IAEA TECDOC SERIES

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Contents and Sample Arguments of a Safety Case for Near Surface Disposal of Radioactive Waste

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CONTENTS AND SAMPLE ARGUMENTS OF A SAFETY CASE FOR NEAR SURFACE DISPOSAL OF RADIOACTIVE WASTE

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INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2017

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FOREWORD

The IAEA has devoted considerable time to developing approaches for conducting safety assessments for near surface radioactive waste disposal facilities within coordinated research projects such as the Improvement of Safety Assessment Methodologies for Near Surface Radioactive Waste Disposal Facilities (ISAM) Project, and the Application of Safety Assessment Methodologies for Near Surface Radioactive Waste Disposal Facilities (ASAM) Project. These projects evaluated safety assessment methods and codes, standardized the method of conducting safety assessments, and applied and tested that standardized method. More recently, the IAEA has widened its focus to address the safety case concept, which, in the context of radioactive waste disposal, is defined as a collection of scientific, technical, administrative and managerial arguments and evidence in support of the safety of a disposal facility.

This broader approach has been elaborated in international projects to define the contents of a safety case and to develop sample arguments for a near surface radioactive waste disposal facility. The Practical Illustration and Use of the Safety Case Concept in the Management of Near Surface Disposal (PRISM) Project addressed the contents and use of the safety case for decision making during the lifetime of a near surface disposal facility. A follow-on project, PRISMA — where the 'A' refers to Application — developed a matrix of sample arguments for a safety case for two hypothetical facilities.

To help Member States in developing safety cases for near surface radioactive waste repositories, this publication summarizes the results of the PRISM and PRISMA projects. The IAEA officer responsible for this publication was K. Moeller of the Division of Radiation, Transport and Waste Safety.

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CONTENTS

1. INTRODUCTION

Many Member States are developing and/or operating near surface disposal facilities for radioactive waste. The International Atomic Energy Agency (IAEA) has spent considerable time developing approaches for safety assessments for radioactive waste disposal sites. The process of disposal facility development and operation typically extends over long periods of time. According to the IAEA , the safety of such disposal facilities has to be demonstrated for time frames "…defined by taking account of national regulations and regulatory guidance, as well as the characteristics of the particular disposal facility, the site and the waste to be disposed of" [1]. Depending on the waste, disposal facility and site, these times can extend hundreds or thousands of years and longer in some cases. Assessments extending over these times involve significant uncertainties associated with the evolution of engineered and natural systems as well as human habits and living conditions.

A step by step approach is recommended for managing disposal facility development, operation and closure over such long time periods. Key decisions have to be made at various stages in the lifetime of the disposal facility based on the recognition that there is a long-term hazard to be managed. Arguments that support each decision have to be developed, clearly recorded and provided to decision makers. In recent years, international organizations including the IAEA and the Organization for Economic Co-operation and Development/Nuclear Energy Agency (OECD/NEA) have applied the concept of the safety case to structure and integrate the information that has to be provided to the decision makers.

Requirement 13 in the IAEA specific safety requirements for disposal of radioactive waste provides broad expectations for the safety case, "The safety case for a disposal facility shall describe all safety relevant aspects of the site, the design of the facility, and the managerial control measures and regulatory controls. The safety case and supporting safety assessment shall demonstrate the level of protection of people and the environment provided and shall provide assurance to the regulatory body and other interested parties that safety requirements will be met" [2].

In the context of radioactive waste disposal, the safety case is a product of an iterative process of developing and updating "a 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].

Any particular safety case includes many different arguments and describes various activities that together provide the basis for the safe disposal of the waste. These arguments and activities may address:

- The presence of appropriate management structures and quality systems;
- The existing regulations and stakeholder interactions;
- The process adopted for the site selection;
- The methodology followed and used for designing the facility;
- Description of the facility and associated site;

- Operational and post-closure safety assessments;
- The management of uncertainties;
- The derivation and implementation of waste acceptance criteria;
- The monitoring programme.

A characteristic of the safety case is that its content necessarily evolves with time and with the decision to be taken during the facility's lifetime.

Increased focus on the concept of the safety case resulted in two international projects. The first, the "PRactical Illustration of the use of the Safety case concept in the Management of near-surface disposal" project (PRISM) addressed the nature and use of the safety case for decision making during the lifetime of a near-surface disposal facility and resulted in the definition of the components of a safety case that are documented in the Matrix of Arguments for a safety case; the MASC matrix

A follow on project, PRISMA–where the 'A' refers to Application, used the MASC matrix for tracking and documenting a safety case and moved from the definition of the components of the safety case provided by PRISM to developing sample arguments (i.e. content) for safety cases for two hypothetical repository programmes. PRISMA concentrated on documenting the basis for decisions made in developing the content of a safety case.

This TECDOC presents a synthesis of these two projects: the components of a safety case defined by PRISM and the sample arguments or content of safety cases for two hypothetical facilities developed by PRISMA. This TECDOC is not a description of either the PRISM or PRISMA projects, but instead presents the results of these projects to assist Member States in developing safety cases for radioactive waste disposal facilities.

The objective of this TECDOC is to give detailed guidance on content and sample arguments for safety cases for radioactive waste disposal to technical experts preparing a safety case, as well as information on the basis for decisions made in developing the content of a safety case for decision makers in the regulatory body and government.

This TECDOC outlines the key uses and aspects of the safety case, its evolution in parallel with that of the disposal facility, the key decision steps in the development of the waste disposal facility, the components of the safety case, their place in the MASC matrix and a detailed description of the development of sample arguments of a safety case for two hypothetical radioactive waste disposal facilities, including the development process used and the modification of the MASC matrix to facilitate their development.

2. KEY ASPECTS AND USES OF THE SAFETY CASE

The following sections present a definition of the safety case, its relation to IAEA requirements and guides, its use and some of the main issues associated with developing a safety case.

2.1.SAFETY CASE DEFINITION

As noted above, in the context of radioactive waste disposal, the safety case is defined as "a 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].

2.2.RELATIONSHIP TO IAEA SAFETY REQUIREMENTS AND SAFETY GUIDES

IAEA GSR Part 4 [3] and SSR-5 [2] safety standards require that a safety case shall be developed, including supporting safety assessments and arguments.

SSR-5 - Requirement 13: "Scope of the safety case and safety assessment requires that 'The Safety Case for a disposal facility shall describe all safety relevant aspects of the site, the design of the facility, and the managerial control measures and regulatory controls'. In addition, SSR-5 requires that "the safety case and supporting safety assessment shall demonstrate the level of protection of people and the environment provided and shall provide assurance to the regulatory body and other interested parties that safety requirements will be met" [2].

These requirements imply that the safety case is a living document to be developed and maintained throughout the lifetime of the waste disposal facility (e.g. siting, design, construction, operation, closure, post-closure control) and that relevant aspects pertaining to the predisposal management of the waste also need to be taken into account. The safety case thus provides a framework to be used to integrate the wide range of information relevant to a disposal facility, and to guide facility development, use, and closure. The safety case includes relevant safety assessments, is used to manage uncertainties, and also includes a demonstration of compliance with the applicable safety requirements and criteria. The purposes of the progressive development, updating, and use of the safety case include ensuring safety and adequate performance of the facility, allowing any necessary corrective actions and measures to be taken in a timely manner, and involving all interested parties (e.g. decision makers, the public, etc.).

The IAEA provides guidance for meeting the safety requirements relating to the safety case and safety assessments [1]. As well as guidance on how to assess, demonstrate and document the safety of all types of radioactive waste disposal facilities. The most important considerations when assessing the post-closure safety of radioactive waste disposal facilities are identified, and guidance is provided on best practice for undertaking such assessments and for presenting the safety case. The guidance provided in Ref. [1] is relevant to organizations developing and operating radioactive waste disposal facilities (i.e. those bearing the responsibility for developing the safety case), as well as to regulatory bodies and those responsible for developing policy, regulations and regulatory guidance that provide the context for the safety case.

The safety case components are identified in Ref. [1] as follows:

- The safety case context;
- The safety strategy;
- Description of the disposal system;
- The safety assessment;
- Iteration and design optimization;
- The management of uncertainties;
- Limits, control and conditions;
- Integration of safety arguments;
- Management system;
- Involvement of interested parties and independent review.

These components and the relationships between them are illustrated in Figure 1.

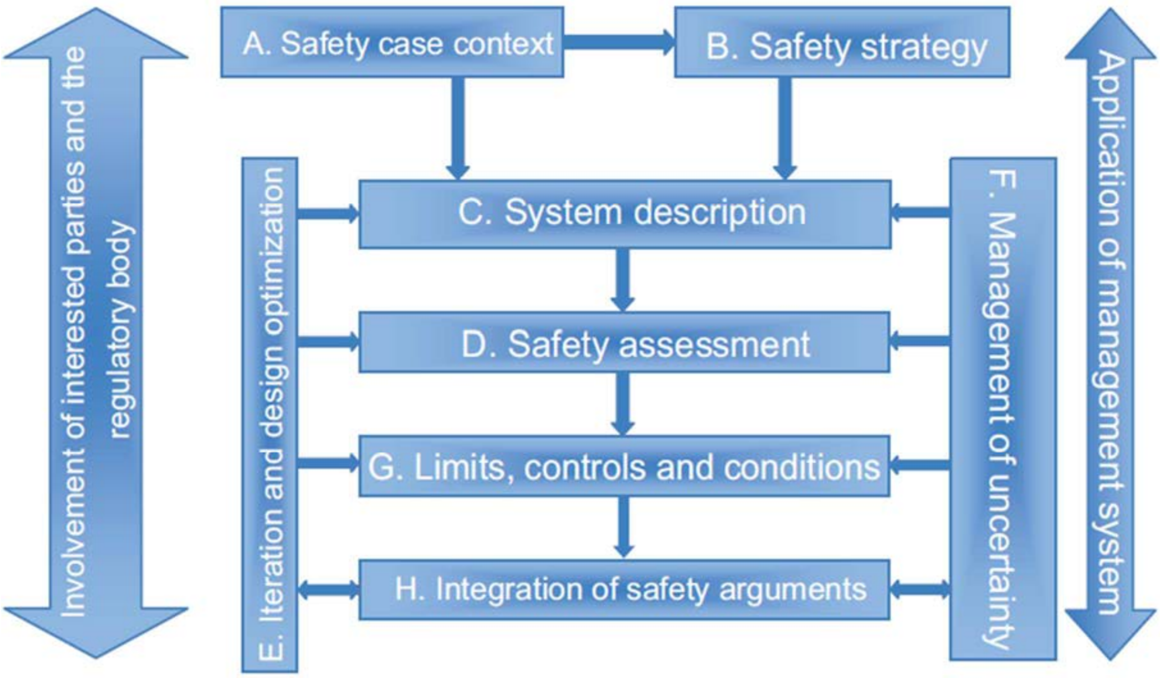

FIG. 1. Components of the safety case [1].

The PRISM project sought to understand, describe and elaborate on the main components of the safety case, based on the collective experiences of its participants in developing safety cases and implementing disposal facilities worldwide. The following paragraphs draw out several key points; further details are provided in Section 5. The examples and discussions provided by the PRISM project are intended to complement the IAEA safety requirements and safety guides (e.g. SSG-23) particularly in the area of what may be expected of a safety case at each stage of near surface disposal facility development.

The PRISMA project developed safety case arguments for two near surface disposal facilities focusing on the basis for decisions made in the development of a safety case.

2.3. COORDINATION, CONSENSUS AND PARTICIPATION IN DECISION MAKING

It is of paramount importance to foster and develop coordination and consensus among operators/licencees, waste producers, regulators, government authorities and other interested parties, including the local community and the general public, so as to support the key decisions made during the lifetime of the disposal facility.

The safety case needs to be developed in parallel with (or as part of) a process that enables and encourages participation of interested parties in relevant decisions. The safety case is a source of information that the different groups need to fulfil their role in the decision making processes.

2.4. PLANNING AND IMPLEMENTING THE DISPOSAL PROGRAMME

The safety case is to be used as a framework for planning and establishing the schedule of actions and activities to be conducted during the lifetime of the waste disposal facility as well as identifying and documenting interdependencies where decisions taken at one step can influence options available at other steps (e.g. site and waste characterization, research, design and engineering work, stakeholder involvement, demonstration of compliance, facility operation, monitoring, closure and any post-closure activities). The safety case is a dynamic, living framework that includes proper documentation of all safety related information and assessments, and it is used and updated more or less continuously to ensure continued adequate levels of safety remain in place throughout the lifetime of the disposal facility.

2.5. INTEGRATING AND ASSESSING UNCERTAINTIES

Uncertainties arise from various different sources and may play a significant role in decision making processes. External uncertainties may be associated with changing regulatory criteria and guidelines, stakeholder inputs, financial shortages and needs, political decisions, the availability of technical resources and skilled staff, or security concerns. Technical uncertainties may arise from a lack of data or information, or the existence of alternative models. Uncertainties may be associated with particular circumstances and phases of disposal facility development and use. Special attention has to be given to the management of uncertainties that evolve with time and the associated programmatic risk posed by those as yet unresolved uncertainties.

Uncertainty and approaches to its treatment may influence public confidence and trust in operators, regulators and technical analysts during decision making and licensing of waste disposal facilities. Once the different types of uncertainty (societal, managerial, environmental and technical) are identified, the safety case can be used:

(a) To help identify appropriate strategies with which to address (manage) each key uncertainty.

(b) To track and record the significance of each uncertainty and how it has evolved and been addressed. If significant uncertainties are identified it may be necessary to modify certain aspects of the safety case, such as the safety strategy or safety concept.

Uncertainties may be identified and develop in parallel with the development of the safety case and they need to be managed at all stages of safety case development.

2.6. ASSESSING COMPLIANCE WITH SAFETY CRITERIA

In general, and based on international guidance, the relevant regulatory authorities for a disposal facility develop and specify specific safety criteria with which the disposal facility has to comply. Such safety criteria may be specified in terms of specific quantitative levels of potential dose and/or risk to workers and the public including potential intruders. Such criteria may be expressed as limits, targets, or guidance levels.

