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The Management System for the Predisposal Management and Disposal of Radioactive Waste

DRAFT SAFETY GUIDE

DS477

Draft Safety Guide



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1. INTRODUCTION

BACKGROUND

1.1 Radioactive 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 [1]. Requirement 7 of GSR Part 5 [2] and Requirement 25 of SSR-5 [3] require that:

“Management systems shall be applied for all steps and elements of the predisposal management of radioactive waste” and “Management systems to provide for the assurance of quality shall be applied to all safety related activities, systems and components throughout all the steps of the development and operation of a disposal facility.”

1.2 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 an efficient and effective manner [4]. The management system incorporates, amongst other elements, quality assurance and quality control systems. Management systems for radioactive waste management are subject to the requirements established in GSR Part 2 [5]. GSR Part 2 emphasizes that leadership for safety, management for safety, an integrated management system and a systemic approach (i.e. an approach relating to the system as a whole, in which the interactions between technical, human and organizational factors are duly considered) are essential to the specification and application of adequate safety measures and the fostering of a strong safety culture. Given the wide range of waste management facilities and activities, it is important that the management system is developed and applied to a specific facility or activity using a graded approach [5].

1.3 Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks [1]. GSR Part 2 establishes requirements for ensuring safety on the basis of the interrelated concepts of leadership for safety and management for safety [5]. Management for safety includes establishing and applying an effective integrated management system that integrates all elements of management so that requirements for safety are established and applied coherently with other requirements, including those for human performance, quality and security; and so that safety is not compromised by the need to meet other requirements or demands. [5].

1.4 This Safety Guide provides specific guidance on meeting the requirements of GSR Part 2 [5] for predisposal management and disposal of waste to provide confidence that the requirements for predisposal management (GSR Part 5) [2] and for waste disposal (SSR-5) [3] will be fulfilled. This Safety Guide was developed based on the content of two previous Safety Guides GS-G-3.3 ‘The

Management System for the Processing, Handling and Storage of Radioactive Waste’¹, and GS-G-3.4, ‘The Management System for the Disposal of Radioactive Waste’², with the intention of consolidating the two guides and updating their content. This Safety Guide identifies the need to consider security as well as safety; requirements and guidance on security are provided in the IAEA Nuclear Security Series publications. The management system supports the achievement of the fundamental safety objective of protecting people and the environment from harmful effects of ionizing radiation [1], and takes into account the interfaces between safety and security [5].

1.5 The development of a management system for an organization will also for example take into account:

- a) Internationally recognized standards such as ISO 9001:2015 [6] for quality management systems and ISO 14001:2015 [7] for environmental management systems;
- 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.
- e) The organization’s jurisdiction, strategic plans, specific duties, and responsibilities, as well as its short-term and long-term objectives.

1.6 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 their compliance. Assessments of the management system (see Section 4) should demonstrate that the management system is performing well, and that the procedures for executing the processes that are controlled under the management system are producing the specified results to satisfy the requirements and achieve intended goals and objectives.

1.7 Application of the requirements and recommendations referred to in the preceding paragraphs relating to the management system for radioactive waste management will contribute to a high level of confidence that:

- a) waste management activities will be conducted in a coherent, coordinated, and controlled manner;
- b) conditioned waste will be of appropriate and consistent quality;
- c) the characteristics of conditioned waste are known sufficiently;

¹ INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for the Disposal of Radioactive Waste, IAEA Safety Standards Series No. GS-G-3.4, IAEA, Vienna (2008).

² INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for the Processing, Handling and Storage of Radioactive Waste, IAEA Safety Standards Series No. GS-G-3.3, IAEA, Vienna (2008).

- d) appropriate records of waste conditioning will be kept that enable waste package identification and decisions on whether the conditioned waste and waste packages meet the waste acceptance criteria for predisposal management and disposal facilities.

1.8 Adherence to the guidance contained in this Safety Guide will also give confidence that a waste disposal facility and its contents will be managed to comply with limits, controls and conditions important to the fundamental safety objective of protecting human health and the environment.

1.9 The prime responsibility for properly executing a particular task (e.g. processing (pretreatment, treatment, and conditioning), storage and disposal, and related activities such as characterization of waste, clearance, and the design, construction, commissioning, operation and decommissioning or closure, as applicable, of predisposal management and disposal facilities) rests with the operator³. The operator's management system should include plans and arrangements for the management system itself to continue for as long as is required to maintain continuous control over the facilities and activities, and to cover all stages of waste management from the generation of waste to its disposal including 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 period. These extended periods influence the long term planning that is necessary to maintain continuity of oversight of the waste disposal facility.

1.10 Processing (pre-treatment, treatment, and conditioning), storage and disposal of radioactive waste involve a variety of technical and managerial activities and may extend over a very long time (e.g. disposal facility operation may potentially last more than a hundred years). These characteristics present a series of challenges for the development, implementation and maintenance of effective management systems for facilities and activities for radioactive waste management. The following aspects warrant particular consideration in developing a management system for programmes for radioactive waste management:

- a) By definition, waste is material for which no further use is foreseen. As stated in Requirement 1 of GSR Part 5 [2]:

“The government shall provide for an appropriate national legal and regulatory framework within which radioactive waste management activities can be planned and safely carried out. This shall include... ..the securing of financial and other resources...”

The provision of funds and the organizational arrangements for predisposal management and disposal 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

³ The Safety Glossary [4] defines the operator as: “Any person or organization applying for authorization or authorized and/or responsible for safety when undertaking activities or in relation to any nuclear facilities or sources of ionizing radiation. Operator includes, inter alia, private individuals, governmental bodies, consignors or carriers, licensees, hospitals, self-employed persons, etc. Operator is synonymous with operating organization.”

funding of the necessary predisposal management and disposal activities 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 (e.g. waste can be stored for years to a few decades). As a consequence, the selection and implementation of waste management and disposal options is sometimes postponed by a series of short term deferrals for additional assessment of the options and, for example, to allow radioactive decay and waste cooling, to facilitate future management.
- c) In accordance with 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, responsibility for the waste always remains with the original generator of the waste. In general, it is preferred that the responsibility for the waste is transferred to the body managing the waste. As stated in Requirement 1 of GSR Part 5 [2]:

"The government shall provide for an appropriate national legal and regulatory framework within which radioactive waste management activities can be planned and safely carried out. This shall include the clear and unequivocal allocation of responsibilities..."

Responsibility and accountability for waste should be clear and fulfilled at all times.

- d) Because the responsibility for waste can change during its management, the waste generator and any organization authorized to undertake waste management activities need to ensure that waste production is minimized and that conditioned waste is compatible with the waste acceptance criteria of the receiving organization. In cases where waste acceptance criteria are yet to be defined, the organization managing the waste needs to ensure that conditioned waste is as likely as possible to be acceptable for the next waste management step.
- e) Responsibility for waste for which the generator can no longer reasonably be held responsible commonly reverts to the responsible national authorities. The transfer and delineation of the limits of this responsibility, with its attendant costs, can become blurred if care is not exercised.
- f) Public and political sensitivities to decisions on the predisposal management and disposal of radioactive waste can impose constraints on waste management and disposal arrangements, timings and the technical options that are feasible.
- g) If definite end points (i.e. discharge, clearance or a specific disposal option) for waste have not been selected, it may be difficult to define the preferable form of the waste material to be produced and held in storage, and the acceptable form for final disposal. In such a situation, the foreclosure of future disposal options (e.g. by choosing to produce an interim waste form that is both unsuitable for disposal and difficult to convert to a form that is suitable for disposal) should be avoided. However, uncertainty about the end point should

not be used as a rationale for not taking steps to ensure that the waste is managed in a safe and environmentally acceptable manner pending disposal. Wherever possible, waste should be stored and contained in a state that is passively safe [2], [3].

- h) The long term nature of waste management means that a waste management facility may be managed by successive generations and may be controlled under a series of different organizations, national and international structures, and management systems; this presents challenges for the maintenance of continuous and consistent management oversight.
- i) Management systems for all waste management activities should encourage the adoption of unified approaches and solutions and international best practices.
- j) The organizations involved in waste disposal 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 for the development of a coherent overall management system for a waste management and disposal programme. Whatever the arrangements, safety and the protection of human health and the environment should always be paramount.
- k) Waste may be managed by a series of organizations that carry out the sequence of required predisposal management and disposal steps. For example, waste generated by one organization may be transferred to another for processing (pretreatment, treatment and conditioning), to another for storage, and to yet another for disposal. Each of these organizations may have its own management system, so that the waste may be controlled under a series of different management arrangements. This could present challenges for maintaining continuous active oversight of the waste, which may be exacerbated by the long term nature of some waste management activities.
- l) In particular, the long term nature of waste disposal means that additional attention should be paid to the following: (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 radioactive waste using the management system until active institutional control ceases; and (iv) Ensuring continuity of understanding, attention and resourcing from one human generation to the next.

1.11 One particular aspect to consider when developing management systems for radioactive waste disposal facilities is that, after the end of active institutional control in the post-closure period, safety, and human and environmental protection will depend on a passive system [3]. The geosphere has several key roles in providing passive safety in radioactive waste disposal systems. A geosphere should be selected that will provide a stable environment for the waste disposal facility, that will provide suitable

conditions for the engineered barriers included in the disposal system, and that will contribute to providing safety through multiple safety functions [3]. A geosphere should be selected that will contribute to containment and isolation of the waste [3]. This is particularly important for waste that may remain hazardous in the long term after 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. Another aspect relating to the long term nature of waste disposal that may affect the development and implementation of the management system is the unpredictability of the future behaviour of populations or environments that may be affected by, or may have an impact on, the waste disposal facility [3].

1.12 In comparison with nuclear power plants, the state of development and the amount of experience with waste disposal facilities is more varied. Although many and various types of near surface waste disposal facility are in operation, there is much less experience with geological disposal, and disposal facilities for spent fuel or high level radioactive waste are not yet operating. Thus, management systems for the research and development, siting, design, construction, commissioning, operation, closure and post-closure stages of waste disposal facilities will have to be developed and improved as knowledge of the development of these facilities is accumulated. The accumulation of management knowledge in the organization, in industry, in the regulatory body, and in and among States is very important. In this regard, independent 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 [3].

1.13 The management systems applied to meet the requirements for both predisposal management and disposal of radioactive waste contribute to applying the fundamental safety principles [1]. Requirements for legal and governmental infrastructure are established in GSR Part 1 [8]. Other technical requirements and guidance relating to the management of radioactive waste are established in other IAEA Safety Standards [2], [3], [9], [10], [11], [12]. The basic requirements for radiation protection are established in GSR Part 3 [13] and the requirements for emergency preparedness and response in GSR Part 7 [14].

1.14 The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [15] should be considered in developing management systems for predisposal management and disposal activities, to give due recognition to the international implications of the activities.

1.15 The management systems discussed in this Safety Guide, are intended to apply to all stages of radioactive waste management, including the period of institutional control in the post-closure period of a disposal facility. Although the guidance on the management system is generally applicable to the period of institutional control after closure of disposal facilities, the guidance is not intended to be unduly prescriptive for this time period in the future. Understanding and knowledge will continue to

grow and should be managed continuously in the organization, the industry, the regulatory body, and among States.

1.16 This Safety Guide will be revised in the light of knowledge and experience gained on new processes, technological developments, changes in the skills and tasks of personnel, and other unforeseen changes.

OBJECTIVE

1.17 The objective of this Safety Guide is to provide guidance on developing and implementing systems for management for safety and protection of human health and the environment during all steps of radioactive waste management, including processing (pretreatment, treatment, and conditioning), storage and disposal, and during related activities, including characterization of waste and clearance, but excluding transport, for which guidance may be found in refs. [16], [17]. This Safety Guide also provides guidance on effective leadership and culture for safety.

SCOPE

1.18 This Safety Guide covers management systems for radioactive waste management including:

- a) processing, comprising:
 - a. pretreatment (e.g. collection, segregation, chemical adjustment and decontamination);
 - b. treatment (e.g. volume reduction, removal of radionuclides from the waste, and change of composition);
 - c. conditioning (e.g. immobilisation, packaging and overpacking);
- b) storage;
- c) disposal (e.g. near-surface, geological, borehole and landfill disposal).

1.19 This Safety Guide does not address management system elements required for transport [17]. This Safety Guide provides guidance on the management system for the management of waste arising from decommissioning; detailed guidance on the management system for decommissioning activities other than the management of waste is provided in SSG-47 [18] and SSG-49 [19].

1.20 This Safety Guide covers management systems for the activities involved in managing all types of radioactive waste. It covers waste from nuclear fuel cycle activities, including:

- a) Mining and processing of uranium ores and thorium ores;
- b) Uranium conversion;
- c) Uranium enrichment;
- d) Fuel fabrication;
- e) Reactor operation;

- f) Management (i.e. processing - including reprocessing, storage, and disposal) of waste fuel;
- g) Waste management (e.g. secondary waste);
- h) Decommissioning and environmental remediation.

1.21 It also covers waste from activities outside the nuclear fuel cycle, including:

- a) Mining and processing of non-uranium minerals and resources (i.e. waste containing naturally occurring radionuclides, such as in fertilizers, oil and gas);
- b) Activities in hospitals;
- c) Activities in laboratories;
- d) Activities in research facilities;
- e) Activities in industry;
- f) Decommissioning or cleanup of facilities where activities have ceased and there is no intention of further use (e.g. workshops used for painting dials with radium).

1.22 This Safety Guide also covers management systems for related processes and activities, including:

- a) Waste generation;
- b) Waste characterization (e.g. to determine the radiological and physico-chemical properties of the waste and enable decisions on clearance);
- c) Design and manufacture of waste containers and waste packages;
- d) Siting, design and construction of waste management facilities;
- e) Safety case development and safety assessment;
- f) Authorization (e.g. licensing);
- g) Commissioning of waste management facilities;
- h) Operation of a predisposal management facility;
- i) Operation of a disposal facility (e.g. the activities, which can extend over several decades, involving receipt of conditioned waste (if it is to be disposed of in packaged form), waste emplacement in the disposal facility, backfilling and sealing, and any other operations in the subsequent period prior to closure);
- j) Closure of a disposal facility;
- k) The period of institutional control for a disposal facility; covering both active control (e.g. security, surveillance and monitoring) and passive control (e.g. preservation of records, and restricted land use) [3].

1.23 This Safety Guide is intended to be used by organizations that are directly involved in, or that regulate, the facilities and activities identified in paras. 1.18 to 1.22 and by the suppliers of nuclear safety related products that are required to meet some or all of the requirements established in Refs. [1], [2], [2], [3], [13] and [14]. It will also be useful to legislators and to members of the public and other parties interested in the safe management of radioactive waste.

STRUCTURE

1.24 This Safety Guide follows the structure of GSR Part 2 [5]. To aid the user, the corresponding requirements of GSR Part 2 [5] are quoted where relevant. Recommendations on the achievement of the fundamental safety objectives are provided in Section 2. Recommendations on leadership in ensuring safety are provided in Section 3. Section 4 describes key points for establishing a radioactive waste management system, including the use of integrated management systems, the use of a graded approach, and considerations of goals, strategies, plans and objectives. Section 4 also provides recommendations on the management of resources, the management processes and activities, and documentation. Recommendations on culture for safety are provided in Section 5. Recommendations on the measurement, assessment, evaluation and improvement of the management system, and the management of contractors and the supply chain are provided in Section 6.

1.25 Appendix I identifies key activities undertaken within predisposal management facilities. Appendix II identifies key management system aspects specific to the operation, closure and institutional control of waste disposal facilities. Appendix III illustrates the graded application of management system requirements.

2. RESPONSIBILITY FOR SAFETY

Requirement 1 of GSR Part 2 [2]: Achieving the fundamental safety objective

“The registrant or licensee – starting with the senior management – shall ensure that the fundamental safety objective of protecting people and the environment from harmful effects of ionizing radiation is achieved.”

2.1 The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation [1]. The senior management⁴ of the operator is responsible for developing objectives, strategies, goals, and plans for activities with a focus on achieving the fundamental safety objective without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks. Safety should be considered first in any business decisions, in any activities and in the associated management system documentation.

2.2 ‘Senior management’ should be specifically identified within the operator’s organization. Senior management should define and implement an organization’s safety policy based on the national policy and strategy.

