GUIDANCE DOCUMENT FOR THE DEVELOPMENT OF SAFETY CASE AND SECURITY PLAN FOR THE BOREHOLE DISPOSAL SYSTEM

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1 INTRODUCTION

1.1 Background

Disposal of radioactive waste signifies the final step in the management process, and disposal facilities are designed, operated and closed with a view to providing the necessary degree of containment and isolation to ensure safety and security. Protecting people and the environment from harmful effects of ionizing radiation is a fundamental safety objective and as a principle:

“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, secure, practicable and environmentally acceptable solutions for its long term management”.

As for all facilities and activities involving radioactive material and radiation, the operator of a disposal facility has the prime responsibility for safety and security and has to assess the safety and security of the facility to demonstrate that the design and operation of the facility are compliant with the relevant safety and security requirements [1].

The safety requirements for radioactive waste disposal entail, among other things, that a safety case be developed together with supporting safety assessment [2]. The safety case and supporting safety assessment provide the basis for demonstration of safety and for licensing. They will evolve with the development of the disposal facility, and will assist and guide decisions on siting, design and operations. The safety case will also be the main basis on which dialogue with interested parties will be conducted and on which confidence in the safety of the disposal facility will be developed.

1.2 Objective

The objective of this document is to provide an up to date guidance to applicants or operators on the framework for a safety case and security plan for the disposal of radioactive wastes, particularly disused sealed radioactive sources (DSRS), using the IAEA Borehole Disposal System (BDS).

1.3 Purpose

This document provides guidance and recommendations on meeting the safety and security requirements in respect of disposal of radioactive waste, specifically for DSRS, in borehole disposal facilities.

Applicants or operators are allowed to take other actions in developing the safety and security case. Nevertheless, the criteria set in this document must be met.

1.4 Scope

This guidance document applies to the disposal of DSRS in borehole disposal facilities. Any safety, security or technical related requirements regarding the storage of DSRS would not be covered in this document. Although this is a guidance document, requirements related to the safety case have been included.

This document assumes that the disposal facility has two main stages, design and implementation. The Design Safety Case is a site specific safety case submitted to the Nuclear Regulatory Authority (NRA) in order to obtain permission to construct a disposal borehole. This assumes that the site characterization program has been implemented and that the data so produced has been incorporated into the design safety case. Implementation of the BDS includes construction of the borehole, waste emplacement, closure and environmental monitoring.

No consideration of site selection, Environmental Impact Assessment, off-site transport, or provision of resources is included in this document. It is assumed that a decision to deploy the BDS has been taken, that a site has been chosen and the necessary resources are in place. Similarly, it is assumed that, if there are relevant local regulations, these are consistent with IAEA Safety Standards and Nuclear Security Publications.

1.5 Definitions and Abbreviations

1.5.1 Definitions

Safety case is the collection of scientific, technical, administrative and managerial arguments and evidence in support of the safety of a disposal facility, covering the suitability of the site and the design, construction and operation of the facility, the assessment of radiation risks and assurance of the adequacy and quality of all the safety related work associated with the disposal facility.

1.5.2 Abbreviations

BDS Borehole Disposal System
DSRS Disused Sealed Radioactive Sources
NRA Nuclear Regulatory Authority
WAC Waste Acceptance Criteria

2 MANAGEMENT SYSTEM

The management system should be developed to cover all aspects of borehole disposal system and the associated activities to be carried out, including all works performed by contractors. The applicant or operator's management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities. The development and maintenance of a safety and security culture in an organization is central to the management system.

As a demonstration that an adequate management system is in place, the following documents should be included (or referenced) in the safety case [3**Error! Bookmark not defined.**]:

- The policy statements of the organization.
- A description of the management system.
- A description of the structure of the organization.
- A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work.

- A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.
- Evidence to show that the management system is both being applied and being complied with.

The operator of a disposal facility has the prime responsibility for safety and security and has to assess the safety and security of the facility to demonstrate that the design and operation of the facility are compliant with the relevant safety and security requirements.

3 THE SAFETY CASE FOR DISPOSAL OF RADIOACTIVE WASTE

This section identifies and provides guidance on the components of the safety case, its development and its role during the development, operation and closure of the borehole disposal facility. The components of the safety case should include the following:

- the safety case context; the safety strategy;
- the disposal system description;
- safety assessments;
- limits, controls and conditions;
- iteration and design optimization;
- uncertainty management; and
- integration of safety arguments.

The safety case represents a management tool that can be used to inform decisions on:

- The design of the facility, for example the potential locations and arrangements of boreholes in a borehole disposal facility.
- The acceptability of particular wastes.
- The limits and conditions that need to be applied.
- Prioritisation of specific data acquisition to address uncertainty.
- The optimisation of radiological protection.

