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Experiences of the Development, Review and Communication of Safety Cases and Safety Assessments for Near Surface Disposal of Radioactive Waste

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EXPERIENCES OF THE DEVELOPMENT, REVIEW AND COMMUNICATION OF SAFETY CASES AND SAFETY ASSESSMENTS FOR NEAR SURFACE DISPOSAL OF RADIOACTIVE WASTE

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EXPERIENCES OF THE DEVELOPMENT, REVIEW AND COMMUNICATION OF SAFETY CASES AND SAFETY ASSESSMENTS FOR NEAR SURFACE DISPOSAL OF RADIOACTIVE WASTE

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2024

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FOREWORD

Virtually all countries have radioactive waste that requires disposal. Some of the more developed countries have several decades of experience in the development, authorization, construction, commissioning, operation, closure and monitoring of near surface disposal facilities, particularly for low level radioactive waste. Many other countries, including those planning to embark on nuclear power programmes, need to include the development and implementation of near surface disposal facilities in their radioactive waste management strategies. In addition, the provision of disposal routes for large volumes of low level waste is a key issue that can limit the progress of remediation and decommissioning activities.

As national programmes for radioactive waste disposal have progressed, considerable effort has been put into developing systematic and internationally recognized approaches for developing safety cases for disposal facilities. Developing the safety case for a disposal facility includes the conduct of safety assessments and the development of multiple lines of reasoning and arguments concerning the characteristics of the site and the facility engineering (i.e. the system of natural and engineered barriers). The safety case also addresses and includes suitable management arrangements and procedures for ensuring quality in all aspects of safety related work.

The IAEA has, over a considerable period, organized various international meetings on the safety of radioactive waste disposal, and has also coordinated a series of multi-year projects specifically on near surface disposal. These projects have included work (i) to benchmark safety assessment models, (ii) to develop improved safety assessment methods, (iii) to apply these improved methods to examples of proposed and existing disposal facilities and consider the regulatory review of their application, (iv) to enhance understanding of the safety case for near surface disposal facilities and (v) to explore approaches for the practical use of the safety case in the living management of near surface disposal facilities. These activities have provided a valuable and productive international forum for discussions, exchange of experiences, development of methodologies and mutual learning on safety assessments for waste disposal facilities, on the development of safety cases for waste disposal facilities, and on the practical use of such safety cases in developing and operating near surface disposal facilities.

In 2016, following the completion of the Application of the Practical Illustration and Use of the Safety Case Concept in the Management of Near-Surface Disposal Project, the IAEA began to facilitate the Forum on the Safety of Near Surface Disposal in 2017. This publication results from the work of the Forum during the period from October 2017 to September 2022.

The IAEA wishes to express its gratitude to all those who assisted in the drafting and review of this publication. The IAEA officer responsible for this publication was D.G. Bennett of the Division of Radiation, Transport and Waste Safety.

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1. INTRODUCTION

1.1. BACKGROUND

Virtually all countries have radioactive waste that requires disposal. Some of the more developed countries have several decades of experience in the development, authorization, construction, commissioning, operation, closure and monitoring of near surface disposal facilities. Many other countries, including those planning to embark on nuclear power programmes, need to include the development and implementation of near surface disposal facilities in their radioactive waste management strategies. In addition, the provision of disposal routes for large volumes of low level waste (LLW) is a key issue that can limit the progress of remediation and decommissioning activities.

As national programmes for radioactive waste disposal have progressed, considerable effort has been put into developing systematic and internationally recognized approaches for developing the safety case to demonstrate the safety of disposal facilities. Developing the safety case for a disposal facility includes the conduct of safety assessments and the development of multiple lines of reasoning and arguments, for example, concerning the characteristics of the site and the facility engineering (i.e. the system of natural and engineered barriers). The safety case also needs to address suitable management arrangements and procedures, among other aspects, for ensuring quality in all aspects of safety related work.

The IAEA has over a considerable period of time organized various international meetings on the safety of radioactive waste disposal, and it has also coordinated a series of multi-year projects specifically on near surface disposal (Safety Assessment of Near Surface Radioactive Waste Disposal Facilities (NSARS) [1], Safety Assessment Methodologies for Near Surface Disposal Facilities (ISAM) [2], Application of Safety Assessment Methods (ASAM) [3], and PRactical Illustration of the use of the Safety case concept in the Management of near surface disposal (PRISM) and PRactical Illustration of the use of the Safety case concept in the Management of near surface disposal - Application (PRISMA) [4]). These projects included work (i) to benchmark safety assessment models, (ii) to develop improved safety assessment methods, (iii) to apply these improved methods to examples of proposed and existing disposal facilities and consider the regulatory review of their application, (iv) to enhance understanding of the safety case for near surface disposal facilities, and (v) to explore approaches for the practical use of the safety case in the living management of near surface disposal facilities. These activities have provided a valuable and productive international forum for discussions, exchange of experiences, development of methodologies and mutual learning on safety assessments for waste disposal facilities, on the development of safety cases for waste disposal facilities, and on the practical use of such safety cases in developing and operating near surface disposal facilities.

The concept of the safety case was the focus of the two IAEA projects documented in Ref. [4]. PRISM addressed the nature and use of the safety case for decision making during the lifetime of a near surface disposal facility and included the development of the Matrix of Arguments for a Safety Case (MASC).

The follow on project, PRISMA, used MASC 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 disposal facility programmes. PRISMA concentrated on documenting the basis for decisions made in developing the content of a safety case. A step by step approach is recommended for managing disposal facility development, operation and closure over such long time periods.

FIG. 1. Organization of the Forum on the Safety of Near Surface Disposal.

Following completion in 2016 of the PRISMA project [4], the IAEA established the Forum on the Safety of Near Surface Disposal in 2017. The Forum is run by the Radioactive Waste and Spent Fuel Management Unit of the IAEA's Division of Radiation, Transport and Waste Safety and comprises four working groups, as shown in Fig. 1.

1.2. OBJECTIVE

The objectives of the Forum on the Safety of Near Surface Disposal are to:

- Provide an enduring forum that will assist Member States to ensure the safety of near surface disposal.
- Assist Member States to improve safety by:
  - Developing guidance, methods and tools as appropriate;
  - Enabling the exchange of information on good practices (e.g. on safety cases, safety assessment, technologies);
  - Providing opportunities for informal review of facilities and safety cases by peers.
- Facilitate education and training of staff.

The objective of this publication is to provide practical information for Member States on strategic decision making concerning the safe management of near surface disposal facilities. Information is also provided on experiences gained during the development and use of safety assessments and safety cases for informing regulatory and operational decisions on near surface disposal, and on areas in which further technical developments might be sought.

The target audience for this publication includes those involved in developing, operating and regulating near surface disposal facilities for radioactive waste and those involved in developing, reviewing and using safety assessments and safety cases for the disposal of radioactive waste.

1.3. SCOPE

This publication is primarily relevant to near surface disposal facilities for radioactive waste. It may also be of interest to those involved in other types of radioactive waste disposal.

1.4. STRUCTURE

The remainder of the publication is structured as follows:

- Section 2 presents and analyses experiences in the use of the safety case in decision making on near surface disposal and suggests a structured approach for using the safety case in decision making.
- Section 3 discusses regulatory experiences and processes relating to near surface disposal.
- Section 4 discusses experiences of post-closure safety assessment for near surface disposal.
- Section 5 provides information on the communication of the safety case for near surface disposal.
- Section 6 presents conclusions from the participants of the Forum on the Safety of Near Surface Disposal.
- The Appendix provides detailed information on regulatory review of the safety case.
- The Annex presents case studies on communication of the safety case for near surface disposal.

2. USE OF THE SAFETY CASE IN DECISION MAKING ON NEAR SURFACE DISPOSAL FACILITES

2.1. BACKGROUND

IAEA Safety Standards No. SSR-5, Disposal of Radioactive Waste [5], defines the safety case as “the collection of arguments and evidence to demonstrate the safety of a facility”. IAEA Safety Standards No. SSG-23, The Safety Case and Safety Assessment for the Disposal of Radioactive Waste [6] further states:

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

The main components of the safety case for a disposal facility for radioactive waste are illustrated in Fig. 2.

The safety case forms the basis of the major decisions taken for the development of a near surface facility for the disposal of radioactive waste (Fig. 3). At every stage of disposal facility development (see Fig. 3), the evolving or living safety case needs to be defensible with respect to the decision to proceed to the next stage. For example, the decision on licensing and operation in Fig. 3 assumes that the site has been selected and characterized, its safety has been assessed, the facility has been designed and constructed, and the safety case is being presented to support the decision to license and operate the facility.

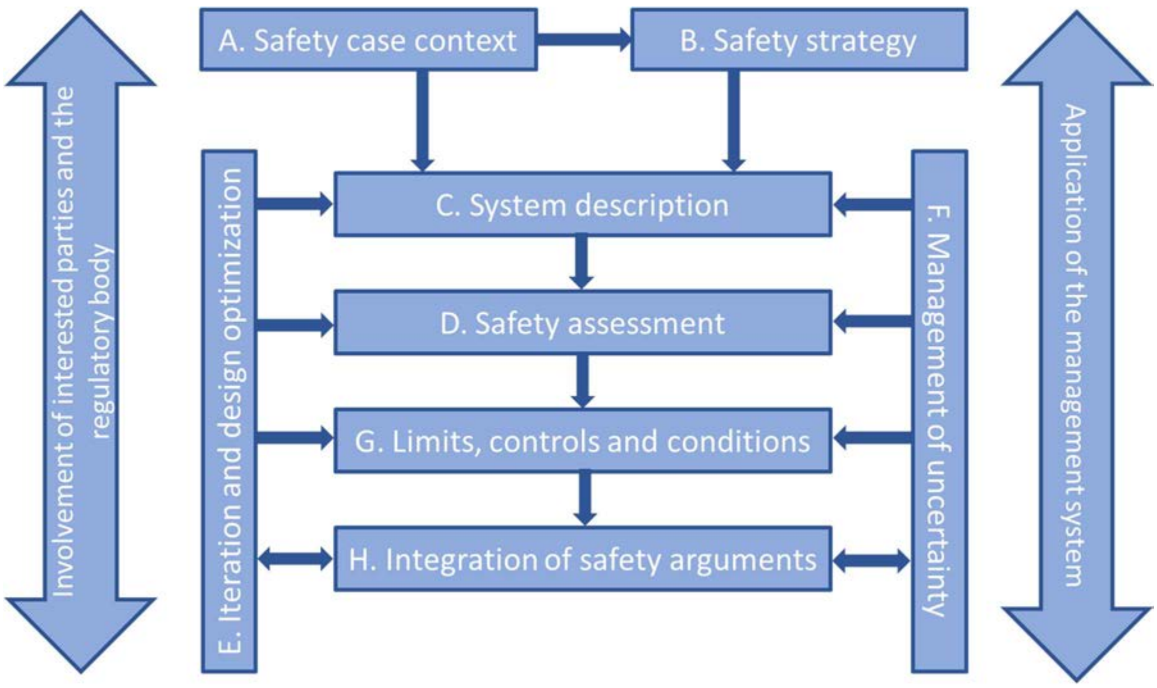

FIG. 2. The main components of the safety case for a disposal facility for radioactive waste (reproduced from SSG-23 [6]).

