managing a waste disposal facility is transferred from one organization to another, records of information about the facility that relate to safety and environmental protection should be made available to the successor organization. The information to be transferred between organizations should be set out in an interface document that describes and specifies the interactions between the organizations.

5.54. Information on a waste disposal facility and its contents may have to be transferred to successive generations. To make it possible for future generations to read, understand and interpret the information, contextual information should be retained and transmitted (e.g. policy for regulating waste; rationale for arguments and choices for safety and environmental protection; language and technical terminology; scientific understanding; methods for collecting, analysing and interpreting measurements) as well as the actual recorded data. Consideration should be given to the information, recording media, equipment and systems that will be needed to ensure as far as possible that the information will be available in the future. No single approach is likely to have all the desirable characteristics necessary to achieve this ideal

objective. For example, a simple robust approach such as recording on paper may not offer the ability to store the large amounts of data that are possible on information systems such as microfiche or in computer based storage. Such systems have much greater storage capacity, but they may be more fragile or may rely on technologies that may become obsolete in relatively short periods of time.

PURCHASING

5.55. Reference [2] requires in paras 5.23–5.25 that:

> "5.23. Suppliers of products shall be selected on the basis of specified criteria and their performance shall be evaluated.
>
> "5.24. Purchasing requirements shall be developed and specified in procurement documents. Evidence that products meet these requirements shall be available to the organization before the product is used.
>
> "5.25. Requirements for the reporting and resolution of non-conformances shall be specified in procurement documents."

5.56. In planning procurement, consideration should be given to the availability and quality of equipment, materials (e.g. cement and backfill) and other items important to safety and environmental protection over the lengthy phases of the lifetime of a waste disposal facility. Consideration should also be given to the fiscal policies and financial arrangements and controls that may be required. Additional recommendations on purchasing are provided in Appendix I, paras I.14 and I.15.

COMMUNICATION

5.57. Reference [2] requires in paras 5.26 and 5.27 that:

> "5.26. Information relevant to safety, health, environmental, security, quality and economic goals shall be communicated to individuals in the organization and, where necessary, to other interested parties.

"5.27. Internal communication concerning the implementation and effectiveness of the management system shall take place between the various levels and functions of the organization."

5.58. In establishing the internal and external communication processes used for waste disposal facilities, it should be recognized that the communication may need to be sustained over a long period of time.

5.59. Internal communication should cover such aspects as:

(a) Management policy, objectives and strategy;
(b) The management system and associated processes and procedures for conducting waste disposal activities;
(c) The current status of waste disposal activities and plans for the future;
(d) Technical and quality issues (e.g. problems having long term implications and their resolution, planned improvements and innovations);
(e) Radiological issues (e.g. trends in doses and in releases to the environment, evaluation of accidents and other incidents);
(f) Regulatory and statutory issues (e.g. new requirements for waste management, radiation related requirements and environmental requirements, and planned measures to meet the requirements).

5.60. External communication should include information on such aspects as:

(a) Present status of operations and plans for the future;
(b) Health and safety, and the environmental, security and economic impacts of the waste disposal activities;
(c) Changes in management arrangements and the continuity of responsible management;
(d) Maintenance of adequate financial resources to support the waste disposal activities;
(e) Opportunities for, and results from, public involvement in decision making;
(f) Responses to questions and concerns.

MANAGING ORGANIZATIONAL CHANGE

5.61. Reference [2] requires in paras 5.28 and 5.29 that:

"5.28. Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified.

"5.29. The implementation of such changes shall be planned, controlled, communicated, monitored, tracked and recorded to ensure that safety is not compromised."

5.62. Roles and responsibilities for safety and environmental protection in waste disposal will continue for a long time, and may change within waste management programmes and organizations. Responsibilities for waste may change between States (e.g. following changes to agreements on the repatriation of waste from fuel reprocessing or of spent sealed sources). Management systems for facilities and activities for waste disposal should be designed to ensure continuity in managing the facilities and activities, and should be able to cope with possible changes in the following, for example:

(a) Land use policies in relation to requirements for institutional control;
(b) The ownership of waste and waste disposal facilities;
(c) Management arrangements;
(d) The regulatory body.