Safety indicators may also be specified in terms of factors other than dose and risk such as radionuclide concentration in a certain environmental medium or radionuclide flux. Such indicators may provide additional information on the performance of the disposal system or parts of it (e.g. certain barriers). Further details relating to the definition and use of such complementary or alternative indicators are provided in Section 6.

Other conditions may also be specified, such as the requirement for optimization. Specific criteria related to protection of the environment and non-human species from both the radiological and non-radiological hazards present in the disposal facility may also be imposed.

The safety criteria can have significant implications for the design of the disposal system (including the facility design and site selection). The safety assessment is the proper vehicle in which to integrate all of the information on, for example, site characteristics, disposal facility design, waste inventory and characteristics, barrier performance and system evolution, so that the performance of the disposal system can be assessed against the applicable safety criteria. The safety case including the safety assessments and compliance demonstrations needs to be updated periodically to take account of new information, so as to support decisions for moving to the next step in the facility's lifetime.

2.7. ASSESSING NEEDS FOR IMPROVEMENT AND CORRECTIVE ACTIONS

In many cases, particularly during operation of disposal facilities, the need may arise for corrective actions (such as an intervention) based on the results of inspection and monitoring. The safety case is the proper vehicle with which to assess and evaluate deviations from compliance and/or expected disposal facility performance. The safety case provides a structure in which to address safety concerns based on actual performance, research and development (R&D) results, characterization and operational and monitoring data.

Enhancement of performance of barriers or vaults is one example of corrective measures that may be considered based on inspections by operators and/or regulatory bodies. In some circumstances reversibility in decisions can be an option to be considered and the concept of retrievability may need to be addressed.

2.8.INFORMATION MANAGEMENT AND RECORD KEEPING

Since the safety case includes the necessary demonstration of compliance with safety criteria and assessments of disposal facility performance at all phases of the disposal facility lifetime, the safety case is the key vehicle for the documentation and maintenance of safety-relevant information and records, including results from site and waste characterization, monitoring, and inspection.

Record keeping is essential for traceability and clear documentation of the motivation (reasons) for decisions and actions taken at each step in the facility development. Routine record keeping using the safety case is complemented by archival of appropriate information on the waste disposal system.

3. SAFETY CASE AND DISPOSAL FACILITY EVOLUTION

IAEA recognizes three main periods in the lifetime of a radioactive waste disposal facility, as shown in Figure 2 [2]:

- Pre-operational period — activities that may be undertaken during the pre-operational period include the decision for action, development of the disposal concept and the safety strategy, site investigation, environmental impact assessment, site selection, initial facility design studies, the development of plans for R&D and monitoring, and the development of the detailed facility design. Construction and licensing of the facility also take place during this period.

- Operational period — the operational period begins when waste is first received at the facility and continues up to the closure of all parts of the facility. During the operational period, construction activities and modifications to operations and remediation of existing disposals may take place at the same time as waste emplacement and closure of other parts of the facility.

- Post-closure period — the post-closure period begins after the facility is closed. After closure, no further waste disposals occur and all engineered barriers are in place. Active (e.g. monitoring) and/or passive (e.g. restrictions on land use) institutional controls may contribute to the safety of certain disposal facilities before and after closure of the facility.

Based on this general framework, the PRISM project viewed the safety case development and disposal facility implementation in a context of a series of decisions that would be taken by several different parties, including the government, operators, regulators, stakeholders, and others. Illustrated in Figure 2 and listed in Table 1 is a typical sequence of key decisions that would be made, and who would make them, during the safety case and disposal facility development and evolution[1]. While stakeholders generally are not decision makers, their input and careful consideration of their concerns is critical to the development of any disposal facility. Note that the development and maintenance of the safety case is the responsibility of the licence holder.

A decision to move from one phase of facility development to another is a strategic step in which it is necessary to consider a range of factors, including safety, legal requirements, costs and available resources, schedules, and stakeholder views. The requirement to provide continuing safety and optimization may necessitate implementation of additional safety measures and corrective actions [2]. All of these requirements and factors may have significant impacts on the schedules and the ultimate decisions made.

Although the safety case may continue to be developed as the project progresses, any version of the safety case presented in support of a decision has to be defensible for that decision.

[1]The approach to developing a safety case depends on national practices and reflects the type of disposal facility and the hazard potential of the waste, as well as the potential types of exposure (existing, planned, or emergency exposure situations) and the magnitude of associated risks. The PRISM and PRISMA projects endorsed the idea of using a risk-informed, graded approach to the development of a safety case.

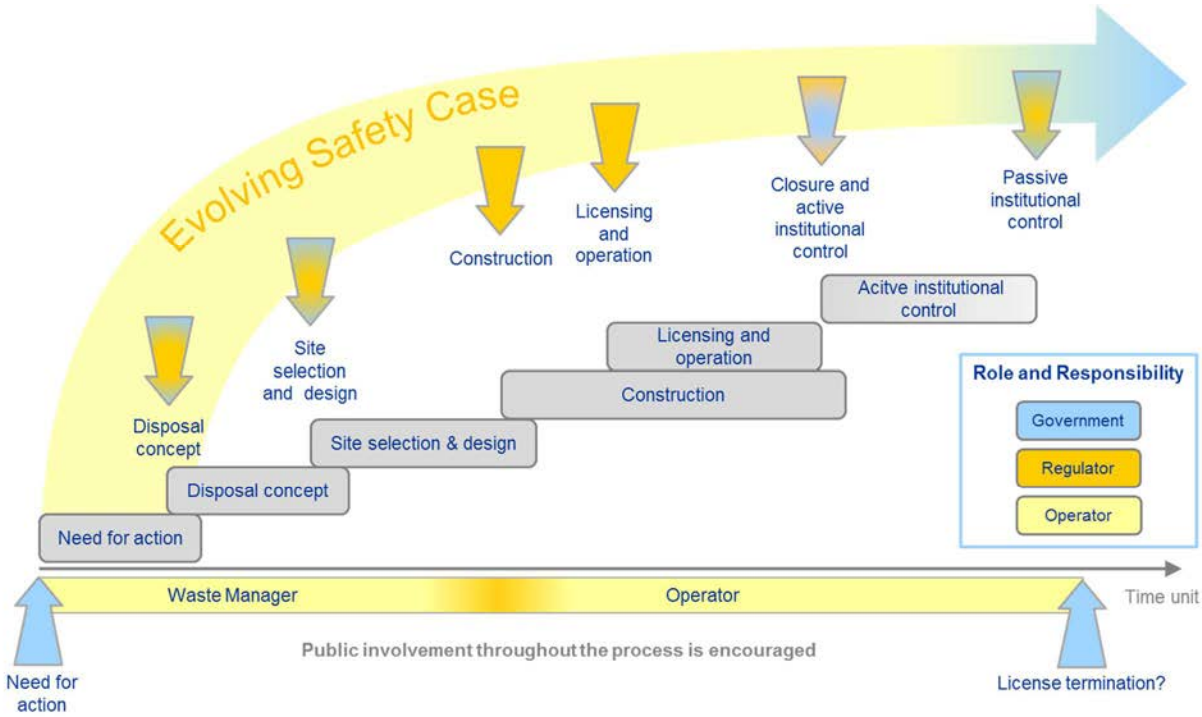

FIG. 2. The typical sequence of key decisions in the development of a disposal facility for radioactive waste.

TABLE 1. KEY DECISION STEPS IN THE DEVELOPMENT OF A REPOSITORY

Decision step	Examples of decisions
1. Need for action	— Decision: go for disposal — Decision to reassess an existing facility
2. Disposal concept	— Decision on the broad disposal concept and Safety Strategy for a given environment and set of conditions (e.g. relating to the waste). For example, engineered vaults, simple mounds or trenches, boreholes
3. Site selection & design	— Decision: choose a site and a corresponding design
4. Construction	— Decision to proceed with construction (operator) — Decision: authorization and/or licence for construction (authorities)
5. Licensing & operation	— Decision to start operations (operator) — Decision: authorization and licence for operation (authorities)
6. Closure & continued institutional control	— Decision to close a facility — Decision to initiate a period of active institutional control
7. Passive institutional control	— Decision to cease active institutional control
8. License termination	— Decision to release a facility from regulatory control

4. DETAILED DESCRIPTION OF THE KEY DECISION STEPS IN THE DEVELOPMENT OF A DISPOSAL FACILITY FOR RADIOACTIVE WASTE

This section includes more detailed discussion of each of the key decision steps.

4.1. NEED FOR ACTION

According to IAEA policy, disposal of radioactive waste is considered the end point of the waste management process. At some stage in the development of a national waste management plan, a disposal option is proposed and implemented for each category of waste requiring disposal [4].

This decision step is to either launch a suitable disposal programme or continue storing radioactive waste. Similar decisions may be required in relation to any potential remediation or upgrades to an existing facility.

4.2. SELECTING A DISPOSAL CONCEPT

The choice of disposal concept has to be made taking account of the volume and hazard posed by the radioactive waste to be disposed (e.g. whether very low level waste (VLLW), low level waste (LLW) or intermediate level waste (ILW) - [4]). Therefore, in order to decide which disposal concept is the most appropriate for a given waste inventory, knowledge is needed on the volume and characteristics of the waste streams and on the different possible disposal options. This decision has to be undertaken in accordance with national strategy, priorities and regulatory framework.

Examples of disposal concepts include: surface disposal in vaults, mounds or trenches, disposal in underground mined-cavities (up to a few tens of metres deep) and disposal in boreholes [2]. Specialized options may be needed to manage particular types of waste such as disused sealed radioactive sources or mining and mineral processing waste. Disposal by shallow burial in conventional landfills (loose tipping of waste in a lined and capped facility at the surface, as often used for non-radioactive waste) could be envisaged for relatively low or very low activity waste classes, depending on the national waste management plan and regulatory framework.

4.3. SELECTING A SITE AND DESIGN

After having selected a disposal concept or in parallel with selection of the disposal concept, a site needs to be selected. Site selection is likely to require site characterization and a programme of communication with regulators and other interested parties. The decision to select a site for a disposal facility is generally made in the context of national strategy and ought to be informed by a wide-ranging, multi-disciplined process that addresses natural site features, waste characteristics, potential disposal facility designs, ensuring compatibility between these system components, and, in particular, regulatory requirements and input from interested parties.

Site selection requires an in depth analysis of the characteristics of the site and an assessment of the safety functions that the site needs to have in order to comply with the performance goals as identified in the safety concept and safety strategy. Investigations during site selection may include: surface features and processes, meteorology, geology, hydrogeology, the tectonic and seismic setting, geochemical properties, environmental change, as well as socio-economic factors such as demography, population distribution and habits, land ownership and use, etc.

Disposal facility design requires the selection and optimization of a system of engineered barriers as necessary, including the waste containers, the waste conditioning materials and matrix, the use of vaults or trenches made from materials with certain properties, drainage systems, cover layers, etc. The continued use of Best Available Technologies (BAT), feedback from other disposal facilities, and optimization may be specified as requirements on design and plans for waste disposal at this stage of the lifetime. Relevant waste characteristics include their radiological, chemical and physical properties and their physical stability and toxicity.

The decision to select a particular site and proceed with facility construction and waste disposal needs to take account of various social, economic and political aspects and ensure that all reasonable measures have been taken into account to protect people and environment from the risks arising from the radioactive waste. Experience confirms that public acceptance is the key factor affecting this decision step.

4.4. DECIDING TO PROCEED WITH CONSTRUCTION

Assuming that a site and concept have been selected, the operator commissions the development of suitably detailed designs and construction plans, and submits the safety case and other necessary documentation to the regulatory bodies for permission to begin construction. Construction would have to comply with all relevant codes of practice and building/engineering standards, and rigorous quality assurance systems and quality controls must be put in place to ensure that the work is undertaken properly and appropriate records are kept.

It may be necessary to demonstrate prior to gaining permission for construction that the proposed construction materials and methods are available and feasible, and that they would not have unduly adverse effects on the performance of the facility. The decision to initiate the construction process is likely to involve several interested parties, including the operator, the regulator(s), and possibly other stakeholders. It is also imperative to involve local interested parties in this decision process.

A key component of the safety case at this step is the safety assessment, based on site characterization information and knowledge of the proposed waste containers and safety characteristics of the engineered system.

Any modifications to the original plans that are suggested during construction ought to go through a formal process of change control and approval that includes updating of the safety case and safety assessment as necessary. The waste acceptance criteria, derived from the safety case are also provided to the regulatory body at this time.

4.5. LICENSING AND START OF OPERATIONS

At this step the operator has to provide the regulator with evidence showing that the disposal facility has been constructed according to the approved design and that there is sufficient confidence that it will perform consistent with the expected evolution described in the safety case.

The regulatory bodies will review the safety case and, provide relevant information to interested parties and the government. The decision to begin disposal may be taken at governmental level.

The decision to grant a licence and begin operation may come with various conditions, including limits on the waste that may be disposed of, a process to address any deviations from those limits, and many requirements for appropriate management systems and controls, quality assurance, recording of information, monitoring, updating of the safety case and safety assessments, provision of information etc. The approved version of the waste acceptance criteria are also documented at this time.

If all required commissioning tests are satisfactory and if the construction has been done in conformity with the requirements and the information provided during the construction step, the licence to operate the facility may be granted.

During the operational period the operator continues to update and use the safety case as a framework for guiding regulatory and stakeholder involvement and the planning, direction and management of all facility operations. The safety case is also updated as a result of new information about the natural barriers obtained during operation and monitoring.

4.6. DECIDING TO CLOSE THE FACILITY

At some point the operator, regulator or government proposes or directs that a disposal facility is closed. A decision to close the facility may be associated with:

- Cessation of all waste shipments;
- Decommissioning of auxiliary facilities;
- Sealing of the facility and construction of the final cover as appropriate to the design;
- Initiation of a transition from operations to a period of continuing active institutional control.

At the time of closure, the safety case, including an assessment of environmental monitoring data, is used to determine the ability to close the facility and it may also be used to inform a decision on the planned length of time for which active institutional control is maintained [5].