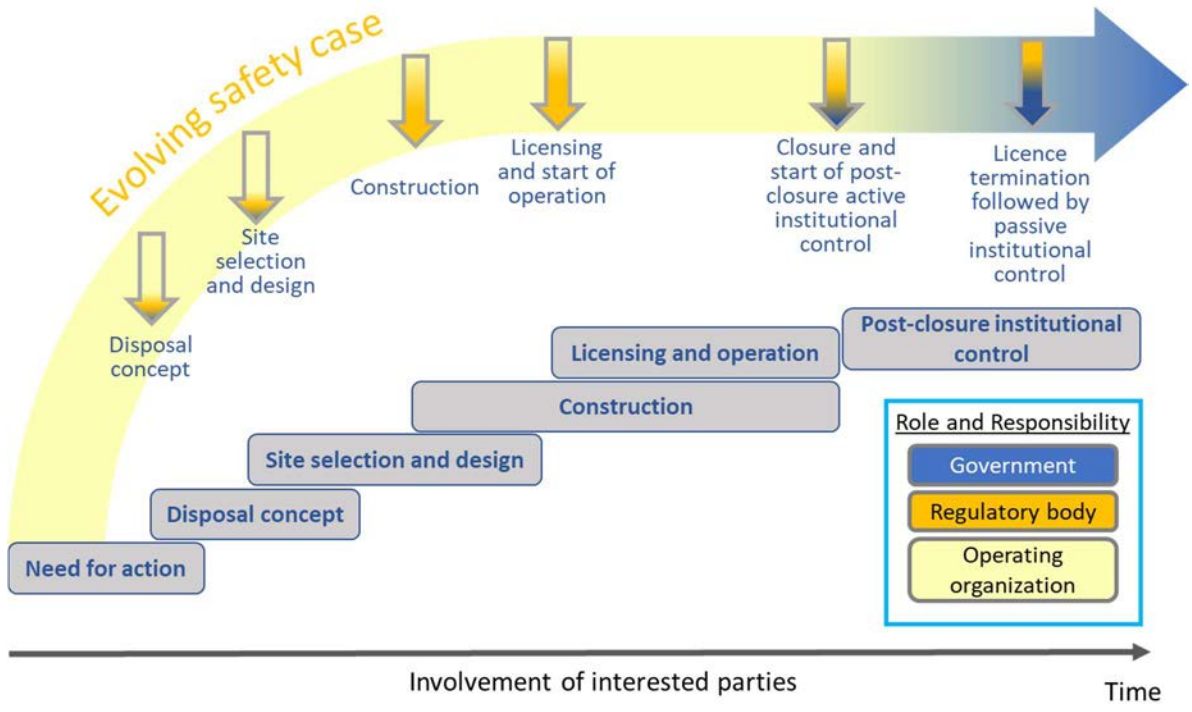

FIG. 3. The typical sequence of key decisions in the development of a disposal facility for radioactive waste (reproduced from Ref. [4]).

The development of the safety case to support decisions to move from one stage of disposal facility development to the next was part of the purview of the PRISM and PRISMA projects [4].

2.2. OBJECTIVES AND APPROACH

The objective of Section 2 of this publication is to document the practices of the use of the safety case in decision making in the framework of safety for near surface radioactive waste disposal facilities. The main audiences for this publication are operating organizations and other organizations and experts involved in the development of safety cases. The information may also assist those involved in the review process and those responsible for the development of acceptance criteria.

This text is a summary of discussions that were guided by a questionnaire sent out to members of Working Group 1, requesting input on how they had used safety cases in making decisions.

The questions asked to the participants were:

- What is the decision you are making?
- Who is deciding?
- What are the alternatives?
- What are the additional factors that affect the decision?
- How was the safety assessment or safety case used in making a decision?

The purpose of the template was not to constrain discussions but to make sure that all the basic components of decision making were addressed. As such, the responses provided information on the use of an existing safety case in developing, defining and refining components of that safety case in support of a subsequent step in disposal facility development or in the ongoing operation of a near surface disposal facility. There was a broad mixture of participants from operating organizations, regulatory bodies, safety assessors, and others involved in decisions relating to the safety case. The working group investigated real examples of whether and how the safety case had been and was being used to help make decisions in the Member States' waste management programmes. Based on the examples studied and existing IAEA guidance, the working group identified general lessons on the use of the safety case in decision making.

The majority of the work was performed during plenaries and associated preparation prior to plenaries. Participants were asked to make presentations on the topic at hand. There was significant change in the make-up of the participants over the life of the project.

The complete list of areas covered by Working Group 1 was as follows:

- Waste acceptance criteria (WAC);
- Facility design;
- Site characterization;
- Site selection.

For each area, and especially for WAC, participants assembled a long list of decisions that individuals and programmes were and are faced with, and topics that could be addressed. A focus on individual issues would provide more insight on those individual topics, but might not lead to the development of a general process for using the safety case in decision making. Therefore, these issues were analysed at a higher, more integrated level to search for commonality in the approach to using the safety case for decision making.

Excluded from Working Group 1's remit were, at one end, the decisions made by the operating organization on safety assessment (a key part of the safety case), such as which models and data to use, and at the other end, decisions taken by the regulatory body in accepting or rejecting a safety case.

Finally, the operating organizations of individual near surface disposal facilities performed extensive work in proposing and analysing options for site selection, WAC, facility design, and site characterization for individual facilities. In many cases the analysis of options took years to complete. Details of these efforts are not included in this publication, which instead captures the high level connections between these decisions and the safety case.

2.3. EXISTING REQUIREMENTS AND GUIDANCE

The IAEA safety standards contain requirements and recommendations on the use of the safety case and safety assessment in decision making (e.g. SSR-5 [5], GSR Part 4 (Rev. 1) [7]). Some safety standards address considerations and recommended practices for using the safety case and the safety assessment in making decisions.

SSR-5 [5] establishes safety requirements relating to the disposal of radioactive waste of all types and sets out the safety objective and criteria for the protection of people and the environment radiation risks.

The series of quotes from SSR-5 [5] below acknowledge or require the use of the safety case and/or the safety assessment in decision making:

— Paragraph 4.6: “The safety case is an essential input to all important decisions concerning the disposal facility.”
— Paragraph 4.12: “A facility specific safety case has to be prepared early in the development of a disposal facility to provide a basis for licensing decisions and to guide activities in research and development, site selection and evaluation and design.”
— Paragraph 4.13: “Safety assessment has to provide input to ongoing decision making by the operator. Such decision making may relate to subjects for research, development of a capability for assessment, allocation of resources and development of waste acceptance criteria.”

SSR-5 [5] is clear that the safety case and safety assessment are integral in decision making for the disposal of radioactive waste, even though the specific decisions to be taken are not spelled out.

SSG-23 [6] provides recommendations on meeting the safety requirements in respect of the safety case and safety assessment for the disposal of radioactive waste. SSG-23 [6] presents a series of statements supporting the use of the safety case and safety assessment in decision making, including the following:

— Paragraph 7.18: “The primary objective of the safety case is to support decision making relevant to the stage of the development, operation and closure of a disposal facility.”
— Paragraph 1.3: “The safety case and supporting safety assessment… will assist and guide decisions on siting, design and operations.”
— Paragraph 2.10: “Safety assessment, monitoring, and research and development programmes should be used to inform management decisions on the operation and closure of the facility.”
  - Paragraph 4.6: “[T]he role of the safety case should be to provide… [s]upport to decision making in the step by step approach to development of a disposal facility”.

SSG-23 [6] makes a number of recommendations regarding the use of the safety case in decision making. First, SSG-23 [6] outlines the scope and timing of decisions, stating in para. 4.65:

> “Early iteration in the decision making process should be undertaken with the available data and capacity for conducting assessment. The iteration needs to proceed only until the assessment is judged to be adequate for its purpose. Furthermore, additional information needs to be acquired only to the extent necessary to improve the basis on which the decisions will be made. Some decisions may necessitate iteration in respect of only one specific aspect of the safety case (e.g. the improvement of the data requirements for a specific model). Other decisions may necessitate more iterations, which may involve revisions of several components of the safety case, such as:
> — The context for the safety case may be adjusted to, for example, treat uncertainties more realistically or to broaden the range of receptors considered;
> — The strategy for safety may be revised;
> — New data about the site may become available and/or the design may have been developed further;
> — Triggered by such changes or by other factors (e.g. the results of peer reviews), the components of the safety case and supporting assessment may need to be revised and developed further.”

SSG-23 [6] also lists critical aspects of decision making including the need to examine alternatives. Paragraph 4.70 states:

> "Examination of alternative means of carrying out a project involves answering the following three questions:
>
> — What are the alternatives?
> — What are the impacts, in particular the advantages and disadvantages, associated with each alternative?
> — What is the rationale for selecting the preferred alternative?"

Paragraph 6.79 of SSG-23 [6] states:

> "Decision making … necessitates comparison of different management options and identification of the option that complies with all of the applicable regulatory requirements and provides an optimal level of protection, with factors such as costs and other detrimental factors taken into account."