When management arrangements for waste disposal facilities are changed (e.g. if public organizations are privatized, if new organizations are created, if existing organizations are combined or restructured, if responsibilities are transferred between organizations, or if operating organizations undergo internal reorganization of the management structure or reallocation of resources), consideration should be given to the possible need to restructure the management system.

6. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

GENERAL

6.1. The processes for measurement, assessment and improvement applicable to the management and control of waste disposal are subject to the requirements established in Ref. [2], and the recommendations presented in this Safety Guide and provided in Ref. [3] should be considered. It should be

noted that the assessment discussed in this section is an assessment of management systems; it is not the same as the safety assessment for a waste disposal facility referred to in previous sections.

MONITORING AND MEASUREMENT

6.2. Reference [2] requires in para. 6.1 that:

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

6.3. Monitoring and measurement of the effectiveness of the management system should be considered for all phases of the waste disposal facility's lifetime. Planning should be done to ensure that these activities will be continued during extended operation and during the possible post-closure phase of active institutional control.

SELF-ASSESSMENT

6.4. Reference [2] requires in para. 6.2 that:

> "Senior management and management at all other levels in the organization shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture."

Assessment of management processes

6.5. In assessments of the management processes for a waste disposal facility, the following should be considered:

(a) Any changes in organizational structure or in the assignment of responsibilities and financial liabilities that could have an effect on the management and control of waste disposal activities. Such changes will have to be considered at the national and even possibly the international level.
(b) The continuation of assessments over extended periods of operation and periods of active institutional control in the post-closure phases.

Assessment of work processes

6.6. Where assessments are performed of work processes used in a waste disposal facility, the following aspects should be confirmed:

(a) During the site evaluation phase: all exploratory data can be traced to their origin, and associated uncertainties are adequately described and explained.
(b) During the design phase: the understanding of the natural geological setting, the design of the facility and the safety assessment for the facility are being developed concurrently, and the final descriptions are adequate and mutually consistent.
(c) During the construction phase:
    (i) The maximum possible amount of information is being gathered about:
        • The nature, before they are breached, of the geological formations that will be encountered.
        • The response of the geological formation and of the geochemical and geohydrological conditions to the perturbations induced by the construction activities.
    (ii) Construction activities are being carried out in a reactive manner to optimize the actual facility layout in relation to the host geological formation.
    (iii) The construction materials are of the required quality.
    (iv) Construction works meet the design requirements.
(d) During the operation phase:
    (i) All prerequisites are being met before waste is emplaced (e.g. waste packages are being checked against the acceptance criteria and the criteria are being satisfied).
    (ii) Waste is being emplaced according to the requirements.
(e) During extended pre-closure and post-closure phases:
    (i) Backfilling, sealing and other activities associated with closure of the facility are being carried out in accordance with the assumptions made in the safety assessment.
    (ii) Required measurements (e.g. groundwater monitoring) are being performed and the associated records are being maintained.
    (iii) Monitoring instrumentation has not degraded in prolonged service and has not been modified without proper change control.
    (iv) The safety assessment is being periodically reviewed in a systematic, planned manner and updated as necessary in the light of

accumulated data, and any necessary actions are being taken to ensure the continued safe behaviour of the facility and its contents.

(v) Information on the condition of the waste disposal facility is retained during jurisdictional transfers of the facility.

INDEPENDENT ASSESSMENT

6.7. Reference [2] requires in paras 6.3–6.6 that:

> "6.3. Independent assessments shall be conducted regularly on behalf of senior management:
>
> — To evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives;
> — To determine the adequacy of work performance and leadership;
> — To evaluate the organization's safety culture;
> — To monitor product quality;
> — To identify opportunities for improvement.
>
> "6.4. An organizational unit shall be established with the responsibility for conducting independent assessments. This unit shall have sufficient authority to discharge its responsibilities.
>
> "6.5. Individuals conducting independent assessments shall not assess their own work.
>
> "6.6. Senior management shall evaluate the results of the independent assessments, shall take any necessary actions, and shall record and communicate their decisions and the reasons for them."