It is essential that a disposal facility is closed in accordance with the assumptions made in the safety case, and is not abandoned in an ‘unclosed’ state.

4.7. PASSIVE INSTITUTIONAL CONTROL

Active institutional controls are assumed to end at some time in the future consistent with regulations in a given country and the hazards posed by the waste. The decision to cease active institutional control could be made once significant radioactive decay has occurred and the associated risks have decreased sufficiently and implies that the passive institutional control period is initiated. The safety case is the primary framework for assessing and quantifying the remaining hazards and risks associated with the waste and is used to help guide any decision to withdraw active controls. After the end of active institutional control, safety relies only on passive measures, such as land use restrictions, that have been approved by regulatory bodies and/or the government.

4.8. LICENCE TERMINATION

Depending on the national legislation, the licence may be terminated at the end of the period of active institutional control or at a later time. In some cases, the licence may be transferred to the national government. As long as a licence is in force, this implies that an organization is responsible for managing and monitoring the disposal facility.

The decision to terminate or transfer the licence is taken by the regulatory body.

5. COMPONENTS OF THE SAFETY CASE

As listed in Section 2.2, IAEA has identified the main components of the safety case [1]. Figure 1 illustrates how the components of the safety case are structured and how they interact to produce a defensible safety case for presentation to decision makers.

5.1 SAFETY CASE COMPONENTS AND SAFETY CASE SUBCOMPONENTS

PRISM used the components of a safety case identified in Ref. [1] as the rows in the MASC matrix. PRISM then further divided the components of a safety case into subcomponents. For example, the main component, “safety context,” was divided into the following subcomponents:

- National strategy;
- National legal framework;
- Regulations;
- International commitments;
- International guidance;
- Licensing process;
- Financial considerations.

The following subsections describe each main component in detail.

5.2 SAFETY CASE CONTEXT

PRISM identified the following subcomponents of the safety case context.

TABLE 2. SAFETY CASE CONTEXT SUBCOMPONENTS

Safety case context	— National strategy
	— National legal framework
	— Regulations
	— International commitments
	— International guidance
	— Licensing process
	— Financial considerations

The national strategy and framework need to be in place in order to make appropriate decisions. The safety case context takes into consideration national regulations and international requirements, in particular the radiation protection criteria. It is important that the safety case context also takes account of financial aspects, specifically, financial guarantees and financial planning, including funding and budget constraints and national priorities.

5.3 SAFETY STRATEGY

The safety strategy is the approach to achieving safety and is established early in the safety case development process. The safety strategy sets out the means whereby the safety objectives are achieved and sets out the main safety principles such as defence in depth or passive containment that form the basis of the disposal concept. The safety strategy applies throughout the facility lifetime. This approach ensures compliance with the safety criteria and other regulatory requirements and the use of good practices. The safety strategy is not expected to change over time. Thus in case of changes, a process for documenting and justifying the changes to the safety strategy has to be provided and approved by the regulatory body. Consequences of changes in the safety strategy on the previous decisions steps need to be assessed and documented.

The safety strategy explains the role and the importance of containment and isolation as important safety functions as described in [2]. The safety strategy also ensures that the disposal concept in conjunction with the natural system, and in particular the different components, can be demonstrated to provide for protection of human health and the environment. The safety strategy has to be established taking into account the concept of the graded approach described in Ref. [3], meaning that the safety strategy is commensurate with the magnitude of the potential impacts of the disposal facility on human health and the environment. The safety strategy also addresses the approach taken to integrate and manage uncertainties.

Finally, the safety strategy has to ensure compatibility with the strategy for predisposal management and the predisposal management safety case, and other interdependent activities throughout the facility's lifetime.

The following components of the safety strategy, Table 3, are considered to be important, although this list is not exhaustive.

TABLE 3. SAFETY STRATEGY SUBCOMPONENTS

Safety strategy	— Management of uncertainties
	— Robustness
	— Demonstrability
	— Multiple safety functions
	— Passive safety
	— Graded approach

5.4 DESCRIPTION OF THE DISPOSAL SYSTEM

The system description records all information and data about the natural and engineering components of the disposal system, and the waste to be disposed. This information provides the basis for the safety assessment. The system description evolves and matures as the project progresses. Through an iterative process, the relevant uncertainties are identified and documented in the description of the disposal system.

In brief, the 'system description' component includes consideration of the aspects identified in Table 4.

TABLE 4. SYSTEM DESCRIPTION SUBCOMPONENTS

System description	— Waste characteristics — Design — Site characteristics — Safety functions

5.5 SAFETY ASSESSMENT

Safety assessment is an essential part of the safety case as it quantifies the potential radiological impact of the repository on human health and the environment. In doing so, the safety assessments evaluate the interactions between the different components of the facility and assess the consequences of those interactions on safety. Safety assessment explicitly addresses possible future states of the repository system, i.e. scenarios. The results of the safety assessment can be presented in terms of various performance indicators e.g. risk, contaminant fluxes, concentrations, and/or radiation doses.

Types of safety assessments associated with an evolving safety case include:

- Post-closure radiological impact assessment: in accordance with the safety concept developed in the system description and based on the available knowledge, a comprehensive quantitative analysis of the long-term evolution of the disposal system is performed using a systematic approach in which different scenarios are investigated.

- Barrier performance: quantitative performance assessment of the characteristics of the site and of the engineered barriers and their reliability with time. This performance assessment addresses the robustness of the disposal concept as well as the role of passive safety and emphasizes the importance for safety of multiple safety functions.

- Operational safety.

- Non-radiological environmental impact: radioactive waste may contain potentially hazardous non-radioactive components. Non-radiological impacts arising from the disposal facility are addressed as required by the relevant environmental protection legislation.

In brief, the ‘safety assessment’ component includes consideration of the subcomponents identified in Table 5.

TABLE 5. SAFETY ASSESSMENT SUBCOMPONENTS

Safety assessment	— Non-radiological environmental impact — Management systems — Operational safety — Post-closure radiological impact assessment — Site and engineering

5.6 OPTIMIZATION

The facility design is developed through a sound and systematic process in which alternatives are considered and reasons why they were rejected documented.

Optimization of a disposal facility is a continuous process that involves decisions on design, operations and environmental monitoring, although most decisions are usually made before the start of operations. However, as a result of new information or changing disposal needs, changes to the disposal facility can occur over time.

In brief, the 'optimization' component includes consideration of the subcomponents identified in Table 6.

TABLE 6. OPTIMIZATION SUBCOMPONENTS

Iteration and design optimization	— Optimization — Importance of engineering/science — Comparison of options — Flexibility to address new information and disposal needs

5.7 MANAGEMENT OF UNCERTAINTIES

Management of uncertainties is a key component of the safety case that permeates every other safety case component. As required by the IAEA , uncertainties are characterized with respect to their source, nature and importance and are, wherever practicable, quantified [3]. The safety case addresses uncertainties and their implications in a graded approach with emphasis on those that are most important to safety.

5.8 LIMITS, CONTROLS, AND CONDITIONS

Safe operation of a disposal facility requires the establishment of limits, controls, and conditions that have to be complied with. For example, limits are placed on the waste categories and the inventory of waste to be disposed. Typically these limits and conditions are derived from a combination of specific regulatory requirements and the site-specific safety case and safety assessments. These limits and conditions are not restricted to radiological aspects. They could also be related to chemical and physical characteristics of the waste, as well as to specifications on the design of the engineered barriers. The operational limits and conditions are proposed by the operator in the safety case and approved by the regulator.

Monitoring programmes may be developed and implemented to provide evidence that the disposal facility is performing as expected and that system components are fulfilling their safety functions [5]. Monitoring activities include establishing background levels and measuring potential releases to environmental media (e.g. soil, surface water, ground water and atmosphere). Such monitoring needs to be undertaken systematically throughout the lifetime of the disposal facility. On the basis of monitoring data, system performance is reviewed and if necessary corrective actions are considered.

A key condition for any repository operator or regulator is to ensure that the waste disposed to any repository is consistent with the safety case for the facility. This is achieved by setting waste acceptance criteria that include requirements derived from the safety case. The criteria may cover a range of different characteristics of the waste e.g.:

- Limits on the categories of waste acceptable for disposal;
- Constraints on the total quantity or concentration of certain radionuclides or on;
- Limits on certain chemical materials that might enhance contaminant transport;
- Limits on voidage;
- Requirements for the use of certain sorts of container;
- Specifications for waste conditioning;
- Controls on physical properties of the waste.

As well as setting various waste acceptance criteria on the basis of the safety case, it is necessary to put in place practical systems and processes to manage waste acceptance. For example, these include, managing waste receipts to ensure that the total radiological capacity of a repository is not exceeded, ensuring that consignments are approved and properly documented and putting in place arrangements for non-conforming waste packages.

In general, the limits, controls and conditions subcomponents of a safety case include:

TABLE 7. LIMITS, CONTROLS AND CONDITIONS SUBCOMPONENTS

Limits, controls and conditions	— Conditions from the designer and/or regulator, including waste acceptance criteria — Limits (dose, risk, activity limits, etc.) — Control (conformity, monitoring, surveillance)

5.9 INTEGRATION OF SAFETY ARGUMENTS

The safety case itself is an ‘Integration of safety arguments’. However, the integration of safety arguments is included as a major component of the safety case to assure that the following subcomponents are addressed:

TABLE 8. INTEGRATION OF SAFETY ARGUMENTS SUBCOMPONENTS

Integration of safety arguments	— Comparison with criteria — Additional measures to increase confidence — Complementary indicators — Independent review (quality and reliability) — Plan for addressing unresolved issues

5.10 MANAGEMENT SYSTEM

Development of the safety case and safety assessments has to be conducted within a management system that can assure an adequate level of quality. The management system relies on a safety policy endorsed by the management, staff that ensure that primary importance is given to safety and that implements a continuous willingness to continuously improve safety. Reviews and audits of the management system provide assurance that the required level of quality has been achieved.

The management system includes a description of the operator's organization, the different responsibilities of the hierarchy system, training, quality assurance, and the establishment of procedures. The internal organization of the regulator is also described paying attention to different functions and specific responsibilities.

The management system includes a planned and systematic set of procedures for carrying out and documenting the various steps in the safety case development process providing confidence that the input data, models and results are of sufficient quality. The management system also monitors and controls staff competence to ensure that a continuous and integrated safety programme is in place and a sound safety culture developed.

Based on the above discussion, the management system subcomponents are listed in Table 9.

TABLE 9. MANAGEMENT SYSTEM SUBCOMPONENTS

Management system	— Organizational aspects
	— Staff competence
	— QA/QC
	— Record keeping and traceability

5.11 INVOLVEMENT OF STAKEHOLDERS AND REGULATORS

The involvement of stakeholders and regulators is considered an essential component of the safety case development given their importance in the decision making process. PRISM believes that a structured process of interaction and communication needs to be established in order to ensure that all communication is open, traceable, and transparent.

Early involvement of stakeholders and regulators is part of building confidence in the safety of the disposal facility. Providing for independent reviews by stakeholders and regulators of all aspects of the safety case is an important consideration for building confidence.

PRISM participants have identified the following subcomponents (Table 10) for the 'Involvement of stakeholders and regulators' component of the safety case:

TABLE 10. INVOLVEMENT OF STAKEHOLDERS AND REGULATORS SUBCOMPONENTS

Involvement of stakeholders and regulators	— Involvement of public and other interested parties — Regulatory oversight — Early and continuous involvement — Independent reviews

6. THE MASC MATRIX

The major components of the safety case, as defined by the IAEA in Ref. [1], the subcomponents of a safety case listed in Section 5, and the typical decision steps in the development of a repository provided in Section 4 were combined into the MASC matrix (Table 11). The MASC matrix was developed to serve the following purposes:

- To serve as a checklist to make sure that all relevant safety case components have been addressed throughout the lifetime of a facility.
- To assess the relative importance of safety case arguments at all the stages throughout the lifetime of the disposal facility.
- To serve as a useful tool for programmatic risk assessment and to evaluate possible implications of incomplete or inadequately addressed components of the safety case on subsequent repository development. Section 6.2 provides additional information and examples of so-called ‘Programmatic Risk Assessment’.

The role of the MASC matrix is not intended to provide specific information on each component of the safety case but is intended to provide a framework for assurance that each of the components of the safety case has been addressed at the right decision step and with the appropriate level of importance. In this regard, the MASC matrix is a valuable tool for the operator and the regulator for developing, or reviewing a safety case and for assuring completeness and traceability of safety case decisions.

In addition, PRISM took on the task of assigning relative importance to the components of a safety case at different stages of repository development.

The relative importance of each cell of the MASC matrix, for an ideal safety case, has been scored by attributing a number varying from ‘0’ to ‘3’ to each cell of the MASC matrix where:

- Number ‘3’ means that this argument for the considered decision step is essential.
- Number ‘2’ means that this argument for the considered decision step is significant.
- Number ‘1’ means that this argument for the considered decision step is of value but less significant.
- Number ‘0’ means that ‘this argument is not applicable to this decision step.’

An overall consensus was reached on the relative importance of each safety case component at each decision step. Table 12 provides summary results.

TABLE 11. THE MASC MATRIX

Main decision making steps	Need for action	Disposal concept	Site selection and engineering design	Construction		Operation		Closure	Passive institutional control period	Post-licensing
	Decision: go for disposal and/or **Decision** for reassessment of an existing facility	**Decision** on the disposal concept and the Safety Strategy in a given environment (conditions)	**Decision:** choose the site and associated design	**Decision** for construction (operator)	**Decision:** authorization and/or licence for construction (authorities)	**Decision** to operate (operator)	**Decision:** authorization and licence for operation (authorities)	**Decision** to close	**Decision** to initiate the passive institutional control period	**Decision whether** or not to release the regulatory control
Safety case context										
National strategy										
National legal framework regulations										
International commitments										
International guidance										
Financial considerations										
Management										
Management system										
— Organisation										
— Staff competence										
— Q/A										
— Record keeping / traceability										

TABLE 11. THE MASC MATRIX (cont.)