2.3 The senior management of an organization responsible for a waste management facility or activity should be accountable and responsible for managing the facility or activity and demonstrating its safety, consistent with both national policy and strategy for radioactive waste management, and regulatory requirements. The senior management should ensure that each step of radioactive waste management, from generation to disposal, has consistent objectives and goals in order not to compromise the safety of the subsequent steps in the waste management process. Undertaking this task should involve the development of a safety case, including consideration of: the characteristics and quantities of the radioactive waste to be managed; the site or sites available and its/their characteristics; available options for excavation and construction of facilities; available engineering techniques; operating procedures, and the legal and regulatory infrastructure and regulatory requirements.

2.4 Senior management of an organization that generates waste should at the time of waste generation ensure that adequate funding is available for the current waste management step and for subsequent waste management steps leading to and including disposal. Senior management of the waste generating organization should ensure that adequate resources are available to manage and ensure safety of the facilities and activities.

2.5 The clear allocation of accountabilities and responsibilities is essential to ensure safety in the management of radioactive waste including both predisposal management and disposal activities. The senior management should ensure that it is clear within the management system when, how and by whom decisions are to be made. It is possible that the management of radioactive waste will involve the transfer of radioactive waste from one operator to another, or that radioactive waste management may

⁴ The IAEA Safety Glossary [4] defines senior management as: “The person or persons who direct, control and assess an organization at the highest level.”

even involve another State. In all situations, continuity of responsibility for safety is necessary throughout, and appropriate management arrangements should be put in place for the transfer of waste to ensure that it is clear where the responsibility lies and the exact point at which the transfer of responsibility takes place. These management arrangements should also include provision for the transfer of records and required knowledge. The responsible body at any given time, i.e. the operator should have an adequate management system to meet the requirements of GSR Part 2 [5] to ensure that safety is not compromised. If the license is terminated at any time, then the government should ensure that the body responsible for safety for both the facility and the waste is clear [8]. In some instances, e.g. following closure of a disposal facility or at the end of active institutional control, the responsibility may be transferred to the government itself. In such instances, the government should take over responsibility for record keeping, knowledge management, and other institutional control measures.

2.6 The senior management of a generator of radioactive waste should liaise with the relevant regulatory body and operators of waste management facilities to ensure that the waste can be safely managed through all steps of the waste management process including disposal.

2.7 The operator should supply all the information that is required by the regulatory body, and should initiate interactions with the regulatory body as soon as possible and before conditioning of the waste.

2.8 If management and control of a site is necessary following termination of a licence, government should provide for the management that is required. For example, management arrangements may be required for monitoring and for ensuring security.

2.9 Because of the nature of radioactive waste management there may be occasions when no private owner of the waste is identified, e.g. orphan sources, or the operator/responsible body is the government. In such cases, the government should have identified and delegated clear responsibilities to individuals with strong and effective leadership capabilities to ensure safety.

2.10 In accordance with GSR Part 1 [8]:

“The government shall make provision for appropriate research and development programmes in relation to the disposal of radioactive waste, in particular programmes for verifying safety in the long term.”.

Because of the longevity of some waste management facilities, especially disposal facilities, this research may need to be initiated well in advance of operation and be capable of assessing long term behaviour and consequently informing the development of waste acceptance criteria. The research and development activities involved in developing and assessing the safety of a proposed waste disposal facility can be conducted both in the laboratory and in the field. There is always residual uncertainty in the conclusions that may be drawn from these activities about the behaviour to be expected for the waste disposal facility, particularly in the long term. This uncertainty should be recognized and managed.

2.11 Under senior management direction and oversight, emergency plans, procedures, and other arrangements, including for training, drills and exercises, should be developed, implemented, reviewed, updated and maintained in line with Requirements 25 and 26 of GSR Part 7 [14]. Hazard assessment should be performed in line with Requirement 4 of GSR Part 7 [14] to provide a basis for developing and implementing a graded approach to preparedness and response for a nuclear or radiological emergency that reflects the characteristics of the waste, of the waste management facility, and of the site and its vicinity, at each stage in the lifetime of the facility (e.g. operation, decommissioning, closure, post-closure).

3. LEADERSHIP FOR SAFETY

Requirement 2 of GSR Part [2]: Demonstration of leadership for safety by managers

“Managers shall demonstrate leadership for safety and commitment to safety.”

3.1 Senior management should recognize that individuals and the culture for safety of an organization may be influenced through leadership. To improve the culture for safety and help individuals to develop professionally, managers at all levels should demonstrate their commitment to safety as an overriding priority in resource allocation, in business planning, in documentation and in all activities. It is particularly important for senior management to demonstrate both a proactive and long-term approach to safety issues in decision-making. Managers should also show commitment to the implementation and continuous improvement of the radioactive waste management system by both their words and actions to foster a strong safety culture.

3.2 The interactions between humans, technology and organizations affect safety. Senior management should make arrangements to ensure that methods are incorporated in the management system to identify and manage human, technological and organizational factors affecting safety.

3.3 Senior management should promote and exercise open and effective communication at all levels on safety and safety related requirements. Senior management should share information concerning radioactive waste management to personnel frequently and consistently. Any information with a bearing on safety, human health, environmental protection, security, quality, human-and-organizational-factor, societal and economic elements should be communicated to the personnel and other relevant interested parties. The senior management should also regularly seek feedback on how effective the leadership is in ensuring and improving safety and the management system, and should take corrective actions as necessary.

3.4 Senior management should set an example for safety, for example, by showing the highest standards of personal integrity, through their direct involvement in training and in oversight of important activities. Individuals in an organization generally seem to emulate the behaviours and values that their leaders demonstrate.

3.5 Managers should, through their own actions, promote safe ways of working, be visibly involved in safety-related activities and reinforce good practices. Managers should develop the values and behavioural expectations of the organization, while setting an example of how to promote these values and encouraging expected behaviours. Managers should also be able to recognize any deterioration in safety performance and/or safety related attitudes, and take immediate actions to respond to the situation.

3.6 Managers should promote ways for the entire personnel to participate in the implementation and continuous development of the management system including, where relevant, other parties that are affected by the activities of the facility, e.g. the public, waste generators, organizations managing the waste further on in the management process and any sub-contractors that are used. The participation in implementation and improvement activities gives the personnel better understanding of the

management's perceptions and beliefs concerning the importance of the management system and the need to achieve the policies and objectives of the organization. It also motivates personnel to share these perceptions and beliefs and to attain higher levels of performance.

3.7 Managers at all levels in the organization should possess leadership capabilities. Managers should also have administrative and 'people management' competences, and communication and interpersonal skills. Managers should develop their skills and support their subordinates to systematically develop their skills and solve problems and conflicts. Management should be familiar with the requirements and special characteristics of their subordinates' work. The performance of managers and their professional development should be assessed on a regular basis. The management should also ensure that their leadership, communication and interpersonal skills are systematically developed.

4. MANAGEMENT FOR SAFETY

RESPONSIBILITY FOR THE MANAGEMENT FOR SAFETY SYSTEM

Requirement 3 of GSR Part 2 [2]: Responsibility of senior management for the management system

“Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety.”

Requirement 7 of GSR Part 5 [2]: Management systems

“Management systems shall be applied for all steps and elements of the predisposal management of radioactive waste.”

Requirement 25 of SSR-5 [3]: Management systems

“Management systems to provide for the assurance of quality shall be applied to all safety related activities, systems and components throughout all the steps of the development and operation of a disposal facility. The level of assurance for each element shall be commensurate with its importance to safety.”

4.1 The senior management of the operator is responsible for the management system and for ensuring that it is established, implemented, assessed and continuously improved. The senior management should ensure that all activities comply with the requirements of the management system and should retain overall responsibility when an external organization is involved in the work of developing all or part of the management system. The senior management should ensure that the management system continues to be properly implemented, assessed, and improved during periods of organizational change by, amongst other things, ensuring that new staff, including leaders and managers, possess the necessary competencies and are suitably qualified and experienced.

4.2 Senior management should put in place arrangements to ensure management at all levels demonstrate commitment to the establishment, implementation, assessment and continuous improvement of the management system. The processes for fulfilling the responsibilities of senior management in relation to the management and control of radioactive waste are subject to the requirements established in GSR Part 2 [5], and the guidance presented in this Safety Guide; the guidance in Ref. **Error! Reference source not found.** should also be considered.

4.3 The management system should be aligned with the goals and strategies of the organization and should contribute to their achievement. The management system should achieve and enhance safety by:

- a) bringing together in a coherent manner all of the requirements for managing the organization;
- b) describing the planned and systematic actions necessary to provide adequate confidence that all of these requirements are satisfied;

- c) ensuring that security, quality, technology and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.

4.4 Safety should be paramount within the management system, overriding all other demands. Because of a combination of the long term nature of waste management and the probability that the waste may be managed in a number of different facilities prior to disposal, the management system should be capable of dealing with long term aspects, such as changes in responsibilities and interdependencies between waste management facilities and processes.

4.5 A management system should be planned, documented and implemented that covers all of an organization's operations, and the system should be continuously assessed, maintained and improved. As a whole, the system should be well-balanced, recognizing the potential needs of other facilities within the waste management process.

4.6 In the management system, the organizational structure and the responsibilities, authorities, and decision-making procedures of the personnel and processes should be defined taking into account their safety implications. The organizational structure should be justified. The identification of responsibilities is particularly important for waste management as the waste generator may hand over responsibility for its safe management to a variety of different waste management facility operators. The point at which responsibility changes should be clearly defined and documented within the management system, ensuring that safety is not compromised. Operator's management systems should contain contingency measures in the event that acceptance criteria are not met.

4.7 An individual reporting directly to senior management should have specific responsibility and authority for:

- a) coordinating the development and implementation of the management system, and its assessment and continual improvement;
- b) reporting on the performance of the management system, including its influence on safety and safety culture, and any need for improvement;
- c) resolving any potential conflicts between requirements and within the processes of the management system.

4.8 In deciding on the individual manager to be responsible for the management system for a waste management programme or organization, the senior management of that organization should ensure, when defining duties, that all the waste management activities are covered in a comprehensive and coherent manner and that these activities are covered continuously over the period that associated safety, human health and environmental protection, security, quality, human-and-organizational-factor, societal and economic concerns continue. This is especially pertinent for geological disposal facilities where there could be responsibilities that extend for long periods of time.

4.9 For each process, a designated individual should be given the authority and responsibility for:

- a) Developing and documenting the process and maintaining the necessary supporting documentation;
- b) Ensuring that there is effective interaction between process interfaces;
- c) Ensuring that process documentation is both internally consistent, and consistent with the facilities and activities;
- d) Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation;
- e) Monitoring and reporting on the performance of the process;
- f) Promoting improvement in the process;
- g) Ensuring that the process and any subsequent changes are aligned with the goals, strategies, plans and objectives of the organization.

4.10 Roles and responsibilities for safety, and human and environmental protection in waste management and 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. in accordance with agreements on the repatriation of waste following fuel reprocessing). Management systems for facilities and activities for waste management and disposal should be designed to ensure continuity in managing the facilities and activities, and should be able to cope with possible changes, for example, in the following:

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

4.11 When management arrangements for waste management and 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 an operator undergoes internal reorganization of its management structure or reallocation of resources), consideration should be given to the possible need to adapt the management system while ensuring that the management system continues to be properly implemented, assessed, and improved.

Goals, strategies, plans and objectives

Requirement 4 of GSR Part 2 [5]: Goals, strategies, plans and objectives

“Senior management shall establish goals, strategies, plans and objectives for the organization that are consistent with the organization’s safety policy.”

4.12 Senior management should derive goals, strategies, plans and objectives that are consistent with government policies and strategies on radioactive waste management and that recognize the long term safety aspects that are involved in radioactive waste management. The strategies and plans should include appropriate means of considering, in decision making, the concerns and expectations of interested parties (including the public and especially the local population). The strategies and plans should be communicated effectively and consulted upon. Radioactive waste management strategies should be developed taking full advantage of opportunities and synergies arising from international cooperation and experience where appropriate.

4.13 The senior management should recognize that radioactive waste management programmes may be affected by many factors. In particular, the senior management 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 radioactive waste management, including waste disposal, and industry norms and standards that currently constitute an accepted management system, will evolve over the extended period of time for which waste management activities may continue. Policy decisions (e.g. regarding reprocessing of spent fuel) and technological innovations and advances may lead to changes in the overall waste management strategy. However, senior management will retain its responsibility for facilities and activities, and continuous, demonstrable commitment by management to improve its management system will remain a prerequisite to ensuring safety and protection of human health and the environment.

4.14 Senior management should be responsible for establishing the policies of the organization and for documenting them in the management system. Senior management should also ensure that the management system is updated if goals, strategies, plans, policies or objectives are changed. Hence, the management system will consist of a dynamic collection of living documents.

4.15 The policies should:

- a) state that safety has overriding priority;
- b) comply with national policies, strategies and related regulations on radioactive waste management;
- c) take account of public attitudes, concerns and expectations about safety, and human and environmental protection, extended restrictions on the use of land and geological resources, etc. and other concerns of interested parties;

- d) be appropriate to the purpose and the activities of the organization and contain statements on safety, human health and environmental protection, security, quality, human-and-organizational-factor, societal and economic considerations;
- e) limit and constrain impacts on the environment and future generations;
- f) include a commitment to comply with management system requirements and to seek continual improvement;
- g) be aligned with, and support the development of a strong safety culture;
- h) provide an appropriate framework for action and for establishing and reviewing goals and objectives at all levels. Where possible, goals and objectives should be measurable;
- i) be reviewed periodically for their continuing suitability and applicability;
- j) be effectively communicated, understood and followed within the organization;
- k) commit to minimizing any waste arising;
- l) commit to re-using or recycling materials as appropriate;
- m) commit to disposing of waste in a safe manner as soon as reasonably practicable;
- n) commit management to providing adequate financial, material and human resources.

4.16 Senior management and all other individuals should demonstrate their commitment to the policies.

4.17 The management system for a radioactive waste management programme, or for an organization carrying out this work, should specify the requirement to periodically review the policies of the programme and of the organizations involved in it. Reviews of the policies, strategies, plans and goals of a radioactive waste management organization should take account of:

- a) changes in legislation and guidance on waste management;
- b) changes in regulations or in the regulatory body responsible for waste management and the environment;
- c) changes in national policies and strategies for waste and for the environment;
- d) international developments (e.g. standards, conventions, agreements on information exchange);
- e) technological advances;
- f) lessons from experience;
- g) non-conformances, corrective and preventive actions, and results of assessments;
- h) results of domestic and international assessments and developments;

- i) results of internal and external audits, peer reviews and inspections (including those conducted by the regulatory body) of waste management programme activities (including on-site inspections at the facility);
- j) results of environmental and other types of monitoring and surveillance.

4.18 The establishment of strategies, goals, plans and objectives is a primary role of senior management, and senior management should provide the direction for the organization and whilst also ensuring a high level of safety. This is particularly important in radioactive waste management because of the long time periods involved, the interdependencies and the potential changes in responsibility. All personnel within the organization should understand the direction set by senior management and should feel personally accountable for meeting its objectives. As a minimum, the priorities and objectives of the organization should be such as to ensure that regulatory requirements continue to be met.

4.19 The policies of a waste management organization should cover safety, human health and environmental protection, security, quality, human-and-organizational-factor, societal and economic elements, but should also reflect the commitment of senior management to attaining their goals and objectives, their priorities, and the means by which continual improvement will be implemented and measured, including the items listed in para. 4.17.

Interaction with interested parties

Requirement 5 of GSR Part 2 [5]: Interaction with interested parties

“Senior management shall ensure that appropriate interaction with interested parties takes place.”

4.20 In particular, GSR Part 2 [5] requires in paras. 4.6 and 4.7 that:

“4.6. Senior management shall identify interested parties for their organization and shall define an appropriate strategy for interaction with them.

4.7. Senior management shall ensure that the processes and plans resulting from the strategy for interaction with interested parties include:

- a) Appropriate means of communicating routinely and effectively with and informing interested parties with regard to radiation risks associated with the operation of facilities and the conduct of activities;
- b) Appropriate means of timely and effective communication with interested parties in circumstances that have changed or were unanticipated;
- c) Appropriate means of dissemination to interested parties of necessary information relevant to safety;
- d) Appropriate means of considering in decision making processes the concerns and expectations of interested parties in relation to safety”.