6.8. Assessments to verify the implementation and effectiveness of the management system of a waste disposal facility may be performed by:

(a) An organizational unit within the waste disposal organization itself, provided that the assessors do not assess their own work, are independent of cost pressure or production pressure and are independent of the line management responsible for managing and implementing the process being assessed;

(b) The waste generator;

(c) Other organizations in the waste management programme served by the waste disposal facility;
(d) The responsible national authorities and international organizations;
(e) A separate organization employed by the waste generator;
(f) One or more equivalent qualified organizations in a peer review.

MANAGEMENT SYSTEM REVIEW

6.9. Reference [2] requires in paras 6.7–6.10 that:

> "6.7. A management system review shall be conducted at planned intervals to ensure the continuing suitability and effectiveness of the management system and its ability to enable the objectives set for the organization to be accomplished.
>
> "6.8. The review shall cover but shall not be limited to:
>
> — Outputs from all forms of assessment;
> — Results delivered and objectives achieved by the organization and its processes;
> — Non-conformances and corrective and preventive actions;
> — Lessons learned from other organizations;
> — Opportunities for improvement.
>
> "6.9. Weaknesses and obstacles shall be identified, evaluated and remedied in a timely manner.
>
> "6.10. The review shall identify whether there is a need to make changes to or improvements in policies, goals, strategies, plans, objectives and processes."

6.10. In conducting planned reviews of the management system, consideration should be given to whether the structure and content of the management system are still suitable, adequate and effective, especially during the extended pre-closure and post-closure phases (e.g. the period of prolonged active institutional control). In such management system reviews, account should be taken of experience from managing the waste disposal facility and of experience from other waste disposal facilities, both in the State and in other States.

6.11. Reviews of the management system for a waste disposal organization should be performed:

(a) On all aspects of the management system on a scheduled periodic basis (e.g. no less frequently than once every three years). The frequency should only be reduced, especially during an extended phase such as the post-closure phase, with justification and with the agreement of the regulatory body.
(b) Whenever there are major changes in organization or applicable legislation.
(c) Whenever there are major changes in waste disposal activities.
(d) Whenever significant conditions adverse to quality are detected in the management system.
(e) To verify the adequacy of any corrective action that has been implemented.

6.12. Reviews may be focused on, for example:

(a) The waste disposal activities under the control of the organization being assessed.
(b) The performance of the waste disposal facility, as determined by direct or indirect measures of the performance of the engineered systems, and natural and induced physical behaviours (e.g. groundwater movement, geological response to the heat load on the facility due to waste). Performance is assessed in comparison with the technical specifications, the actual evolution of the waste and the waste disposal facility over time in comparison with their original baseline characteristics and their expected evolution, and the safety assessment for the facility.

NON-CONFORMANCES AND CORRECTIVE AND PREVENTIVE ACTIONS

6.13. Reference [2] requires in paras 6.11–6.16 that:

> "6.11. The causes of non-conformances shall be determined and remedial actions shall be taken to prevent their recurrence.
>
> "6.12. Products and processes that do not conform to the specified requirements shall be identified, segregated, controlled, recorded and reported to an appropriate level of management within the organization.

The impact of non-conformances shall be evaluated and non-conforming products or processes shall be either:

— Accepted;
— Reworked or corrected within a specified time period; or
— Rejected and discarded or destroyed to prevent their inadvertent use.

"6.13. Concessions granted to allow acceptance of a non-conforming product or process shall be subject to authorization. When non-conforming products or processes are reworked or corrected, they shall be subject to inspection to demonstrate their conformity with requirements or expected results.

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

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

"6.16. Potential non-conformances that could detract from the organization's performance shall be identified. This shall be done: by using feedback from other organizations, both internal and external; through the use of technical advances and research; through the sharing of knowledge and experience; and through the use of techniques that identify best practices."