Main decision making steps	Need for action	Disposal concept	Site selection and engineering design	Construction		Operation		Closure	Passive institutional control period	Post-licensing
	Decision: go for disposal and/or **Decision** for reassessment of an existing facility	**Decision** on the disposal concept and the Safety Strategy in a given environment (conditions)	**Decision:** choose the site and associated design	**Decision** for construction (operator)	**Decision:** authorization and/or licence for construction (authorities)	**Decision** to operate (operator)	**Decision:** authorization and licence for operation (authorities)	**Decision** to close	**Decision** to initiate the passive institutional control period	**Decision whether** or not to release the regulatory control
Stakeholder & regulatory process										
Involvement of stakeholders Regulatory process — Management system — Licensing process — Early and continuous involvement										
Optimization										
Optimization										
Uncertainties										
management of uncertainties										

TABLE 11. THE MASC MATRIX (cont.)

Main decision making steps	Need for action	Disposal concept	Site selection and engineering design	Construction		Operation		Closure	Passive institutional control period	Post-licensing
	Decision: go for disposal and/or **Decision** for reassessment of an existing facility	**Decision** on the disposal concept and the Safety Strategy in a given environment (conditions)	**Decision:** choose the site and associated design	**Decision** for construction (operator)	**Decision:** authorization and/or licence for construction (authorities)	**Decision** to operate (operator)	**Decision:** authorization and licence for operation (authorities)	**Decision** to close	**Decision** to initiate the passive institutional control period	**Decision whether** or not to release the regulatory control
Safety strategy										
Robustness										
Demonstrability										
Multiple safety Functions										
Passive safety										
Importance of engineering/science										
Comparison of options										
Graded approach										
System description										
Waste characteristics										
Design										
Site characteristics										
Safety functions										

TABLE 11. THE MASC MATRIX (cont.)

Main decision making steps	Need for action	Disposal concept	Site selection and engineering design	Construction		Operation		Closure	Passive institutional control period	Post-licensing
	Decision: go for disposal and/or **Decision** for reassessment of an existing facility	**Decision** on the disposal concept and the Safety Strategy in a given environment (conditions)	**Decision:** choose the site and associated design	**Decision** for construction (operator)	**Decision:** authorization and/or licence for construction (authorities)	**Decision** to operate (operator)	**Decision:** authorization and licence for operation (authorities)	**Decision** to close	**Decision** to initiate the passive institutional control period	**Decision whether** or not to release the regulatory control
Safety assessment										
Environmental impacts assessment										
Radiological impact and performance assessment										
Operational safety										

TABLE 11. THE MASC MATRIX (cont.)

Main decision making steps	Need for action	Disposal concept	Site selection and engineering design	Construction		Operation		Closure	Passive institutional control period	Post-licensing
	Decision: go for disposal and/or **Decision** for reassessment of an existing facility	**Decision** on the disposal concept and the Safety Strategy in a given environment (conditions)	**Decision:** choose the site and associated design	**Decision** for construction (operator)	**Decision:** authorization and/or licence for construction (authorities)	**Decision** to operate (operator)	**Decision:** authorization and licence for operation (authorities)	**Decision** to close	**Decision** to initiate the passive institutional control period	**Decision whether** or not to release the regulatory control
Integration of safety arguments										
Clear communication and integration of safety arguments										
Additional measures to increase confidence										
— Independent review										
— Complementary safety indicators										
— Multiples lines of reasoning										
R&D										
Plans for addressing unresolved Issues										

TABLE 11. THE MASC MATRIX (cont.)

Main decision making steps	Need for action	Disposal concept	Site selection and engineering design	Construction		Operation		Closure	Passive institutional control period	Post-licensing
	Decision: go for disposal and/or **Decision** for reassessment of an existing facility	**Decision** on the disposal concept and the Safety Strategy in a given environment (conditions)	**Decision:** choose the site and associated design	**Decision** for construction (operator)	**Decision:** authorization and/or licence for construction (authorities)	**Decision** to operate (operator)	**Decision:** authorization and licence for operation (authorities)	**Decision** to close	**Decision** to initiate the passive institutional control period	**Decision whether** or not to release the regulatory control
Limits, control & conditions										
Conditions (designer, regulator,..) Limits (Dose, risk, activity limits…) Control (conformity,..)										
Surveillance										
Monitoring Security										

TABLE 12. THE MASC MATRIX WITH RELATIVE SIGNIFICANCE OF DIFFERENT FACTORS AS DEVELOPED BY THE PRISM PARTICIPANTS

Main decision making steps / Safety case components	Need for action	Disposal concept	Site selection and engineering design	Construction		Operation		Closure	Passive institutional control period	Post-licensing
	Decision: go for disposal or/and **Decision** for reassessment of an existing facility	**Decide** on the disposal concept and the Safety Strategy in a given environment (conditions)	**Decision:** choose the site and associated design	**Decision** for construction (operator)	**Decision**: authorization and/or licence for construction (authorities)	**Decision** to operate (operator)	**Decision:** authorization and licence for operation (authorities)	**Decision** to close and initiate the active institutional control period	**Decide** to initiate the passive institutional control period	**Decide** or not to release the regulatory control
Safety case context	2	3	3	3	3	2	3	3	2	2
Management	1	2	3	3	3	3	3		3	3
Stakeholder & regulatory process	1	2	3	3	3	3	3	3	3	3
Optimization	0	2	3	2	3	2	3	3	0	0
Uncertainties	2	3	3	2	3	2	3		2	2
Safety strategy	1	3	3	2	3	2	3	3	1	1
System description	1	3	3	3	3	1	3	3	1	2
Safety assessment	2	2	3	3	3	3	3	3	1	1
Integration of safety arguments	2	2	2	2	2	2	2	2	1	1
Limits, control & conditions	1	1	3	3	3	1	3	3	3	0

0	Not applicable to this decision step
1	Of value but less significant
2	Significant
3	Essential

6.1.MASC MATRIX — RELATIVE IMPORTANCE OF COMPONENTS

The PRISM project recognized that different safety case arguments have differing levels of importance at different times in the lifetime of the disposal facility (e.g. at each of the key decision steps).

For example, the safety case component ‘integration of safety arguments’ and its subcomponents may be less relevant in the context of decisions related to the ‘need for action’, since there would be no site at that stage and no facility. However, in the following decision steps this safety case component will gain importance because a safety case will need to be developed before starting construction and operations. At the end of the disposal facility lifetime, i.e. the ‘passive institutional control period’, and the ‘post-licensing period’ the importance of the ‘Integration of Safety Arguments’ component in taking the decisions to proceed are judged less relevant since this assessment would already have been performed.

This recognition led to the development of a tool with which to track the development and relative importance of the safety case components at different stages of the disposal facility’s lifetime. The tool takes the form of a matrix and is referred to as the MASC matrix.

From Table 12 it can be seen, for example, that the presence of a national legal framework is considered essential for taking all successive decisions throughout the lifetime of a disposal facility. On the other hand, the subcomponent International Guidance is considered significant for most of the decisions, except at the very start of the process and for the decision to go into the post-licensing phase.

By averaging the cell numbers in the rows representing the safety case subcomponents for each decision step in the MASC matrix, the relative importance of a specific safety case component in each decision step is revealed. The variation of the relative importance of the safety case components in relation to the successive decision steps for an illustrative safety case is shown graphically in Figure 3.

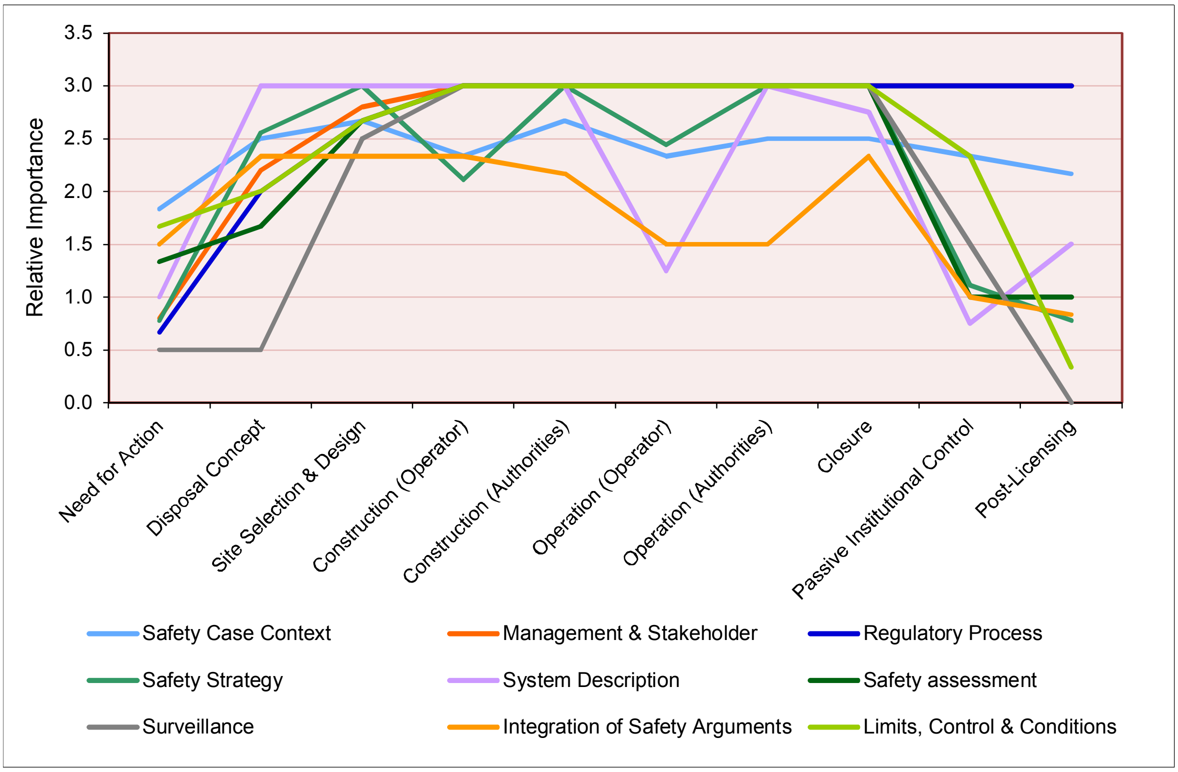

FIG. 3. Relative importance of the safety case components throughout the lifetime of the disposal facility as determined from the MASC matrix for an illustrative safety case.

In general, from the decision to establish a disposal concept up to the closure of the facility, the safety case components are mainly considered essential or significant. The message is that these decisions need to be taken with great care and with due consideration of all underlying aspects.

Actual safety cases were also discussed during the PRISM project through a number of examples provided by Member State participants. These actual safety cases differed from the illustrative case shown in Figure 3 for a number of site-specific reasons.

A similar assessment of the importance of safety case subcomponents was undertaken by PRISM (Table 13). Figure 4 shows a graph of the importance of the safety case context component and its subcomponents at different stages of repository development.

TABLE 13. RELATIVE IMPORTANCE OF THE SUBCOMPONENTS OF A SAFETY CASE THROUGHOUT THE LIFETIME OF THE DISPOSAL FACILITY

Main decision making steps	Need for action	Disposal concept	Site selection & engineering design	Construction		Operation		Closure	Passive institutional control period	Post-licensing
	Decision: Go for disposal or/and **Decision** for reassessment of an existing facility	**Decide** on the disposal concept and the safety strategy in a given environment	**Decision**: choose the site and associated design	**Decision** for construction (operator)	**Decision:** Authorization and/or licence for construction (authorities)	**Decision** to operate (operator)	**Decision:** authorization and licence for operation (authorities)	**Decision** to close	**Decide** to initiate the passive institutional control period	**Decide** or not to release the regulatory control
Safety case context										
National strategy	3	3	3	1	2	1	2	3	3	3
National legal framework	3	3	3	3	3	3	3	3	3	3
Regulations	1	2	3	3	3	3	3	3	3	3
International commitments	2	3	3	2	3	2	2	1	1	1
International guidance	1	2	2	2	2	2	2	2	2	1
Financial considerations	1	2	2	3	3	3	3	3	2	2
Management										
Management system	-	-	-	-	-	-	-	-	-	-
— Organization	0	2	2	3	3	3	3	3	3	3
— Staff competence	0	2	3	3	3	3	3	3	3	3
— Q/A	0	2	3	3	3	3	3	3	3	3
— Record keeping / traceability	3	3	3	3	3	3	3	3	3	3

TABLE 13. RELATIVE IMPORTANCE OF THE SUBCOMPONENTS OF A SAFETY CASE THROUGHOUT THE LIFETIME OF THE DISPOSAL FACILITY (cont.)

Main decision making steps	Need for action	Disposal concept	Site selection & engineering design	Construction		Operation		Closure	Passive institutional control period	Post-licensing
	Decision: Go for disposal or/and **Decision** for reassessment of an existing facility	**Decide** on the disposal concept and the safety strategy in a given environment	**Decision**: choose the site and associated design	**Decision** for construction (operator)	**Decision:** Authorization and/or licence for construction (authorities)	**Decision** to operate (operator)	**Decision:** authorization and licence for operation (authorities)	**Decision** to close	**Decide** to initiate the passive institutional control period	**Decide** or not to release the regulatory control
Stakeholder & regulatory process										
Involvement of stakeholders	1	2	3	3	3	3	3	3	3	3
Regulatory process	-	-	-	-	-	-	-	-	-	-
— Management system	1	2	2	3	3	3	3	3	3	3
— Licensing process	0	1	3	3	3	3	3	3	3	3
— Early and continuous involvement	1	3	3	3	3	3	3	3	3	3
Optimization										
Optimization	0	2	3	2	3	2	3	3	0	0
Uncertainties										
Management of uncertainties	2	3	3	2	3	3	3	3	2	2

TABLE 13. RELATIVE IMPORTANCE OF THE SUBCOMPONENTS OF A SAFETY CASE THROUGHOUT THE LIFETIME OF THE DISPOSAL FACILITY (cont.)