Each of these components is described in more detail in the following sub-sections, which collectively serve as a template for a safety case. The overall purpose of the safety case for a disposal facility is to demonstrate (with an appropriate level of confidence) that, the disposal system is feasible to implement, is and will be safe.

3.1 The Safety Case Context

The safety case context should describe the reasons or justification for the proposed disposal facility and should identify the relevant regulations, safety objectives and assessment timeframes to be considered. It should also describe the status of the waste management program.

Key reasons for a borehole disposal facility may include:

- The existence of radioactive wastes in the country such as DSRSs containing long-lived radionuclides that cannot be managed safely and sustainably in other ways (e.g., recycling, re-use, repatriation).
- The ability to provide a permanently safe, secure and economic solution for the radioactive material at the site or in the country by disposing of it in one or more boreholes, whilst at the same time meeting all relevant standards for safety and environmental protection, etc.

The developer of the safety case should provide evidence to support any such arguments that it puts forward (e.g. relating to a particular site or situation).

3.2 Safety Strategy

The safety strategy should set out how the safety objectives are to be achieved, for example, by describing how the relevant requirements will be fulfilled, such as those for isolation and containment, and for passive safety, robustness, and defence-in-depth [4].

Several aspects of the IAEA borehole disposal system may be viewed as being inherent parts of the safety strategy:

- Isolation would be provided by disposing of the waste at depths of greater than 30 m. The use of a site having low potential for the extraction of natural resources such as water, oil, gas and minerals, and the use of small-diameter, vertical boreholes would reduce the probability of inadvertent future human intrusion into the disposed waste to acceptably low levels.
- Passive safety would be provided by encapsulation and containerisation processes using engineered materials (e.g. stainless steel and concrete) with well-known properties and for which there is long experience in their manufacture and use.
- Containment, robustness and defence-in-depth would be provided by a combination of engineered and natural barriers to radionuclide release and migration, together with appropriate management and administrative controls over manufacture and operations. This combination of barriers provides multiple safety functions.

The developer of the safety case should provide evidence to support any such arguments that it puts forward.

3.3 System Description

The system description should record all of the information and knowledge about the borehole disposal system by thoroughly describing the inventory of wastes, site characterization and its surrounding environment, the waste management facilities and equipment to be used, including the design of the disposal facility (e.g. the location and arrangement of boreholes, the depth of the disposal zone, the design of the engineered barriers and other components). Additionally, it should provide the basis on which all safety assessment is carried out.

3.3.1 Radioactive Materials and Wastes

The safety case document should describe the inventory of radioactive materials and wastes:

i. present at the site;
ii. that are expected to be received at the site; and
iii. that are intended for disposal.

The description should include:

i. the amounts and characteristics of the materials and wastes, as well as the numbers and identifiers of each DSRS, and waste packages.
ii. details of the radionuclides present, the quantities of each radionuclide at a specified time of measurement, and of the waste encapsulation and waste packaging materials and their thicknesses.
iii. any presence of materials that could affect radionuclide release and behaviour in a disposal system, such as organic complexants, liquids and powders.

In addition, an encapsulation plan should describe how it is intended to distribute the inventory of sources between the capsules; this plan should be consistent with operational and post-closure safety. A waste emplacement plan will be required if the post-closure safety assessment relies on an emplacement strategy e.g. the placement of specific sources in a particular borehole location.

3.3.2 Site Characterization

The safety case document should describe the proposed site to perform the waste management activities and disposal. The site should be characterized to the level of detail necessary to demonstrate safety.

Site characterization is a multidisciplinary activity which should be conducted in accordance with a reasoned plan. The site characterization plan should consider geology, geochemistry, hydrogeology, hydrology, seismology, topography, tectonic and seismic conditions, erosion rates, natural resources (e.g. water, oil, gas, minerals), ecology, land use, local populations.

In view of this, the safety case document should include:

- the site characterization plan.
- a description of the site characterization work conducted.
- a description of how the site characterization work was undertaken, controlled and quality assured.
- the results obtained from the site characterization work, and a discussion of the levels of uncertainty associated with the site characterization.

- reasoned interpretations of the site characterization results.

The scope of site characterization work required will depend on:

- The complexity of the site.
- The inventory of wastes for disposal.
- National regulations and approaches to authorization

The safety case document should therefore describe the relationship between the site characterization work and the post-closure safety assessment.

3.3.3 Facilities

The safety case document should describe:

a) The nature of any pre-existing facilities at the site e.g. DSRS storage facility, research reactor, etc.

b) The design of any pre-disposal waste management facilities that are proposed to be brought onto the site.