With respect to the actual decision making process, para. 6.82 of SSG-23 [6] states:

> "Assessment results and their implication for the decisions to be made can be evaluated by means of a qualitative process, involving deliberation of all relevant factors. Quantitative methods such as cost-benefit analysis or multi-attribute utility analysis can be applied to address and balance the various factors relevant for the decisions to be made."

Paragraph 6.83 of SSG-23 [6] cautions:

> "If quantitative assessment methods are applied, these methods should be seen as tools to aid the decision making process, not as a substitute for the process. …The main role of these decision aiding methodologies lies in the analysis and presentation of assessment results in a conceivable and comprehensive way that enables judgements to be made of their respective importance and implications for the decisions required."

SSG-23 [6] notes the need to address uncertainties in decision making and goes further to describe some attributes of, and approaches to, addressing uncertainties and provide a warning on the use of conservative analysis to support decision making:

— Paragraph 4.67: "For some decisions on the optimization of protection and safety, a qualitative approach based on expert judgement and on utilization of the best available and proven technology may be sufficient."
— Paragraph 5.13: "Another strength of the probabilistic approach is that it allows examination of the projected performance of the disposal system under a range of conditions and assumptions, and therefore contributes to the robustness of the safety case and the regulatory decisions."
— Paragraph 5.19: "Caution is necessary, however, because, if misused, results from overly conservative or worst case representations of the disposal system may lead to poor decision making that is based on assessment results that bear little resemblance to the actual performance of the facility."

Paragraph 4.59 of GSR Part 4 Rev. 1 [7] states that "Uncertainties that may have implications for the outcome of the safety analysis and for decisions made on that basis shall be addressed in uncertainty and sensitivity analyses."

SSG-23 [6] specifically addresses the special case of the reassessment of existing facilities and decision making, stating:

- Paragraph 6.88: “For an existing situation, assessments should usually be conducted in two distinct steps. In the first assessment step, it should be determined whether corrective action needs to be considered at all or whether the current condition of the facility is considered acceptable. In the second assessment step, performed only if necessary on the basis of the results of the first step, options to improve the situation should be identified and evaluated.”
- Paragraph 6.89: “In particular for existing facilities, for which several feasible options for corrective actions are available, the comparison of corrective actions should usually be performed iteratively:
  - It may be possible to disregard some options for corrective actions very early on, e.g. because of prohibitive costs or because it soon becomes evident that basic regulatory requirements cannot be met.
  - The assessment of the implications of the remaining options for corrective actions with regard to the factors to be considered in the decision making can be very time consuming and resource consuming. The decision making may even face fundamental difficulties if a basis for determining precise estimates does not exist (e.g. with respect to the durability of structures). Instead of investing great efforts in trying to improve estimates for such factors, their relevance for the decisions to be made should first be examined. It may turn out that prevailing uncertainties in some factors will not influence a particular decision because it is dominated by other factors. If this is the case, the uncertainties can be accepted and further assessment efforts are not necessary in this respect. As a justification for the decision can be provided on the basis of assessment results, the uncertainties in these factors will not interfere with the overall requirement to build confidence in the assessment.
  - In accordance with the graded approach, the level of effort invested in improving data and the modelling should be commensurate with the importance of the various factors for the decisions to be taken. Within an iterative process, the implications of the results and their uncertainties for the decision making can be ‘tested’ to identify those aspects that warrant further refinement on the basis of their relevance for decision making.”

In the most extreme case, SSG-23 [6] discusses decisions that could lead to reversal of earlier decisions. Paragraph 6.74 states:

> “The more general concept of reversibility denotes the possibility of reversing one or a series of steps in the planning or development of the disposal facility. This implies the review and, if necessary, re-evaluation of earlier decisions, as well as availability of the means (technical, financial, etc.) to reverse a step.”

And finally, para. 4.98 of SSG-23 [6] addresses the essential need to fully document decisions:

> “Traceability requires a clear and complete record of the decisions and assumptions made, and of the models, parameters and data used in arriving at a given set of results. …. The records should include structured information on when, on what basis and by whom various decisions and assumptions were made, how these decisions and assumptions were implemented, what modelling tools were used, and what the ultimate sources are for the data.”

While providing a great deal of guidance on decision making, SSG-23 [6] does not address how the safety assessment and the safety case could be used for decision making.

IAEA-TECDOC-1380 [8] addresses the question of how to use the safety assessment to determine waste activity limits, and in doing so slightly modifies the ISAM safety assessment methodology [2]. Figure 4 shows this modified methodology.

Setting waste activity limits is an iterative process starting with either the use of (a) a unit activity for the radionuclide of interest; or (b) the activity of that radionuclide for a predefined inventory.

Starting with a unit activity ought to result in a calculated potential dose less than the radiological protection criteria. The activity limit is then found by scaling up the unit activity to a point where the safety assessment provides a calculated dose or risk that is equal to (or, as needed, less than) the relevant radiological protection criteria (e.g. the dose constraint for exposure of the public).

If the process is started with a predefined inventory, the safety assessment is used to calculate a potential dose from that inventory, and then the activity limits are scaled up or down to yield a dose equal to or less than the radiological protection criteria.

Important decisions relating to the non-quantitative aspects of the safety case are ones of completeness and quality or defensibility. For example, the IAEA has defined and trialled the use of the MASC for assessing the completeness of the components of a safety case at different stages in the development of a near surface disposal facility [4]. The safety case related decisions in this case concern which and how much data and information to gather to complete the MASC in developing and defending the arguments of the safety case (see Table 1 below for an example of a MASC for the first step in the development of a near surface disposal facility — the need for action).

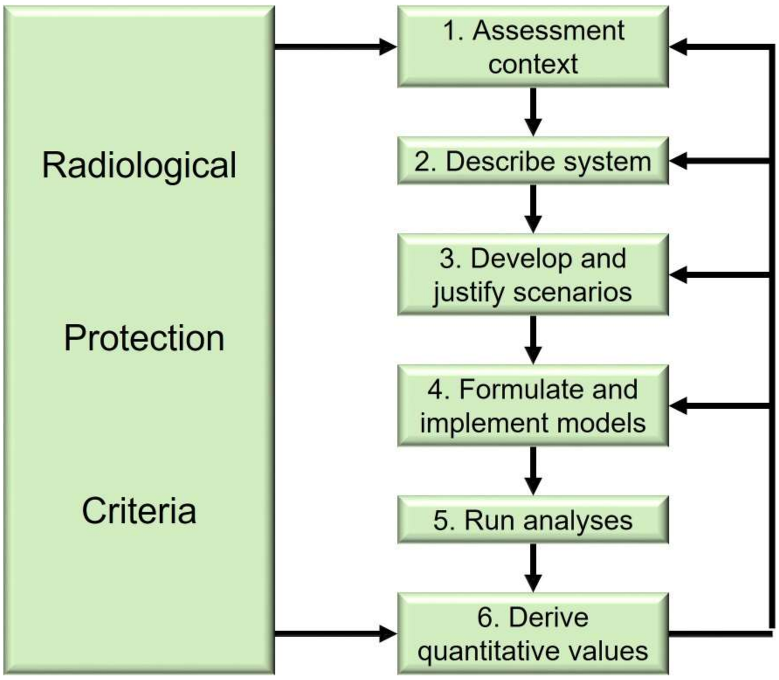

FIG. 4. Approach to defining waste activity limits (reproduced from Ref. [8]).

TABLE 1. THE PRISM MASC MATRIX [4]

General Data				
Name				
Country				
Audience				
Disposal facility				
Main decision-making steps	**NEED FOR ACTION**			
Decision alternatives	Storage, disposal, export to a foreign country			
RECOMMENDED DECISION				
DECISION SUMMARY				
	Basis for the decision	**Rationale for the decision**	**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				
Management and Stakeholder				
INVOLVEMENT OF STAKEHOLDERS				
MANAGEMENT SYSTEM				
– Organization				
– Staff competence				
– Quality assurance				
– Record keeping/traceability				
REGULATORY PROCESS				
– Management system				
– Licensing process				
– Early and continuous involvement				
Safety Strategy				
OPTIMIZATION				
MANAGEMENT OF UNCERTAINTIES				
ROBUSTNESS				
DEMONSTRABILITY				
PASSIVE SAFETY				
IMPORTANCE OF ENGINEERING SCIENCE				
COMPARISON OF OPTIONS				
GRADED APPROACH				
System Description				
WASTE CHARACTERISTICS				
DESIGN				
SITE CHARACTERISTICS				
SAFETY FUNCTIONS				
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				
– Multiples lines of reasoning				
RESEARCH AND DEVELOPMENT				
PLANS FOR ADDRESSING UNRESOLVED ISSUES				
Limits, Control and Conditions				
CONDITIONS				
LIMITS (Dose, risk, activity limits, …)				
CONTROL (Conformity …)				

2.4. EXPERIENCES AND INSIGHTS

2.4.1. General insights on the decision making process

The following sections describe the results and lessons learned from Working Group 1's discussions on the use the safety case in decision making for the site selection, WAC, facility design, and site characterization. Decision making, by definition, is a choice among alternatives. Paragraph 4.70 of SSG-23 [6] specifically recognizes the need to discuss alternatives in decision making. Examples of the alternatives considered are presented in relation to site selection, WAC, facility design and site characterization. These examples are by no means exhaustive, but provide some basis for discussion of the use of the safety case in decision making. The choice between alternatives is supported by the chosen decision metrics and decision criteria. The decision metrics are the quantities being measured and/or assessed. Decision criteria are values of decision metrics. Some decision criteria are fixed (see (a) in Fig. 5) in that they have a value that is not to be exceeded, except with specific, defensible justification. The other criteria are used to provide information that can be used to, for example, inform the design decisions. An example of a fixed criteria would be an annual dose level set by the regulatory body. An example of a criteria that would be used to provide information would be groundwater flow, which would then be used to inform the design of facility barriers that at the end has to meet the fixed criteria.