Main decision making steps	Need for action	Disposal concept	Site selection & engineering design	Construction		Operation		Closure	Passive institutional control period	Post-licensing
	Decision: Go for disposal or/and **Decision** for reassessment of an existing facility	**Decide** on the disposal concept and the safety strategy in a given environment	**Decision**: choose the site and associated design	**Decision** for construction (operator)	**Decision:** Authorization and/or licence for construction (authorities)	**Decision** to operate (operator)	**Decision:** authorization and licence for operation (authorities)	**Decision** to close	**Decide** to initiate the passive institutional control period	**Decide** or not to release the regulatory control
Safety strategy										
Robustness	0	2	3	3	3	3	3	3	0	0
Demonstrability	0	2	3	3	3	3	3	3	0	0
Multiple safety functions	0	3	3	2	3	3	3	3	2	0
Passive safety	0	3	3	3	3	3	3	3	2	2
Importance of engineering/science	1	2	3	3	3	3	3	3	1	0
Comparison of options	2	3	3	1	3	2	3	3	2	2
Graded approach	2	3	3	0	3	0	3	3	1	1
System description										
Waste characteristics	3	3	3	3	3	1	3	3	0	1
Design	1	3	3	3	3	2	3	3	1	1
Site characteristics	0	3	3	3	3	1	3	3	1	2
Safety functions	0	3	3	3	3	1	3	2	1	2
Safety assessment										
Environmental Impact assessment	2	2	3	3	3	3	3	3	1	1
Radiological impact and performance assessment	2	2	3	3	3	3	3	3	2	2
Operational safety	0	1	2	3	3	3	3	3	0	0

TABLE 13. RELATIVE IMPORTANCE OF THE SUBCOMPONENTS OF A SAFETY CASE THROUGHOUT THE LIFETIME OF THE DISPOSAL FACILITY (cont.)

Main decision making steps	Need for action	Disposal concept	Site selection & engineering design	Construction		Operation		Closure	Passive institutional control period	Post-licensing
	Decision: Go for disposal or/and **Decision** for reassessment of an existing facility	**Decide** on the disposal concept and the safety strategy in a given environment	**Decision**: choose the site and associated design	**Decision** for construction (operator)	**Decision:** Authorization and/or licence for construction (authorities)	**Decision** to operate (operator)	**Decision:** authorization and licence for operation (authorities)	**Decision** to close	**Decide** to initiate the passive institutional control period	**Decide** or not to release the regulator y control
Integration of safety arguments										
Clear communication and integration of safety arguments	3	3	3	3	3	3	3	3	3	3
Additional measures to increase confidence	-	-	-	-	-	-	-	-	-	-
— Independent review	2	3	3	3	3	1	1	3	1	2
— Complementary safety indicators	1	1	1	1	1	1	1	1	1	0
— Multiples lines of reasoning	1	2	2	3	3	1	1	3	1	0
R&D	1	2	2	1	0	0	0	1	0	0
Plans for addressing unresolved issues	1	3	3	3	3	3	3	3	0	0

TABLE 13. RELATIVE IMPORTANCE OF THE SUBCOMPONENTS OF A SAFETY CASE THROUGHOUT THE LIFETIME OF THE DISPOSAL FACILITY (cont.)

Main decision making steps	Need for action	Disposal concept	Site selection & engineering design	Construction		Operation		Closure	Passive institutional control period	Post-licensing
	Decision: Go for disposal or/and **Decision** for reassessment of an existing facility	**Decide** on the disposal concept and the safety strategy in a given environment	**Decision**: choose the site and associated design	**Decision** for construction (operator)	**Decision:** Authorization and/or licence for construction (authorities)	**Decision** to operate (operator)	**Decision:** authorization and licence for operation (authorities)	**Decision** to close	**Decide** to initiate the passive institutional control period	**Decide** or not to release the regulatory control
Limits, control & conditions										
Conditions (designer, regulator,..)	2	2	3	3	3	3	3	3	2	1
Limits (dose, risk, activity limits,..)	2	3	3	3	3	3	3	3	3	0
Control (conformity,..)	1	1	2	3	3	3	3	3	2	0
Surveillance										
Monitoring	1	1	3	3	3	3	3	3	3	0
Security	0	0	2	3	3	3	3	3	0	0

0	Not applicable to this decision step
1	Of value but less significant
2	Significant
3	Essential

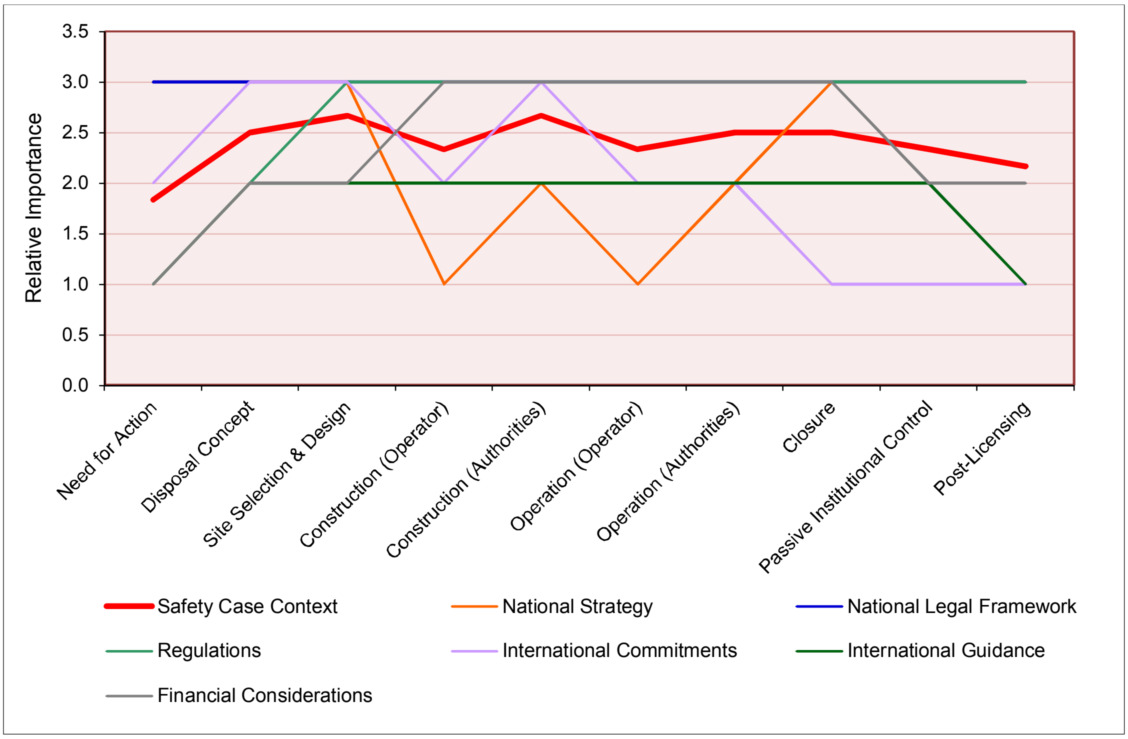

FIG. 4. Relative importance of the safety case context and its subcomponents throughout the lifetime of the disposal facility.

During these qualitative assessments of the components and subcomponents of a safety case, using the MASC matrix, many comments and arguments were provided by PRISM participants to substantiate the numbers assigned to cells of the matrix.

6.2.MASC MATRIX AND PROGRAMMATIC RISK

During PRISM discussions, it became apparent that the matrix could also serve as a useful tool for programmatic risk assessments and to evaluate the possible implications of missing or incomplete safety case components and/or arguments at a particular decision step on the subsequent development of the disposal programme. In this context, the term 'Programmatic Risk' is the risk that the waste disposal programme would have to take additional actions to correct problems arising from previous missing or incomplete safety case components and/or arguments.

In many practical examples provided by PRISM participants, problems arose during subsequent decision steps of the repository programme when safety case topics were inadequately or not properly addressed in earlier decision steps. As a consequence subsequent decisions in the implementation of the repository could be jeopardized, leading to 'Programmatic Risks'. Examples of programmatic risks are:

- Delay of the disposal programme;
- Increased cost;

- Loss of confidence and support from the local community;
- Loss of experience and data;
- A change in the national strategy such as a decision to retrieve waste.

The MASC matrix can be applied to investigate the potential consequences of not addressing or inadequately addressing components of the safety case by asking:

(a) What happens later in the evolution of the safety case if a prior step is missed, not addressed, or poorly addressed?
(b) What happens later if some 'mistakes' are made at a given step?

As an example of programmatic risk, PRISM assessed whether or not properly addressing a particular safety case component in a specific decision step, the national strategy in the need for action, would have negative consequences for the subsequent disposal programme.

For this example it was concluded that, without a national strategy, there may be a lack of consensus between a majority of politicians, the public, and industry and there may be a lack of a clear direction for the further development of the programme. As a consequence, the programmatic risk of failure increases and a large investment may be necessary to keep alternative solutions in the process.

PRISM also discussed examples of an inadequate safety case based on national programme experiences (e.g. [6]). The aim of these practical examples was to demonstrate that programmatic risks are often caused by an inadequate safety case associated with a previous decision step during the implementation of a disposal programme.

Examples presented in PRISM addressed the management system, the interrelation with the predisposal management system, loss of confidence of the public due to delay in non-safety related activities, issues related to stopping and restarting programmes, and a storage facility which was transformed into a waste disposal facility, skipping parts of the safety case development.

From the examples provided it appeared that in practice the most problematic issues in waste management relate to:

- Legacy waste which is not well characterized;
- Inadequately addressed management issues, which can lead to multiple delays or even failures of the disposal programme.

From the examples discussed within PRISM it was concluded that:

- One may leave out or not adequately address a safety case component only if one has a very high confidence that the component is not needed at a site.
- The costs of leaving out or not adequately addressing a safety case component are much higher the later in the repository development the mistake is realized; and
- The less adequate the safety case, the more likely significant consequences arise.

7. SAMPLE ARGUMENTS OF A SAFETY CASE FOR TWO HYPOTHETICAL RADIOACTIVE WASTE FACILITIES

The previous sections presented the components and subcomponents of a safety case for a radioactive waste disposal facility, the major decision steps in the development of a repository, and the integration of the safety case components and the decision steps in the MASC matrix. This leaves the real content of the safety case, the arguments in support of safety still to be addressed. Recognizing this, the IAEA convened another project involving participants from a large number of Member States to address the actual content of a safety case. This project was called PRISMA, where the 'A' represents the Application of PRISM.

A number of options were discussed for developing detailed guidance on the actual arguments for a safety case, i.e. the content of the MASC matrix. Obviously a safety case is a site-specific, repository-specific construct and, as such, the matrix is limited in how far it can go in providing generic guidance on the development of a safety case. Previously developed safety cases have been compared to the MASC matrix and safety cases have been developed using the MASC matrix or the components of a safety case from the MASC matrix. These examples were discussed in PRISM and PRISMA (e.g. [6] and [7]). As noted in Section 6.2, the use of the MASC matrix to evaluate existing safety cases provided insight into programmatic risk resulting from components that were overlooked during the safety case development. However these examples did not provide detailed guidance on the best method of developing a safety case. The main components of a safety case (the rows of the MASC matrix) were used in one example in Ref. [7] by rearranging existing reports and data from a previous waste management programme. However, this example did not present the safety case in support of the decision steps in the development of the repository. Therefore, PRISMA chose to develop generic hypothetical safety cases utilizing the MASC matrix. The outcome of the PRISMA project was not intended to be a complete 'model safety case' because each national situation and each facility is unique. Instead, the resulting MASC matrices were intended to provide examples of the factors and information that need to be considered and addressed in a safety case in support of the decision making during the development of a radioactive waste disposal facility.

7.1 THE PROCESS USED TO DEVELOP SAMPLE SAFETY CASES

Instead of having a group of international experts write recommendations for the content of a safety case, PRISMA chose a hands-on role-playing exercise to develop two sample safety cases. The participants were split into the four groups shown in Figure 5:

- Case definition group;
- Government/regulator group;
- Operator group 1;
- Operator group 2.

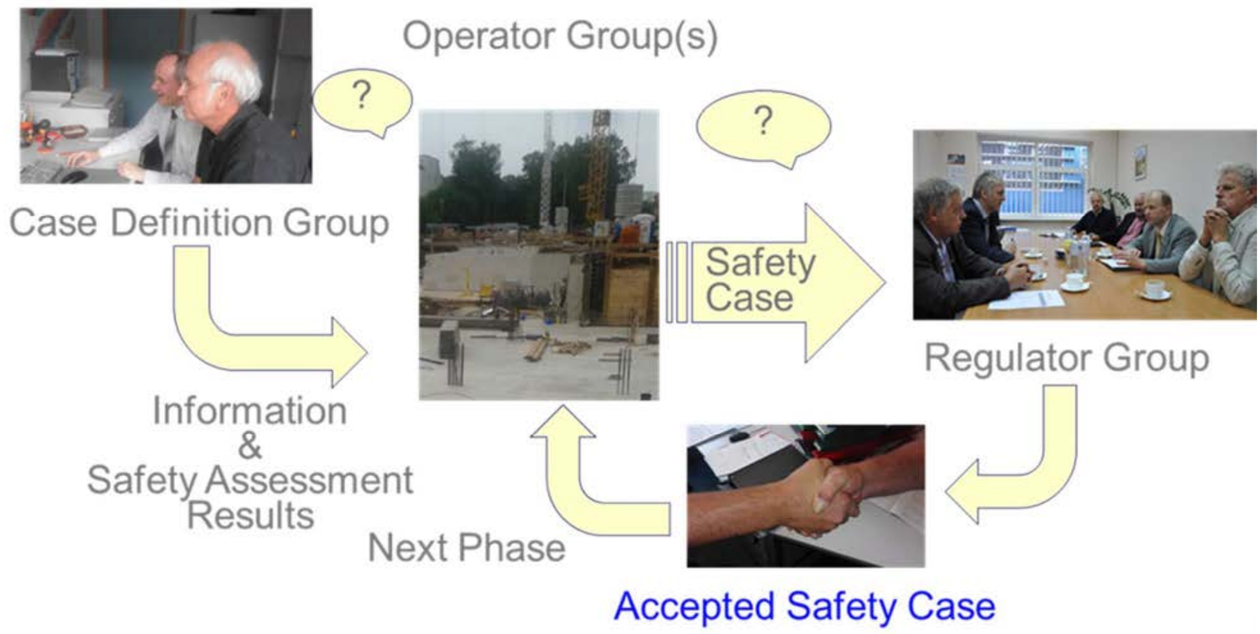

FIG. 5. PRISM groups and their interaction.