   The pre-disposal waste management activities to be performed will depend on the particular wastes in question and are likely to vary from site to site. For example, work with Category 1 and 2 DSRS will require greater radiological shielding and, therefore, different facilities and equipment, than work with Category 3 to 5 DSRS.

c) The design of the disposal facility including:

   i. The disposal borehole(s).
   ii. The components and engineering materials to be used in borehole construction, waste disposal and borehole closure (e.g. the casing, backfilling and sealing materials and their thicknesses).
   iii. The safety functions of each component of the pre-disposal and disposal facilities.
   iv. The proposed or actual locations of disposal boreholes and other boreholes and pre-existing underground structures at the site (e.g. utilities).
   v. The location and depth of the proposed disposal zone(s).

3.3.4 Activities

The safety case document should describe:

i. encapsulation, containerization, borehole construction, commissioning, waste disposal, borehole closure activities to be undertaken, equipment to be used, as well as include detailed operating procedures that will be followed. Confirmation that the borehole can be operated according to the design may involve the emplacement of over-sized, dummy (inactive) waste packages.
ii. measures for mitigating hazards arising from 'off-normal' situations during waste management activities, such as those that might relate to incorrectly labelled sources, dropped waste packages and problems with waste package emplacement in the borehole.
iii. thorough procedures that explain what to do when the unexpected happens.
iv. the level of practical experience that exists for each activity

3.4 Safety Assessment

Safety assessment is the main component of the safety case which is needed to assess the potential exposures to radiation of workers and the public during the range of waste management activities and after the closure of the disposal facility. This is to demonstrate that the waste management system and its components have been designed and will be operated in a way that provides the appropriate level of protection [5].

3.4.1 Operational Safety

The safety case should be supported by safety assessment of the operations to be carried out. This assessment should consider both normal and 'off-normal' situations, the latter including accidents, component failures and other unexpected circumstances. The potential for 'off-site' releases and impacts on the local population should also be assessed.

The assessment should be used to:

i. show that the operations have been optimized by, for example, appropriate use of exposure time, distance and shielding to show that worker doses are as low as reasonably achievable
ii. assist in deriving appropriate waste acceptance criteria (WAC).

The safety case should include an emergency plan and associated procedures that demonstrate that appropriate preparations have been undertaken or are planned in accordance with the requirements of [6], but reflecting the limited scale and potential for emergency situations at a waste management and borehole disposal facility.

3.4.2 Post-Closure Safety Assessment

The primary purpose of the post-closure safety assessment is to demonstrate that the proposed borehole disposal will be safe and meet the regulatory dose or risk criteria. The IAEA has developed a generic post-closure safety assessment for borehole disposal of DSRS [7] and this work can be referred to where relevant. Nevertheless, it is expected that a site-specific post-closure safety assessment that takes account of the particular inventory of wastes for disposal and uses site-specific data, on geology, geochemistry, hydrology and borehole geometry should be included in the safety case.

The following sub-sections discuss the various components of the post-closure safety assessment [9]

3.4.2.1 Assessment Context

The safety assessment context is intended to clarify what is going to be assessed and why it is going to be assessed. In addressing the assessment context, information should be provided concerning the following key aspects:

i. Purpose of the Assessment

Safety assessments of radioactive waste in the borehole disposal facilities should have the principal purpose of demonstrating that an acceptable level of protection of human health and the environment will be achieved both now and in the future. In addition to this overall demonstration of safety, there can be a variety of additional purposes, such as derivation of quantitative acceptance criteria. However, the purpose of conducting an assessment may vary from considering initial ideas for disposal concepts using simple calculations, to support for a licence application for disposal or for upgrading the safety of an existing facility; requiring detailed, site specific safety assessment to demonstrate compliance with regulatory criteria.

The target group (e.g. regulators, operators, waste producers, public, local, regional and national politicians) to whom the outcome of the safety assessment will be presented should also be considered as this will play a role in defining relevant assessment end-points, assumptions concerning the disposal system, justification of the assessment scenarios, as well as the approach for presentation of the assessment results.

ii. Regulatory Framework

In undertaking safety assessment, it is necessary to consider the regulatory requirements that are relevant as well as international guidance on the regulation of radioactive waste disposal such as the IAEA Principles of Radioactive Waste Management [10], the Safety Requirements for Near Surface Disposal of Radioactive Waste [11], the Safety Guide on Safety Assessment for Near Surface Disposal of Radioactive Waste [12]

iii. Assessment End-Points

The end-points of an assessment need to be well defined to correspond with the safety assessment purpose, the associated regulatory framework, and it should take into account the assumptions made concerning timescales and critical groups. An additional consideration is the trend in safety case development not to rely on evaluation of just a single end-point, such as individual dose or risk. Multiple lines of reasoning may be useful since the use of a wider range of arguments and end-points will help to establish the adequacy of the safety case. A variety of additional indicators may be used to complement those of dose and risk (such as radionuclide fluxes and concentrations).