4.21 Several broad considerations relating to satisfying the expectations of present and future interested parties should be taken into account when developing the management system for waste management. The requirements of some interested parties (e.g. the regulatory body) must be complied with, while the expectations and preferences of some other interested parties may never be complied with entirely. When developing the management system for waste management, many issues may be sufficiently important to warrant consideration, such as:

- a) legal aspects (such as state and provincial laws and regulations relating to occupational or ‘conventional’ health and safety, non-radioactive hazardous materials, mining);
- b) restrictions on the transport of radioactive material and hazardous materials across local jurisdictional boundaries;
- c) physical protection and security provisions that may be required, as appropriate, for nuclear and other radioactive material;
- d) operational limitations, including those derived from agreements with the responsible national and local authorities or organizations or operating logistics;
- e) the needs, expectations and concerns of the organizations successively managing the waste (e.g. regarding the adequacy of the activities performed by organizations undertaking earlier steps in the waste management chain, and the ability of the subsequent organizations in the sequence to continue the work);
- f) public attitudes, concerns and expectations about safety, and human and environmental protection in relation to waste management in the long term (e.g. concerns about the consequences of discharges, the adequacy and reliability of long term organizational and financial arrangements, site selection and site characterization processes, the degree of confidence in operational and long term safety, and the protection of human health and the environment, the ability to respond to problems that may arise);
- g) public concerns and cultural expectations related to restrictions on the use of land and geological resources;
- h) 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, political choices about activities and sustainable development).

4.22 In general, but with the possible exception of circumstances relating to security and commercial confidentiality, open communication should be promoted and exercised at all levels of the organization and with interested parties in accordance with the strategy for interaction with interested parties. Working closely with interested parties during the life of a waste management facility will build better relationships and foster closer understanding of issues, and this should in turn facilitate the resolution of issues that may arise.

4.23 The management should ensure that all necessary arrangements are put in place for informing the public and other interested parties about the impacts (e.g. radiation risks) associated with conducting waste management activities prior to starting those activities and during the conduct of the activities. The interested parties should be identified in the management system, which should also define a process and procedures for communicating with interested parties on matters related to waste management (e.g. safety, and human and environmental protection and emergency arrangements). Through the process and procedures, the organization may understand and give attention to interested parties' needs and expectations. The process and procedures should include activities such as identifying interested parties and documenting all relevant information regarding their interests and involvement. The process should also include, where appropriate, actions for resolving conflicts between interested parties' requirements.

4.24 In establishing the internal and external communication process and procedures that should be used in programmes and organizations carrying out radioactive waste management and disposal, it should be recognized that the communication may need to be sustained over a long period of time.

4.25 Internal communication should cover such aspects as:

- a) management policy, objectives and strategy;
- b) the management system documentation;
- c) assessments of safety culture and self-assessments;
- d) the management system and associated processes and procedures for conducting waste management activities;
- e) planned organizational changes;
- f) the safety case for the facilities and activities, the status of waste management activities, and plans for the future;
- g) technical and quality issues (e.g. problems having long term implications and their resolution, planned improvements and innovations);
- h) radiological issues (e.g. trends in doses and in releases to the environment, evaluation of accidents and other incidents);
- i) regulatory and statutory issues (e.g. the preparation of information to fulfil regulatory requirements and licence conditions, preparation for new laws and requirements on radiological protection and safety, on waste management and on environmental protection).

4.26 External communication should include information on such aspects as:

- a) the safety case for the facilities and activities, the status of operations, and plans for the future;
- b) safety, human health and environmental protection, security and economic impacts of the waste management activities;

- c) changes in management arrangements and the continuity of responsible management;
- d) maintenance of adequate financial resources to support the waste management activities;
- e) opportunities for, and results from, public involvement in decision making;
- f) responses to questions and concerns.

Interdependences

Requirement 6 of GSR Part 5 [2]: Interdependences

“Interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option, shall be appropriately taken into account.”

4.27 The management system should consider the interdependencies among the various steps and processes in radioactive waste management from waste generation up to and including disposal.

4.28 In recognition of the interdependences between the various steps in waste management, the impacts to subsequent steps should be identified and documented. This will require coordination of activities and the timely exchange of information. For example, for sealed sources purchase details should be preserved, together with a history of their usage, and records of any instances of damage. With the possible exception of emergency situations, waste generators and organizations managing waste should not treat, condition or store waste or do anything that will make the waste more difficult to manage at a later stage in the waste management process.

4.29 The management system should describe the interactions and relationship between the steps in radioactive waste management so that the safety and the effectiveness of the radioactive waste management steps may be considered in integrated manner. This includes the identification of waste streams, the characterization of waste, and the implications of conditioning, storing and disposing of waste. Compatibility and optimization, as discussed in paragraph 3.22 of GSR Part 5 [2], should be addressed and described in the management system.

THE MANAGEMENT SYSTEM

Integration

Requirement 6 of GSR Part 2 [2]: Integration of the management system

“The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised.”

4.30 The various aspects required within the management system should be brought together coherently. This means that the management system must be integrated to include all of these aspects. This integration should simplify the system by identifying synergies and, thereby, ensuring easier compliance with standards and requirements, and facilitating consistency of approach. This is

particularly important with respect to radioactive waste management because of the long term nature of some of the activities, the potential for responsibilities to change, and the interdependencies between different stages of the management process. There may be a need to consider and address interdependences between related organizations (e.g. the responsible national and local authorities, regulatory bodies) having a role in decision-making regarding waste management systems and implementation plans.

4.31 The integrated management system should provide assurance that radioactive waste management and related activities will comply with all applicable requirements, respecting the principle of carrying out work correctly the first time.

4.32 The integrated management system should be developed so that it covers all activities to be carried out during radioactive waste management, including disposal. This includes the safety assessments conducted to evaluate all aspects of facilities and activities that are relevant to safety, and human and environmental protection, and the structuring and presentation of safety arguments and supporting evidence in the safety cases for the waste management and disposal facilities. The management system should also provide for the identification of measures to be taken during the period of institutional control after closure of disposal facilities.

4.33 In developing the management system, senior management should integrate and ensure the coherence of the overall strategy for the waste management and disposal programme with the detailed processes, specific equipment and intended outputs, and the criteria for the characteristics and properties of conditioned waste and waste packages that are set for disposal. Requirements on waste management and disposal are provided in GSR Part 5 [2] and SSR-5 [3]. Further guidance on the management of radioactive waste from nuclear reactors and nuclear fuel cycle facilities is provided in SSG-40 [20], SSG-41 [21], and from the use of radioactive material in medicine, industry, agriculture, research and education in SSG-45 [22], and on the disposal of waste in SSG-14 [9], SSG-23 [10], SSG-29 [11], and SSG-31 [23]. Basic requirements for radiation protection are established in GSR Part 3 [13] and requirements for emergency preparedness and response are established in GSR Part 7 [14].

4.34 The integrated management system should include plans and arrangements for the management system itself to continue for as long as is required. Continuous institutional control should be maintained over licensed waste management facilities. For some facilities including disposal facilities institutional control may need to extend for a period after closure of the facility. The potential need for an extended period of institutional control over a facility influences the long term planning that is necessary for maintaining the management system.

4.35 Emergency drills and exercises, and documentation and reviews of emergency arrangements should be continued throughout periods of storage and until the withdrawal of institutional control over disposal facilities.

4.36 In developing a waste management strategy, the entire process should be considered, including the processes by which waste is generated and characterized, and all of the subsequent steps involved in the predisposal management of waste and waste disposal. In this way, an integrated overall process will be developed. The management system should be designed to accommodate future technological advances and changes in waste acceptance criteria that could have implications for operation of the waste disposal facility.

4.37 The management system should provide for the development of detailed processes for waste management to be informed by safety assessment, and there should be an iterative coupling between activity and facility design and safety assessment. For example:

- a) Tentative specifications for conditioned waste and waste packages should be developed when the sequence of waste management activities is first conceived;
- b) The level of safety, and human and environmental protection provided by various combinations of processes, and waste 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.

4.38 The management system should include a process and procedures that provide for this 'design-assessment cycle' to be repeated, usually several times. This will result in a set of activities, waste characteristics, facility specifications and associated safety assessments that will guide the development of the entire set of waste management activities.

4.39 When developing the plans, goals and objectives that define the strategy for achieving the integrated objectives of the waste management organization and programme, interactions with interested parties should be considered. Long term aspects should also be considered such as:

- a) providing adequate resources, taking account of the amounts and types of waste to be managed and the storage and disposal options that have been adopted. The adequacy of resources should be reviewed periodically, particularly for facility development and operational periods that may extend over decades;
- b) preserving technology and knowledge, and transferring knowledge to people joining the programme or the organization in the future;
- c) retaining or transferring ownership of waste and waste management facilities;
- d) succession planning for the organization's technical and managerial human resources;
- e) continuing arrangements for interacting with interested parties.

4.40 If the waste being managed has long term safety, human health and environmental protection, security, quality, human-and-organizational-factor, societal and economic implications, it should be

recognized that people in future generations who were not originally interested parties will inherit responsibility for managing the waste and the associated facilities. 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.

Graded approach

Requirement 7 of GSR Part 2 [2]: Application of the graded approach to the management system

“The management system shall be developed and applied using a graded approach.”

4.41 In particular, GSR Part 2 [5] requires in para. 4.15 that:

“4.15. The criteria used to grade the development and application of the management system shall be documented in the management system. The following shall be taken into account:

- a) The safety significance and complexity of the organization, operation of the facility or conduct of the activity;
- b) The hazards and the magnitude of the potential impacts (risks) associated with the safety, health, environmental, security, quality and economic elements of each facility or activity;
- c) The possible consequences for safety if a failure or an unanticipated event occurs or if an activity is inadequately planned or improperly carried out.”

4.42 Organizations involved in waste management and disposal should identify the significance of the various facilities (including equipment and waste) and activities to safety, human health and environmental protection, security, and quality requirements. Resources should then be selectively allocated, and processes selectively designed, to control the facilities and activities effectively and efficiently, with safety, and human health and environmental protection being of primary importance. Controls will vary for different waste management and disposal facilities and activities, and should be defined according to the safety significance of the facilities and activities.

4.43 The application of the graded approach is intended to guide the degree of control applied to an item so that it reflects the importance of its function. Grading should not be used as a justification for not applying all of the necessary management system elements, required quality controls, meeting regulatory requirements, or for performing less than adequate technical assessments of items that are less important to meeting safety, human health and environmental protection, security, and quality requirements. Grading should not be used to accept inadequate practices. Grading does not mean excluding determination of the adequacy of any activity affecting safety, human health and environmental protection, security, and quality requirements. Grading means making the stringency of the controls by which the adequacy of such activities is evaluated commensurate with the importance of the activities.

4.44 The method for applying the graded approach should be documented in the management system. Effective management involves the selective application of controls to activities on the basis of fundamental factors important to meeting the safety, human health and environmental protection, security, and quality requirements, such as:

- a) the quantities and potential hazards of the waste, the necessary degree of isolation, and time-scale of the hazard;
- b) the potential dispersibility and mobility of the waste forms and the necessary degree of containment;
- c) the interval before disposal;
- d) experience with, and maturity of, the technology;
- e) the reliability of equipment and its function in relation to safety, and human health and environmental protection;
- f) the complexity and degree of standardisation of the activities;
- g) the novelty and maturity of the activities, particularly for 'first-of-a-kind' activities;
- h) the size of the organization, the number and complexity of interfaces and the safety culture;
- i) public perception of radiation hazards and radioactive waste;
- j) government policy e.g. on the nuclear industry and radioactive waste management;
- k) consideration of possible future human activities, as appropriate.

4.45 A graded approach should be adopted (e.g. on the basis of the findings of a hazard and operability (HAZOP) study or other appropriate safety assessment studies) in applying the management system to aspects of waste disposal activities such 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 human health and environmental protection;
- o) need for, and detail of, environmental monitoring.

4.46 One example of the graded approach is the classification of radioactive waste [24]. This waste classification should act as a guide in indicating the hazard posed by the waste, but other factors will determine the actual risk e.g. the mobility of the waste (solid, liquid or gaseous), the integrity of the packaging, the containment provided by the facility etc. The classification of radioactive waste should be used to guide activities associated with planning disposal and at any stage between the generation of waste and its disposal. For very low level waste, the extent of control required is generally minimal. For higher level waste classifications, a greater degree of control should be applied.

4.47 Appendix III illustrates the graded application of management system requirements, by illustrating possible differences between the level of controls used to manage radioactive waste produced in a mining operation and those used to manage spent ion exchange resins generated in a nuclear power plant.

Documentation

Requirement 8 of GSR Part 2 [5]: Documentation of the management system

“The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use.”

4.48 In particular, GSR Part 2 [2] requires in paras. 4.16-4.20 that:

“4.16 The documentation of the management system shall include as a minimum: policy statements of the organization on values and behavioural expectations; the fundamental safety objective; a description of the organization and its structure; a description of the responsibilities and accountabilities; the levels of authority, including all interactions of those managing, performing and assessing work and including all processes; a description of how the management system complies with regulatory requirements that apply to the organization; and a description of the interactions with external organizations and with interested parties.

4.17. Documents shall be controlled. All individuals responsible for preparing, reviewing, revising and approving documents shall be competent to perform the tasks and shall be given access to appropriate information on which to base their input or decisions.

4.18. Revisions to documents shall be controlled, reviewed and recorded. Revised documents shall be subject to the same level of approval as the initial documents

4.19. Records shall be specified in the management system and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable.

4.20. Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and with the obligations for knowledge management 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. “

4.49 The documentation of the management system should be developed to be understandable, unambiguous and user friendly. Documents should be controlled, readable, complete, readily identifiable and easily available at the point of use.

4.50 Documents may include: policies; safety cases; safety assessments and other reports; processes and procedures; instructions; specifications and drawings (or representations in other media); training materials; and any other texts that describe processes and activities, specify requirements or establish product specifications. These documents should be controlled. All individuals involved in preparing, revising, reviewing or approving documents should be specifically assigned this work, be competent to carry it out and be given access to appropriate information on which to base their decisions. It should be ensured that document users are aware of and use appropriate and correct documents.

4.51 Waste management activities may vary greatly in size and complexity, may involve a number of organizations and may continue over extended periods (e.g. a long standing industrial operation that generates waste, the operating and decommissioning periods in the lifetime of a nuclear power plant, the storage of waste awaiting disposal, disposal of the waste and institutional control during the post-closure period of a disposal facility). Both management practices and operating processes may evolve significantly. Particular attention should be paid to ensuring that the documents used to control work processes remain relevant, current, understandable and available to the diverse organizations involved and in the situations in which they are and will be used.

4.52 Traceable records should be created that describe and characterize the waste that is being managed. The records should include various types of information such as 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 specific and total activity of radionuclides in the waste;
- d) The specific and total activity of fissile nuclides in the waste;
- e) The type of package;
- f) The dose equivalent rate at the package surface;
- g) The level of surface contamination on the package;
- h) The total weight of the waste;
- i) The package filling date or period
- j) The methods and instruments etc. used to describe and characterize the waste.

4.53 The range of information and the level of detail to be recorded should be specified in the management system, taking account of the graded approach. The management system should provide for the information recorded to be checked periodically against the actual state of the waste, updated as necessary, and managed to preserve knowledge concerning the results of waste processing (pretreatment, treatment, and conditioning), storage and disposal. Information about the waste important to safety, human health and environmental protection, security, and quality should be retained and controlled for as long as any concern about the waste persists.

4.54 Records should also be created and retained to describe the history of waste facilities, such as data obtained during facility design, construction, operation and closure. These records could include:

- a) Authorizations (e.g. licences);
- b) Commissioning certificates;
- c) The safety case and safety assessments;
- d) An environmental impact study;

- e) Peer review reports;
- f) Technical specifications and amendments;
- g) Design options, concepts, documents, calculations and drawings;
- h) Records of the facility actually constructed ('as-built' records);
- i) Approved design changes;
- j) Procurement records for structures, systems and components;
- k) Operating procedures;
- l) Records of the implementation, review, updating and maintenance of emergency arrangements, including records of training, exercises, response to actual emergencies and lessons drawn from them, and corrective actions implemented;
- m) Waste emplacement plans;
- n) Records generated during facility operation, including records of emplaced waste packages;
- o) Records of assessments, inspections and verifications of all processes and activities;
- p) Records of any non-conformances and corrective actions;
- q) Records of the training, experience and qualification of personnel.