The role of the case definition group was to provide the participants with data and information needed to create a safety case at each decision step. In addition to the input of data needed to start the development of a safety case for a given decision step, the case definition group also provided additional data on request. The amount of additional data that could be requested was limited by the case definition group to mimic the conditions of the development of a real repository. In addition, the case definition group performed probabilistic safety assessments on request. In response to requests for additional data, the case definition group provided different data to the two operator groups. This was to assure that all of the key elements of the MASC matrix were addressed and that two identical safety cases were not produced.

Each operator group's role was to develop a safety case in support of decision making at each relevant step of repository development. Their responsibility was to provide clear documentation of their recommended decisions and all supporting evidence and the logic behind those decisions. To develop the safety case, each operator group had to interact with the case definition group and the government/regulator group. Interaction between the two operator groups was discouraged to ensure the independent development of the two safety cases.

The roles of the government and the regulator were merged into one government/regulator group. This permitted the government to take the decision on the need for action at the very beginning and the licence termination at the very end of the evolution of a safety case (see Figure 2). In between, the government/regulator group took on the role of the regulator in interactions with the operator groups.

The process started with the case definition group defining the waste management problem to be addressed by the operator groups and providing the necessary data for each decision step to begin. In parallel, the government/regulator group developed criteria by which to judge the safety case arguments of the operators. These criteria were supplied to the operator groups.

Each operator group developed a safety case for each decision step that, in turn, was reviewed by the government/regulator group. The operator groups populated a modified MASC matrix for each decision step (tailored to the needs of PRISMA) and developed their arguments and reasoning for the decision at that particular step.

The operator groups interacted as necessary with the case definition group and the government/regulator group, exchanging questions and answers during each stage of decision making. These interactions were documented as part of the overall process. The government/regulator group evaluated the operator group's safety case in support of each decision step and recorded their decision and the basis for their decision. In the event of a negative decision, the government/regulator group supplied the relevant operator group with the reasons for rejecting the operator group's safety case. The final documentation included completed MASC matrices for the operator groups and the government/regulator group, video summaries of each decision step, and text files documenting the exchanges between the groups. The video summaries were recorded at the end of each decision step and consisted of a debriefing presenting the essence of the arguments leading to the specific decision.

To facilitate data and knowledge transfer, the IAEA provided a SharePoint access site. Folders were setup for the storage and tracking of the development of safety cases for each decision step.

All the available information regarding the development of the sample safety cases was uploaded to the SharePoint site that served as a repository for all related documents (MASC matrices, text files, supporting references, presentations, and videos).

7.2 MODIFICATION OF THE MASC MATRIX TO FACILITATE THE DEVELOPMENT OF SAFETY CASE ARGUMENTS

A number of modifications were made to the original MASC matrix (Table 11) to facilitate the development of content for a safety case. First each decision step was given its own work sheet. This allowed for further modification by adding columns to the matrix to document: who created the matrix, when it was created, the decision alternatives, the decision, the basis for the decision, supporting information for the decision, uncertainties that could affect the decision, and recommended expertise that may be needed to support the decision.

The rows of the MASC matrix were also the subject of minor rearrangement. 'Stakeholder' was removed from the combined component 'stakeholder and regulatory process' so that the regulatory process became a stand-alone component while 'management' was merged with 'stakeholder' into one component. 'Optimization' became a subcomponent of the 'safety strategy'. The component 'surveillance' that originally was a subcomponent of 'limits, controls & conditions' was raised to the components level. This new arrangement of components and subcomponents was conceived as a potential improvement to the grouping of the safety case components previously presented by the IAEA [1].

Shown below in Table 14 is an example of the modified MASC matrix for the first decision step – need for action.

Once these modifications were accepted, no further modifications were allowed during the development of sample safety case input. Recommendations for further changing the MASC matrix derived from using the matrix to develop safety case input were accumulated and are reported in Section 7.5.2.

TABLE 14. EXAMPLE OF THE MODIFIED MASC MATRIX TO FACILITATE THE SAFETY CASE DEVELOPMENT

Name: Country: Audience: Disposal facility: PRISM Task working Group:				
Main decision making steps	Need for Action			
Decision Alternatives: Recommended Decision: Decision Summary:	Storage, disposal, delayed disposal, export to a foreign country			
	Basis for the decision	Support for the decision (rationale, references, etc.)	Uncertainties that could affect the decision	Recommended expertise supporting the decision
Safety case context				
National strategy				
National legal framework				
Regulations				
International commitments				
International guidance				
Financial considerations				

TABLE 14. EXAMPLE OF THE MODIFIED MASC MATRIX TO FACILITATE THE SAFETY CASE DEVELOPMENT (cont.)

	Basis for the decision	Support for the decision (rationale, references, etc.)	Uncertainties that could affect the decision	Recommended expertise supporting the decision
Management & stakeholder				
Involvement of stakeholders				
Management system				
— Organization				
— Staff competence				
— Q/A				
— Record keeping / traceability				
Regulatory process				
— Management system				
— Licensing process				
— Early and continuous involvement				
Safety strategy				
Optimization				
Management of uncertainties				
Robustness				
Demonstrability				
Multiple safety functions				
Passive safety				
Importance of engineering/science				
Comparison of options				
Graded approach				
System Description				
Waste characteristics				
Design				
Site characteristics				
Safety functions				

TABLE 14. EXAMPLE OF THE MODIFIED MASC MATRIX TO FACILITATE THE SAFETY CASE DEVELOPMENT (cont.)

	Basis for the decision	Support for the decision (rationale, references, etc.)	Uncertainties that could affect the decision	Recommended expertise supporting the decision
Safety assessment				
Environmental impact assessment				
Radiological impact and performance assessment				
Operational safety				
Surveillance				
Monitoring				
Security				
Integration of safety arguments				
Safety arguments				
Additional measures to increase confidence				
— Independent review				
— Complementary safety indicators				
— Multiple lines of reasoning				
R&D				
Plans for addressing unresolved Issues				
Limits, control & conditions				
Conditions (designer, regulator...)				
Limits (dose, risk, activity limits...)				
Control (conformity...)				

7.3 CASE DESCRIPTION

Safety cases were developed for two different hypothetical near surface radioactive waste disposal facilities. They reflect the reasoning behind the main decision points according to the results of the PRISM project as referred to in Table 11. A generic country setting was developed with enough variance to allow for two separate radioactive waste disposal facilities with different safety cases. The setting was made as realistic as possible to ensure that the development of the sample safety cases and their utilization of the MASC matrix would be applicable to actual safety case development and evaluation.

7.3.1 Country description

The size of the notional country is considered to be at a medium scale, to provide sufficient space within that country for siting potential radioactive waste disposal facilities (Figure 6).

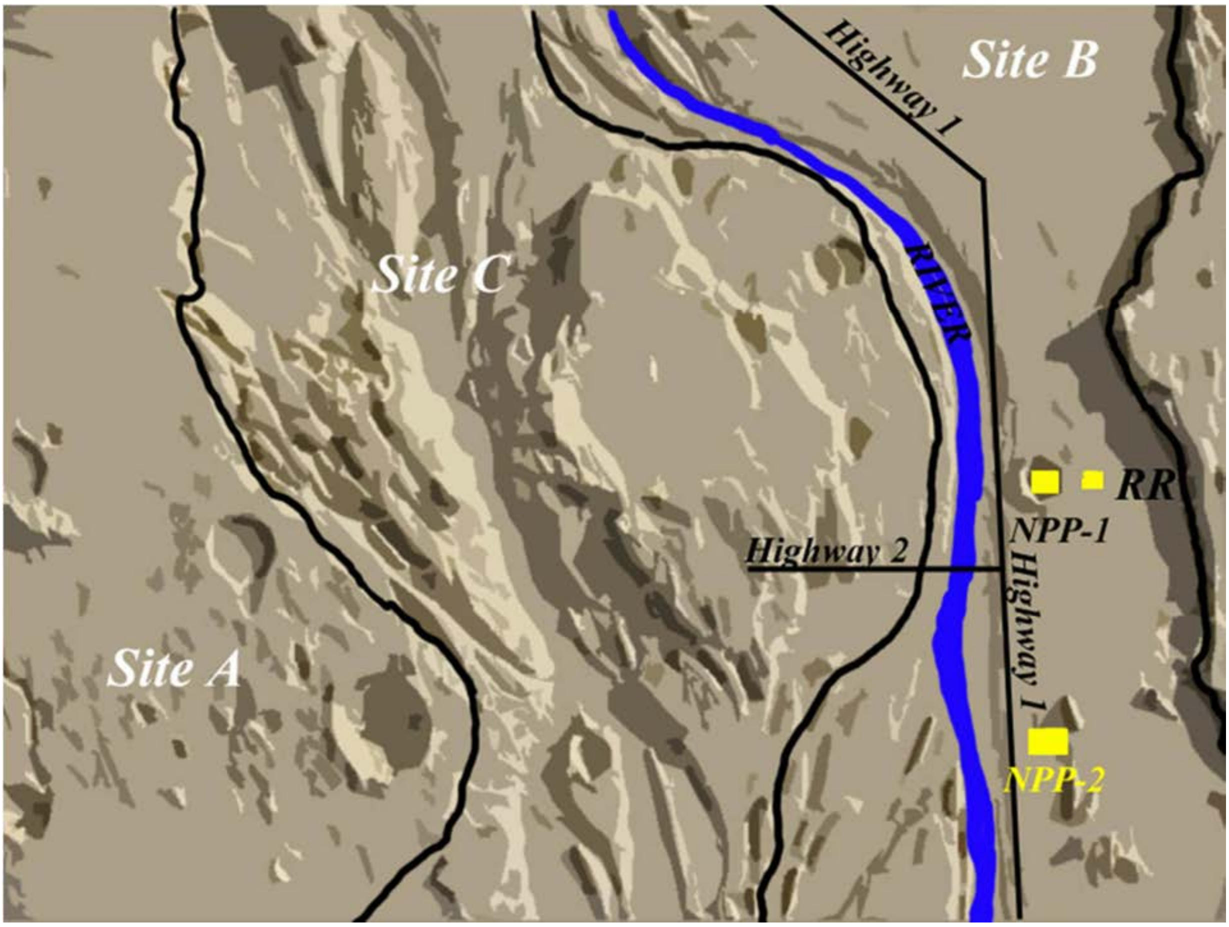

FIG. 6. Overview of the generic country indicating infrastructure, drainage system and relief.

The population density over the country is quite variable with rural and urban areas considered in the siting process. The population density decreases from east to west. The country has two nuclear power plants with two reactors operating at each plant. There is also a small research reactor that is no longer in operation. The country has decided to phase out the use of nuclear power and the power plants are scheduled to cease operation in approximately two decades. Storage capacities for the operational waste are assumed to be exhausted by then. The decommissioning of the power plants is assumed to generate a notable amount of low level decommissioning waste to be managed. Legal framework

The country has signed the Joint Convention on the management of radioactive waste and nuclear fuel and receives technical cooperation support from the IAEA.

Regarding the management of high level waste, spent fuel, and intermediate level waste, the country has signed an agreement with another country, which will accept these waste types for disposal. Low level waste remains to be disposed of. Very short lived waste is assumed to be stored for decay and disposed of as non-radioactive waste after having reached the relevant safety levels.

The regulatory framework for the operation of the nuclear power plants is in force and complete. As the regulatory framework for radioactive waste management has yet to be established, the nuclear power plant operator is responsible for the management of the radioactive waste. The nuclear power plants are regulated by the Ministry of the Environment, which is also working to complete the regulatory framework for radioactive waste management. The regulatory framework for radioactive waste management is expected to be completed during the development of any repository.

7.3.2 Inventory

The inventory of the waste to be disposed of within the country is well known and has been quantified in detail and included in the SharePoint site. The total activity of that waste is set to 1.55 E+16 Becquerel. The operational waste incurred so far is already conditioned within the storage facilities. The total volume of the conditioned waste is estimated not to exceed approximately 50 000 m^3. This includes the decommissioning waste deriving from the nuclear power plants and the research reactor.

Most of the waste is short lived. Only a small amount of long-lived waste is to be considered for disposal within the country.

7.3.3 Geology

In order to create a geological setting that is not too complicated for this exercise, the country is divided into three main geological settings, simply named site A, B and C, each consisting of a uniform distribution of rock types (Figure 7).