iv. Assessment Philosophy

The assessment philosophy is an expression of the extent to which the assessment is designed to provide "realistic" estimation of potential impacts for comparison with the assessment end-points, or whether more cautious, or pessimistic assumptions should be adopted for the purposes of demonstrating compliance with safety requirements.

v. Disposal System Characteristics

The borehole disposal system can be considered to consist of: the near field, the geosphere, and the biosphere. However, it is useful to provide, within the assessment context step, a brief overview of the present-day system and to document any associated fundamental assumptions. As part of the initial description of the system, assumptions concerning future human actions should be defined, such as the level of technological development, type of society, and the basis for its habits and characteristics. Similarly, assumptions concerning the characteristics of any groups of people, who might potentially be exposed to radionuclides migrating from the disposal facility, should also be defined. Alternatively, they can be defined during the scenario development and justification process. What is important is that these assumptions are clearly identified and as far as possible justified at either of these two stages of the assessment process.

vi. Assessment Time Frames

The BDS should ensure equitable protection of both current and future generations and this will involve balancing greater certainty for shorter time periods with increasing uncertainty over longer time periods. The timeframe for the post-closure safety assessment should be defined, recognizing the inherent limitations and uncertainties in assessment approaches, as well as constraints on the scientific credibility of long term estimates of borehole disposal facility performance, which could be influenced by large-scale environmental changes. The timescale of interest for an assessment is a function of the nature of the borehole disposal system and the external influences on it, and the longevity of the radionuclides in the wastes. Therefore, the timescales of an assessment should be justified on a case-by-case basis, although some may also stem from regulatory requirements (e.g. institutional control period).

A. Description of Disposal System

The disposal system description needs to collate information on:

i. the near field- e.g. waste types, waste forms, waste inventory, waste emplacement practices, engineered barriers, facility dimensions;
ii. the geosphere - e.g. lithology, hydrogeology and transport characteristics; and
iii. the biosphere - e.g. exposure pathways, human habits and behaviour.

This aspect of the safety assessment is important as it provides the information about the disposal system upon which the safety assessment will be carried out. It is necessary to ensure that the data collected are sufficient for the assessment context and appropriate description of the system. The limited availability or adequacy of data is an important factor in many safety assessments and hence when developing the system description, it is important to be aware of and to document any assumptions made and the associated uncertainties.

B. Development and Justification of Scenarios

A logical and traceable process should be followed and documented to identify a set of scenarios for assessment. Each scenario represents a potential future of the disposal system and will comprise a combination of events and processes that could occur and influence the disposal facility. Different methods exist for the development of scenarios. For example, some methods focus on assembling scenarios from lists of features, events and processes (FEPs), while other methods focus more on the safety functions of the disposal system components (these are sometimes referred to as Structures, Systems and Components (SSCs)). In the second case, scenarios are formed based on events and processes that could cause the loss of one or more of the safety functions.

Whichever scenario development method is used, it is important that the safety assessment document describes fully the reasons for the choices and decisions made during scenario development, and demonstrate that a sufficient range of scenarios have been developed to adequately capture the uncertainty associated with the potential range of future disposal system behaviours.

C. Formulation and Implementation of Models

Conceptual models should be described for the FEPs that are relevant and potentially significant to safety at and around the disposal site. For example, conceptual models may be needed for:

- Groundwater saturation and flow.
- Engineered barrier degradation (e.g. cement degradation and steel corrosion).
- Radionuclide release and migration (e.g. by diffusion and/or advection as affected by retardation processes such as sorption).
- Surface hydrology.
- Water abstraction from boreholes or wells and water uses (e.g. drinking, irrigation).

Appropriate mathematical descriptions for the relevant conceptual models should be developed, documented, verified and validated as far as possible, and the safety assessment documents should show that the models used in the post-closure safety assessment are fit for their intended purpose.

D. Presentation and Analysis of Results

The safety assessment documents should describe and refer to the results from the safety assessment calculations for each of the scenarios and calculation cases undertaken. Results should be presented in a form that allows proper comparison against the relevant regulatory safety criteria. In addition to presenting overall results such as potential dose or risk, it is good practice to present a range of other results from the safety assessment calculations to aid understanding of the behaviour of the disposal system and its safety functions, and of how safety is provided for each of the key radionuclides. For example, the safety assessment documents may present modelling results showing the time 'histories' of how much of each radionuclide decays within the capsule and the waste package, and how much is released from the waste container to the geosphere and from the geosphere to the biosphere. The safety assessment documents should present results from any uncertainty and sensitivity analyses conducted. Such results can help in understanding the significance of individual scenarios, calculation cases and parameters, and in the overall safety of the facility.