Non-conformances

6.14. A procedure should be established to control non-conforming items and processes; this should include:

(a) Segregation of non-conforming items to prevent them from being used or transferred to another organization before the non-conformance is resolved;
(b) Positive identification of non-conforming items and process equipment (e.g. tagging, labelling, stickers, marking);
(c) Resolution of the non-conformance (e.g. rework, repair, use as is or reject) and determination of the causes for the non-conformance so that

corrective actions can be taken to prevent the non-conformance from recurring.

6.15. The consequences of the non-conformance of an item should be evaluated to assess whether the item can be accepted and used as it is or whether it should be reworked or repaired to bring it back into conformity with specified requirements. If none of these options is practicable, the item should be rejected (e.g. waste packages returned to their source).

6.16. In the case of a waste package for which neither repair nor rejection is a viable option, consideration may need to be given to reworking the package, by repackaging, overpacking or taking other measures to bring it back within the requirements for waste disposal as specified in the acceptance criteria. Any non-compliance (e.g. a design fault, defective package material or damage induced by the emplacement operation) that is detected after the waste has been emplaced should be rectified as far as possible. If rectification of the non-compliance is not possible, the implications for waste disposal should be subjected to a detailed analysis and any possible consequences identified should be dealt with by other means.

6.17. A process should be developed for preparedness to respond flexibly in the event that the characteristics of the host geological formation encountered are found to deviate significantly from what was expected.

Corrective actions

6.18. Non-conformance data should be periodically analysed to identify quality trends and should be reported to the responsible manager for review and corrective action to remove the underlying causes of the non-conformances.

Preventive actions

6.19. In the case of underground repositories, because of the irreversible nature of disturbing a host geology, the cost and difficulty of retrieving waste after emplacement, and the intended finality of waste disposal, great emphasis should be placed on establishing procedures for identifying potential non-conformances and for taking action to prevent their occurrence. Care should be taken to optimize working methods at the outset of each phase, for example:

(a) For the production of waste packages, and starting as early as possible: training waste producers in the conditions for acceptance at the waste disposal facility.
(b) For site evaluation: maximizing the knowledge drawn from non-invasive exploration of a site.
(c) For design: coordinating effectively the interaction between the activities in facility design, site characterization and safety assessment.
(d) For construction: disturbing the host geological formation as little as possible and leaving it intact around major discontinuities and zones of structural weakness.
(e) For operation: emplacing waste packages intact, emplacing backfill to the intended density and installing seals reliably.
(f) For the post-closure phase: making extended monitoring as effective and efficient as possible.

Careful attention should be paid when organizational arrangements are modified.

IMPROVEMENT

6.20. Reference [2] requires in paras 6.17 and 6.18 that:

> "6.17. Opportunities for the improvement of the management system shall be identified and actions to improve the processes shall be selected, planned and recorded.
>
> "6.18. Improvement plans shall include plans for the provision of adequate resources. Actions for improvement shall be monitored through to their completion and the effectiveness of the improvement shall be checked."

6.21. Experience and lessons learned from incidents and events and from accumulated knowledge should be reviewed periodically and should be used in deciding on improvements to the management system and the waste disposal activities themselves. Benchmarking by interaction with other operators regionally, nationally and internationally, as appropriate and practicable, may also give rise to ideas for improvements that warrant consideration. Action plans should be developed that identify how, where and when improvements may be made to the management system and to work processes. These plans

should specify how the improvements will be evaluated so as to demonstrate that they have been achieved.

Appendix I

ASPECTS OF MANAGEMENT SYSTEMS SPECIFIC TO THE PHASES OF OPERATION, CLOSURE AND POST-CLOSURE ACTIVE INSTITUTIONAL CONTROL FOR DISPOSAL FACILITIES FOR RADIOACTIVE WASTE

GENERAL

I.1. This appendix provides recommendations on aspects of management systems that are specific to the phases of operation, closure and post-closure active institutional control for disposal facilities for radioactive waste, to supplement the recommendations in the body text of this Safety Guide.

I.2. There should be a documented process for the transfer of structures, systems and components and related records from one phase to another (e.g. construction to operation, operation to closure, or closure to post-closure). This process can also cover the changing of the organization conducting the activities in the respective phases.