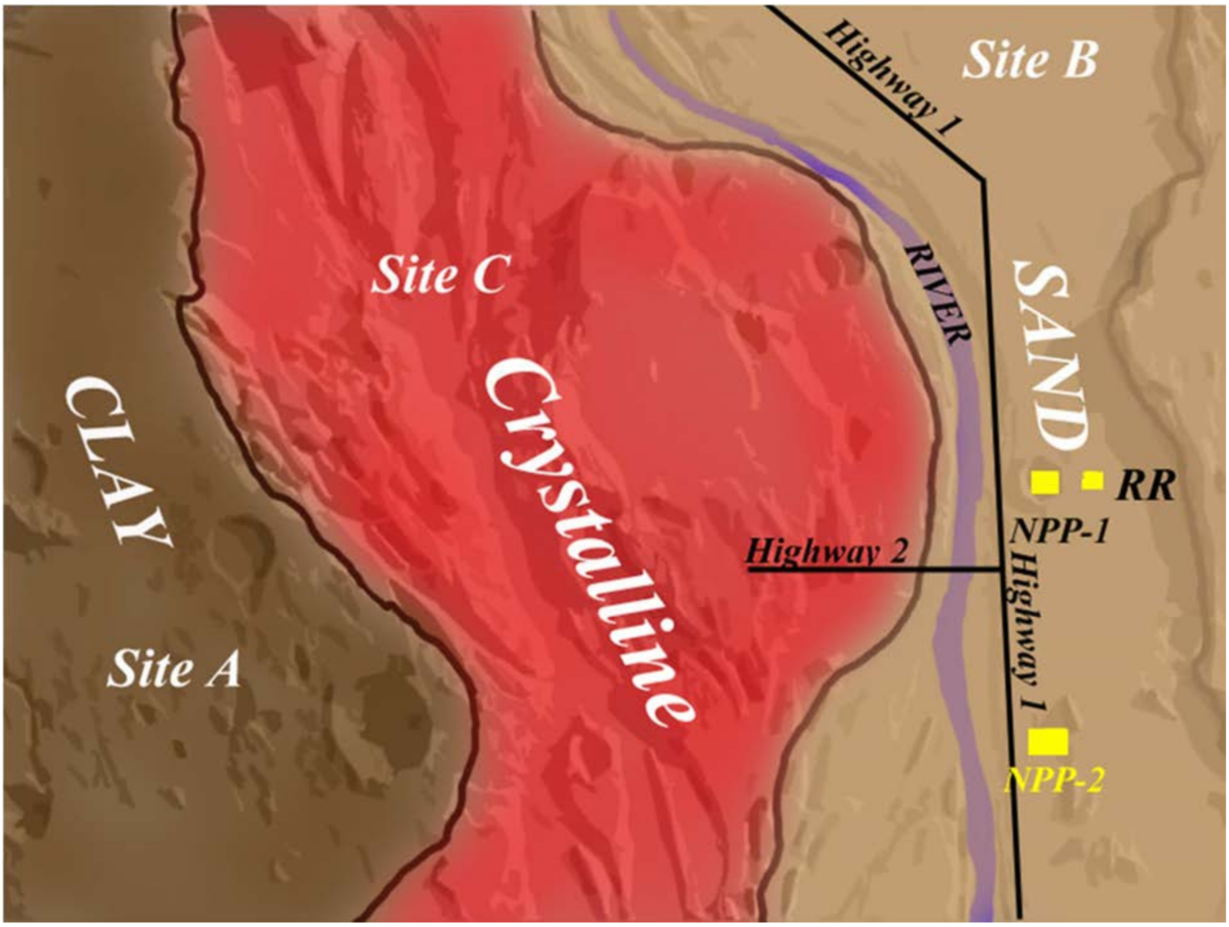

FIG. 7. Distribution of main rock types over the country.

Site A:

The setting is situated in the western part of the country and consists of a relatively homogeneous low permeable formation with a thickness of more than 50 m. The region is known to have a very low seismicity. The relief can be regarded as a low mountain range.

Site B:

This section of the country is represented by a thick layer of homogeneous sand without much relief. Tectonic features have not been recognized and the level of geological exploration in the area is relatively high due to the well-developed infrastructure.

Site C:

The middle of the country is represented geologically by a large crystalline rock body with an intensive relief. The geological database in this part of the country is poor.

7.3.4 Climate and hydrology

Site A:

The climate in the area is humid and stable. The water table is known to be a few metres below ground. There are no large rivers present.

Site B:

The climate is unstable (hard to predict for the far future, precipitation is likely to increase) and humid. The site is not likely to be regularly flooded.

The water table is at 4–6 m. The aquifer is supplying the existing population.

Site C:

The climate is semi-arid. The water table is at 20–100 m depending on the elevation of the regarded area.

7.3.5 Socioeconomic factors

Site A:

This site is located in a rural area close to a national park. Drilling permits are expected to be difficult to obtain in the national park area. Endangered species are known to be present within the park area. A strong public opposition to a radioactive waste disposal project in site A is probable.

Site B:

The nuclear power plants in site B are located within an urban area with residential zones relatively close to the power plants. Due to the vicinity of the nuclear power plant and the fact that the plant provides jobs for citizens living in the area public acceptance for a radioactive waste disposal site is to be expected.

The sand is a potential natural resource that might be exploited in the future.

An environmental impact assessment has been made for the nuclear power plants. If a radioactive waste disposal facility is sited here, cumulative effects from the reactors and the waste disposal facility need to be taken into account.

Site C:

The public has displayed a neutral attitude towards the project. There are no product labels associated with the region that could be negatively impacted by a waste disposal facility.

7.3.6 Infrastructure

The country's infrastructure generally decreases from east to west.

Site A:

This site represents the rural part of the country and is characterized by poor infrastructure and the lowest population density. The transport distance from the storage facilities to a potential waste disposal facility in this region is the longest within the country.

Site B:

The urban region provides good access and infrastructure in the relevant areas.

The closest houses are located a few hundred metres from the site. Good access is provided by a well-developed road network. There is a river nearby. A radioactive waste disposal site could be located near a nuclear power plant. A good monitoring network for the nuclear power plant already exists and only small adaptations for an adjacent waste disposal facility would be necessary. The area is covered by the security concept of the nuclear power plant.

Site C:

Some good transportation routes characterize the infrastructure of this site. Road upgrades would probably be necessary. The transport distance would be intermediate in comparison to the alternative sites. The density and distribution of settlements allows the planner to avoid the vicinity of housing.

7.4 DEVELOPMENT OF A SAFETY CASE FOR EACH DECISION STEP FOR TWO HYPOTHETICAL REPOSITORIES

This section summarizes the development of sample safety case arguments for two hypothetical repository projects.

Following is a summary of each decision step evaluated by the PRISMA project. It is important to note that the PRISMA project did not have time to consider all of the decision steps.

7.4.1 Decision step 1: need for action

The decision at this step is to either launch a suitable disposal programme and decide on the timing for it or continue storing radioactive waste. Similar decisions may be required in relation to any potential remediation or upgrades to an existing facility.

7.4.1.1 *Summary of the briefing by the case definition group*

The country is of medium size and has two nuclear power plants, each of which operates two reactors. One small research reactor is not in operation. The country has signed the Joint Convention and receives technical cooperation support from the IAEA. There is an agreement with another country to take all the high level waste, intermediate level waste and spent fuel. The nuclear power plants are scheduled to close down in about 20 years. The storage for operational waste is assumed to be completely full by then and a lot of low level decommissioning waste may arise. The nuclear power plants' operator is currently responsible for the management of all radioactive waste and is regulated by the Ministry of Environment.

A regulatory framework for the operation of the nuclear power plants exists. There is no complete regulatory framework for RWM. The country is not overpopulated, has good infrastructure and a humid to semi-arid climate.

7.4.1.2 *Summary of criteria set by the government/regulator group*

The government/regulator group developed criteria for the operator's safety case evaluation and placed them into three categories; essential, significant, and "of value but less significant". The group focused primarily on the essential criteria but the ones rated significant were studied as well.

The essential criteria to be considered were the national strategy and the national legal framework as far as they were in force or existing. Additionally there was the agreement with another country to accept the high level and intermediate level waste and spent fuel. As the country received technical support the application of IAEA standards and guidance were obligatory [1]. The government/regulator group focused on the precision given by the operator for the waste characterization. Uncertainty management for the waste characterization was considered as well.

7.4.1.3 *Decisions of operator groups 1 and 2*

The decision of both operator groups was to go for disposal without delay.

7.4.1.4 *Decision of the government/regulator group*

The government/regulator group accepted the operator's proposal to go for disposal now, but in addition the regulator formulated some recommendations which the operator is expected to comply with (or start complying with) at the next decision step.

7.4.1.5 *Arguments for the decision*

The national strategy and the national legal framework were in place or under development. The decision conforms to the Joint Convention. The required documentation management system as it is applied for the nuclear power plants can be applied. Ninety percent of the waste is characterized. The operator could not provide information on the historical waste, on the waste that will arise from decommissioning, or on the waste from the research reactor. For this reason it was recommended that the operators provide information on waste characterization of existing waste and expected inventory for future waste (operational and decommissioning) for the next step. Another recommendation was to provide an outline for the record keeping for the disposal.

7.4.2 Decision step 2: disposal concept

At decision step 2, the decision is made on the disposal concept and the safety strategy in a given environment.

7.4.2.1 Summary of the briefing by the case definition group

The country's geological setting can be split up into three regions. In the western part of the country near surface, a low permeable formation with a thickness of approximately 50 m predominates. This area named site A has no seismicity and a low relief. The ground water table is estimated to be generally at a few metres below the surface. The eastern part of the country, named site B, is the most urbanized one and consists of predominantly sandy high permeable layers. There is an important drainage system nearby and the groundwater table at the site is continuously shallow. The geological database is relatively complete for site B. Tectonic features have not been recognized in this region. Site C is situated in the center of the country. The geology consists of a crystalline rock body that is expected to be fractured. However little is known about the details of the geology of this region.

The radioactive waste to be disposed of is characterized in a detailed inventory that was made available to the groups. This comprised a list of radionuclides and half-lives allocated to the radionuclides. The total activity amounts to 1.55 E+16 Bq with most of the waste being short lived with a small amount of long-lived waste. The total volume of conditioned waste was estimated not to exceed 50 000 m^3 including decommissioning waste.

7.4.2.2 Summary of criteria set by the government/regulator group

The government/regulator group developed a wide range of criteria for the evaluation of the operator groups' proposals. The most important criteria are:

- Are the proposed disposal concept and alternative options in line with the national strategy, national legal framework, regulations, international commitments and international guidance?
- Did the operator proof an adequate record keeping system?
- Is a management system applied to provide for the assurance of quality?
- Did the operator proof the feasibility of the design?
- Is long term safety provided by passive means?
- Is the design of the concept presented in a clear way to allow verification of the application of safety principles?
- Retrievability is required for surface disposal but not for subsurface disposal.

7.4.2.3 Decisions of operator groups 1 and 2

Operator Group 1 proposed a single subsurface disposal facility with two concepts referring to either a silo or a tunnel design at an intermediate depth. The alternatives considered were borehole-, surface-, subsurface- and geological disposal.

Operator group 2 proposed to develop two facilities located at the same site. Regarding long-lived low level waste, two possible facilities were considered. For long lived waste a tunnel, tens of metres below the surface, was proposed. For the short lived low level waste two concepts were proposed: 1) concrete reinforced above ground vaults; 2) clay trenches a few metres below ground. For both concepts a multi-layer cover was envisaged.

Alternatives that had been studied were borehole and geological disposal.

7.4.2.4 Decision of the government/regulator group

The waste to be disposed of is low level, but it contains a fair amount of long lived radionuclides that cannot be accepted in a surface disposal facility.

The two operators proposed to dispose of the waste in sub surface disposal facilities. Operator group 1 considered a single facility while operator group 2 considered two separate facilities located at the same site in order to separate the long lived waste from the short lived waste.

The proposed disposal concept of Group 1 were evaluated by the government/regulator group and judged acceptable. The government/regulator group felt that the disposal concept was robust and the safety functions acceptable.

The concepts presented by operator group 2 were accepted with the inclusion of the following three conditions to be enforced by the government/regulator group:

(a) Identify the facilities' safety functions and prove their independence;
(b) Also study the possibility to have a single facility for all types of waste (cost-benefit).

7.4.2.5 Arguments for the decision

Discussion centered on the content of the national strategy, national legal framework and existing regulations to create a sound base for the decision making process.

The waste in the disposal facility is supposed to be retrievable for the surface disposal concepts at any moment in time, but this is not required for geological disposal.

The government/regulator group analysed the operators' proposed safety strategy for the disposal concepts but did not require a preliminary safety assessment prior to their decision on the disposal concept.

Regulatory limits for alpha and beta emitters were taken into account in the government/regulator group's decision.

Operator group 1 and the government/regulator group agreed on the fact that short lived low level waste and long lived low level waste can be disposed of in one facility.

In addition the following key issues were discussed between the government/regulator and the operator groups:

- Expertise in mining in the country;
- Uncertainty of the classification of the waste;
- The proof of funding for future steps;
- The need for comparing different options;
- Arguments on the demonstrability of the proposed option.

7.4.3 Decision step 3: site selection and engineering design

This decision step is dedicated to selecting a suitable site for the radioactive waste facility and the engineering design associated with the chosen site.

7.4.3.1 Summary of the briefing by the case definition group

The briefing for decision step 3 provides more details on the three characterized zones of the country.

Site A is characterized by a stable humid climate and a relatively homogeneous low permeable formation with a thickness of more than 50 m. The water table is a few metres below ground. The area shows very low seismicity. Site A is located in a rural area close to a national park, where it appears to be difficult to obtain drilling permits etc. Endangered species are known to be present. Strong public opposition against a waste disposal project is to be expected. The infrastructure is poor. The transport distance from the nuclear power plants, where the waste is generated and stored, is the longest for this site.

At site B the climate is humid. However the climate is considered to be unstable and therefore hard to predict far into the future. It is likely that precipitation may increase. The near-surface geological strata consist of a thick layer of homogeneous sand. The water table is at 4–6 m. The sand is a potential natural resource and the aquifer is an existing water supplier. The site is located near a nuclear power plant where there is good public acceptance and good access and infrastructure. The closest houses are approximately 300 m away. A river is 100 m away. The site is not likely to be regularly flooded. An environmental impact study had been carried out for the nuclear power plants but cumulative aspects (also for operational dose limits) need to be taken into account. A good monitoring network for the nuclear power plants exists and only small adaptations for an additional disposal facility would be necessary. The area is covered by the security concept of the nuclear power plant.

Site C is located in the middle of the country with a medium level population density. The public is neutral to the project. Crystalline rocks are the general rock types that are present in the region. They are expected to be of low permeability but there is potential for fractures and tectonic disturbances in the area and probably a complicated geology. The geological database is poor.

The climate is semi-arid and the water table is at 20–100 m below the surface. There is some good infrastructure that would be useable for waste transport to a disposal facility.

7.4.3.2 Summary of criteria set by the government/regulator group

One crucial criterion was the question of whether the site selection and design are in line with the national strategy and the national legal framework and the regulations. Funding of current and later stages needs to be guaranteed. It was requested that the management system be regularly recertified through audits. Regarding optimization it was required that different sites had been taken into consideration, the design had been presented in the previous step and the inventory information had been updated. Identified uncertainties were to be specified and discussed. Demonstrability was an issue but was not described as a criterion in a strict sense. Multiple and independent safety functions were required by the regulator. The description of the repository design needs to allow the reviewer to make his own verifications. An in-depth site characterization was required to evaluate the suitability of the site to host the disposal facility. This requirement corresponds with the criteria for a preliminary safety assessment that shows that the proposed site and concept would meet the regulatory limits. Retrievability was considered essential.