E. Building Confidence in Post-Closure Safety

In order to build confidence, the post-closure safety assessment document should present a series of arguments that are intended to build confidence in safety. Briefly, these may include defence in depth and multiple lines of reasoning, institutional control and environmental monitoring, natural analogues and the adoption of a conservative approach.

Uncertainty or sensitivity analysis should be used to demonstrate defence in depth: that the safety of the system is not unduly reliant on any one feature of the design or the assumptions made in the safety assessment; further, that if one barrier were to fail prematurely, safety would still be preserved to an acceptable extent. Such analyses could also support multiple lines of reasoning by citing a series of arguments, any one of which could be used to justify the safety of the facility.

Further confidence in the post-closure safety of the disposal system may be derived from the study and discussion in the safety case documents of natural and anthropogenic analogues of barrier materials. Such analogues may provide a visual and/or readily understandable argument for the longevity of stainless steel and concrete structures, and may provide support for the conceptual models used in the safety assessment to represent processes such as concrete degradation and radionuclide retardation [13].

Evidence of the use of a conservative approach in the post-closure safety assessment should be presented. For example:

- Some scenarios (such as there being defects in all of the capsules) may have a very low probability of occurrence.
- Some models (such as instantaneous release of radionuclides to groundwater following container failure) may be pessimistic.
- Some parameter values (such as assigning a sorption distribution coefficient of zero to a radionuclide for which no site-specific data exists) may be pessimistic.

3.5 Iteration and Design Optimization

Iteration and design optimization involves the development and improvement of the design for the waste management activities and the borehole disposal facility so that, for example, the design to be implemented makes optimal use of the site. Safety assessment may be used to identify site characterization tasks to examine design options and may be seen as the principal tool for directing these activities.

The safety case document should describe the process by which the design was finalized by describing, for example, any options that were considered and rejected. An option may be rejected for many reasons including safety, security, feasibility, cost, concerns of interested parties etc. If this is done, and if the regulatory constraints are complied with, the design may be considered to be optimized. The safety case should aim to show that the locations and depth of the borehole(s) and the disposal zone(s) make optimal use of the geological and hydrogeological characteristics of the site.

The IAEA Borehole Disposal System has a fixed design and its components were optimized during its development by examining a wide range of options [14]. This historical information may be referred to in the safety case. Any deviation from the fixed design must be justified on grounds of safety, security, feasibility, cost, etc. and the overall design must be shown to comply with the regulatory constraints.

3.6 Management of Uncertainty

Uncertainty management recognizes that some level of uncertainty is inevitable and this needs to be acknowledged, evaluated and acted upon. In many cases this will be done routinely within the safety assessment. Beyond this, the safety case should describe the operator's process for addressing unresolved or unforeseen issues that are potentially significant to safety. An example might be discovery of unexpected ground conditions during drilling of the disposal borehole.

3.7 Limits, Controls and Conditions

The safety case and supporting assessment should be used to assist in the establishment of limits, controls and conditions to be applied to all work and activities that have an influence on the safety of the facility as well as the waste that will be disposed of in the facility. Limits, controls, and conditions are necessary as they allow the waste management facilities to be operated and closed safely. For example, limits on the activity of sources or waste packages that can be accepted for conditioning will help to prevent undue radiation exposure to workers.

The applicant or operator of the waste management disposal facility should, as part of the safety case documentation, describe the limits, controls and conditions that are to be applied. These should be consistent with the safety case and relevant safety assessments (including those for operational and post-closure safety). An important category of limits, controls and conditions is the waste acceptance criteria, which define the type of waste that can be accepted, usually for storage or disposal.

Examples of the types of waste acceptance criteria that may be defined in the IAEA Borehole Disposal System include:

- The physical form of the waste (e.g. solids only).
- The use of standard, defined waste packages.
- The maximum thermal power of the waste packages.
- Surface dose rate limits for capsules, storage containers, and waste packages.
- Limits on specific radionuclides and fissile materials.
- Limits on removable surface contamination.

The safety case and supporting assessment should include appropriate plans and procedures for waste characterization and quality assurance of facility construction and closure works that allow checking of compliance with the limits, controls and conditions. In particular, the safety case and supporting assessment should address procedures for managing non-compliant situations (e.g. waste that does not meet the waste acceptance criteria).

3.8 Integration of Safety Arguments

The safety case and supporting assessment should include a synthesis of all of the available evidence, arguments and analyses conducted and which lead to the conclusion that the proposed activities can be safely and securely managed. This synthesis should explain how relevant data and information have been considered, how models have been tested, and how a rational and systematic assessment procedure has been followed.