ESTABLISHING PROCEDURES

I.3. Activities for which there should be procedures during the operational, closure and post-closure phases include:

(a) Planning and scheduling of the receipt of waste packages;
(b) Handling and control of waste packages before emplacement;
(c) Inspection of packages upon receipt, during operation and at closure;
(d) Repackaging;
(e) Waste transport and emplacement;
(f) Backfilling and sealing;
(g) Monitoring waste after emplacement;
(h) Maintenance of the facility;
(i) Control of records generated;
(j) Emergency preparedness and response;
(k) Environmental, structural and geological monitoring;
(l) Procurement and control of spare parts and materials;
(m) Periodic safety review.

MANAGEMENT OF WASTE PACKAGES

I.4. The management and control of the waste packages received should ensure that they are within specified limits and conditions, which includes:

(a) Identifying the waste packages;
(b) Corrective action on, including segregation of, non-conforming waste packages;
(c) Identifying quantities of waste and activity levels;
(d) Identifying the chemical content and physical properties of the waste;
(e) Using appropriate repackaging methods;
(f) Maintaining inventories;
(g) Controlling access;
(h) Controlling records generated.

I.5. If the waste disposal facility is of a type that accepts waste without packaging (e.g. waste from mining and milling activities), processes for the management and control of waste without packaging should be developed.

MAINTENANCE OF THE FACILITY DURING OPERATION

I.6. Before the commencement of waste emplacement, the operating organization should prepare a programme for maintenance of the waste disposal facility that is in line with the type of facility. Personnel with experience in maintenance should develop the maintenance programme before operation begins, and pertinent information from designers, construction organizations and other operating organizations should be used as the basis for the maintenance programme.

I.7. Owing to the potentially long period of waste emplacement, consideration should be given to the following points for the successful implementation of the maintenance programme:

(a) Planning and prioritization of maintenance work over an extended period of time;
(b) Continued availability of qualified personnel with suitable skills over the period of time;
(c) Continued availability of spare parts, special tools, equipment and materials;

(d) Performance of the required inspections and tests at specified time intervals.

SURVEILLANCE OF THE FACILITY

I.8. A programme for the surveillance of the facility should be established and implemented as necessary and feasible. It should consist of planned activities carried out to verify that the facility is operating within the design limits and conditions and to detect any deterioration of structures, systems and components that could result in unsafe conditions. It should be recognized that the behaviour of the waste disposal facility, especially in the post-closure phase, will normally evolve only very slowly.

FACILITY RECORDS

I.9. Records should be created and retained that describe the history of the waste disposal facility and related activities, as discussed in Section 5 of this Safety Guide. Particularly, records relating to the operation, closure and post-closure phases of the waste disposal facility may include:

(a) Records of discharges (liquid and gaseous);
(b) Maintenance records for the facility and emplaced waste packages;
(c) Non-conformances and corrective actions on the facility;
(d) Non-conformances and corrective actions relating to emplaced waste packages;
(e) Identification of emplaced waste;
(f) Results of inspections and tests;
(g) Records of periodic safety reviews.

PERIODIC SAFETY REVIEW

I.10. Periodic safety reviews should be performed as necessary and as required to substantiate the continued safe and reliable operation of the facility and control in the closure and post-closure phases. The responsible organization should define the scope and objectives of each safety review. The safety review process should:

(a) Confirm that the waste disposal facility is safe for a defined period of future storage;
(b) Confirm that the emplaced waste packages are safe for a defined period of future storage;
(c) Assess the effects of ageing, so as to estimate conservatively the ability of structures, systems and components to maintain their design safety margins;
(d) Assess the effects of ageing, so as to estimate conservatively the ability of emplaced waste packages to maintain their design safety margins;
(e) Assess the original safety assessment against current safety standards and requirements;
(f) Identify improvements that are reasonably achievable.