4.55 Senior management should decide whether the records are to be stored at the waste management facility, elsewhere, or at several diverse locations.

4.56 Arrangements should be made to ensure that records are maintained for the appropriate period of time (e.g. the period for which the waste 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, and on the activities and half-lives of the radionuclides involved; the arrangements and retention periods should be approved as required by the responsible national and local authorities and the regulatory body.

4.57 Records that need to be retained for an extended period should be subject to regular, periodic and systematic review to examine the implications of any changes that have occurred in regulatory requirements and in legislative, organizational, technical and scientific circumstances.

4.58 Records for a waste management or 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 regulatory body and the responsible national and local authorities. The status of the records should be assessed periodically. When unpredictable events lead to the inadvertent destruction of records, the

status of surviving records should be assessed and the importance of their retention and their necessary retention period should be re-evaluated.

4.59 The quality of the recording media and the conditions of storage of records relating to waste management and disposal facilities should be such that the information will be preserved throughout the required retention period. The need to preserve the records for long periods of time for waste storage and disposal facilities has to be taken into account in selecting the format and media to be used for records.

4.60 Where records are preserved electronically, the records should be backed-up, retrievable and readable for the entire retention period required. This will require periodic updates of software and computer hardware, and migration of the data, and may involve the use of controlled non-proprietary systems. Irrespective of the storage media used, consideration should be given to the storage of multiple copies in several diverse locations with independent protection systems.

4.61 When responsibility for managing waste is transferred from one organization to another, relevant records and information about the waste and the associated facility should be transferred to the successor organization. The information to be transferred between the organizations should be set out in an interface document that describes and specifies the interactions between the organizations.

4.62 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 collated, retained and transferred (e.g. policy on waste management, the regulation of the facility; the rationale for arguments and choices for safety, and human health and environmental protection; language and technical terminology; scientific understanding; methods for collecting, analysing and interpreting measurements) as well as the actual records. The safety case for a facility can be used as a vehicle for the integration and documentation of this type of information. 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. Further guidance on the preservation of records, knowledge and memory across generations with particular regard to geological disposal facilities can be found in Ref. [23].

4.63 The safety case should set out the arguments to justify the approach that has been adopted to ensure safety. Because of the extended periods over which waste management is necessary and, in some cases, because of political sensitivities (e.g. that surrounding the siting of disposal facilities), it is especially important to record the reasons why decisions were made, and to make this information available and easily traceable for both current and future generations.

MANAGEMENT OF RESOURCES

Requirement 9 of GSR Part 2 [2]: Provision of resources

“Senior management shall determine the competences and resources necessary to carry out the activities of the organization safely and shall provide them.”

4.64 Resource management necessary for managing and controlling radioactive waste is subject to the requirements established in GSR Part 2 [5], and the guidance presented in this Safety Guide and in Ref. **Error! Reference source not found.** should be considered.

4.65 Waste management activities 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 sufficient resources for facilities and activities for waste management, to satisfy the demands imposed by the safety, human health and environmental protection, security, quality, human-and-organizational-factor, societal and economic aspects associated with the full range of activities involved and the long duration of the activities.

4.66 The reliability and the effectiveness of waste management will depend on the involvement of all personnel in the organization. The management system should include procedures to ensure that there are sufficient numbers of personnel, that these personnel have adequate individual competences and qualifications necessary for the tasks allocated to them, and that the personnel understand, in particular, the safety, and human health and environmental protection implications of their work.

4.67 In a typical waste management process, each step is dependent upon the requirements for the activities in the previous step being satisfactorily met. Staff responsible for the operation of facilities in which radioactive waste is generated and/or managed should go through a specified training programme to ensure that they understand sufficiently the processes involved and the interrelationships of all steps in the process of waste management, and are aware of the potential consequences for safety, environmental protection, and the generation of waste of operator error. Without such understanding, for example, a waste package could be produced that would not meet the acceptance criteria for subsequent processing, storage or disposal or that could present a hazard.

4.68 Personnel designated to select process technologies for radioactive waste management should be trained and qualified to perform their functions. For all stages of radioactive waste management, the operator should ensure that the operating, maintenance and technical staff understand the nature of the waste and its associated hazards, the relevant operating procedures and the associated procedures to be followed in the event of an incident or accident.

4.69 Human resource planning by senior management for waste management activities of long duration, e.g. disposal, should incorporate measures to ensure the continuing availability of a sufficient number of competent personnel. For a waste disposal facility this includes the period after waste emplacement but prior to closure, and the period of active institutional control during the post-closure period. In these periods there is a risk of a reduction in the intended level of human resources.

4.70 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. Senior management should make provisions to ensure that training and re-training needs are reviewed on a planned basis and updated as required. Training and re-training should include familiarization with the management system of the organization.

4.71 Re-training should be arranged to ensure that personnel adequately understand the implications of changes such as:

- a) Modifications to equipment and materials;
- b) The installation of new equipment;
- c) Changes in procedures;
- d) Changes in technologies for waste management or disposal;
- e) Any tightening or relaxation of controls (e.g. on the number of waste packages that may be moved at any given time);
- f) The introduction of additional control points;
- g) Changes in legislative and regulatory requirements;
- h) Other factors associated with waste disposal activities.

4.72 Accumulated experience, including lessons learned from operations, incidents and events should be reviewed periodically and used in revising training programmes and in future decision making. Because of the longevity of waste storage and disposal facilities, it should be recognized that roles will change. The knowledge that individuals possess should, therefore, be captured and managed as a resource.

4.73 Knowledge management includes the assessment, structuring and integration of data and information into an interpreted, synthesized form that embodies the current knowledge and understanding on the matters concerned. The preservation and transfer of knowledge can also be considered from the point of view of risk management. The risk perspective raises the question of priorities: although ideally all information and knowledge should be preserved, practical efforts should be guided by considerations of the risks arising from the failures in this respect. Sometimes good syntheses of the information and knowledge may be more useful to future generations than the original vast amount of information (e.g. individual waste transfer notes).

4.74 Responsibilities, mechanisms and schedules for providing the necessary funds should be planned in advance before the funds are needed. In particular, the funds that will be necessary should be ensured before the waste is generated.

4.75 Senior management should ensure that management systems for waste management activities 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 waste management activities 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 and build appropriate risk and contingency factors 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.
- f) Experience has shown that costs for large projects tend to increase as compared with initial estimates.
- g) If several organizations are involved in the waste management activities, the necessary financial arrangements may be complex. The establishment of an adequate degree of confidence in the arrangements so that the necessary continuity of funding throughout the entire series of waste management activities is ensured may be problematic.

4.76 The operator should ensure that adequate commercial arrangements are in place to manage each of the identified waste streams and to ensure that these arrangements are likely to endure for the period required to complete the waste management programme. Because of the difficulties identified in para. 4.75, regulators and governments should ensure that adequate contingency planning is included in these arrangements. If the financial arrangements prove to be inadequate, then government may have to take measures to ensure that the waste continues to be managed safely.

MANAGEMENT OF PROCESSES AND ACTIVITIES

Requirement 10 of GSR Part 2 [5]: Management of processes and activities

“Processes and activities shall be developed and shall be effectively managed to achieve the organization’s goals without compromising safety.”

4.77 In particular, GSR Part 2 [5] requires in paras. 4.28 – 4.32 that:

“4.28. Each process shall be developed and shall be managed to ensure that requirements are met without compromising safety. Processes shall be documented and the necessary supporting documentation shall be maintained. It shall be ensured that process documentation is consistent

with any existing documents of the organization. Records to demonstrate that the results of the respective process have been achieved shall be specified in the process documentation.4.29. The sequencing of a process and the interactions between processes shall be specified so that safety is not compromised. Effective interaction between interacting processes shall be ensured. Particular consideration shall be given to interactions between processes conducted by the organization and processes conducted by external providers.

4.30. New processes or modifications to existing processes shall be designed, verified, approved and applied so that safety is not compromised. Processes, including any subsequent modifications to them, shall be aligned with the goals, strategies, plans and objectives of the organization.

4.31. Any activities for inspection, testing and verification and validation, their acceptance criteria and the responsibilities for carrying out such activities shall be specified. It shall be specified when and at what stages independent inspection, testing and verification and validation are required to be conducted.

4.32. Each process or activity that could have implications for safety shall be carried out under controlled conditions, by means of following readily understood, approved and current procedures, instructions and drawings. These procedures, instructions and drawings shall be validated before their first use and shall be periodically reviewed to ensure their adequacy and effectiveness. Individuals carrying out such activities shall be involved in the validation and the periodic review of such procedures, instructions and drawings.”

4.78 The processes required to manage and dispose of waste consist of sequences of tasks that determine, alter, modify or otherwise affect important properties of the waste and any waste packaging and containers. These processes:

- a) May be manual or automated;
- b) May change the physical or chemical characteristics of the waste;
- c) May be performed at any stage from the generation of the waste to its ultimate disposition (e.g. discharge, clearance or disposal).

4.79 Processes for predisposal management and disposal of radioactive waste are subject to the requirements established in GSR Part 2 [5], GSR Part 5 [2], and SSR-5 [3], and the guidance presented in this Safety Guide and in Ref. **Error! Reference source not found.**, SSG-40 [20], SSG-41 [21], SSG-45 [22], SSG-14 [9], SSG-23 [10], SSG-29 [11], SSG-1 [12], and SSG-31 [23].

The design of processes

4.80 The design of processes should in general take account of the hierarchy of hazard controls which involves, in order of decreasing effectiveness; hazard elimination, hazard substitution, engineering controls, administrative controls and the use of personal protective equipment. In the context of radioactive waste management examples of hazard elimination would include minimizing waste production or the recycling of a disused sealed radioactive source. An example of hazard substitution would be the use of a linear accelerator instead of a sealed radioactive source for radiation therapy. Examples of engineering controls would be the use of shielding or remote handling technologies. Administrative controls should be used to limit exposure and ensure that doses to workers are consistent with the relevant dose constraint for the situation. Personal protective equipment should be used where necessary for example to avoid skin and/or internal contamination.

4.81 The design of processes for predisposal management should take account of the detailed sequence of steps that will be involved, and issues relating to the specific work processes and products (e.g. waste packages); for example:

- a) Use of protective clothing and/or shielded equipment and facilities for radiation protection;
- b) The use of special handling equipment, tools and techniques for the emplacement and retrieval of waste packages in storage facilities;
- c) Testing and assay requirements (e.g. equipment, methods and materials);
- d) The design of non-intrusive systems and methods for chemical analysis that are used to characterize waste so as to allow the methods to be used to examine waste packages that may have degraded while in storage.
- e) The design of waste packages and containers with detailed specifications for the package structure and the packaging (container) material;
- f) The design of transport packages and containers, and of storage facilities in advance of development of a disposal facility taking account of uncertainty in its possible design;
- g) The possible failure of waste packages and containers due to long term interactions between waste, packaging materials and the storage environment;
- h) Events or other processes that could lead to compromising the integrity of waste packages and containers during storage;
- i) The possible need to modify or re-engineer the design of waste packages and containers to incorporate new technology or to be compatible with new storage or disposal arrangements.

- j) The possible need to relocate waste packages if problems arise after they have been placed in storage (e.g. threats to the integrity of packages or to a storage building).
- k) The need for equipment to be maintained and/or replaced during operations and possible need for any specialized equipment in the future.

4.82 The design of processes for waste disposal should take account of the detailed sequence of steps that will be involved and issues relating to the specific work processes; for example:

- a) Careful planning of exploratory geological investigations to minimize disruption to the integrity of the geological medium;
- b) Planning for the sealing of exploration boreholes that are no longer of use and that might affect the safety of the disposal system.
- c) Precise excavation of underground cavities to minimize damage to the surrounding geology;
- d) Protection of waste packages and containers from degradation (e.g. from rockfall, from corrosion) before the facility is closed, but also during handling and storage periods before emplacement;
- e) Use of protective clothing and/or shielded equipment and facilities for radiation protection;
- f) The use of special handling equipment, tools and techniques for the emplacement and retrieval of waste packages in disposal facilities;
- g) The installation and inspection of engineered barriers (e.g. buffers, backfills, seals, closure components);
- h) Any requirements for monitoring and/or retrievability.

4.83 In experiments and pilot scale tests carried out to support the design of processes that are to be implemented on a production scale either in predisposal management or waste disposal, the aim should be:

- a) To provide assurance that it will be possible to quantify, either by direct measurement or by process control, the important waste form parameters and characteristics (e.g. mass of fissile material, isotopic composition, chemical composition and physical state, decay heat) necessary to control the intermediate processes involved in treating, handling, storing and transporting the waste ;
- b) To determine those process variables that are critical to the acceptability of the end product and in the case of a disposal facility its long term behaviour and safety.

4.84 Investigations that are performed to support the design of processes and that employ simulated waste or simulated waste constituents should be focused on ensuring that:

- a) The waste compositions examined are, as far as it is possible, representative of the actual waste to be processed;

- b) Any anticipated conditions that may result in a significant reduction in the quality of the conditioned or processed waste are considered.

4.85 It should be borne in mind that previously unrecognized variations (e.g. in the composition of waste streams identified during monitoring for clearance purposes) could necessitate adjustment of the design of processes or of the specifications for the materials currently being used.

Inspection, testing, verification and validation of processes

4.86 For each process, the necessary inspection, testing, verification, and validation and monitoring activities should be specified, as described in paras. 4.101 and 4.102 and in Section 6. Note that Section 6 relates to monitoring of the management process itself, whereas paras. 4.101 and 4.102 relate to inspections and monitoring activities as part of waste management; inevitably, however, there is some duplication because some monitoring activities satisfy both purposes. Acceptance criteria for each process, and the responsibilities for the performance of the activities, should be specified as described in para. 4.162. It should also be specified if processes or activities are to be performed by individuals or organizations other than those that are ultimately responsible for the processes.

4.87 All the management and work processes necessary to satisfy the safety, human health and environmental protection, security, quality, human-and-organizational-factor, societal and economic requirements associated with managing and disposing of waste should be identified, developed, implemented, maintained and appropriately reviewed. Improvements should be carried out in a controlled fashion. The management system for a programme of waste management activities may incorporate the individual management systems of a series of operators carrying out successive steps in the predisposal management and disposal of waste. In developing the management processes for waste management and disposal activities, care should be taken:

- a) To ensure the continuity of control of the waste and waste management activities;
- b) To maintain linkages and relationships between organizations if more than one organization is involved;
- c) To allow for the potentially long duration of the waste management activities;
- d) To ensure safety, and human health and environmental protection will be maintained throughout the long lifetime of a disposal facility.

4.88 The management processes should be established, implemented, assessed and continuously improved in a controlled manner. The processes should be suitable for the relevant stage of the waste management programme. The development of each process should ensure that the requirements, interfaces, interactions with other processes, and the risks relating to the activities have been identified and taken into consideration. All process sequences and interfaces should be defined and implemented so that safety is not compromised.

4.89 Processes should be specified, and the designated process owner should be identified by the senior management. His or her authorities and responsibilities should be documented. For example, the following processes should be considered:

- a) research and development;
- b) safety case development;
- c) environmental protection;
- d) environmental monitoring and surveillance;
- e) control of products;
- f) traceability of waste;
- g) condition monitoring, particularly during any long-term storage period prior to disposal and closure of a disposal facility;
- h) retrieval of waste;
- i) control and transfer of records;
- j) development of waste acceptance criteria;
- k) acceptance of waste, and transfer of responsibility (process to ensure that waste transferred meets the acceptance criteria);
- l) radiation protection;
- m) ensuring legal compliance;
- n) risk management;
- o) information management;
- p) grading of the application of management system requirements;
- q) management system process management;
- r) decision making;
- s) communication with interested parties;
- t) knowledge management;
- u) human resources management;
- v) procurement;
- w) management of organizational change and resolution of conflicts;
- x) documentation of the management system;
- y) measurement, assessment and improvement of the management system;

z) interactions between the management system processes;

aa) record-keeping for the waste predisposal management and disposal activities.

4.90 The possibility of human error in work should be taken into account when defining processes and activities. The processes should be planned so as to identify and minimize potential human errors.