Important decision criteria for a near surface disposal facility would include dose and risk constraints. With a few possible exceptions, e.g. dose to workers, radionuclide concentrations in leachate, some criteria are not directly measurable or it might not be possible to define criteria. An example of this is post-monitoring period barrier evolution and performance. This cannot be directly measured, so decision criteria can only be set using modelled values. Instead they are considered in safety assessment as a combination of decision metrics such as those listed in the previous sections. For example, precipitation, infiltration, groundwater gradients, rock permeabilities, porosities, and sorption properties combine to produce estimates of radionuclide transport from the facility to the accessible environment. An almost infinite combination of parameter values for these metrics can produce the same radionuclide transport rates and concentrations. At a higher level, this natural barrier is combined with the alternative facility designs to yield the same post-closure doses and risks. Decision criteria are used to inform subsequent stages of decision making. However, decisions are generally not based on one metric but are a combination of all metrics considered to support an overall decision. Setting of decision criteria includes consideration of the information that the decision step is trying to determine (see (b) in Fig. 5).

The ultimate aim is an acceptable safety case and this is much more elusive and difficult to define. The IAEA has defined the components of a safety case in SSG-23 [6] and analysed the types of arguments that can be included in safety cases (e.g. in Ref. [4]), and there are many well documented safety cases among the Member States. The difficulty is in deciding which arguments to make and which evidence to gather and present in developing an acceptable safety case, including how to address uncertainties. Acceptable implies acceptance by stakeholders, such as the regulatory body or other interested parties, including the public.

The relationships between the safety assessments that calculate potential doses and risks (to demonstrate compliance with the dose and risk criteria) and the safety case are documented in the safety case. Said simply, without an adequate safety case, no confidence can be ascribed to the calculated doses and risks from the safety assessment. The safety case forms the basis for the assumptions and construction of the safety assessment as well as informing parameter choices that are consistent the safety case knowledge of the site and facility.

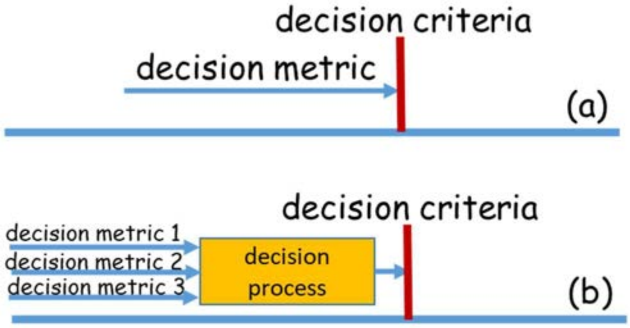

FIG. 5. The relation between decision metrics and decision criteria: (a) decision criteria directly related to the decision metric; and (b) combined decision criteria (courtesy of P. Davis, Envirologic and J. Perko, SCK•CEN).

2.4.1.1. Roles and responsibilities

Working Group 1 participants had different experiences of and opinions on the identity of the decision maker when it comes to selecting a site, choosing a facility design or defining the WAC. The safety standards clearly define these decisions as being the responsibility of the operating organization. Although clearly no WAC or facility design can be implemented without the acceptance of the regulatory body, the purview of Working Group 1 is that the use of the safety case in decision making is the responsibility of the operating organization. The operating organization develops the safety case and the operating organization uses the safety case to select a site, define the WAC, design a facility, and control the receipt of waste at the facility. And while the regulatory body could have an influence on site selection and site characterization, those decisions almost always reside with the operating organization.

The roles and responsibilities at different stages of disposal facility development are described in TECDOC-1814 [4]. In brief, three main roles can be distinguished:

- The government has overall responsibility for decisions on nuclear activities and radioactive waste disposal;
- The role of the operating organization is to develop and operate a safe disposal facility;
- The role of the regulatory body is to ensure that the operating organization is a suitable organization and sites and operates in an appropriate and safe way.

2.4.1.2. Uncertainty and decision making

Uncertainty in decision making is fundamentally different and not directly related to technical uncertainty, that is, uncertainty in data and parameters, uncertainty in features, events and processes (FEPs) (and scenarios), or other uncertainty in the safety assessment. It is entirely possible that, for a given choice between alternatives, decision making is insensitive to technical uncertainties. For example, uncertainties in the porosity of the natural barrier might not be a determinate in a choice between two facility caps or covers in facility design. Uncertainty in the parameters of natural barriers might not be different between two sites in the site selection process, excluding that uncertainty from the decision. And the ultimate decision — on whether the site is safe — might not be affected by many of the technical uncertainties.

For example, a disposal facility at a site in a very arid climate in an isolated region might be safe, even with large uncertainty in the parameters that control radionuclide transport. Another example might be a disposal facility at a site in a very humid environment close to population centres, whose safety is reliant on engineered barriers. Again, the uncertainty in radionuclide transport through the natural barriers would not be a determinate in whether or not the site is safe.

Thus, the key to managing (i.e. identifying, quantifying, propagating and reducing) uncertainties is to focus on their impacts on decisions, rather than the absolute or relative uncertainty.

Uncertainties associated with site selection, facility design, establishment of WAC, and site characterization derive from uncertainties in a number of factors, including in: the inventory, parameters and processes that control the release, leaching and transport of radionuclides; conceptual and mathematical models; and human behaviour (receptors). Uncertainties can broadly be categorized as scenario, model, and parameter uncertainties.

2.4.1.3. Scenario uncertainty

Scenarios can be used to represent possible the future evolution of a disposal system and have often been characterized as comprising sets or series of FEPs. From this point of view, decisions on site selection, WAC, facility design and site characterization can be related to the consideration of scenarios, even if facility conditions are not expected to change over time. However, in the experience of the Working Group 1 participants, the consideration of scenarios when making such decisions was almost exclusively implicit and qualitative, with only a few decisions being influenced by an explicit, structured and quantitative assessment of scenarios in safety assessment.

The use of the safety assessment in setting WAC provides an example of the structured, quantitative approach to decision making. Members of Working Group 1 who used the safety assessment to set the activity limits, analysed sets of scenarios. In each case, the most restrictive scenario analysed was chosen as the basis for setting activity limits. Whether the scenario related to the operational or post-closure period, to normal operations or to unexpected events including accidents, or to the expected post-closure evolution or to human intrusion, or to the gas, groundwater or surface water pathway, the most restrictive scenario on an radionuclide by radionuclide basis was used in setting activity limits.

Similar choices of scenarios (i.e. conservative) were employed by Working Group 1 members who used the safety assessment to decide among alternative facility designs.

In one case, a participant described the use of sensitivity analysis to investigate the final activity limits and provide assurance that the facility would be safe even for more extreme scenarios.

In general, operational scenarios were the most limiting for short lived radionuclides (e.g. ^{60}Co), release and leaching followed by radionuclide transport in groundwater were the most restrictive scenarios for long lived, non-sorbed radionuclides (e.g. ^{10}Be, ^{14}C and ^{129}I), and long lived sorbing radionuclides (e.g. ^{94}Nb) were the most limiting for human intrusion scenarios.

The final decision on the activity limits involved not only identifying the limiting radionuclides, but also assessing the cumulative impacts of multiple radionuclides, waste packages and waste streams.

2.4.1.4. Model uncertainty

A conceptual model is a set of qualitative assumptions used to describe a system (or part thereof). These assumptions would normally cover, as a minimum, the geometry and dimensionality of the system, initial and boundary conditions, time dependence, and the nature of the relevant physical, chemical and biological processes and phenomena.

In general, conceptual model uncertainty, although inherent in safety assessment and throughout safety case development, was with a few exceptions, not addressed in decision making. An exception was the use of different conceptualizations for processes within engineered barriers (continuum transport versus fractured media).

2.4.1.5. Parameter uncertainty

Here, parameters are defined as the safety assessment inputs that can take particular values. Metrics, like hydraulic conductivity, that become input parameters, are discussed below. By this definition, parameter uncertainty only pertains to decisions made using the safety assessment, which for Working Group 1 included decisions regarding facility design and the WAC. In almost every case considered by Working Group 1, conservatism was relied on to address parameter uncertainty. The same approach (conservatism) is relied on within TECDOC-1380 [8]. In one Working Group 1 example, a model that relied on the lower bound of sorption parameters was used to define the activity capacity of the site. A measure of the conservatism was then provided by comparison with a model based on the best estimate sorption values. Conservatism might provide a degree of confidence to the safety assessment results and the associated WAC, but it might also produce results that are either unduly pessimistic (resulting in unnecessary limits on the WAC and facility operations and additional costs) or might provide the wrong basis for decision making. An example would be the fact that more conservatism is given to radionuclides with stronger sorption compared to more mobile radionuclides. In practice, this means that the WAC penalizes strongly sorbed radionuclides much more and so biases the decision.

Defining conservatism when the specific criteria are not direct inputs to the safety assessment is much more difficult. For example, the safety assessment can be used to identify a waste package lifetime that results in adequate safety. Conservatism could then lengthen that lifetime. As discussed previously, however, estimates of the waste package lifetime are based on combinations of other factors, and variations of these factors can all yield the same waste package lifetime. In addition, conservatism is already inherent in these WAC parameters, so there is a risk of placing further conservatism on top of existing conservatism.

2.4.1.6. The safety case and uncertainty

The most critical uncertainties are those found in the safety case and not quantified in the safety assessment. It is the safety case that defines and manages uncertainty by performing phenomenological studies, deciding what data to collect, where to collect it, what methods to use in collecting data, and ensuring adequate quality assurance and quality control throughout the process of data collection and analysis. The safety case includes the system description that forms the basis for the safety assessment and from which the safety strategy is defined (e.g. including the relative reliance placed on natural and engineered barriers).

2.4.1.7. Stage of disposal facility development

The decisions addressed by Working Group 1 cover almost all stages of disposal facility and safety case development (see Fig. 2 above), with setting and adjusting WAC possibly preceding site selection and continuing until closure. Site selection comes early in disposal facility development. Site characterization begins during site selection and, according to some participants, continues throughout operations. Facility design starts during site selection at which point redesign is possible, and may even be likely, and continues through operation. Optimization is a key driver for facility design.