I.11. The inputs to the periodic safety reviews should include data on operational performance, results from surveillance and inspections, results from testing in the framework of ageing programmes, data on radiation levels at the facility, details of radiological and industrial safety performance, and details of unplanned radioactive releases to the environment. The results of periodic safety reviews should be used:

(a) To confirm that the waste facility or individually emplaced packages or items are in accordance with the design specifications;
(b) To identify and evaluate factors that could affect safe operation during the projected design period;
(c) To revise the existing safety case to satisfy current safety standards and requirements.

EMERGENCY PREPAREDNESS AND RESPONSE

I.12. Possible emergencies that could occur during operation and during the closure phases should be specified. Resources for implementing contingency plans should continue to be made available. Personnel responsible for implementing emergency plans should receive training, including the testing of emergency plans and procedures through drills, exercises and public information activities. Emergency plans and procedures should be revised and improved as a result of feedback from drills, exercises and public information activities.

HOUSEKEEPING AND CLEANLINESS

I.13. Maintaining the cleanness of the facility should be considered an essential activity, and standards for housekeeping should be set and maintained. It should be recognized that the area of a waste disposal facility can be very large, for example:

(a) A vast area for a near surface waste disposal facility;
(b) A very long access tunnel for a geological waste disposal facility.

PURCHASING

I.14. Extended phases of operation, closure and post-closure active institutional control (i.e. monitoring) may lead to the following unusual conditions arising:

(a) Replacement parts or materials may no longer be available. In this situation, the parts or materials may be manufactured, provided that all the specifications for the original parts or materials can be satisfied, or that substitute items, including those of commercial grade, may be acquired following approval by the organizational unit having overall responsibility for design. If the original structures, systems and components were procured as commercial grade items without specifically identified requirements, it may be appropriate, after a review of the nature and application of the structures, systems and components, for spare parts or materials to be procured on a similar basis.
(b) It may not be possible to establish what the specifications were for the original procurement. In this situation, an engineering evaluation should be conducted and new specifications should be established and documented. Interfaces and interchangeability should be taken into account in this evaluation, and it should be ensured that functions for safety and environmental protection are not adversely affected and that they are in accordance with regulatory requirements.
(c) If the requirements change, it may not be desirable to procure replacement items to the same technical specifications as were applied in the procurement of the original items. In this situation, the items should be procured to specifications made on the basis of an engineering evaluation that integrates the revised requirements.

I.15. Optimum inventory levels of spare parts should be identified and maintained. Minimum quantities of spare parts should be established for the purpose of reordering when the minimum level has been reached. These minimum levels should be reviewed periodically and adjusted on the basis of factors including usage, maintenance experience, cost and lead time.

EFFLUENT MONITORING

I.16. As part of the design and safety assessment for the facility:

(a) Discharge pathways for gaseous and liquid radioactive and toxic releases from the facility to the environment should be identified;
(b) Methods and procedures should be documented for on-site and off-site effluent monitoring and control for gaseous, liquid and particulate radioactive and toxic releases;
(c) Effluent monitoring, as necessary and feasible, should be conducted to ensure that releases are maintained within the specified limits and conditions.

SIGNPOSTING

I.17. The facility and the surrounding area should be uniquely and permanently signposted to provide the public with the required level of detail concerning the potential hazards associated with the waste disposal facility.

Appendix II

GUIDANCE ON CONTROLLING THE COMPUTER MODELLING OF DISPOSAL FACILITIES FOR RADIOACTIVE WASTE

GENERAL

II.1. Computer modelling and models of the behaviour of a waste disposal facility and its surroundings are used to carry out safety assessments during all phases of activities relating to waste disposal. Technical issues concerning the selection, development, modification, maintenance, verification and validation of computer models are adequately covered in other codes and standards and technical guides (see, for example, Refs [21–23]) and are not addressed here. This appendix focuses on the control of computer modelling.

PLANNING FOR COMPUTER MODELLING

II.2. Planning for computer modelling of a waste disposal facility should lead to specifications for:

(a) The data required;
(b) The systems and subsystems to be modelled;
(c) The modelling methods;
(d) The activities required to select, develop, modify, verify and validate the computer models.