Special processes

4.91 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 radio-assay);
- 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 (e.g. the welding of lids onto certain types of waste containers or the backfilling of a waste disposal facility).

4.92 Special processes used in predisposal management include:

- a) Analytical methods such as sampling protocols for waste characterization or process control;
- b) Monitoring of discharges;
- c) Monitoring for clearance purposes;
- d) Non-destructive examination and testing;
- e) Welding;
- f) Heat treatment;
- g) Painting and coating of containers of waste that generate high radiation fields.

4.93 Special processes associated with waste disposal include:

- a) Non-destructive examination and testing of waste packages (e.g. radiography in real time or otherwise, gamma and neutron radio-assay techniques);
- b) Corrective action (e.g. closure welding of lids on overpacks) for waste containers that do not comply with specified requirements;
- c) Remote analytical methods including sampling methods (e.g. for controlled emplacement of backfill materials in the high radiation fields around emplaced waste packages).
- d) Some waste emplacement activities (e.g. large spent fuel containers and supercontainers).
- e) Engineered barrier construction and installation.

4.94 Processes may need to be derived for waste packages that 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).

4.95 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.

4.96 In validating non-destructive gamma or neutron radio-assay techniques:

- a) Algorithms for validating radionuclide contents should be validated with empirical data;
- b) Objects to be measured (e.g. waste or 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.

4.97 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 samples and conditions, methods, equipment and qualification of personnel, the special processes should be revalidated.

4.98 For long term waste management activities, future infrastructural requirements should be specified and the management should develop plans to ensure that these will be met. In such planning, consideration should be given to the continuing need for support services, for spare parts for equipment that may eventually no longer be manufactured during the long operational period of the facility, for equipment upgrades to meet new regulations and make operational improvements, and for the evolution and obsolescence of computer hardware and software.

4.99 Procedures should be established to ensure that the status of waste being processed and the status of equipment, tools, materials and other items important to safety are known and controlled at all times so that:

- a) Required tasks, inspections or tests are not inadvertently omitted;
- b) Non-conforming equipment is not installed, used or relied upon;
- c) Tools or items of test equipment of indeterminate status (e.g. possibly damaged, defective or out of calibration) are not used;
- d) Non-conforming materials and items (e.g. immobilizing agents, waste forms, containers) are identified, segregated and not processed further until the non-conformance is resolved.

Inspection and testing

4.100 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 management and disposal processes are controlled, and that conditioned waste meets design specifications. Similarly, it should be ensured that the disposal facility conditions at waste emplacement meet the design

specifications and expected initial state. Acceptance criteria should be specified for each inspection step in the activities associated with waste management and disposal.

4.101 Inspections carried out as part of waste management activities should include:

- a) Inspection at source of items important to safety, and human health and environmental protection for which the quality is difficult to verify upon receipt;
- b) Inspection on receipt of items important to safety, and human health and environmental protection, including verification of related certification and documentation;
- c) Inspection, and testing on receipt, of characteristics of commercial grade items that are important to safety, and human health and environmental protection;
- d) Inspection of installed items that are important to safety, environmental protection including witnessing of equipment and/or system operational tests;
- e) Appropriate acceptance inspections to validate structures, systems and components;
- f) In-process inspection of waste treatment and waste immobilization processes;
- g) Inspection of processes used for qualification or acceptance of waste forms (e.g. non-destructive assay or real time radiography);
- h) In-process inspection of waste packaging processes;
- i) Final inspection of waste forms and waste packages destined for storage and transport;
- j) Inspection of characteristics of waste packages that are critical to complying with the transport regulations;
- k) Regular and non-invasive inspection of the integrity and identification of waste packages in storage;
- l) Regular inspection to verify the operability of equipment or systems used for the prevention, detection or mitigation of accidents.

4.102 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 human health and environmental protection for which the quality is difficult to verify upon receipt;
- d) Inspection on receipt of items important to safety, and human health 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 human health and environmental protection;

- f) Inspection of installed items that are important to safety, environmental protection or the safety case, including witnessing of equipment and/or system operational tests;
- g) Appropriate acceptance inspections to validate structures, systems and components;
- h) In-process inspection of waste emplacement and engineered barrier installation 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.

4.103 For tests designed to verify the required durability of a waste package, analytical methods should be used that have been demonstrated to be effective on the materials to be tested and demonstrated to be representative of (or more severe than) the environmental conditions that the waste package will encounter in storage or subsequent disposal.

Verification

4.104 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 level of independent inspection should be commensurate with the significance of the activity to safety, and human health and environmental protection. Hold points may be waived if a satisfactory justification on grounds of safety, and human health and environmental protection or quality is documented and approved.

4.105 Personnel other than those who prepared the waste packages should independently verify the conformance of the waste packages to the waste specifications or acceptance criteria for the facility. The manner in which such verifications are carried out will vary according to the type of waste package. For low level radioactive waste packages that can be handled manually, verification may consist of directly examining and measuring the characteristics of the individual waste packages. This method is unlikely to be acceptable when dealing with intermediate level radioactive waste or high level radioactive waste because of the high radiation fields this waste generates. For packages containing waste of these types, verification should be carried out using a combination of more indirect methods, such as:

- a) surveillance of the waste management processes (e.g. waste immobilization by cementation, inspection of package closure welds);

- b) sample checks on activities critical to the quality of waste packages (e.g. production of metal used to fabricate metal containers, preparation of concrete for overpacks);
- c) remote measurement of radiation fields of packages;
- d) sample examination of the data recorded for each waste package;
- e) swabbing to check for external contamination;
- f) periodic visual or video checks of external appearance;
- g) periodic measurement of critical dimensions or photogrammetry to detect swelling of packages.

4.106 If the reports and records from the production of waste packages do not make it clear that the waste packages meet the acceptance criteria for disposal (e.g. because the waste packages were produced prior to the setting of acceptance criteria for a disposal facility), it should be verified that the waste packages are adequately characterized and that they meet the disposal requirements. If the waste packages do not meet the requirements, the need to rework the packages and the need to evaluate the organization (and the intended processing methods) that will perform the reworking to bring the waste to a qualified condition should be considered.

Validation

4.107 Validation of work processes, where feasible, should include:

- a) Determining the process variables that should be controlled to ensure the adequacy of waste management and disposal activities;
- 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 waste forms and packages;
- d) Establishing an appropriate justified test programme to verify the specified quality of the waste at various stages of processing, with a view to ensuring the required quality of the final outputs (e.g. discharged or cleared materials, final waste package), and determining the susceptibility of waste packages to degradation under postulated storage, handling and disposal conditions.

4.108 Process validation should be performed in accordance with documented and approved procedures, and the results should be reported. Appropriate reports and records should be kept and made available to all subsequent waste processors, operators of storage facilities and consignors (originators of shipments) and to the management responsible for the waste disposal facility.

The safety case for waste management facilities and activities

Requirement 13 of GSR Part 5 [2];

The operator shall prepare a safety case and a supporting safety assessment. In the case of a step by step development or in the event of modification of the facility or activity, the safety case and its supporting safety assessment shall be reviewed and updated as necessary.

Requirement 12 of SSR-5 [3];

A safety case and supporting safety assessment shall be prepared and updated by the operator, as necessary, at each step in the development of a disposal facility, in operation and after closure. The safety case and supporting safety assessment shall be submitted to the regulatory body for approval. The safety case and supporting safety assessment shall be sufficiently detailed and comprehensive to provide the necessary technical input for informing the regulatory body and for informing the decisions necessary at each step.

4.109 The senior management of the operator is responsible for developing, implementing and maintaining a safety case, on the basis of which decisions on facility operation, decommissioning (e.g. for a storage facility) and closure (for a disposal facility) have to be made.

4.110 The management system interacts with the safety case in several ways:

- a) The management system is an important element of the safety case [10] and [26]. The management system should ensure that all requirements for, and of, the safety case are satisfied and the commitments made in the management system and safety case are implemented. The management system should, provide confidence in the delivery of the relevant requirements for site selection and characterization, facility design, construction, operation and decommissioning or closure. Each of these broad activities is addressed in subsequent sub-sections.
- b) The management system should include documented processes and procedures to ensure the quality of all activities associated with the safety case and safety assessment, such as data collection and modelling. The safety case for a disposal facility will need to deal with particular uncertainties due to the length of the assessment period and other factors related to modelling of the long term evolution of the site.
- c) For a disposal facility, the management system should ensure that both pre-closure and post-closure safety requirements are met.
- d) The management system should identify the process for developing and applying waste acceptance criteria commensurate with the relevant safety case (including as appropriate the safety case for the subsequent waste management facility).

- e) The safety case should be reviewed periodically to ensure the validity of the contents, taking into account experiences, new technologies, changes to the regulations etc. The reviews should be documented. The management system should include processes and procedures for the safety case to be updated as further information becomes available and for managing uncertainties and risks.

4.111 The safety case, together with the management system, should enable the parties involved to judge the level of safety, and human health and environmental protection provided by the waste management programme throughout its development and as new information is obtained regarding waste management and disposal. In addition to the careful management of the processes and activities that directly determine the level of safety, and human health and environmental protection, the activities involved in assessing and demonstrating safety, and human health and environmental protection should be managed (e.g. site characterization, facility design, environmental impact assessment, establishment of waste acceptance criteria, planned and systematic methods for waste emplacement and inspection, collection of operational data, facility monitoring and the use of surveillance systems). All of the relevant activities should be described in the safety case, which should provide reliable arguments and evidence to demonstrate the continuing level of safety, and human health and environmental protection provided by the facility.

4.112 The safety case should be provided to the relevant regulatory body for review in support of licencing and other regulatory (e.g. compliance assurance) processes. 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 management system should ensure that the requirements and assumptions of the safety case and applicable laws, regulations and licence conditions continue to be met. As the facility may be in operation for a long time the management system should be capable of modification as further information becomes available.

4.113 The senior management should make arrangements in the management system (e.g. by establishing technical specifications based on the safety case and safety assessments) to ensure that the facility is designed, constructed, operated and decommissioned or closed (as appropriate to the particular facility) in accordance with the safety case. The senior management should also include arrangements in the management system for the specification of waste acceptance criteria and other controls and limits to be applied at the facility.

4.114 The operator should retain all the information relevant to the safety case and the safety assessments for the facility and has to retain operation and inspection records that demonstrate compliance both with regulatory requirements and with the operator's own technical specifications, waste acceptance criteria and other controls and limits. Such information and records should be retained with other important records, as described in paras. 4.52 - 4.63.

Safety case development and safety assessment

4.115 Requirements and guidance on the management system for development of the safety case and the conduct of safety assessments for predisposal management and for radioactive waste disposal facilities is provided in GSR Part 5 [2], GSG-3 [26], SSR-5 [3], and SSG-23 [10]. The following aspects should be taken into account in developing a management system for the development of the safety case [10]:

- a) The need for well defined, consistent and transparent criteria according to which the safety case is evaluated and decisions are made;
- b) The need for internal and external audits, as appropriate, to determine the adequacy of the management system and its implementation;
- c) The need to document and enhance the qualifications, competence and credibility of those developing and reviewing the safety case and conducting safety assessments, for example, through the provision of training programmes and through their participation in international projects;
- d) The need for transparency and public involvement in the processes for development and review of the safety case;
- e) The need to ensure consideration of international recommendations, safety objectives, safety assessment methodologies, time frames, disposal concepts, etc. in the development of the safety case;
- f) The need to develop and maintain the competence and knowledge of the operator and the regulatory body over the whole project time frame.

4.116 The management system should include a planned and systematic set of procedures for carrying out and documenting the various steps in the process for providing confidence that the input data, models and results are of good quality. The need to build confidence in the results of safety assessment necessitates the application of programmes to ensure the quality of the various elements of the assessment from the earliest stage in the development of a disposal facility. The management system should, in particular, include processes and procedures covering traceability and transparency, research and development, the treatment of uncertainty, and optimization.

Traceability and transparency

4.117 Traceability requires a clear and complete record of the decisions and assumptions made, and of the models, parameters and data used in arriving at a given set of results. Traceability also encompasses the possibility to trace back to the origin of the data and other information used in the safety case. Thus, a coherent referencing system supporting the safety case should be established. The records should include structured information on when, on what basis and by whom various decisions

and assumptions were made, how these decisions and assumptions were implemented, what modelling tools were used, and what the ultimate sources are for the data.

4.118 Transparency requires openness, communication and accountability. This implies that the safety case and safety assessment should be documented in a clear, open and unbiased way that, for example, recognizes both the features of the waste management and disposal system that provide safety benefits and the uncertainties. The aim should be to provide a clear picture of what has been done in the assessment, what the results and uncertainties are, why the results are what they are, and what the key issues are, in order to inform decision makers. To increase transparency, it may also be appropriate to make the safety case documentation available to the public and to ensure that it is prepared in a manner and at a level of detail that is suitable for the intended audience.

Research and development

4.119 Requirement 10: of GSR Part 1 [8] and paragraph 3.13 of SSR-5 [3] address, the responsibilities of government and the operator to conduct or commission appropriate research and development work in relation to the disposal of radioactive waste, in particular programmes for verifying safety in the long term. The operator should conduct or commission the research and development work necessary to ensure that the planned technical operations can be accomplished practically and safely, and that this can be demonstrated. The operator should take account of international experience and lessons learned from other countries, and should conduct or commission the research work necessary to investigate and understand the disposal system, and to support understanding of the processes on which the safety of the facility depends. The operator should also carry out all the necessary investigations of materials in the facility, and obtain all the data necessary for safety assessment and assess their suitability.

4.120 Depending on national requirements and arrangements, the operator should develop and maintain a high level document that describes the research and development programme. This document should describe conducted, ongoing, and planned research relevant to the safety of the facility, and integrate the research outputs that support the safety case. The research and development programme should address the scheduling of activities and how the research and development programme will tie in with future safety case development, safety assessment and design work, and physical waste management activities.

4.121 The research and development activities involved in developing and assessing the safety of a waste disposal facility can be conducted both in the laboratory and in the field. There is always uncertainty in the results from research and development activities for example, concerning the expected behaviour of the geology of the waste disposal facility. This uncertainty should be recognized in the management system for such activities:

- 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 affect groundwater flow and shorten the time for any contaminants leached from the waste in the disposal facility to return to the accessible environment.

- b) The migration of contaminants from a disposal facility (e.g. in groundwater or gas) will normally be expected to occur very slowly. In developing supporting evidence for the safety case, it is challenging to extrapolate from experiments on short term groundwater movement to the very long time periods involved for the disposal facility. To develop a basis for the safety case, arguments concerning safety, and human health 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 assessment results. 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.

Treatment of uncertainties

4.122 There are always uncertainties. This is particularly relevant when considering and modelling the behaviour of natural systems, but it is also true of engineered systems. Further uncertainties relate to the behaviour of human populations and to future change. The management system should ensure that uncertainties are as far as possible identified and the basis for their estimation is clearly documented.

4.123 It should be recognized that at any particular stage of a waste disposal programme, the data available may not fully provide the required level of confidence, particularly if the data are in large part derived from:

- a) Generic (non site-specific) studies;
- b) Estimated values;
- c) Extrapolated values;
- d) Studies that were conducted for other purposes.

4.124 In such cases a pragmatic approach should be taken to compile data as needed for preliminary safety assessments and safety case development on the basis of expert judgement and elicitation. The compilation and use of such data should be clearly described, justified and recorded. As more data are collected, for example during a site characterization programme, the level of reliance on generic studies and on estimated and extrapolated values should decrease, and the level of confidence in the data and in the safety case should increase.

4.125 When statistical data are used that have been compiled on a large-scale (e.g. regional) basis (e.g., on geological or hydrogeological characteristics), explicit consideration should be given to how

such data can be applied to the particular the site of the disposal facility and its immediate surroundings. Similarly, explicit consideration should be given to how data collected at small-scales (e.g. in the laboratory) can be applied at the scale of the disposal system. The management system should address these issues of scaling of data.

4.126 Computer software and models will be used during all stages of waste management and disposal activities, including during the design stage. Appropriate means should be provided for verifying and, to the extent possible, validating such software and models.

Optimization

4.127 Optimization should be considered at all stages during process development and throughout the lifetime of waste management facilities, including as appropriate site selection and characterization, facility design, construction, operation and decommissioning or closure [2], [3]. The management system should include a process for using the safety case and safety assessment to guide decision-making on which management options represent the optimum choice in each circumstance.