The primary message from participants with regard to decision making at the disposal facility development stage was, to the extent possible, to minimize programmatic risk. Herein, programmatic risk is considered to be the risk that a decision taken at an earlier stage of disposal facility development will have to be reversed at a later stage with significant negative consequences. The most discussed example associated with programmatic risk was setting the WAC. Regardless of the stage of facility development, the WAC need to be set with all subsequent stages in mind. In most cases considered by the working group the generation of waste preceded the development of the disposal facility, and the waste generator had to proceed using at least preliminary WAC in the absence of a site or a safety case. These preliminary WAC have to be reviewed, updated and refined as needed, as a site is selected and the disposal facility develops. The WAC might need to be adjusted as a result of proposals to accept new waste streams or to make changes to an existing waste stream, to the facility design and, perhaps most importantly, to take account of an evolving safety case, for example, based on an increasing knowledge of the site and waste characteristics. The challenge is to set preliminary and subsequent WAC such that waste will not have to be removed and repackaged at a later stage of disposal facility development, while at the same time, recognizing that the WAC may be expanded later based on increasing confidence in the facility safety.

2.4.1.8. Possible relations between the decision and the safety case

In general, two types of relations between the safety case and decisions can be distinguished. First, a limited number of decisions are based on the quantitative relation between the safety assessment component of the safety case and the decision. Decisions related to the quantitative results of the safety assessment include components of the WAC and aspects of the facility design.

Second, and much more frequent, decisions are qualitatively related to the remainder of the safety case, including the qualitative aspects of the safety assessment. In other words, the decisions — be they on site selection, WAC, facility design, or site characterization — are not quantitatively related to risk and dose criteria through the safety assessment. Instead, they are related to non-quantitative aspects of the safety case. In some cases, stakeholders may have views that affect decisions on the development of near surface disposal facilities. Sometimes these requirements are linked to the national waste classification, for example, the prohibition of intermediate level waste from disposal in near surface disposal facilities. These prescriptive requirements can also include more detailed and technical constraints, such as limits on void space, limits on the volume of free liquids inside waste containers, and the prohibition of the disposal of bituminous waste. Such prescriptions allow disposal programmes to proceed with the development of preliminary WAC prior to the development and use of a site specific safety case. The problem discussed in Working Group 1 was the need or desire to dispose of wastes that did not comply with prescriptive requirements, but where the site specific safety assessment and/or the rest of the safety case could include these wastes without exceeding dose or risk constraints. The regulatory body may, on a case by case basis, accept the site specific assessment as a justification to override prescriptive requirements.

2.4.1.9. Methodology and documentation related to the decision making process

Decision making can be done by expert judgement or by following a formal decision making process. There are benefits to following a formal decision making process that is documented such that the key parameters and factors that inform the decision are identified. Several techniques are designed specifically for the explicit consideration of a wide range of factors that can influence decisions. These techniques involve assigning a relative importance to each of the factors in making a specific decision.

A number of external factors, such as cost and public acceptance, could affect the decision. A formal decision making process is most often used in site selection. Whether or not the external factors actually affected the decision was somewhat dependent on whether the decision was a direct outcome of the safety assessment or not. For example, activity limits derived from the safety assessment were, in all cases presented, not changed by consideration of external factors. For decisions that did not utilize safety assessment, expert judgement was used in weighing these external factors. Cost was consistently mentioned as an external factor that could affect decisions, but no Working Group 1 member had an example where cost was a primary factor in an actual decision.

2.4.1.10. Addressing programmatic risk

Programmatic risk arises from taking a decision that may later have to be reversed. Overall, perhaps the largest programmatic risk — a risk that could affect all decisions — is a change in policy governing the disposal of radioactive waste or in the regulations. Such changes were identified in the PRISM and PRISMA projects [4] as the most significant and frequent programmatic risk.

After changes in policy and regulations, site selection probably has the largest programmatic risk. After site selection has been completed, however, reversing or revising any of the later decision steps probably presents a lower programmatic risk but could still result in additional costs, programmatic delays, and perhaps loss of public trust.

Setting WAC can present significant programmatic risk, as the WAC can change throughout disposal facility development. Working Group 1 participants involved in operating facilities also identified the potential need to change the WAC based on new waste streams, changes in facility design, and changes in the knowledge about the site.

In all cases discussed, basing the WAC on conservative parameters and assumptions minimized programmatic risk arising from changes in site understanding. To do this, however, conservatism needs to be truly demonstrated and defended. The examples of more restrictive WAC in the development of the disposal facility show that conservatism is difficult to demonstrate. Moreover, changes in design, changes in policy and regulations, and changes in the system knowledge (via site characterization) among other factors, could conceivably result in the WAC being more restrictive than before. Such changes could result in repackaging, additional waste treatment or, in the worst case, retrieval of disposed waste.

2.4.2. Detailed insights on the decision making process

This section provides more detailed insights into decisions for the selected list of areas, namely site selection, site characterization, waste acceptance criteria and design. Each area is described by four subsections stemming from the template given to the participants and encompasses the alternatives that were considered, the decision metrics, decision criteria and the relation between the decision and the safety case.

2.4.2.1. Site selection

Every site selection example presented to Working Group 1 involved at least two stages, starting with an initial list of candidate sites, the use of exclusion criteria to yield a subset of sites, and a final selection of the candidate site. The candidate site was then to be investigated and potentially used for the near surface disposal facility. The approach generally follows that described in Appendix I of IAEA Safety Standards Series No. SSG-29, Near Surface Disposal Facilities for Radioactive Waste [9]. Critically, there was little support for the idea of finding the best site mainly because of:

(1) The difficulty in defining the meaning of 'best' and to demonstrate that the site is truly best;
(2) The realization that equivalent site safety can be provided by different combinations of factors for different sites and designs.

Instead, the site searches generally focused on acceptable sites, where 'acceptable' means that the combination of site characteristics, engineering and WAC are likely to provide adequate safety. For the siting of near surface facilities the clear aim remains finding an acceptable safe solution rather than finding the 'best' site.

(1) Alternatives considered

First, countries generally screen for sites at which a near surface disposal facility might be developed. Once a site is chosen, they then decide on an exact location within that site for the construction of the disposal facility. For site screening, in the examples presented to Working Group 1 as many as 34 alternative sites [10] to as few as three were considered within a single country. In some countries, candidate sites were distributed across the entire territory, in others they were within a predefined area or limited to existing nuclear zones or sites where local authorities showed an interest.

(2) Decision metrics

General agreement was observed for decision metrics between different countries when it came to site selection. First, metrics were divided into natural and anthropogenic. Natural metrics focus on the ability of the site to isolate radionuclides from the accessible environment. Such metrics include, among other factors, precipitation rates, topography, infiltration rates, groundwater flow velocities, rates and magnitudes of seismic activity. Anthropogenic metrics include population density, transportation times and distances and availability of mineral resources.

(3) Decision criteria

Finally, Working Group 1 discussions addressed the issue of whether or not public acceptance ought to be a criterion, especially for site selection. The metric of public involvement was strongly supported by Working Group 1 participants. Some programmes, such as the programme on geologic disposal in the United Kingdom, go further and require public acceptance for site selection. Working Group 1 felt it highly desirable that the public supports all decisions but did not reach a consensus on making public acceptance a criterion, that is, a requirement to proceed.

(4) Relation between the decision and the safety case

Decisions related to site selection were not based on the safety assessment. When it comes to making decisions using the safety case, site selection deserves special attention because the selection of a site generally precedes the development of the safety case. However, the metrics presented for site selection are generally components of the safety case or its subcomponent, the safety assessment. What most of these components lack at the time of site selection are data from site characterization.

Site selection and site characterization can add confidence to the safety assessment and safety case by exclusion. For example, many programmes exclude areas of known mineral and other reserves, thereby minimizing the probability of future human intrusion — a critical and difficult issue for safety assessment to address. Site characterization might result in less uncertainty and, therefore, provide additional confidence but it can also be viewed as adding confidence by excluding potential parameter values, process models and/or scenarios.

2.4.2.2. Site characterization

Site characterization includes desktop, laboratory and field studies of geology, geohydrology, geochemistry, tectonics and seismicity, surface processes (e.g. erosion, flooding, landslides), meteorology and features associated with human activities including infrastructure, mineral resources and land use (see Appendix II of SSG-29 [9]).

Site characterization does not initially sound like a decision problem. The directive to 'characterize the site' seems like a well defined task that could be subcontracted to a consulting company who would deliver a characterized site.

However, site characterization is anything but a straightforward exercise with a predetermined endpoint. To begin with, there is no definition of a 'characterized site,' no universal agreement on how to go about characterizing a site, and no agreement on the level of uncertainty acceptable in site characterization.

Perhaps a few words on what site characterization decisions are not about will help elucidate site characterization decisions.

Generally, investigators attempt to use all available existing data and analyses (desktop studies). Therefore, the decisions are rarely about desktop versus laboratory or field studies. In fact desktop studies form the basis for site selection, which is conducted prior to formal site characterization.

Next, decisions are rarely about the method of obtaining new data — laboratory versus field studies. In general, laboratory studies focus on detailed investigation of processes or parameters where conditions can be controlled and at a scale unaffected by field scale variability (i.e. heterogeneity).

And lastly, one specific type of data collection — drilling boreholes — combines data collection in a manner that eliminates or minimizes specific decisions between the type of data collected. For example, data gathered from the drilling of a single borehole usually includes defining lithology and stratigraphy with the collection of hydrologic, hydrochemical, and geophysical data. Said another way, the decision to drill a borehole is a single decision to collect many types of data at one location.

The real site characterization decisions are about what data are needed to support safety assessment modelling and the need for the safety case to demonstrate sufficient understanding of the site and the disposal system, and that means deciding what types of data to collect (e.g. hydrologic, geochemical, geophysical), where to collect them and, the most difficult decision, when characterization is complete.

(1) Alternatives considered

When it comes to site characterization, the alternatives are numerous, almost infinite. Alternatives for characterization include different locations for exploratory boreholes, different depths for those boreholes, different processes to investigate (e.g. chemical, hydrological, geophysical), different phenomena to investigate (e.g. faulting, flooding, natural resource extraction), with different approaches and extents for investigating these same processes and phenomena.