During the planning stage, the iterative nature of the site characterization, facility design and safety assessment (see paras 5.5 and 5.34) should be considered.

II.3. During planning, the following items should be considered:

(a) Context and purpose of the analyses to be performed;
(b) Phenomena that have a bearing on the final outcome of the selection of the waste package and on the facility, including phenomena that could change the state of a system;
(c) The use of qualified data as far as possible;
(d) The manner of indicating where real data rather than assumed data are used;
(e) Model selection and development;

(f) Verification requirements (verification plan);
(g) Validation requirements (validation plan);
(h) Requirements for sensitivity analysis;
(i) Requirements for uncertainty analysis;
(j) Assumptions made or to be considered for both waste packages and the facility.

WORK CONTROL

II.4. Procedural methods or instructions should be used for:

(a) Selecting the modelling approach;
(b) Developing the model;
(c) Verifying the model;
(d) Validating the model or determining the potential for errors;
(e) Correcting errors and non-conformances;
(f) Performing sensitivity investigations;
(g) Generating uncertainty estimates;
(h) Considering assumptions.

II.5. Sources of data used to develop or select the model should be identified and maintained. Examples of sources are:

(a) Existing data sets;
(b) Literature searches;
(c) Laboratory experiments;
(d) Tests and field observations;
(e) Known geological phenomena;
(f) Seismic analyses;
(g) Structural codes and models;
(h) Engineering codes and standards.

Links between these data sources should be recorded.

II.6. Arrangements should be introduced to ensure that:

(a) Modelling methods are adequate;
(b) Processes are expressed in a quantitative mathematical form;
(c) Data are available to evaluate physical constraints and boundary conditions;

(d) The system to be modelled is adequately characterized and specified;
(e) There is a suitable linking of models of different parts of the waste disposal system so that reliable evaluations may be performed when specific models are integrated;
(f) Consistent assumptions are applied to all models.

MODEL SELECTION

II.7. The normal continual evolution of models that accompanies the growing understanding of the waste disposal system requires that the models be evaluated carefully before their application in a formal safety case. An accepted process and sound technical judgement should then be used in selecting the modelling activities. All basic assumptions should be carefully analysed, with due account taken of the specific areas relating to the waste package and the facility.

II.8. The final selection of the model to be developed or to be used should be reviewed and approved. The justification should show that the model will adequately represent the system or subsystem and is appropriate to the current stage of the analysis for the waste package and the facility. The justification of the selection should be documented.

II.9. If the development of a new model is required, phenomena that are considered to be decisive to the final results and conclusions — including those phenomena that comprise the whole system, its components and their interrelationships — should be reviewed and approved, or at least explicitly agreed upon by all concerned, prior to model development. Phenomena that are thought to be capable of changing the state of the system and phenomena that could make a significant contribution to the overall radiological impact should be identified.

II.10. To ensure that the model selected is adequate for the application, the review and approval process should cover:

(a) The modelling possibilities available for a particular analysis;
(b) Development processes, including verification and validation histories;
(c) Inherent assumptions and limitations, including simplifications to solvable expressions obtained;
(d) The sensitivity to various ranges of input data and coefficients;
(e) Stability characteristics of the numerical methods applied to the model.

MODEL DEVELOPMENT

II.11. When a new model is to be developed, the requirements specified during planning should be followed. A development plan should define the development sequencing, reviews, verification and validation that are to be performed.

II.12. When a subsystem analysis is necessary, a strategy and specific criteria for the selection of subsystem models should be specified and subjected to review and approval. Confirmation that these criteria have been satisfied should be recorded.

II.13. Where long term behaviour is an essential element of the model, the correlation between theory and experiment and extrapolation from available natural analogues should be documented, as necessary and as feasible.

II.14. Possible inefficiencies and instabilities that could introduce inaccuracies if the application requires the coupling of models should be identified so that they can be prevented from arising.

II.15. Changes to be made to models owing to increasing knowledge of the system, or resulting from conditions not considered in the original development or during subsequent development stages, should be controlled and should be subjected to the above requirements.