Siting and site characterization for facilities

4.128 Siting and site characterization are important processes for waste management facilities. This is especially the case for disposal facilities because the site forms part of the disposal system and contributes to the fulfilment of the safety functions for disposal.

4.129 Characterization of a potential site for a disposal facility typically involves initial desk-based studies of published information (for example on the geography - climate, population, topography, land uses etc. - and geology and hydrogeology of the site/region), followed by more detailed surface and subsurface investigations and activities at the site itself and supporting laboratory studies. The aim of such investigations and activities may be to: (i) evaluate candidate disposal sites; (ii) obtain information to determine the suitability of a site for a disposal facility; (iii) determine the radiological conditions at a site; and/or (iv) support evaluation of the long term performance of a disposal facility at the site through safety assessment. For geological disposal facilities, in particular, sufficient knowledge and understanding of site characteristics and conditions should be demonstrated prior to intrusive investigations.

4.130 The management system should include a process and procedures for developing and implementing a reasoned, scientifically-based, site characterization programme. The site characterization programme should be designed to collect information as necessary to assess and demonstrate safety, and human health and environmental protection. The process should include procedures for periodic review and modification of the site characterization programme as data are collected.

4.131 Although political aspects are important throughout the lifetime of a waste disposal facility, including in the period before a waste disposal facility is sited, the initiation of technical activities relating to site characterization may heighten the political aspects, especially when field surveys begin.

4.132 In accordance with the graded approach, the scale and duration of a site characterization programme should reflect the level of the hazard posed by the waste to be managed and the complexity of the situation. The site characterization programmes for a small waste store, and for a borehole disposal facility for a small inventory of disused sealed radioactive sources [12], might be considerably less extensive than that for a geological disposal facility for high level waste. The management system should enable the extent and focus of the site characterization programme to be established based on the level of hazard and the needs of the safety case.

4.133 A systematic process should be defined and applied for collecting and analysing site characterization and environmental data in support of site selection, and for the development of the safety case. Such data should be collected prior to facility construction, during the construction, during operation, and after the closure of a disposal facility as required by the safety case.

4.134 All data should be collected in accordance with the requirements of the management system to ensure their quality. Written procedures should be developed and used to ensure that data collected are of high quality and that the methods used and data collected are fully and thoroughly documented. The data should be traceable to their origin and should be developed into a coherent, well-documented description and interpretation of site characteristics. If an adequate management system is not implemented for data gathering activities, then a lack of confidence in the quality of the data (i.e. in their accuracy, applicability, completeness or quantity) may preclude their use and/or lessen the degree of confidence in the safety case.

4.135 The process and procedures on site characterization included in the management system should facilitate the development of the safety case and the conduct of safety assessments, and should allow for the prompt identification of potentially significant gaps in information.

Design of facilities

4.136 The design process for a waste management facility or 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 human health and environmental protection should be refined iteratively to establish a robust safety case and well-founded technical specifications.

4.137 Particular consideration should be given to the design of facilities and activities for the predisposal management of heat-generating waste in storage (including the processing and interim storage of liquid high level waste (e.g. [27], [28], [29], [30]) and the storage of waste spent fuel (e.g. [31]) and for the thermal dimensioning of disposal facilities which involves determining appropriate combinations of waste thermal power, waste package and disposal tunnel spacing, and temperatures particularly in the engineered barrier system, given the environmental conditions and thermal properties of the disposal site (e.g. [32], [33]).

4.138 In managing the development of a design for a waste disposal facility, it should be recognized that the design process will be associated with the concurrent development of the safety case in accordance with Requirement 12 of SSR-5 [3], 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 human health and environmental protection that will be provided by the assumed facility design and the associated combinations of waste and 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.

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

4.140 In designing both predisposal management facilities and activities, and disposal facilities, consideration should be given to incorporating measures for ease of operation, optimization of activities and workers' exposures, inspection of waste prior to closure, maintenance of structures, systems and components, monitoring, and closure or decommissioning of the facilities.

4.141 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.

4.142 There are always uncertainties in data. This is particularly relevant when considering data on natural systems (as noted above), but it is also the case when considering data on engineered structures and components. The management system should ensure that uncertainties in data and the basis for their estimation are clearly documented so that they can be taken into account during the design and assessment process.

4.143 Before and during the process of designing a waste management or disposal facility, advantage should be taken of lessons learned, and knowledge and experience available from comparable existing facilities and current projects, including those conducted in other countries and internationally.

Construction of facilities

4.144 The management system should include a process and procedures to ensure that facilities are constructed in accordance with the conditions of the licence, the assumptions and the designs included in the safety case reviewed by the regulatory body, and any other relevant requirements (e.g. for environmental protection during site characterization).

4.145 The management system should establish clear lines of communication between the organizations involved in safety assessment, facility design and construction, and procedures should be put in place for the control and issue of design information and work instructions. The operator should ensure that there is regular and frequent communication and progress reporting amongst the organizations involved in safety assessment, facility design and construction.

4.146 The management system should ensure that prior to starting construction, the construction organization confirms that the information it has from the design process is up to date and properly informed by current understanding of site conditions. Procedures should also be included for the gathering of information during construction (e.g. on the nature of the geological formations and their physical-mechanical and hydrogeochemical responses to the construction activities), for the interpretation of this new information, and for the updating of the safety case and the facility design, as necessary.

4.147 The management system should include a process and procedures for the operator, particularly of disposal facilities, to carry out appropriate monitoring to determine the extent of disturbance caused by intrusive site characterization activities and by construction, operation and closure of the facility. In any case, excavation and construction activities should be carried out in such a way as to avoid unnecessary disturbance of the hydrogeochemical environment.

4.148 The approach used for the construction of waste disposal facilities should be sufficiently flexible to allow for variations encountered (e.g. in rock or groundwater conditions) to be managed. The management system should include procedures to demonstrate that any changes to the construction approach and/or to the facility design or detailed layout are consistent with safety.

Operation of facilities

4.149 The management system should include a process and procedures to ensure that facilities are operated in accordance with the conditions of the licence and the assumptions and the designs included in the safety case reviewed by the regulatory body.

Identification and characterization of waste

4.150 The management system should include a process and procedures for the recording of appropriate data with which to identify and characterize waste at each step in the waste management programme. Waste items (e.g. individual waste packages) should be identified in a unique way and the identification should be traceable to the associated records. The procedures should include consideration

and specification of the level of variability and uncertainty in the waste characterization data that are acceptable. Records should be kept of the contents of individual waste packages and containers, particularly in cases where the waste stream may be heterogeneous.

4.151 Subsequent to the closure of a container and final non-destructive testing or radio-assay, tamper-indicating devices should be attached to the container to ensure that it can be verified that its radionuclide content remains as recorded.

4.152 It should at any time be readily possible to establish the history of a waste item from its documentation. The status of a waste item should be marked either directly on the item, or in documents that are traceable to the item, or both, depending on the circumstances. Consideration should be given to the effects of any marking of waste packages on their degradation. The status of a waste item may in addition be indicated by means of tags, stamps or other suitable means.

4.153 The procedures should take account of the need for continued identification and characterization of waste even if a waste item is divided or modified.

4.154 The procedures should recognize that for waste items that may need to be stored for extended periods of time (including waste items that have been emplaced in an operating disposal facility that has not yet been closed), and especially where the storage conditions are potentially corrosive, the method(s) used for the physical identification of waste items should be suitably durable.

Waste specification

4.155 Waste specifications should be developed to identify the required radiological, physical and chemical characteristics of the waste form and of conditioned waste, including the waste package. The specifications should also identify which materials resulting from activities in predisposal management can be discharged or cleared.

4.156 The feasibility of satisfying the waste acceptance criteria of all the successive waste management steps should be taken into account when defining waste specifications. The waste specifications should be consistent with the safety assessments for the activities, especially the safety assessments for waste storage and disposal.

4.157 Specification of waste characteristics alone may be insufficient, given the impracticality of testing some active waste forms and waste packages. In such cases, the waste specifications should identify the feed material(s) and the acceptable variation in the composition of the feed material(s), so that any unexpected variation in the feed material(s) prompts a non-conformance designation and/or a reassessment. The critical operating parameters of any processes that produce conditioned waste should also be defined (e.g. maximum temperatures).

4.158 The specification for conditioned waste should be derived and agreed upon between all the interested and affected parties. These normally include:

- a) The operator of the disposal facility;

- b) The generator of the waste;
- c) The owner of the waste (where appropriate);
- d) Operators of predisposal management facilities;
- e) The regulatory body.

4.159 The waste specifications should be used by any organizations that supply services, waste packages or conditioned waste.

Waste acceptance

4.160 Waste acceptance criteria should be derived by the operator of a facility that are consistent with the safety case for the facility. The waste acceptance criteria should also be consistent with other relevant constraints, including those related to waste transport. The waste acceptance criteria should be discussed with, and explained to, the waste producer(s) or supplier(s), and agreed with the regulators.

4.161 Procedures for waste acceptance should be used by the operator of the facility to ensure that the facility only accepts suitable waste and can, therefore, be operated safely, in accordance with the safety case. The procedures for waste acceptance should include provisions for safely managing waste that fails to meet the waste acceptance criteria; for example, by taking remedial actions or by returning the waste [2].

4.162 Prior to placing waste packages in a storage facility, measures should be taken as appropriate to ensure that:

- a) The waste packages meet the waste acceptance criteria for the facility;
- b) Waste packages are properly identified;
- c) The required documentation and records are available and acceptable;
- d) All necessary processes for waste treatment and conditioning have been undertaken and completed satisfactorily;
- e) Levels of surface contamination and surface dose rates meet requirements;
- f) Waste packages do not show signs of unacceptable deterioration;
- g) Measures for criticality control are in place, are effective and are maintained;
- h) The intended movements of waste packages within the storage facility can be performed safely, preclude inadvertent criticality and optimize occupational exposures;
- i) Procedures are in place for:
 - a. Monitoring the integrity of waste packages;
 - b. Controlling environmental conditions in the store (e.g. temperature, humidity, ventilation) and performing associated monitoring;

- c. Maintaining surveillance of the store and of the status of equipment to allow for its maintenance and replacement as needed and for accident detection and mitigation of consequences;
- d. Ensuring that waste packages can be readily identified, located and accessed for inspection and retrieval.
- j) Suitable locations and space exit within the facility for the waste packages.

4.163 Prior to emplacing waste packages in a disposal facility, measures should be taken as appropriate to ensure that:

- a) The waste packages meet the waste acceptance criteria for the facility;
- b) The waste packages are properly identified;
- c) The required documentation and records are available and acceptable;
- d) All necessary processes for waste treatment and conditioning have been undertaken and completed satisfactorily;
- e) Levels of surface contamination and surface dose rates meet requirements;
- f) The waste packages do not show signs of unacceptable deterioration;
- g) Measures for criticality control are in place, are effective and are maintained;
- h) Intended movements of waste packages within the disposal facility can be performed safely, preclude inadvertent criticality and optimize occupational exposures.
- i) Procedures are in place for:
 - a. Monitoring the integrity of waste packages;
 - b. Controlling environmental conditions in the disposal facility (e.g. temperature, humidity, ventilation) and performing associated monitoring;
 - c. Maintaining surveillance of the store and of the status of equipment to allow for its maintenance and replacement as needed and for accident detection and mitigation of consequences;
 - d. Ensuring that waste packages can be readily identified, located and accessed for inspection.
- j) Suitable locations and space exit within the facility for the waste packages. The management system for geological disposal facilities may need to include a process and procedures to ensure the suitability of the host rock surrounding the disposal locations, e.g. [34]. Such a process might, for example, seek to avoid locations in highly fractured or hydraulically conductive rock.

Waste emplacement and installation of engineered barriers

4.164 Waste disposal facilities include a system of engineered and natural barriers. The engineered barriers often comprise metallic, alloy, concrete or other waste containers, concrete based structures (walls, vaults, tunnel backfills, linings and seals etc), clay based barriers (caps, buffers) and barriers comprised of other materials such as sand, salt, crushed rock, etc.

4.165 The management system should include processes and procedures to ensure that only appropriate materials are used in constructing the engineered barriers and that the engineered barriers are manufactured and emplaced or installed in accordance with the design requirements as specified in the facility design assessed in the safety case and reviewed by the regulatory body. One approach to dealing with this need is the compilation of relevant information and project planning in 'production line reports' (e.g. [35] and references therein) and the development of associated procedures and arrangements for inspection.

4.166 Such procedures and arrangements should address issues including, materials supply, materials quality confirmation, the interim storage of materials under suitable environmental conditions, barrier manufacture and installation, barrier inspection and testing. The management system should take account of the various constraints that may be imposed on barrier manufacture and emplacement or installation e.g. by environmental conditions, interactions between different materials, interactions with other on-going construction processes, the required rates of waste disposal and engineered barrier installation, etc.

4.167 Consideration should be given to the particular demands that will be placed on the systems structures and components in the facility under the conditions that may occur. Waste stores may experience considerable temperature changes. Waste disposal facilities may be variously hot, dry and dusty, humid or wet. Account should also be taken of the constraints that will exist on operations, for example due to space and access restrictions, and high radiation fields.

4.168 The management system should include procedures for fully documenting the inventory of waste received at the facility, including details of the quantities of radionuclides present and relevant properties of the waste forms and the locations of the waste packages emplaced in the facility.

Decommissioning and/or closure of facilities

4.169 The management system should include a process and procedures to ensure that facilities are decommissioned or closed in accordance with the conditions of the licence and the relevant decommissioning plan and safety case.

4.170 The management system for decommissioning of facilities, including predisposal management facilities, is discussed in GSR Part 6 [36]. In particular, Requirement 7 of GSR (Part 6) [36] requires that the operator's management system covers all aspects of decommissioning. The management system should enable the planning and implementation of decommissioning so that it can be accomplished safely. Decommissioning should be conducted by suitably qualified and experienced personnel and

controlled by the use of procedures. The operator should ensure traceability for all waste generated during decommissioning. The operator should maintain up to date records of the waste generated, stored in the facility, or transferred to another authorized facility, specifying its quantities, characteristics, treatment methods and destination.

4.171 Requirement 19 of SSR-5 [3] requires that a disposal facility should be closed in a way that provides for those safety functions that have been shown by the safety case to be important after closure. Plans for closure, should be well defined and practicable, so that closure can be carried out safely at an appropriate time. Consideration should be given to the possible need to seal any preferential pathways that may have been introduced as a result of site characterization or other investigations, construction and operation of the disposal facility.

4.172 The period after closure of a disposal facility will be very long. Therefore, appropriate management processes need to be in place to ensure that the disposal system remains safe and that records are adequately maintained. Plans should be prepared for the period after closure to address institutional control and the arrangements for maintaining the availability of information on the disposal facility [3]. These plans shall be consistent with passive safety features and should form part of the safety case on which authorization to close the facility is granted [3].

Monitoring of facilities

4.173 The management system should include a process and procedures to ensure that facilities are monitored in accordance with the conditions of the licence and the assumptions included in the safety case reviewed by the regulatory body.

4.174 The monitoring requirements in this Section relate to monitoring of the facilities and waste and not to monitoring of the management system itself which is covered in Section 6.

4.175 Prior to construction and operation of a disposal facility, monitoring should be carried out to gather information and, thereby, provide a 'baseline' on the environmental and radiological conditions at the site.

4.176 During the operation of predisposal management and disposal facilities, monitoring should be carried out to gather information to confirm the conditions necessary for the safety of workers, members of the public and protection of the environment. Monitoring should also be carried out during the operational period to confirm the absence of any conditions that could affect the subsequent safety of the site after facility decommissioning or closure. The management system should as necessary include procedures to deal with monitoring of active control systems (e.g. temperature, humidity controls, alarm systems), of waste package integrity, and of any other equipment e.g. for the detection and mitigation of accidents, and the maintenance of waste package identification measures.

4.177 Particular consideration should be given to the need to develop monitoring programmes and techniques appropriate for use during long periods of waste storage, facility operation, and institutional control. The need to develop, initiate and sustain the monitoring programme during the post-closure

period for a waste disposal facility should also be considered, consistent with the requirements of the safety case. Further guidance on monitoring and surveillance of radioactive waste disposal facilities is provided in SSG-31 [23].