The synthesis should address all relevant aspects and requirements [15], including the importance of safety, the requirement for passive safety, the level of confidence that exists in understanding the disposal system, disposal system design principles (multiple safety functions, containment, isolation), the steps in the disposal system development process (site characterization and facility design, construction, operation, closure) and assurance measures (waste acceptance criteria, monitoring and surveillance, institutional controls and the applicant or operator’s management system).

The synthesis should acknowledge any limitations of currently available evidence, arguments and analyses, and should highlight the principal grounds on which a judgement has been made that the planning and development of the waste management and disposal system should nevertheless be continued.

4 INVOLVEMENT OF INTERESTED PARTIES

Involvement of interested parties aims to provide understanding and develop long-term public acceptability for waste management policy and corresponding facilities. Improving the involvement of interested parties has allowed some national programs to move forward after encountering significant resistance [16]

The overarching principle for such involvement is to demonstrate respect, which includes:

- Being inclusive of interested parties with a recognized role
- Listening to understand issues and concerns
- Recognizing the values of interested parties
- Acknowledging the need to build and maintain trust
- Displaying openness and transparency
- Exhibiting accountability

National norms and requirements for involvement of interested parties vary from non-interactive informational presentations and listening campaigns, to interactive dialogue and consultation, and finally to partnership and joint decision making. These aspects of respect represent attributes of good communication with the goal of establishing and maintaining constructive dialogue. Dialogue should help to ensure that the appropriate information is provided and appropriate responses are made to the concerns of all those who have an interest in the development of the facility.

National norms and requirements differ as to the role and influence of interested parties in decision making. Understandably, the safety case and supporting safety assessment should demonstrate the level of protection of persons and the environment in a manner reasonable for a variety of interested parties and provide assurance that the safety requirements will be met [4]. Additionally, the safety case documents should explain the purpose and processes of involvement of interested parties that have occurred and are planned in the future, and clarify how the issues raised have been, or will be, addressed.

The Regulatory Authority represents an important interested party for the implementing organization. National norms and requirements for interactions between the implementer and regulator vary, but unless the level of interaction and timeframe is specified, early and frequent interactions, will likely help to maintain a fruitful relationship. Note that the Regulatory Authority has its own responsibilities for dialogue with interested parties, which include [5]

- Setting up appropriate means of informing parties in the vicinity, the public and other interested parties, the media about the safety aspects (including health and environmental aspects) of facilities and activities and about regulatory processes.
- Consulting with parties in the vicinity, the public and other interested parties, as appropriate, in an open and inclusive process.

Dialogue with interested parties will be facilitated by safety case documentation that is well-presented and easily understandable. A useful tool in these circumstances is a well-written high level summary that provides a succinct description of the proposed facility and explains why it is needed and why it will be safe.

5 SECURITY PLAN

A security plan should include all information necessary to describe the security approach and system being used for protection of radioactive material and waste. The level of detail and depth of content should be commensurate with the security level of the materials and wastes covered by the plan.

Reference [16] provides guidance and recommended measures for the prevention of, detection of, and response to malicious acts involving radioactive sources; it also addresses how to prevent the loss of control of such sources.

5.1 Contents of a Security Plan

A security plan should include all information necessary to describe the security approach and system being used for protection of the source(s). The level of detail and depth of content should be commensurate with the security level of the source(s) covered by the plan. The following topics should typically be included:

1. A description and categorization, of the sources.
2. The location of the DBS relative to areas accessible to the public.
3. Local security procedures.
4. The objectives of the security plan for the DBS, including:
    a. the specific concern to be addressed: unauthorized removal, destruction, or malevolent use;
    b. the kind of control needed to prevent undesired consequences including the auxiliary equipment that might be needed;
    c. the equipment or premises that will be secured.
5. The security measures to be used, including:
    a. the measures to secure, provide surveillance, provide access control, detect, delay, respond and communicate;
    b. the design features to evaluate the quality of the measures against the assumed threat.
6. The administrative measures to be used, including:

a. the security roles and responsibilities of management, staff and others;

b. routine and non-routine operations;

c. maintenance and testing of equipment;

d. determination of the trustworthiness of personnel;

e. the application of information security;

f. methods for access authorization;

g. security-related aspects of the emergency plan, including event reporting;

h. training;

i. key control procedures.

7. The procedures to address increased threat level.
8. The process for periodically evaluating the effectiveness of the plan and updating it accordingly.
9. Any compensatory measures that may need to be used.
10. References to existing regulations or standards.