MODEL SENSITIVITY

II.16. The sensitivity of model calculations to variations in inputs should be investigated. The method to be used should be specified. The models should be verified and validated prior to investigations of their sensitivity. The strategy, technique, sample size, analyses and results should be reviewed to confirm that they are appropriate and accurate.

UNCERTAINTY ANALYSIS

II.17. Sources of uncertainties in the data and analyses should be identified and quantified, as necessary and as feasible.

II.18. The method of performing the uncertainty analysis and presenting the results should be specified.

II.19. Reviews should be performed to confirm the adequacy of the method and the reasonableness of the results and conclusions.

MODEL VERIFICATION

II.20. A method for carrying out model verification should be developed. The extent of verification should be determined during planning, and the verification should be performed by individuals other than those who developed the model being verified.

II.21. The model verification process should confirm and demonstrate that:

(a) The model and/or corresponding computer program is a proper mathematical representation of the conceptual model;
(b) The equations have been correctly encoded and solved;
(c) The computer program functions correctly under the set of conditions that bound its intended usage.

II.22. The model verification should include:

(a) In-process and final checking of the computer program during and after development to ensure that it is correct;
(b) Subjecting the method of checking to approval;
(c) Comparison of the computed results with the solutions to the problem;
(d) Final testing conducted using problem sets as described in the test plan.

II.23. If another computer program is to be used for verification, it too should be subjected to verification. The verification plan should contain:

(a) The model attributes to be tested;
(b) The type of test to be performed;
(c) The acceptance and/or rejection criteria;
(d) The requirements for recording results;
(e) The test history.

II.24. Calculations should also be verified. Simplified calculations may be used for this purpose. If differences arise that substantially modify the final results

and conclusions of the original calculations, a more complete and thorough review should be conducted. The analyses, assumptions, initial conditions, boundary conditions and results should be documented. For field and laboratory activities, appropriate verifications should be specified.

MODEL VALIDATION

II.25. A thorough understanding of the model and its range of applicability should be obtained, and where possible the expected level of error should be determined and recorded. The requirements that have to be satisfied to demonstrate that the model and/or computer programs derived from it provide a good representation of the real process should be determined and specified in a validation test plan. The test plan should specify the validation method, for example comparison with field and laboratory data or comparison with natural systems, and should define the model features to be tested and the data to be used to test them. To the extent necessary and feasible, a programme of investigation should be carried out at the candidate site to determine key model parameters for matching the model to the site. Descriptions for each validation test case should be prepared and should be reviewed for approval. This review should ensure that an appropriate method of collecting the data is specified. Persons conducting these reviews should be independent of those carrying out the work.

MODEL REVIEW AND UPDATING

II.26. Models should be reviewed at specified intervals and updated and revalidated as required. The review process should ensure that the models represent the latest data and the current revision of the waste package or the facility system or subsystem that is the object of the safety assessment.

CHANGE CONTROL

II.27. The integrity and configuration of the model should be maintained and protected by identifying and controlling software components of the model, changes to the software and data sets used, and the supporting documentation for the software. Arrangements should be made to ensure that:

(a) Computer program components are identified;
(b) It is clear at which point in the development a component becomes subject to configuration control;
(c) Proposed changes to components receive the same level of review as originals and are handled comprehensively and accurately;
(d) Approved changes are introduced and circulated with corrected documentation and computer program changes;
(e) The computer program and supporting documentation are verified and the computer program is revalidated.

TRACEABILITY OF DATA

II.28. The sources of data used in modelling that will affect or support conclusions on siting should be retained throughout the development of the model. Intermediate iterations and the final model should be traceable to and supported by the acquired input data. Adequate cross-referencing to specific data should be provided. The data format should be such that it can be reviewed and checked.

RECORDS

II.29. The following are examples of records and documents that should be retained:

(a) Justification of model selection;
(b) Confirmation that selection criteria have been satisfied;
(c) Experimental data relating to the model;
(d) Results of sensitivity and uncertainty analyses;
(e) Reports showing that the required verification of tests has been performed;
(f) Records showing that the current version of the program has been validated.

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