4.178 The management system should include procedures for responding to monitoring information and for communicating with interested parties on monitoring information.

Management of the supply chain

Requirement 11 of GSR Part 2 [2]: Management of the supply chain

“The organization shall put in place arrangements with vendors, contractors and suppliers for specifying, monitoring and managing the supply to it of items, products and services that may influence safety.”

4.179 In particular, GSR Part 2 [5] requires in paras. 4.33-4.36 that:

“4.33. The organization shall retain responsibility for safety when contracting out any processes and when receiving any item, product or service in the supply chain

4.34. The organization shall have a clear understanding and knowledge of the product or service being supplied. The organization shall itself retain the competence to specify the scope and standard of a required product or service, and subsequently to assess whether the product or service supplied meets applicable safety requirements.

4.35. The management system shall include arrangements for qualification, selection, evaluation, procurement and oversight of the supply chain.

4.36 The organization shall make arrangements for ensuring that suppliers of items, products and services important to safety adhere to safety requirements and meet the organization’s expectations of safe conduct in their delivery.”

4.180 The supply chain typically includes: designers, vendors, manufacturers and constructors, employers, contractors, subcontractors and consigners and carriers who are supplying safety related items and services. The supply chain can also include other parts of the organization and/or parent companies. Because of the very long time periods involved in radioactive waste management, the responsible organization must plan how it will manage the availability and quality of equipment, and the procurement of any structures, systems or components that need to be replaced. This may be achieved by ensuring that procurement organizations do not cease operation without prior warning, by ensuring that there is a diversity of supply or by ensuring that the organization has sufficient spare parts. In some instances, research and development may be required to provide forewarning of potential failure of equipment or structures, systems or components, or to identify potential replacements. In addition, procurement plans also have to consider the fiscal policies and financial arrangements that need to be in place to accommodate these long term requirements.

4.181 The management system should include the necessary documentation and arrangements to control outsourced processes and the supply chain. It should be recognized that the prime responsibility for the safe management of radioactive waste still remains with the owner of the waste, i.e. the organization that contracts the services, items or processes. Services, items and processes contracted to other organizations should be controlled through contractual arrangements that, for example, include the following:

- a) management system requirements;
- b) specifications;
- c) validation and verification requirements;
- d) regulatory requirements;
- e) resource requirements;
- f) exclusions and expectations.

4.182 Potential suppliers should be provided with a clear description of the contracted items and/or services. The process to be used for evaluating potential supplier's proposals and selecting suppliers should also be made available. Suppliers should be accepted based on their capability to meet the purchasing requirements. Use of an approved and preferred supplier list prevents redundant effort in procurement and helps ensure consistency of acceptance of the suppliers. Acceptability of proposals and suppliers should be based on appropriate selection criteria, such as the competence and qualifications of the staff identified to manage and conduct work, the proposed approach for supplying the items and/or services, the track record of the organization(s) being subcontracted, client and third party audits of suppliers and subcontractors, costs, and the acceptability of any gaps in the supplier's proposals. The contract should be awarded to the supplier that best fulfils the selection criteria. The details of the procurement process including the reasons for selecting the chosen supplier, and the contract documentation should be recorded.

4.183 In planning for procurement, consideration should be given to the availability and quality of equipment (e.g. monitoring instrumentation), materials and other items important to safety, and human health and environmental protection over the extended periods of waste storage and disposal. Consideration should also be given to the fiscal policies and financial arrangements and controls that may be required.

4.184 The supplier's management system should be reviewed and accepted in advance, which should include oversight of subcontractors. Oversight of contractors should include surveillance, inspection of activities, on-going monitoring, measurements, periodic review by experts, acceptance of plans and deliverables, and review of changes to activities.

5. CULTURE FOR SAFETY

Requirement 12 of GSR Part 2 [2]: Fostering a culture for safety

“Individuals in the organization, from senior management downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture.”

5.1 In particular, GSR Part 2 [5] requires in para. 5.1 that:

“5.1. All individuals in the organization shall contribute to fostering and sustaining a strong safety culture.”

5.2 Senior management should be committed to developing a culture for safety and should communicate, demonstrate and foster it to the organization.

5.3 Senior managers and all other managers should advocate and support the following:

- a) A common understanding of safety and of a culture for safety, including: awareness of radiation risks and hazards relating to work and to the working environment; an understanding of the significance of radiation risks and hazards for safety; and a collective commitment to safety by teams and individuals;
- b) Acceptance by individuals of personal accountability for their attitudes and conduct with regard to safety;
- c) An organizational culture that supports and encourages trust, collaboration, consultation and communication;
- d) The reporting of problems relating to technical, human and organizational factors and reporting of any deficiencies in structures, systems and components to avoid degradation of safety, including the timely acknowledgement of, and reporting back on actions taken;
- e) Measures to encourage a questioning and learning attitude at all levels in the organization and to discourage complacency with regard to safety;
- f) The means by which the organization seeks to enhance safety, and to foster and sustain a strong culture for safety, and to use a systematic approach (i.e. an approach relating to the system as a whole in which the interactions between technical, human and organizational factors are duly considered);
- g) Safety oriented decision making in all activities;
- h) The exchange of ideas between, and the combination of a culture for safety and a culture for security.

5.4 Organizations involved in waste management should have a strong culture for safety. A strong culture for safety is a foundation that supports continuous success of activities through the management system. A culture for safety is also an important aspect of organizational effectiveness, safety performance and human performance. A questioning attitude to prevent mistakes and a 'no-blame' culture, including commitment, reflection and freedom to express ideas and self-reflection should be demonstrated by all individuals. This will ensure that safety requirements are met and the waste management system will be continuously improved and maintained.

5.5 The management system should support rather than impede the development, implementation and continued enhancement of a strong culture for safety, and should promote the adoption of best practices, regardless of the type, scale, complexity, duration and evolution of the activities for waste management. The management system for waste management activities should support a culture for safety, and environmental protection throughout all levels of the organizations involved, and for all stages in the lifetime of a waste management facility. The management system should establish an environment in which staff can raise safety issues without fear of penalty, harassment, intimidation, retaliation or discrimination.

5.6 As indicated above, in common with all nuclear facilities, facilities that manage radioactive waste need to be operated by individuals and organizations with a strong culture for safety. However, the nature of many radioactive waste management facilities is different to that of nuclear power plant. For example, the time periods are considerably longer and, in the case of disposal facilities, there are different safety hazards to consider. This results in different safety cultural aspects, for example:

- a) Workers need not only consider immediate and short term safety aspects, but should also consider the longer term safety implications of their activities, which in some instances might not be manifested until several generations later.
- b) Because waste may be transferred to other organizations, the safety impact of a worker's or organization's actions might not impact on themselves, but on the receiving organization.
- c) Mistakes in waste management could lead to non-conforming waste, which consequently becomes an orphan waste with no readily identified treatment and disposal route. Hence, although there may be no immediate safety consequence, there may be an increase in the nuclear legacy left to subsequent generations.
- d) Workers particularly at underground facilities may be exposed to conventional safety risks that are greater than those posed radiologically and need to act accordingly.

5.7 The identification of deficiencies should be not viewed as a negative, but as an opportunity for improvement. Corrective actions should be completed in a timely fashion.

5.8 Senior management should ensure that the working conditions and arrangements promote a strong culture for safety and improve employee's motivation and competence. Senior management

should ensure that the management of work performance and related incentives encourage safe ways of working.

DRAFT

6. MEASUREMENT, ASSESSMENT AND IMPROVEMENT OF THE MANAGEMENT SYSTEM

Requirement 13 of GSR Part 2 [2]: Measurement, assessment and improvement of the management system

“The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety.”

6.1 In particular, GSR Part 2 [2] requires in paras. 6.1 – 6.8 that:

“6.1 The effectiveness of the management system shall be monitored and measured to confirm the ability of the organization to achieve the results intended and to identify opportunities for improvement of the management system.

6.2 All processes should be regularly evaluated for their effectiveness and for their ability to ensure safety.

6.3 The causes of non-conformances of processes and the causes of safety related events that could give rise to radiation risks shall be evaluated and any consequences shall be managed and shall be mitigated. The corrective actions necessary for eliminating the causes of non-conformances and for preventing the occurrence of, or mitigating the consequences of, similar safety related events shall be determined and corrective actions shall be taken in a timely manner. The status and effectiveness of all corrective actions and preventative actions taken shall be monitored and shall be reported to the management at an appropriate level in the organization.

6.4 Independent assessments and self-assessments of the management system shall be regularly conducted to evaluate its effectiveness and to identify opportunities for improvement. Lessons and any resulting significant changes shall be analysed for their implications for safety.

6.5. Responsibility shall be assigned for conducting independent assessments of the management system. The organizations, entities (in-house or external) and individuals assigned such responsibilities shall be given sufficient authority to discharge their responsibilities and shall have direct access to senior management, In addition, individuals conducting independent assessments of the management system shall not be assigned responsibility to assess areas under the responsibility of their own line management.

6.6. Senior management shall conduct a review of the management system at planned intervals to confirm its suitability and effectiveness, and its ability to enable the objectives of the organization to be accomplished, with account taken of new requirements and changes in the organization.

6.7. The management system shall include evaluation and timely use of the following:

- a) Lessons from experience gained and from vents that have occurred, both within the organization and outside the organization and lessons from identifying the causes of events
- b) Technical advances and results of research and development;
- c) Lessons from identifying good practices.

6.8. Organizations shall make arrangements to learn from success and from strengths for their organizational development and continuous improvement.”

6.2 If the waste being managed has long term safety, human health and environmental protection, security, quality, human-and-organizational-factor, societal and economic implications, people in future generations who were not originally interested parties will inherit responsibility for managing the waste and the associated processes and storage and disposal facilities. The management system should include provision for its own review in a planned manner to maintain confidence that it is sustainable and will evolve to accommodate changes in management philosophies and strategies to meet the needs of future interested parties.

6.3 Monitoring⁵ and measurement of the effectiveness of the management system should be considered during all stages of radioactive waste management. Planning should be done to ensure that these activities will be continued during the long periods of waste storage, disposal facility operation and institutional control of a disposal facility.

6.4 The processes for measurement, assessment⁶ and improvement applicable to the management system for control of waste management, including disposal, are subject to the requirements established in GSR Part 2 [2], and the guidance presented in this Safety Guide and in Ref. **Error! Reference source not found.** should be considered.

6.5 Self-assessment of management processes in a waste management programme or organization should include consideration of:

- 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 management activities. Such changes will have to be considered at the national level and even possibly at the international level;

⁵ In para. 6.3 ‘monitoring’ refers to monitoring of the management system as opposed to monitoring in Section 4, which relates to monitoring of the facility and the waste.

⁶ Note 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 management facility referred to in previous sections.

- b) the continuation of assessments over long periods of waste storage, disposal facility operation and institutional control of a disposal facility.

6.6 Where assessments and self-assessments are performed on work processes used in a waste management programme or a waste management organization, the following aspects should be confirmed:

- a) Process variables and controls have not changed from those values established in the original validated processes accepted by the regulatory body.
- b) Required inspections and measurements are being performed and the associated records are being maintained.
- c) The ownership and characteristics of waste are traceable through any jurisdictional transfers of waste, and proper controls are implemented during storage.
- d) The instrumentation used to monitor or control waste management activities has not degraded in service and has not been modified without proper change control.
- e) Critical parameters of the waste acceptance criteria or specifications are being controlled within established limits.
- f) Facilities are being operated in accordance with the requirements.
- g) Waste management activities are conducted in conformity with their safety, and human health and environmental assessments.
- h) Waste packages and containers qualified by performance based testing are used within their qualification limits.
- i) Requirements resulting from regulatory authorizations and associated conditions that relate to waste acceptance criteria and/or specifications have been addressed and are being met.

6.7 Assessments to verify the implementation and effectiveness of the management system of a waste management programme or an individual waste management organization may be performed by:

- a) an organizational unit within the 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) the operator of the disposal facility;
- d) other organizations in the waste management programme;
- e) the responsible national or local authorities

- f) the responsible international organizations;
- g) a separate organization employed by the waste generator;
- h) one or more equivalent qualified organizations in a peer review.

6.8 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 if the waste management activities continue for a long time. In such management system reviews, account should be taken of experience from managing the waste management facilities and programme, and of experience from other facilities and programmes in the State and in other States.

6.9 Reviews of the management system for a waste management programme, or for an individual waste management organization, should be performed:

- a) for all aspects of the management system on a scheduled periodic basis. The frequency of such scheduled reviews should be justified and agreed with the regulatory body;
- b) whenever there are major changes in the organization or in the applicable legislation, regulations etc;
- c) whenever there are major changes in waste management 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;
- f) to take account of experience and lessons learned from internal and external incidents and events, and of accumulated knowledge, which should be reviewed periodically taken into account to improve the management system.

6.10 Reviews of predisposal management may be focused on, for example:

- a) The waste management activities (e.g. conditioning, packaging, storage) under the control of the organization being assessed;
- b) The quality of waste packages produced by the organization.

6.11 Reviews of waste disposal may be focused on, for example:

- a) The waste disposal activities (e.g. site characterization, disposal concept and facility design, safety case development, research and development, excavation, waste emplacement, engineered barrier construction, disposal facility operation, closure and control) under the control of the organization being assessed.
- b) The safety case and the performance of the waste disposal facility as may be determined by direct or indirect monitoring of the disposal system. Performance may be assessed by making comparisons with the technical specifications, between the observed evolution of

the waste and the waste disposal facility and the original baseline characteristics and their expected evolution as documented and considered in the safety case for the facility.

6.12 Waste management organizations should establish procedures for identifying potential non-conformances and for taking action to prevent their occurrence. This is particularly important when waste management activities are carried out by a number of organizations, when organizational arrangements change, and during lengthy periods of storage.

6.13 A procedure should be established to control non-conforming items including:

- 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) extent of condition, 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;
- d) once a non-conformance is identified, the non-conformance is evaluated to determine its significance and to identify the appropriate corrective action strategy;
- e) appropriate follow up, as necessary, to evaluate the effectiveness of corrective actions.

6.14 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 and the management system should describe how such rejected items are to be addressed, controlled and managed.

6.15 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 into compliance with the requirements for waste storage and/or disposal as specified in the acceptance criteria. Any non-compliance that is important to safety that is found at a later stage (e.g. a design fault, defective package material or damage affecting the integrity of the package) should be rectified as far as possible. If rectification of the non-compliance is not possible, its impact on further steps in waste management, including disposal, should be subjected to a detailed analysis and any possible consequences identified should be dealt with by other means.

6.16 Non-conformance data should be analysed periodically to identify quality trends in conditioned waste, and these analyses should be reported to the responsible manager for review. Corrective actions should then be initiated to remove or eliminate the underlying causes of the non-conformances where these are important to safety.

6.17 For geological disposal facilities 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.

6.18 Geological disposal facilities are especially sensitive to non-conformances because of the irreversible nature of disturbing the host geology and the cost and difficulty of retrieving waste. Operators of such facilities should, therefore, optimize working methods at the outset of each stage, for example:

- a) for the production of waste packages: provide guidance and training to waste producers on the acceptance criteria at the waste disposal facility as early as possible;
- b) for site characterization: maximising the knowledge drawn from non-invasive investigations of a site, in addition to the use of selective and justified invasive methods such as borehole investigation;
- c) for environmental impact assessment: monitoring of the environment, minimal disturbance of the environment, and protection of non-human species;
- d) for design: coordinating the interaction between the activities in facility design, site characterization and safety assessment;
- e) for construction: disturbing the host geological formation as little as possible especially close to major discontinuities and zones of structural weakness;
- f) for operation: emplacing waste packages intact and without significant damage, emplacing backfill to the intended density and installing seals reliably in accordance with the design requirements;
- g) for the post-closure period: making any required monitoring as effective and efficient as possible;
- h) for the post-closure period: arranging for the most effective and efficient means of records keeping.

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

6.20 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 to the waste management 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 to demonstrate that they have been achieved.

6.21 Continual improvement goals should be embedded in the organization's plans and objectives to demonstrate that continual improvement process is part of the normal business of the organization; to show that it is an integral part of business activity; and to demonstrate that senior management is fully committed to its success.