(2) Decision metrics

Decision metrics for site characterization are very similar to those for site selection; they include, but are not limited to, the geology, rates of surface erosion, rates and magnitude of seismic activity, rates and direction of groundwater flow, and the geotechnical properties of the soil and bedrock. Determinants of the rate of groundwater flow within the facility include the thickness, permeability and slope of covers, the permeability of monoliths and vaults, and the permeability of the materials that surround the monoliths and vaults. Decision metrics for groundwater flow in the vicinity of the facility site include the geometry of geologic layers, their permeability and porosity, and the directions and magnitude of hydraulic gradients. Finally, precipitation (and meteorology in general) is a metric that affects other metrics including erosion and surface and groundwater flow.

(3) Decision criteria

There can be no criteria set for most of the metrics listed in the previous sections. For example, precipitation, infiltration, groundwater gradients, rock permeabilities, porosities and sorption properties combine to produce estimates of radionuclide transport from the facility to the accessible environment. An almost infinite combination of parameter values for these metrics can produce the same radionuclide transport rates and concentrations. At a higher level, this natural barrier is combined with the alternative facility designs to yield the same post-closure doses and risks. Therefore, setting and/or trying to achieve criteria for these metrics has little meaning or value.

(4) Relation between the decision and the safety case

Most decisions related to the site characterization, are not related quantitatively to risk and dose criteria through the safety assessment. Instead, they are related to non-quantitative aspects of the safety case. Important decisions relating to the non-quantitative aspects of the safety case are ones of completeness and quality or defensibility. Here, safety case related decisions concern which and how much data and information to gather. Deciding when the collected data are sufficient to defend safety case arguments is particularly difficult.

2.4.2.3. Waste acceptance criteria

Of all of the potential uses of the safety case (and safety assessment) in decision making, defining WAC was the highest priority for the members. Therefore, Working Group 1 began its efforts by reviewing past and proposed uses of the safety case for setting WAC, with a focus on the use of the safety assessment component of the safety case.

The IAEA Nuclear Safety and Security Glossary [11] defines WAC as:

> "Quantitative or qualitative criteria specified by the regulatory body, or specified by an operator and approved by the regulatory body, for the waste form and waste package to be accepted by the operator of a waste management facility."

GSR Part 5 [12] is more specific, stating that WAC specify:

> "the radiological, mechanical, physical, chemical and biological characteristics of waste packages and unpackaged waste that are to be processed, stored or disposed of; for example, their radionuclide content or activity limits, their heat output and the properties of the waste form and packaging."

The majority of Working Group 1 used the safety assessment component of the safety case to decide on activity levels for their waste packages, waste streams or entire facilities on a radionuclide by radionuclide basis, both to achieve long term safety and protect workers involved in waste handling, and to protect the public and workers during the transport of radioactive material. The activity levels were defined according to the methodology described in TECDOC-1380 [8]. Working Group 1's assessment of the use of this methodology to set activity levels concluded the following:

— Generally, the methodology presents a sound approach to setting activity levels.
— However, Working Group 1 recommends a more holistic approach of considering other WAC, facility design alternatives, and changes in the disposal facility system description in one integrated analysis.
— Working Group 1 was concerned about the reliance on conservatism in the methodology, and the associated potential for calculating overly restrictive activity limits.

Further, the maximum acceptable quantity of long lived radionuclides to be disposed of, limits for the waste inventory, packaging criteria for all waste streams, limits for the number of waste packages, limits for the void fraction within a waste package, concentration limits for radionuclides, and limits on fissionable material for prevention of criticality are also defined within a safety case.

In addition, participants described the use of the safety case to define:

(a) Physical dimensions of waste packages;
(b) Prohibited wastes that degrade facility safety systems;
(c) Limits on prohibited materials;
(d) Limits for concentrations of hazardous substances;
(e) Limits for physical properties of bulk/containerized waste materials.

The safety case and safety assessment can be used in managing waste acceptance by ensuring that any new waste fits within the envelope of the previously defined WAC. On the other hand, the safety case can be used to optimize waste acceptance at existing facilities with limited capacity.

Not making a decision (i.e. not setting WAC) was also a possible decision considered by at least one member of the working group. This option was not chosen, however, owing to the safety and cost implications of long term storage and the SSR-5 [5] requirement to have WAC.

(1) Alternatives considered

The alternatives considered can be thought of as implicit when using safety assessment to decide on activity limits. Take, for example, the use of the approach described in TECDOC-1380 [8] — here the ISAM methodology [2] is inverted to search for activity limits that maximize the activity of the type and amount of waste that can be safely disposed of, while assuring that the calculated potential doses or risks are within the safety criteria for the site. The alternatives implicitly considered are all of the higher activities not chosen because their associated doses or risks would be above the safety criteria and all of the lower activities not chosen because they would result in stricter than necessary limitations on the acceptance of waste. Other decisions involving limits (i.e. maximum acceptable half-life of radionuclides, limits for the void fraction of waste package, limits for fissionable material, limits for concentrations of hazardous substances) can be treated in essentially the same way. That is, exceedance of safety limits would rule out certain alternatives and other alternatives are ruled out because they would be more restrictive than the chosen alternative.

Other WAC-related decisions and alternatives were discussed (e.g. relating to types of waste packaging). Often these are not explicitly quantified in safety assessment, but are nevertheless sometimes used as the basis for authorization conditions (see Section 3).

(2) Decision metrics

The primary decision metrics discussed for WAC were activity limits per package, per vault or per disposal facility. Other decision metrics included, but were not limited to, the quantity of long lived radionuclides, half-lives of radionuclides, void volume, heat output, and waste package lifetime. When deciding on suitable decision metrics, it is important to be aware of the effects of implicit assumptions that may affect the outcome of the analysis. For example, the decision on whether to average activity per package, per vault or per disposal facility can be important.

(3) Decision criteria

WAC are set by the facility operating organization using a combination of metrics to allow the facility to operate while adhering to the risk and dose criteria. Once established, these WAC become criteria that are measurable and enforceable.

(4) Relation between the decision and the safety case

WAC comprise a complex set of waste, waste package, and other characteristics, all of which are addressed in the safety case. The use of the safety assessment has been utilized to make decisions regarding a few of these characteristics, the main characteristic being activity limits. In this case, a metric (radionuclide activity) becomes a criterion (activity limit) via the use of the safety assessment.

Radionuclide activity is a direct input to the safety assessment component of the safety case. To set activity limits, operating organizations generally use the procedure laid out in TECDOC-1380 [8]. Briefly stated, in this approach multiple safety assessment calculations, each with different radionuclide activities, are performed in search of the greatest calculated activity values that produce risks or doses that meet the risk or dose constraints. In this example, the safety assessment (of the safety case) is a decision aiding, almost a decision making, tool.

The WAC can be a direct input to the safety assessment. For example, near surface disposal facilities generally have limits on the amount of long lived radionuclides that can be accepted. Radionuclide half-lives are direct inputs to the safety assessment. Evaluating the disposal system's safety performance for different quantities of long lived radionuclides can help set limits on specific radionuclides.

In some cases the regulatory body sets predefined or prescriptive requirements that affect decisions on the development of near surface disposal facilities. Sometimes these requirements are linked to the national waste classification. For example, the prohibition of intermediate level waste from disposal in near surface disposal facilities. These prescriptive requirements can also include more detailed and technical constraints, such as limits on void space, limits on the volume of free liquids inside waste containers, and the prohibition of the disposal of specific waste matrices or the amount of some components (e.g. cellulose, chloride). Such prescriptions allow disposal programmes to proceed with the development of preliminary WAC prior to the development and use of a site specific safety case. The problem discussed in Working Group 1 was the need or desire to dispose of wastes that did not comply with prescriptive requirements, but where the site specific safety assessment and/or the rest of the safety case could include these wastes without exceeding dose or risk constraints. The regulatory body may, on a case by case basis, accept the site specific assessment as a justification to override prescriptive requirements.

External factors are those that may affect a decision, but that are not directly included in the decision process. For example, TECDOC-1380 [8], used to set activity limits for the WAC, is based on technical considerations. Cost and public acceptance are examples of external factors that might affect an operating organization's final choice of activity limits, but are often not included in the technical decision process.

External factors that could affect a decision on facility design and WAC include:

- Package size and weight.
- Hazardous components and characteristics. For example, what if waste meets radiological criteria, but contains high concentrations of heavy metals, asbestos etc?
- Package integrity, compressive strength.
- Operational considerations, including dose to workers.
- Changes in radioactive waste management policy.
- Optimal use of disposal facility capacity.
- Prescriptive requirements set in regulations, such as maximum void space, percent liquids, maximum free space for containers, and avoidance of criticality.
- Waste generator needs and constraints.

Other factors become external because they form the basis of the decision process. In setting the WAC, for example, the facility design is predefined and forms the basis of safety assessment calculations used to set the WAC.

2.4.2.4. Facility design

Facility design decisions described by the working group participants included, but were not limited to, the type and design of the disposal facility cover, the physical layout and orientation of the site, alternatives for managing the water that might enter the facility, the selection of backfill material, and the configuration for the emplacement of waste package and ‘monoliths’ (overpacks containing several waste packages).

In most cases, facility design decisions focused on the consideration of possible design options and engineering alternatives, such as those to limit water inflows (e.g. cover design) and to keep water that enters the facility away from the waste canisters (e.g. by avoiding bathtub scenarios and maintaining unsaturated conditions inside the facility).

(1) Alternatives considered

In many cases the facility design is predefined and forms the basis of safety assessment. The design alternatives for the purpose of the optimization that have been evaluated include:

- Placing waste monoliths close together or spaced apart;
- Filling spaces between waste monoliths with permeable material or not.
- Trying to seal the system against water versus allowing water to flow through the facility but bypass the waste, for example, by providing walls an.d/or a permeable floor to avoid bathtub scenarios;
- Design or redesign based on a choice between a saturated, very low flow disposal facility and an unsaturated disposal facility;
- Alternative dimensions, shapes, slopes, structures and orientations of the near surface disposal facility.

(2) Decision metrics

Decision metrics for facility design included, but were not limited to, rates and direction of surface drainage, distance between vaults and/or monoliths and waste packages, amount and rate of groundwater flow contacting waste packages, and strength of vaults and monoliths. Determinants of the rate of groundwater flow inside the facility include the thickness, permeability and slope of covers, the permeability of monoliths and vaults, and the permeability, porosity and sorption characteristics of the materials that surround the monoliths and vaults.