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Annex 1: Example of a Quality Management Framework

Plan	Do [Note 1]	Check [Note 1]	Act [Note 1]	Notes
		Design safety case		
Definition of the inventory for disposal.	a. Use equipment with up-to-date calibration to establish the nature and number of the sources: the radionuclides, their activity (type and amount), their physical dimensions and unique identifiers. b. Where possible identify the sources in the IAEA Catalogue of Sources. c. Ensure that the inventory for disposal is commensurate with the inventory assumed in the safety case d. Create records of the measurements performed, the nature of the sources and their location [Note 2].	Examine records to establish that a. Equipment used was fit for purpose and calibration was up to date; measured activities/dates tally with expected decay from as-manufactured values; b. source properties tally (where possible) with the IAEA Catalogue of Sources c. Inventory is commensurate with the one used in the safety case d. Records are adequate	a. If the deviation is significant for safety, redo the measurement with suitable and properly calibrated equipment; explore the reasons for any discrepancy between current and historical activity values b. explore the reasons for any discrepancy c. Either extend the safety case to accommodate any additional sources or remove additional sources from inventory for disposal d. Assess potential impact of any deviations and consider what action to take [Note 3]	[Note 1] All activities are to be performed by suitably qualified and experienced persons (SQEP). Operator to define what qualifications and experience are sufficient to carry out SQEP roles. Regulatory body to approve these profiles [Note 2] These records will later be extended to provide documentation of the further processing of the sources as they move towards disposal including their final location within the disposal facility [Note 3] When assessing the impact of any deviation the following factors should be considered: • Can the deviation be easily remedied?

Plan	Do [Note 1]	Check [Note 1]	Act [Note 1]	Notes
				• Can the deviation be accommodated within the existing safety case? • Does the safety case need to be modified? • Does the activity need to be re-done?

Plan	Do [Note 1]	Check [Note 1]	Act [Note 1]	Notes
Site characterization	a. Identify and document the site characteristics assumed in the safety case. These may be classified under surface processes, geology, hydrogeology and geochemistry. b. Develop the specification for the site characterization programme c. Engage a competent body to implement the site characterization programme d. Ensure that samples are properly identified, recorded, stored and traceable commensurate with the specification e. Document the activities of, and the data produced by, the site characterization programme and interpret the results f. Confirm that the discovered site properties are	Confirm that: a. The site properties required by the safety case have been correctly identified b. Specification is adequate c. bodies performing site characterization works are accredited/ competent including use of laboratories and any equipment d. record keeping meets the specification e. the activities have been performed according to the specification, the data are adequate and the interpretation is reasonable. Consider need for independent third party review f. Check that safety case remains valid	a. Revisit safety case and properly identify the needed site properties b. Revise specification c. Train or change body performing the work and, if necessary, re-do d. Modify record keeping and consider the need to re-do the sampling or tests e. Consider need for independent third party review f. Consider extension to site characterization programme or modifications of design and safety case	[Note 4] The BDS generic safety assessment assumes a reference design and both will need to be adapted to incorporate site-specificity so as to produce a site-specific safety case. Site characterization will indicate whether the site-specific safety case properly represents the actual site properties. If the results of the site characterization programme are not consistent with the safety case then some degree of iteration will be needed between the design, the safety case and additional site measurements.

Plan	Do [Note 1]	Check [Note 1]	Act [Note 1]	Notes
	commensurate with the safety case [Note 4]			
Design	a. Modify the reference design, if required, to accommodate the inventory for disposal, site-specific issues and availability of materials b. Confirm that the design changes are acceptable	a. Check that the design is consistent with the safety case b. Check that the design changes are appropriate and that adequate safety levels are achieved	a. Change the design or re-do the safety case b. Assess potential impact of any deviations and consider what action to take [Note 3]	
Demonstration of safety	a. Produce a safety case corresponding to the proposed design, site and inventory to demonstrate safety during pre-disposal, borehole operation and post-closure including any emergency procedures b. Develop a proportionate management system to include training, where necessary, in radiation protection and other relevant areas [Note 5]	a. Check the adequacy of the safety case. Arrange for independent third party review b. Check the adequacy of the management system and its implementation. Consider the need for independent third party review	a. Revise safety case. Respond to independent third party review comments b. Revise management system. Respond to independent third party review comments	[Note 5] The management system should ensure that the operator has control and responsibility for all activities at its site and for ensuring that any work carried out is performed by an appropriate body or individual to an appropriate specification.