Requirement 14 of GSR Part 2 [2]: Measurement, assessment and improvement of leadership for safety and of safety culture

“Senior management shall regularly commission assessments of leadership for safety and of safety culture in its own organization.”

6.22 Organizations should commit to the achievement of high standards of safety by using self-assessment to maintain and develop the ability to manage safety effectively. Self-assessment allows organizations to evaluate their safety performance by reference to internal indicators, or by comparison with the performance of other organizations. Self-assessment may involve self-evaluation, self-inspection, or self-audit, and may also be extended to contractor organizations.

6.23 Senior management should make arrangements to measure the effectiveness of leadership and safety culture and to demonstrate the performance of the leadership. Different tools could be used such as:

- a) surveys;
- b) interviews;
- c) observations;
- d) functional analysis.

6.24 Safety performance indicators should be developed. Examples of such indicators are:

- a) percentage of safety improvement proposals;
- b) number of safety inspections conducted by senior management;
- c) number of safety audit recommendations implemented during a period.

6.25 The results of the assessments of the leadership and safety culture, including the safety performance indicator scores should be made visible and communicated within the organization. The organization should follow the corrective actions process to improve and foster a learning attitude.

APPENDIX I

KEY ACTIVITIES FOR PREDISPOSAL MANAGEMENT FACILITIES

DESIGN STAGE ASPECTS

I.1 The following activities should be considered when a decision is made to carry out operations involving the management of radioactive materials:

- a) review of government policies and the regulatory framework to establish national and regulatory expectations and align plans with the national waste strategy and regulatory requirements;
- b) establish the location of the facility, take account of environmental conditions, and safety and radioactive waste management aspects (e.g. the distance from populations centres and the availability of transport links from the facility to waste management sites);
- c) establish an integrated waste strategy and an integrated waste management programme;
- d) establish / upgrade the waste inventory;
- e) establish steps in for the management of the radioactive materials and radioactive waste;
- f) establish initial waste acceptance criteria for storage and disposal;
- g) establish links with upstream and downstream facilities;
- h) take decommissioning into account;
- i) establish requirements for the design of the facility and for records management;
- j) identify research and development needs and activities to fill important gaps in knowledge;
- k) participate in dialogue with regulators and government to identify, document and understand all applicable requirements;
- l) repeat steps (a) to (k) through concept development, detailed design and construction stages, growing the database of information, requirements and an auditable trail of decisions.

OPERATIONAL STAGE ASPECTS

I.2 The following activities should be considered when radioactive materials are introduced into the facility:

- a) review of government policies and the regulatory framework to establish how operations and operating experiences comply with national expectations and regulatory requirements;
- b) upgrade waste inventory with operational data;
- c) register and record all normal waste arisings, and those outside the normal arisings;

- d) establish and monitor the behaviour of radioactive waste and other hazardous materials related to the radioactive waste;
- e) evolve, via links established earlier, waste disposal criteria, onward disposition criteria, storage criteria;
- f) improve and add detail to the integrated waste strategy, and plan and apply the waste management hierarchy to implement optimal waste management as information on the facility evolves;
- g) incorporate any new requirements into the operation of the facility and the records of waste management;
- h) continue to develop and refine the design and construction of the facility to take account of new information ensuring continued compliance with the licence / authorization;
- i) continue to participate in dialogue with regulators and government to identify, document, understand and comply with all applicable requirements;
- j) repeat steps (a) to (i) through the commissioning, operation and shutdown stages, growing the database of information, requirements and an auditable trail of decisions.

DECOMMISSIONING STAGE ASPECTS

I.3 The following activities should be considered when decommissioning a waste management facility:

- a) review of government policies and the regulatory framework to establish national expectations and regulatory expectations and align plans with the national waste strategy and regulatory requirements;
- b) upgrade waste inventory via techniques including monitoring;
- c) use the waste inventory and other (e.g. site-survey) information to establish the scope and condition of the waste remaining within the facility;
- d) establish and monitor the behaviour of radioactive waste;
- e) update the waste inventory to include all waste identified;
- f) consider the options for onward disposition of the waste;
- g) improve and add detail to the integrated waste strategy, and plan and apply the waste management hierarchy to implement the optimal waste management;
- h) incorporate any new requirements into the decommissioning process and records management;
- i) continue to participate in dialogue with regulators and government to identify, document, understand and comply with all applicable requirements;
- j) at the end of decommissioning, detailed documentation should be produced to describe the decommissioning activities undertaken and the physical condition of the facility at the end of the decommissioning stage.

APPENDIX II

KEY MANAGEMENT SYSTEM ASPECTS SPECIFIC TO OPERATION, CLOSURE AND POST-CLOSURE ACTIVE INSTITUTIONAL CONTROL OF RADIOACTIVE WASTE DISPOSAL FACILITIES

GENERAL

II.1. This appendix identifies key aspects of management systems that are specific to the operation, closure and post-closure active institutional control of disposal facilities for radioactive waste, to supplement the main text of this Safety Guide.

II.2. There should be a documented process for the transfer of structures, systems and components and related records from one stage to another (e.g. from construction to operation, from operation to closure, from active to passive institutional control). This process should also cover the possible changing of the organization conducting the activities in the respective stages (e.g. from one operator to another, from an operator to government).

ESTABLISHING PROCEDURES

II.3. Items for which there should be procedures during the operation closure and post-closure control of radioactive waste disposal facilities include:

- a) management decision-making;
- b) ensuring that the organization has a sufficient number of suitably qualified and experienced staff;
- c) staff training;
- d) development, review and approval of the management system and its elements;
- e) communication within the waste management programme;
- f) communication with external interested parties;
- g) preparing for and dealing with accidents, incidents and emergencies;
- h) specified processes and special processes (see paras. 4.89 to 4.99);
- i) the quality of all activities associated with the safety case and safety assessment;
- j) updating the safety case to take account of new information;
- k) the quality of the input data, models and results;
- l) traceability and transparency of documentation
- m) research and development
- n) the treatment of uncertainty

- o) optimization;
- p) site characterization
- q) design work and iteration between facility design and safety assessment;
- r) ensuring facilities are constructed, operated, decommissioned or closed, and monitored in accordance with the conditions of the licence, the relevant decommissioning plan, and the assumptions and the designs in the safety case reviewed by the regulatory body;
- s) control and issuing of design information and work instructions;
- t) gathering of information during construction, operation, and decommissioning or closure;
- u) demonstrating that any changes to the construction approach and/or to the facility design or detailed layout are not inconsistent with safety;
- v) monitoring during construction, operation and closure and, where appropriate, in the post-closure period;
- w) recording of appropriate data with which to identify and characterize waste at each step in the waste management programme;
- x) waste acceptance;
- y) monitoring the integrity of waste packages;
- z) where appropriate, controlling environmental conditions in the store and disposal facility (e.g. temperature, humidity, ventilation) and performing associated monitoring;
- aa) maintaining surveillance of the facility and of the status of equipment to allow for its maintenance and replacement as needed;
- bb) ensuring that waste packages can be readily identified, located and accessed for inspection and retrieval from storage;
- cc) ensuring that only appropriate materials are used in constructing engineered barriers and that the barriers are emplaced or installed as specified in the facility design assessed in the safety case and reviewed by the regulatory body;
- dd) documenting the inventory of waste received at the facility, including details of the quantities of radionuclides present and relevant properties of the waste forms and the locations of the waste packages emplaced in the facility;
- ee) responding to monitoring information
- ff) communicating with interested parties on monitoring information;
- gg) identifying potential non-conformances and for taking action to prevent their occurrence.

MANAGEMENT OF WASTE PACKAGES

II.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.

II.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

II.6. Before the commencement of waste emplacement, the operator 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 operators should be used as the basis for the maintenance programme.

II.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 competent, suitably qualified and experienced personnel over the entire 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.

FACILITY RECORDS

II.9. Records should be created and retained that describe the history of the waste disposal facility and related activities, as discussed in Section 4 of this Safety Guide. Records relating to operation, closure and the post-closure period of a 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

II.10. During operation and the period of active control, periodic safety reviews should be performed as necessary and as required to substantiate the continued safe and reliable operation of the facility. The responsible organization should define the scope and objectives of each safety review. The safety review process should, as appropriate:

- a) confirm that the waste disposal facility is safe;
- b) confirm that the emplaced waste packages are safe;
- c) assess the effects of ageing, so as to assess the ability of structures, systems and components to fulfil their safety functions;
- d) assess the original safety assessment against current safety standards and requirements;
- e) identify improvements that are reasonably achievable.

II.11. The inputs to the periodic safety reviews should include data on operational performance, results from surveillance and inspections, results from testing e.g. in the framework of ageing and site characterization and environmental monitoring 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 and closure;
- c) to update and revise the existing safety case and demonstrate that the facility meets safety standards and requirements.

EMERGENCY PREPAREDNESS AND RESPONSE

II.12. A graded approach to preparedness and response shall be developed and implemented to provide an adequate basis for defining arrangements for preparedness and response for nuclear or radiological

emergencies. These arrangements shall be commensurate to the hazards identified and take into account the characteristics of the waste, of the waste management facility, and of the site and its vicinity, at each stage in the lifetime of the facility (e.g. operation, closure, post-closure). The approach to preparedness and response for a nuclear or radiological emergency shall be based on hazard assessment performed in line with Requirement 4 of GSR Part 7 [14].

HOUSEKEEPING AND CLEANLINESS

II.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

II.14. The extended duration 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, that spare parts or materials are 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 human health 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.

II.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

II.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.

APPENDIX III

ILLUSTRATION OF THE GRADED APPLICATION OF MANAGEMENT SYSTEM REQUIREMENTS

III.1. [this is an excellent candidate for an annex] Table 1 describes a simplified and hypothetical application of the graded application of management system requirements to two different activities:

- a) maintaining sump pumps in a uranium mine;
- b) treating spent resins from an ion exchanger in a nuclear power plant.

III.2. Different levels of control were implemented on selected aspects (training, inspection and records) associated with the successive steps in each activity. Each aspect was assigned a grade between A and E. An aspect that receives a grade A requires the high level of control appropriate for a complex, multistage and potentially high consequence step. An aspect that receives a grade E requires a lower level of control that is adequate for a single and relatively simple step having low possible consequences. The nature and extent of the provisions that are put in place to satisfy the management system requirements were then determined as a function of the assigned grades.

III.3. Note that the graded application of the requirements for a management system can only properly be achieved by first assessing the actual processes that are to be implemented with regard to those factors (listed in para. 4.44) that are important to the organization in meeting its overall requirements. Procedures, training programmes, records management provisions, etc., can then be established that will make the processes both effective and efficient. Many common aspects of waste management activities that can be applied in a graded manner in this fashion are listed in para. 4.45. When changes are made to a management system that has been established on a reasoned basis, care should be exercised to retain a sufficient level of confidence that the requirements will continue to be met.

TABLE 1. OUTLINE OF OPERATIONAL ACTIVITY

Mining		Nuclear Power Plant	
Underground sump pumps are brought to the surface for maintenance. Waste mud and scale segregated from the pumps are disposed of.		Resin in the ion exchangers that is approaching its saturation level is either reconditioned for further use or treated, packaged and stored for eventual disposal.	
Step 1: Initial inspection of equipment and/or material			
	Mining	Nuclear Power Plant	
	Grade Description	Grade	Description
Description of step	<p>Pumps brought to the surface are placed in a receiving area and checked for surface contamination with a handheld monitoring device.</p> <p>If the contamination is above a certain limit, the pump is sent for decontamination before being sent to the maintenance workshop.</p>		<p>The external field of an ion exchange resin column is measured with a remote monitoring instrument. If the measurement indicates that the resin may be approaching its saturation limit, the resin is inspected and a decision is taken on whether the resin can be reconditioned to bring it back to a usable condition or whether it should be prepared for eventual disposal as radioactive waste.</p>
Training	<p>C A training programme is required to train and qualify personnel to use the radiation measuring equipment; such training should be provided.</p>	A	<p>Inspecting the resin involves taking a sample from the ion exchanger and using specialized inspection equipment to analyse it. The results of this analysis should be assessed and categorized.</p> <p>This requires a high degree of experience, and specialized training to conduct the inspection and to assess and categorize the data should be provided. The required training should include qualification in radioactivity analysis.</p>
Records	<p>C Measurements of the surface contamination on the pump are recorded on a pre-printed form that serves as the record.</p>	A	<p>The inspection equipment produces a graphic printout. An analysis report from the analyst that includes the categorization of the data is attached to the printout. The analysis report supports the decision making for the further steps (reconditioning or preparation for disposal).</p>

TABLE 1. OUTLINE OF OPERATIONAL ACTIVITY (cont.)

Step2: Segregation and decontamination and/or reconditioning of equipment and/or material for reuse			
	Mining		Nuclear Power Plant
	Grade	Description	Grade Description
Description of step		Contaminated pumps are segregated and sent to a decontamination bay for washing with a high pressure water jet. A handheld contamination monitoring device is used to measure the contamination levels.	Resin to be reconditioned is treated in a multistage chemical reduction process until specified reconditioning levels are obtained. The resin is then put into storage for reuse. (Resin to be prepared for disposal is discussed under steps 3 and 4.)
Training	E	The operator should undergo on the job training in the washing process and training in safety, and human health and environmental protection and/or radiation protection	C Specialized training should be put in place for personnel operating the resin reconditioning equipment.
	C	A training programme should be put in place to train and qualify personnel to use the radiation measuring equipment.	
Records	C	Measurements are recorded on a pre-printed form that serves as the record.	C A form is completed specifying which reconditioning procedure was used to return the resin to a usable condition.

TABLE 1. OUTLINE OF OPERATIONAL ACTIVITY (cont.)

Step 3: Waste processing		
	Mining	Nuclear Power Plant
	Grade Description	Grade Description
Description of step	Contaminated material (i.e. mud and oxidized scale) removed from the pump surface by the washing process is deposited into the wash bay sump, from where it will be pumped to a tailings impoundment.	Resin to be disposed of is chemically treated and immobilized in a solid form.
Training	E On the job training to operate the pump for the wash bay sump should be provided.	B Training to operate the equipment for the chemical treatment and immobilization process should be provided.
	B Training and qualification in the use of radiation measuring equipment should be provided.	
Inspection	D The pump is measured after washing, using a handheld instrument to determine the contamination level.	B Samples of the chemically treated and immobilized waste are taken for confirmatory testing.
Records	E If the activity measured on the washed pump is below the allowable level, the pump is sent to the workshop for maintenance. If it is above the limit, washing is repeated until a level below the allowable limit is reached. A form is completed recording the measurements.	C A record is generated of the key process parameters and chemicals used to treat and immobilize the resin.

TABLE 1. OUTLINE OF OPERATIONAL ACTIVITY (cont.)

Step 4: Waste packaging		
	Mining	Nuclear Power Plant
	Grade Description	Grade Description
Description of step	No packaging of the mining sump pump waste (mud and scale) is required because the waste will be pumped to a tailings impoundment.	The immobilized resin is sealed in stainless steel canisters. The welding of the cap onto the canister is inspected using dye penetrant testing. The canisters are then placed into purpose built concrete drums which, when sealed, form the waste packages. The activity of the sealed concrete drum (waste package) is measured using a handheld instrument.
Training	Not applicable	A Training on how to fill and seal a canister should be provided.
		B Training and qualification for the inspector for dye penetrant testing should be provided.
		B Training and qualification in the use of handheld radiation measuring equipment should be provided.
Records	Not applicable	C A record of the dye penetrant test is produced and maintained.
		C A record of the contents of the waste package and the external activity level of the package is produced.
		C The record of the process and chemicals that were used to reduce the resin is attached to the waste package.

TABLE 1. OUTLINE OF OPERATIONAL ACTIVITY (cont.)

Step 5: Waste storage and/or disposal

	Mining		Nuclear Power Plant	
	Grade	Description	Grade	Description
Description of step		The mining pump sump waste is pumped to a tailings impoundment.		The resin waste packages from the nuclear power plant are stored for eventual emplacement in a disposal facility.
Training	D	The operator should undergo on the job training in the pumping process.	B	Specialized training, including training in radiation protection measures, should be provided to the operator of the waste transfer and storage equipment.
Records	C	Pumping measurements are recorded on a pre-printed form that serves as the record.	C	A form is completed specifying where the waste packages have been stored, and is cross-referenced to the records of the chemical treatment and immobilization processing and the canister seal testing.

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