(3) Decision criteria

The decision criteria related to design can use a combination of the above mentioned metrics, depending on the decision objectives. For example, the choice between different types of design (e.g. vault, silo) can be based on the vicinity of groundwater, precipitation, and the geotechnical properties of the soil and bedrock. The criteria could be based on the best available techniques, cost, robustness, risk and dose.

On the other hand, if the objective is the optimization of the existing design, the decision criteria might relate to cost, effect on safety functions, robustness, reduction of uncertainties, operational safety and even the delay of the project for some alternatives.

(4) Relation between the decision and the safety case

The facility design is mostly a direct input to the safety case and safety assessments. Only in few cases the safety assessment was used to evaluate a number of alternative designs in search of an optimum design. The optimization objective can be the relevant dose and risk constraints, improved robustness of the system or cost.

2.4.3. Lessons learned on the use of the safety case in decision making

The following are the main conclusions of Working Group 1 on the use of the safety case in selecting a site for a near surface disposal facility, choosing a facility design, setting WAC, and identifying and meeting site characterization needs:

- Decisions on site characterization and site selection, WAC and facility design would benefit from a more systematic and structured approach to decision making. This recommendation does not preclude or endorse the use of multi-attribute methods. However, it does recommend the use of their components, specifically the explicit identification of all factors affecting a decision and, at a minimum, the discussion of the relative importance of each factor.
- Existing IAEA requirements and guidance are clear on the need to use the safety case in decision making, but less clear on how to use the safety case to make decisions.
- The IAEA has provided detailed information on how to make one critical decision: setting activity limits for the WAC. That information, found in TECDOC-1380 [8], is based on using the safety assessment in an iterative mode to define activity limits for waste packages, groups of packages, or entire facilities.
- Participants have used the safety assessment to define other WAC parameters and features of the facility design, but have done so in a less structured way when compared to the systematic approach described in TECDOC-1380 [8].
- When the safety assessment was used, multiple scenarios were simulated with the choice of the most limiting scenario used in decision making. Working Group 1 notes that the use of the most limiting scenario might not be necessary or optimal.
- Both deterministic and probabilistic methods have been used in addressing parameter uncertainty when the safety assessment was used.
- Deterministic and probabilistic methods both sometimes rely on conservatism to address uncertainty.
- Adding conservatism to decision making increases already existing conservatism in the safety assessment and the safety case.
- Conservatism in the safety assessment and the safety case precludes optimal decision making and could result in overly restrictive decisions.
- Conflict can sometimes exist between prescriptive guidance and requirements, and the results of the safety assessment. For example, safety assessments for the near surface disposal of bitumenous waste and waste containing organics might demonstrate adequate safety but regulatory guidance and/or requirements might preclude from the acceptance of such waste.
- Few WAC parameters are explicitly incorporated in safety assessment models precluding the use of the safety assessment for defining WAC. For example, even if there is a limit on the amount of liquids that can be present in a waste package, there might not be a parameter for this in the safety assessment.
- Decisions are sometimes made with the use of more detailed process models and/or expert judgement.
- Changes in policy, regulations and decisions on site selection carry the largest programmatic risk (i.e. that a decision taken would later have to be reversed).
- The evolving nature of the WAC introduces programmatic risk. Most programmes assume that their conservative approach to setting the WAC minimizes programmatic

risk. However, Working Group 1 was not presented with examples supporting this contention.

- A specific and difficult situation arises when setting the WAC in the absence of a site or a disposal facility design, when waste generators need WAC to continue operations.
- Communication between the waste generator, the regulatory body, the public and the operating organization was identified as the key component of making good decisions.

2.5. CONCLUSIONS AND RECOMMENDATIONS

The following ten steps, based on what has been learned by Working Group 1, lay out a suggested approach for using the safety case to aid decision making in the development of a near surface disposal facility. Working Group 1 recommends that all interested parties be involved in all of the steps of decision making. Whether that involvement entails interested parties simply being informed, or actually being part of the decision making team depends on the individual programme and situation, but the involvement of interested parties is essential to the process.

(1) Identify the stage of disposal facility development

The stage of the disposal facility determines not only the type of decisions, but also the relevant stakeholders end external factors influencing the decisions (see Fig. 3).

(2) Define the decision

Define the decision under consideration with as much specificity as possible (e.g. activity limits for a waste package versus activity limits for a disposal facility).

(3) Generate alternatives

Decisions, by definition, are choices among alternatives. This step in the decision making process calls for the identification of all reasonable alternatives for the decision at hand. Explicitly document each alternative and whether they are implicit or explicit.

(4) Identify the decision metrics

Decision metrics are those measures that are evaluated in assessing adherence to the acceptance criteria, as well as those that measure the degree to which external factors could affect the decision. Dose and risk are decision metrics, whereas dose and risk constraints are acceptance criteria (see Fig. 5 above).

Activity limits provide a good example. Activity is a metric, a quantity, that is measured or assessed and is related to the acceptance criteria (dose or risk constraints) through the safety case via the safety assessment.

Other decision metrics have no associated acceptance criteria. Attributes or external factors to consider such as cost, public acceptance, or requirements for impacts to be as low as reasonably achievable can be considered using decision metrics, but are often not associated with defined acceptance criteria. For cost, the actual decision metric could be defined in terms of currency amounts, for example. Polling could be used to provide a decision metric for public acceptance, as could a measure based on expert judgement. A decision metric for determining whether an impact is as low as reasonably achievable could be derived from a cost versus risk reduction curve.

(5) Define the decision acceptance criteria

Decision acceptance criteria set limits on the possible decisions. At the highest level, decision criteria include the dose and risk constraints for safety. There may be very select instances where the decision maker chooses an alternative that exceeds these limits. However, in general, acceptance criteria ought not to be exceeded. Decision acceptance criteria could be set at lower levels that are tiered from and related to the highest level criteria of dose and risk.

Decision acceptance criteria could also include external factors, such as cost, if there are absolute limits to these factors, such as a limit on the available finances. The implication would be that any alternative that exceeds the available finances would not be considered further. In some cases, financial considerations are factored into decisions on near surface disposal of waste through the charges paid by waste generators to the operating organization of the disposal facility, but in some cases these costs are not explicit (e.g. the State covers all of the costs).

(6) Define the relation between the decision metrics and the safety case

As discussed throughout Section 2, some decision metrics, like radionuclide activities, are direct inputs to the safety assessment. However, safety assessments are relatively simple in their representation of most of the WAC, most site characteristics and most facility design attributes. Also, some parameters, such as the lifetimes assigned to waste packages or monoliths depend on, and can be derived from, more detailed parameters. These more detailed parameters are often not explicit in the safety assessment. This is not a fatal flaw, as the effects of all of these are included in the safety case. However, their absence from, or simplification in, the safety assessment means that their impact on the higher level acceptance criteria cannot be quantified, or can only be approximated, and their interrelations cannot be quantified in decision making.

This step, therefore, asks the decision maker to define the relation between the decision metrics and the safety case whether the relation is through the safety assessment or not. The MASC matrix developed in the PRISM project [4] (see Table 1) can be used for this purpose.

(7) Assess the impact of each alternative on each decision metric

In perhaps the simplest example, the impacts of alternative activity limits on meeting the dose and or risk constraints (acceptance criteria) are quantified by employing the approach from TECDOC-1380 [8].

At the next level of complexity, alternatives are at a level too detailed for direct input into the safety assessment. Alternative waste packages, for example, have decision metrics (e.g. thickness of the canister, amount of free liquids, corrosion rates) that are combined in submodels or adjunct models outside of the safety assessment. A limited set of alternative waste packages are thus defined and evaluated, and the results serve as input into the safety assessment.

It is also possible that the decision metrics have no link to the safety assessment and, therefore, no link to the associated acceptance criteria. Cost and public acceptance are such metrics that may be considered in decision making, but that have no relation any acceptance criteria (i.e. they do not feature in WAC). That said, the impact each alternative being considered has on these metrics can still be assessed. For example, each alternative waste package or each alternative site (during site selection) will have an associated cost to be considered.

(8) Screen out alternatives that do not meet the acceptance criteria

Acceptance criteria define limits that are not to be exceeded. This step involves screening out all alternatives that exceed the acceptance criteria. Once again, using radionuclide activity limits as an example, all alternative activities associated with safety assessment results that exceed dose and/or risk constraints would be eliminated from further consideration, just as they are in TECDOC-1380 [8]. Any of the alternative waste packages that result in doses and risks that exceed the acceptance criteria would also be eliminated from further consideration.

The doses or risks being compared are not measured values. They are estimates based on a set of parameters and assumptions with their own, usually unquantified, uncertainties. Reduction of those uncertainties (e.g. as a result of further site characterization work) could reduce the calculated dose but have no effect on the actual dose. Therefore this decision process keeps all the alternatives that meet the acceptance criteria at this step.

(9) Choosing among the acceptable alternatives

At this step, all alternatives remaining in the process meet the acceptance criteria (i.e. lead to doses and risks that are at or below dose and risk constraints). The decision then is to select an alternative — either at this stage or as part of later optimization studies. It would seem like the simple choice would be to select the alternative with the lowest dose or risk, but the decision is more complicated than that.

First, the external factors and metrics that could affect the decision (e.g. cost, public acceptance) need to be considered. The decision maker needs to decide on the relative importance of these factors and if any of these are overriding, for example whether cost is more important than public acceptance. The answers are site and project specific, and it may be that they all have equal weight.

Next, the decision maker correlates the value of each alternative with each external decision metric. In the above example, is the decision maker might establish the cost of each alternative or the level of public support shown.

In the decision process detailed in this publication, no numeric values are assigned to the remaining decision metrics, nor are they ranked.

Finally, the decision process leading to the choice of the selected alternative needs to be completely transparent, fully documented, and discussed with the regulatory body and interested parties, including in the case of the WAC, the waste generators.

(10) Estimating and accounting for programmatic risk

Programmatic risk (i.e. the risk that a given decision will have to be reversed at a later time) needs to be managed together with other risks. It needs to be identified, quantified to the degree possible, propagated within the overall decision to be made, and minimized if necessary. Quantification can be as simple as using the most basic definition of risk — probability multiplied by consequence. In this case, the probability is the likelihood that a decision might need to be reversed, and the consequence could be the cost of such a reversal, the extra time take, or the loss in public confidence.