Plan	Do [Note 1]	Check [Note 1]	Act [Note 1]	Notes
Implementation				
Encapsulation and containerization	a. Specify and procure capsules and containers from a manufacturer certified to ISO 9001 or to an operator-approved quality plan [Note 6] (example appended) b. Establish facilities for storage, encapsulation and containerization taking into account the inventory for disposal c. Develop waste acceptance criteria and procedures for addressing non-compliant sources and capsules d. Establish procedures for encapsulation and containerization and associated inspections and tests e. Establish contingency plans to respond to unsatisfactory encapsulation or containerization	a. Check approval of specification; check certification of manufacturer to ISO 9001 or, alternatively, check quality plan. In either case check documentation of manufacturing process b. Check that as-built design corresponds to design safety case c. Check adequacy of WAC and procedures for addressing non-compliant sources and capsules d. Check compliance with procedures for encapsulation and containerization and associated inspections and tests e. Check adequacy of contingency plans to respond to unsatisfactory encapsulation or	a. Either change manufacturer or revise quality plan; consider re-doing manufacture b. Consider whether as-built design can be accommodated within design safety case; otherwise re-do manufacture or change design safety case. c. Revise WAC and/or procedures d. Assess potential impact of any deviations and consider what action to take [Note 3] e. Change contingency plans to make them adequate f. Assess potential impact of any deviations and consider what action to take [Note 3] g. As e	[Note 6] A QP defines the acceptable level of quality specified by the operator and describes how this will be ensured. Typically, it will list the actions to be performed, the document, drawing or procedure relevant to that action, the person or body responsible for performing the action, any hold point or requirement for witnessing the action, a space for approval by signature and, finally, any additional certificates required to support satisfactory completion of the action

Plan	Do [Note 1]	Check [Note 1]	Act [Note 1]	Notes
	f. Perform encapsulation and containerization and associated inspections and tests and follow contingency plans if necessary; generate the associated records g. If needed, remove encapsulated /containerized sources to temporary storage and record	containerization f. Check encapsulation and containerization records to ensure due process followed g. Check appropriate records were made		
Decommission storage, encapsulation and containerization facilities	a. Develop decommissioning plan including a disposal route for any waste produced by decontamination (usually to landfill), any need for interim storage and procedures for clearance b. Decommission, generate associated documentation	a. Check feasibility of decommissioning plan b. Check decommissioning documentation (after this has occurred)	a. Address shortcomings in decommissioning plan b. Assess potential impact of any deviations and consider what action to take [Note 3]	
Borehole construction	a. Specify the borehole design and engage a suitably experienced borehole construction body to work to an operator-approved quality	Check borehole design and specification; check qualifications/ experience of the body; check quality plan a. Witness borehole	a. Revise design and/or specification; engage a more suitable body to perform the activity; revise QP b. Assess potential impact of any deviations and consider	

Plan	Do [Note 1]	Check [Note 1]	Act [Note 1]	Notes
	plan b. Implement borehole construction c. Generate records according to quality plan (QP)	construction; lower dummy container to confirm adequate straightness and depth b. Check records against QP	what action to take [Note 3] c. As b	
Commissioning	a. Develop commissioning plan b. Specify and manufacture oversize dummy container c. Prepare as-built drawings based on downhole logs d. Implement commissioning plan	a. Check commissioning plan b. Check dummy containers made to specification c. Check as-built borehole drawings against design d. Confirm satisfactory commissioning	a. Revise commissioning plan b. Consider re-supply c. Evaluate significance of deviations and either justify proceeding with borehole or seal up the borehole and construct another [Note 3] d. As c [Note 3]	
Emplacement of containers in the borehole	a. Produce procedures specifying the work to be performed b. Implement the emplacement c. Generate records	a. Check procedures specifying the work to be performed b. Witness the emplacement c. Check adequacy of records	a. Revise procedures b. Assess potential impact of any deviations and consider what action to take [Note 3] c. As b	
Borehole closure	a. Produce procedures specifying the work to be performed b. Implement the closure c. Generate records	a. Check procedures specifying the work to be performed b. Witness the closure c. Check adequacy of records	a. Revise procedures b. Assess potential impact of any deviations and consider what action to take [Note 3] c. As b	
Environmental	a. Specify short-term	a. Check short-term	a. Revise short-term	

Plan	Do [Note 1]	Check [Note 1]	Act [Note 1]	Notes
monitoring - short-term	monitoring programme (ie before and immediately following closure) to demonstrate absence of environmental contamination on the surface b. Identify and engage suitably qualified body to perform short-term monitoring programme c. Generate records	monitoring programme b. Check suitability of body engaged to perform the work; consider use of independent third party measurement c. Check records and compare results of measurements against expected behaviour	monitoring programme b. Train or change body engaged to perform the work c. Assess potential impact of any deviations and consider what action to take [Note 3]	
Environmental monitoring - long-term [Note 7]	a. Specify long-term monitoring programme, if required, to demonstrate absence of environmental contamination to interested parties b. Perform long-term monitoring programme c. Generate records	a. Check short-term monitoring programme b. Check suitability of body performing the monitoring; consider use of independent third party measurement c. Check records and compare results of measurements against expected behaviour	a. Revise short-term monitoring programme b. Train or change body performing the monitoring c. Assess potential impact of any deviations and consider what action to take [Note 3]	[Note 7] The scope and the duration of any long-term environmental monitoring on the site are issues that will need to be agreed between the operator, the regulatory authorities and local interested parties