7.4.3.3 Decisions of operator groups 1 and 2

Operator group 1 chose site C and proposed a single repository with a tunnel design.

Operator group 2 initially also proposed site C with a subsurface design with one entrance but with two separate facilities, one for long lived low level waste and one for short lived low level waste. Due to unfavourable results from safety assessments operator group 2 reviewed the site selection decision and selected site B with a similar design. Safety assessments for the long lived low level waste drove operator group 2 to refine a design for that waste type with additional air filtration but retaining one entrance with two near surface facilities.

7.4.3.4 Decision of the government/regulator group

For both operator groups the government/regulator group considered the safety case for siting and design of the proposed disposal facility to be acceptable, subject to a list of conditions.

7.4.3.5 Arguments for the decision

The selection of the site by operator group 1 had been based on a multi decision criteria analysis for site selection. Regarding the technical characteristics operator group 1 stated that preliminary site investigation confirmed the assumptions. Attention had been paid to the existing infrastructure, especially to the expansion of transportation routes. Potential pathways for contaminants had been evaluated, especially towards the ecologically sensitive area towards the national park. Societal characteristics had been analysed, in particular the public participation and attitude towards the project. It was suggested to improve the geological database by further site investigation work, aspiring in particular to reduce or eliminate programmatic risks. The group’s experience in mining led them to choose a tunnel design for the facility.

The government/regulator group accepted the proposal from operator group 1, but required regular compliance reporting. Another condition was aimed at the protection of the national park during the preparation of the site for the proposed facility.

Operator group 2 selected site B adjacent to two existing nuclear power plants as the preferred site based on the following key factors:

- Availability of detailed information about the site because of the adjacent existing nuclear facilities;
- Public support;
- Use of existing infrastructure.

Although the government/regulator group's review listed a large number of issues that were not adequately addressed, the operator's proposals were accepted in both safety cases. Consistent with the government/regulator group's decision on operator group 1's proposal, they required a compliance report and consideration of the potential cumulative impact of the waste disposal site and the adjacent nuclear power plants.

7.4.4 Decision step 4: construction

Decision step 4 is the decision to begin construction of the facility on the selected site with the approved design. This decision is usually based on a licence.

7.4.4.1 Summary of the briefing by the case definition group

Investigation for site A confirmed a thick low permeable layer (more than 50 m). The water table is at a depth of 2–3 m. Very slow groundwater movement is confirmed. The small population in the area has been opposing the idea of a disposal facility; moreover they communicate very well with the press and national NGOs. Endangered species are known to be present and may need to be relocated and alternative biotopes may need to be provided.

The water table for site B is at approximately. 5 m. The sand is very suitable for construction purposes and as such used as a resource at several points in the area. There is still good public acceptance.

The public at site C is still neutral to the project. The general rock type is known to be of low permeability. The water table ranges between 40 and 50 m below ground level (significantly deeper in the mountainous region). A highly permeable feature intersecting the repository footprint is considered to be possible.

Existing literature values are accepted as bounding ranges by the regulator for all sites.

7.4.4.2 Summary of criteria set by the government/regulator group

In decision step 4 basically all safety arguments apply. Of special importance is that for the first time a full safety assessment is required.

The regulator particularly focused on the following points:

- Passive safety (by natural and engineered barriers);
- Radiological impact and performance assessment (long term, taking into account human intrusion);
- Operational safety;
- Monitoring (including baseline monitoring);
- Security;
- Complementary safety indicators (e.g. assessment of chemotoxicity of leached waste, travel time of radionuclides, extent of plume and concentrations in groundwater);
- Limits (e.g. inventory limits).

7.4.4.3 Decisions of operator groups 1 and 2

Operator group 1 and operator group 2 decided to apply for a construction licence on sites B and C based on successful safety assessments.

7.4.4.4 Decision of the government/regulator group

The government/regulator group considered the safety case for construction of the proposed disposal facilities for both operator groups acceptable, subject to the following conditions:

- Compliance reporting: the licencee has to provide the regulator with information about compliance with the requirements of the act and regulations, and with the licence conditions for the previous quarter year within twenty eight (28) days of the end of each quarter.
- Construction of items important for safety: it is necessary that the licencee seek approval for construction of items important for safety identified in the safety case.

7.4.4.5 Arguments for the decision

At decision step 4 all safety arguments become relevant. However the regulator put special emphasis on the point that overall safety was demonstrated by radiological and environmental safety assessments. Within this context the main driving factors for the decision were the following points:

- Experiments support compliance with designed properties.
- All assessment results are in compliance with regulatory requirements.
- An independent review has been performed.
- Complementary safety indicators are analysed (concentration in groundwater, travel time, extent of plume, chemotoxicity).
- Waste acceptance criteria and waste volume limits are established.

7.4.5 Decision step 5: operation

Decision Step 5 leads to the beginning of the operation of the radioactive waste facility which is based on a licence that has to be granted before the operation may start.

7.4.5.1 Summary of the briefing by the case definition group

For operator group 1 the access to the repository level is constructed and the mining of the galleries has begun. Pilot drilling encountered an open fracture. The fracture is a single feature with high permeability and wet.

Due to phase out of the use of nuclear power, operator group 2 expects that the nuclear power plants will be decommissioned and all radiation will be removed. The start of construction brought a broader public awareness of the project and public opinion changed. A part of the population is still supportive of the waste disposal facility while another part of the population has turned against the facility and is considering legal action.

7.4.5.2 Summary of criteria set by the government/regulator group

During the operation step operational safety assessment, waste acceptance criteria, management controls (e.g. QA and documentation), surveillance, and limits, control, and conditions were most significant.

It is necessary that the operators have the most recent and relevant regulatory criteria in order to produce a high quality application.

The operators need to establish detailed waste acceptance criteria to ensure that waste received for disposal meets the applicable controls, limits, and conditions. Waste acceptance criteria need to be communicated to waste generators. Verification of waste acceptance documentation is required for all waste.

Radiological and non-radiological monitoring and observation ensure that criteria are being met after approval to begin operations is provided. Monitoring has to include establishment of a proper baseline [5].

Identification of licence conditions from previous steps and a technical basis for the demonstrability of operations were required by the government/regulator group.

A full operational safety assessment has to be performed including ALARA considerations.

7.4.5.3 Decisions of operator groups 1 and 2

During construction of their tunnel, operator group 1 discovered a single wet fracture. The result of an assessment was that the wet fracture would bring water in contact with waste and lead to a violation of regulatory limits.

Additional site characterization revealed the size and orientation of the fracture which was comparable to other existing fractures. The source of the groundwater within the fracture was confirmed, it was coming from surface water. Operator group 1 then adapted the design by a minor relocation of the tunnel shaft to account for the presence of the fracture and sought confirmation from a new safety assessment that the radiological impact was below the regulatory limits, which it was. After demonstrating that the removal of excess water from the fracture during construction would have no adverse effect on the national park, operator group 1 completed construction and applied for permission to operate the repository.

Operator group 2, faced with a change in public opinion, established a public acceptance plan and submitted it to stakeholders. The regulator agreed to provide support to the public engagement process. The plan defined risk mitigation methods that included public communication and a transparent approach to stakeholder engagement.

A monitoring plan was developed and the design plan for construction was presented to the government/regulator group. An operational safety case including security considerations was also delivered to the government/regulator group. Other items considered were infrastructure needs and logistics, social & economic impacts during construction and financial constraints.

7.4.5.4 Decision of the government/regulator group

The regulator approved the decisions to begin operations.

7.4.5.5 Arguments for the decision

The potential operators proposed to dispose of low level waste in a near surface disposal facility. Previous regulatory approval was given for construction of the facility. The operator addressed all previous licence conditions and addressed all regulatory concerns with the proposed operational plans. The operator provided information to demonstrate that the facility can be safely operated and meets applicable regulatory requirements.

The regulator has to base its decision on materials provided by the operator that demonstrate that the facility will be operated safely. Expertise in the following areas is necessary;

- Operational safety assessment;
- Radiation health physics and radiological monitoring;
- Quality assurance;
- Project management.

Regulations were in place, establishing requirements for monitoring, operational safety assessment, quality assurance, surveillance, and appropriate limits, controls, and conditions. Funds were available to begin operations.

At the operations step, the decision is not based on the national framework. The decision is based solely on the demonstration that the facility can be operated safely and will meet all applicable regulatory requirements.

7.5 LESSONS LEARNED

A number of lessons were learned in the development of these safety cases for two hypothetical repositories. They are summarized in the following sections.

7.5.1 From operator and regulator groups

Perhaps the most important lesson learned in developing safety case input is not about the input itself but about the tendency of the operators to avoid certain types of uncertainty in decision making. The uncertainties that had been encountered and then avoided included: a lack of understanding of the natural system at one site; and the potential effect of public opposition at another site. In neither case were these uncertainties insurmountable. One operator group could have invested in additional site characterization to reduce parameter uncertainty while the other could have developed a strategy to deal with the public opposition. However, instead of dealing with these uncertainties, the operators chose, in one case, to move to another site and in the other case to employ a sophisticated barrier system. In the case where the site was moved, it was to an area where passive safety could not be relied upon, thereby also requiring a sophisticated barrier system.

Next, decision makers have a difficult time making decisions. Some decisions taken by the regulator were linked to conditions that had to be fulfilled in the next decision step even though those conditions were not needed for the decision at hand. This tendency to keep options open was also exposed by the perceived need, and thus requirement for, future R&D, which by definition, could not be related to the decision at hand. Alternatively the regulator could have requested that the operator meet the required conditions before accepting the operator's proposal. Another indication of this tendency to avoid decisions is the use by the government/regulator group of the word 'acceptable' instead of 'accepted' indicating an open instead of concluded decision.

It is important to note, that at the end of the day, the government/regulator group never rejected a site selection or repository design proposed by either operator group.

The shared file storage and retrieval system worked well for archiving and accessing files that were used during the safety case development and evolution. The SharePoint site was very useful for exchanging working files (e.g. matrices at different processing status, auxiliary files supporting the matrices) and for enhancing the interaction between the operator groups and the government/regulator group.

Earlier and be more frequent communication between the government/regulator group and the operator groups would be beneficial, as communication between the groups resulted in significant changes to the safety cases. Capturing questions and answers between the operator groups, the case definition group, and the government/regulator group is critical.

7.5.2 Lessons learned about the MASC matrix

The MASC matrix was found to be very useful by the developers of sample safety case input. The development of criteria for the judging of safety case arguments by the government/regulator group is a significant addition to the MASC matrix. However, while the MASC matrix was found to be useful in identifying programmatic risks, once identified, the programmatic risks were not tracked well in the MASC matrix.

As a result of this exercise, participants recommended a number of improvements to the MASC matrix. These included:

1. Change the title of 'involvement of stakeholders' to 'influence of stakeholders on the decision';
2. Plans for addressing **unresolved** issues could be better named 'Plans for addressing **unexpected** issues';
3. Link the cells in the MASC matrix to this TECDOC which provides an explanation of each cell;
4. Provide a glossary for MASC terminology;
5. Consider re-organizing decision step 2 and decision step 3 recognizing the inherent link between site selection and disposal concept;
6. 'Multiple safety functions' is not sufficient for describing multiple barriers. Therefore, consider adding multiple barriers as a subcomponent of the safety case;
7. 'Safety functions' may be better titled 'safety systems';
8. Clarification is needed for the 'engineering/science' subcomponent;
9. Clarification is needed for the term 'safety arguments';
10. Examples would be useful for 'multiple lines of reasoning';
11. Consider a separate and different MASC matrix for the regulator and the operator;
12. Consider dividing the MASC matrix into required elements and optional elements;
13. It is recommended that a line be added after 'science/engineering' for experience, which can be very important in immature programmes (to consider experience or bring in experience from other programmes);
14. 'Management system' needs to be removed from the MASC matrix under regulatory process if the MASC matrix is applied to an operator. The operator has no say in the management system of the regulator;
15. Change the MASC matrix to the restructuring of the rows as shown in Table 15.

TABLE 15. PROPOSED RESTRUCTURING OF THE ROWS OF THE MASC MATRIX

Main decision making steps			Operation
Decision alternatives: Decision:			
	Priority	Criteria	Request for additional information
Safety case context			
— QA – Quality assurance	2	A QA programme for operations has been established and is auditable.	
— Documentation	2	Provide documentation of all aspects of the safety case with special emphasis on the systems important to safety.	
Engineering/science	2	Engineering/science has been completed to support the operations, and, if necessary, will be continued during operations.	
Experience	2	Relevant experience in similar and analogous systems has been considered.	
Comparison of options	0	Not applicable.	
Graded approach	1	If a graded approach to operations is used, then the significant operational processes have been identified.	

(blue)	Recommended structural change to the MASC matrix
(yellow)	Indicates changed text
0	Not applicable to this decision step
1	Of value but less significant
2	Significant

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LIST OF ABBREVIATIONS

ALARA	as low as reasonably achievable
ASAM	application of safety assessment methodologies
BAT	best available technologies
GSR	general safety standards
IAEA	International Atomic Energy Agency
ILW	intermediate level waste
ISAM	Integrated Safety Assessment Methodology
LLW	low level waste
MASC	matrix of arguments for a safety case
NGO	non-governmental organization
NSARS	Near-Surface Radioactive Waste Disposal Facilities
OECD/NEA	Organisation for Economic Co-operation and Development/ Nuclear Energy Agency
PRISM	Practical Illustration of the use of the Safety Case concept in the Management of near-surface disposal
PRISMA	Application of the Practical Illustration and Use of the Safety Case Concept in the Management of Near-Surface Disposal Project
QA	quality assurance
R&D	research and development
SL waste	short lived waste
SSG	specific safety guide
SSR	specific safety requirements
VLLW	very low level waste

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