3. REGULATORY EXPERIENCES AND PROCESSES RELATING TO NEAR SURFACE DISPOSAL FACILITIES

3.1. BACKGROUND

Long time frames associated with post-closure safety assessments and the safety case pose unique challenges for regulatory reviews and for the communication of the basis for regulatory decisions to the public.

Assessments extending over these timescales involve significant uncertainties associated with the evolution of engineered and natural systems, as well as human habits and living conditions.

The process for regulatory reviews of safety assessments and the safety case needs to recognize and manage these uncertainties, evaluate and assess the adequacy of the analyses and documentation provided transparently, and effectively communicate the basis for decisions.

Requirement 13 of SSR-5 [5] states:

> "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."

As discussed above, key decisions are 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 need to be developed, clearly recorded and provided to decision makers. In recent years, the IAEA and the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD/NEA) have developed and used the concept of the safety case to structure and integrate the information that has to be provided to the decision makers (see SSR-5 [5], SSG-23 [6], OECD 2020 [13], OECD 2017 [14]).

A practical challenge for regulatory reviews is the long term, iterative nature of the safety assessment process (see para. 1.18 of SSR-5 [5]). Multiple reviews of the safety case and safety assessments will be needed over a period of decades during the disposal facility lifetime as the facility is proposed, licensed, constructed, operated and closed. Technical challenges for reviews are linked to the uncertainties associated with modelling of natural and engineered systems, especially over the very long post-closure time frames considered (i.e. hundreds to thousands of years).

Safety assessment plays a key role in:

- Helping to gather and structure information relating to the understanding of the disposal system;
- Identifying uncertainties regarding aspects of the disposal system and guiding necessary research and development work aimed at reducing uncertainties;
- Guiding waste management practices (e.g. waste packaging and conditioning);
- Developing and operating radioactive waste disposal facilities (e.g. by contributing to assessments of waste stream acceptability and disposal facility capacity);
- Demonstrating the safety of disposal facilities to different interested parties.

Given the significance of the safety assessment to regulatory decision making, it is important that the process by which regulatory authorities review safety assessments is systematic and defensible, and based on clear regulatory requirements and guidance. Special emphasis is also placed on the importance of effective communication with interested parties throughout the process.

Regulatory reviews of safety cases and safety assessments for radioactive waste disposal facilities are principally conducted to assist regulatory decision making on the authorization of the disposal facility. Regulatory reviews focus on determining whether the safety case and safety assessment demonstrate that the disposal facility complies with the safety objective and principles, and with regulatory requirements, criteria and guidance. Such regulatory reviews are distinct from, but often supplemented by, scientific peer reviews, which can focus on specific scientific and technical areas and/or on comparisons with international standards and practices. Effective regulatory reviews and communication of those reviews can also significantly contribute to increased public confidence in the process of regulation and the safety of the disposal facility. Conversely, insufficient or poorly implemented reviews can damage public confidence.

3.2. OBJECTIVES AND APPROACH

The primary objective of Section 3 of this publication is to provide information on best practice in the management and conduct of regulatory reviews of post-closure safety assessments for near surface radioactive waste disposal facilities. The information focuses on the safety assessment itself — rather than the broader safety case of which it forms part — but wider aspects are considered where appropriate. The section discusses both how to conduct reviews and how to judge the acceptability of safety assessments.

Moreover, Section 3 highlights the importance of clearly established responsibilities and integration of expectations between the government, regulatory bodies and the operating organization from the beginning of the process. Emphasis is placed on the critical importance of effective communication between all involved parties with clear communication plans starting from the very beginning of the process.

The main audiences for this section are regulatory authorities and other organizations and experts involved in conducting such reviews. The information may also assist those involved in developing and operating repositories to determine what to present in a safety assessment that will be subject to regulatory review. However, no template is provided for the reporting of a safety assessment.

It might not always be possible for a regulatory body to use all this information in conducting a review — in particular if resources are very limited. In such cases, the information is to be used to the extent practicable. Advice on how to focus a review where resources are limited is provided.

The information provided is intended to apply to the review of safety assessments for disposal facilities over the entire facility lifetime (e.g. proposed, operating, closed and undergoing reassessment). The information can be used when reviewing parts of a safety assessment and draft safety assessments, as well as complete safety assessments. Therefore, the information is specifically intended for application within a stepwise approach to disposal facility development and operation.

Some of the concepts in this section were originally drafted by the Regulatory Review Working Group, under the auspices of the ASAM project. The draft document produced for ASAM has been updated and enhanced by the Working Group on Regulatory Experiences and Processes in the IAEA Forum on the Safety of Near Surface Disposal. These projects focused on safety assessment of near surface radioactive waste disposal facilities. However, this regulatory review guidance, though developed for near surface disposal facilities, is also largely applicable to the review of safety assessments for geological disposal of radioactive waste — though further issues may need to be considered. Findings from the European Pilot Study on the Regulatory Review of a Safety Case for Geological Disposal of Radioactive Waste [15] were also integrated into the current publication.

In addition, although the information was written primarily with the post-closure period in mind, almost all of it will be equally relevant to an evaluation of public health and safety during the operational period — though again further issues may need to be considered. An effective review process begins with the initiation of a project to consider near surface disposal. The process for regulatory reviews therefore needs to be integrated into planning from the beginning.

Although the information in this publication provides a framework for the review of safety assessments, it does not replace the need for site specific guidance, communication and review plans, which will need to be tailored to specific national circumstances, the stage of disposal facility development, and the level of advancement of the safety case.

3.3. EXISTING REQUIREMENTS AND GUIDANCE

3.3.1. IAEA publications

Regulatory reviews of the safety case and safety assessment are specifically addressed in IAEA safety standards and have been the topic of other international projects. A variety of IAEA Safety Standards Series publications and TECDOCs were considered during the preparation of this section, including SSR-5 [5], SSG-23 [6], SSG-29 [9], and IAEA Safety Standards Nos GSG-3, The Safety Case and Safety Assessment for the Predisposal Management of Radioactive Waste [16], GSG-13, Functions and Processes of the Regulatory Body for Safety [17] and SSG-35, Site Survey and Site Selection for Nuclear Installations [18]. Specific requirements related to regulatory reviews are found in SSR-5 [5], for example, Requirement 2 states:

> "The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for the development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met."

Paragraph 3.10 of SSR-5 [5], specifically addressing regulatory reviews, states:

> "The regulatory body has to document the procedures that it uses to evaluate the safety of each type of disposal facility, the procedures that operators are expected to follow in the context of licensing, important decisions prior to licensing and licence applications. It also has to document the procedures that it follows in reviewing submissions from operating organizations to assess compliance with regulatory requirements."

Requirement 14 of SSR-5 [5] emphasizes the importance of the documentation of the safety case and safety assessment to support an effective review:

> "The safety case and supporting safety assessment for a disposal facility shall be documented to a level of detail and quality sufficient to inform and support the decision to be made at each step and to allow for independent review of the safety case and supporting safety assessment."

An important objective of a regulatory review of a safety assessment includes a determination of whether the safety assessment has been conducted in an acceptable manner (quality, breadth and depth) and whether it is fit for purpose. Any judgement as to whether a particular safety assessment is fit for purpose needs to take account of the status of the disposal facility (e.g. whether the facility is proposed, operational, or closed and undergoing reassessment), the extent of available information, and the associated assessment context.

Findings from the review of safety assessments and safety cases make a significant contribution to regulatory decisions on whether to proceed with the next step in the authorization process for a disposal facility. Findings from the reviews of safety assessments and safety cases also provide the primary means of assessing compliance with quantitative performance requirements (e.g. dose and risk criteria) and determining appropriate authorization limits, conditions and controls.

It is important to note that:

- Confidence in regulatory decisions and the regulatory authority depends on the quality of the review process as well as on the quality of the safety assessment and safety case.
- The nature of a safety assessment review needs to be commensurate with the status of the disposal programme and disposal facility.
- Proof of the safety of waste disposal cannot in the absolute sense be provided by a safety assessment that covers hundreds or thousands of years. Rather, a standard of 'reasonable assurance' or 'reasonable expectation' is generally applied.

The need to plan for updates is identified in IAEA requirements and guidance. For example, para. 4.6 of GSR Part 4 (Rev. 1) [7], states:

> "the safety assessment shall be updated as necessary through the stages of the lifetime of the facility or activity, so as to take into account possible changes in circumstances (such as the application of new standards or new scientific and technological developments), changes in site characteristics, and modifications to the design or operation, and also the effects of ageing."

Paragraph 4.13 of SSR-5 [5] specifically addresses the iterative nature of the safety assessment process, stating:

> "Safety assessment in support of the safety case has to be performed and updated throughout the development and operation of the disposal facility and as more refined site data become available. Safety assessment has to provide input to ongoing decision making by the operator. Such decision making may relate to subjects for research, development of a capability for assessment, allocation of resources and development of waste acceptance criteria."

Paragraph 4.8 GSR Part 4 (Rev. 1) [7] addresses considerations related to the timing of safety assessment updates, stating:

> "The frequency at which the safety assessment shall be updated is related to the radiation risks associated with the facility or activity, and the extent to which changes are made to the facility or activity. As a minimum, the safety assessment shall be updated in the periodic safety review carried out at predefined intervals in accordance with regulatory requirements. Continuation of operation of such facilities or conduct of such activities is subject to being able to demonstrate in the reassessment, to the satisfaction of the operating organization and the regulatory body, that the safety measures in place remain adequate."

SSG-23 [6] provides several recommendations related to maintenance of the safety assessment and safety case for a disposal facility. Some examples are provided below:

— Paragraph 4.13: "Within the step by step approach, the scientific understanding of the disposal system and the design of the disposal facility should be progressively advanced, and the safety case should become more focused on key areas of concern. It should not only be scientific understanding that is advanced, but also an understanding of the important contributors to risk. At each step (i.e. at each major decision point), safety assessment should be performed in a manner that will enable the current level of understanding of the disposal system to be evaluated and the associated uncertainties to be assessed before decisions are made to proceed to the next step. The safety case and supporting safety assessment should be reviewed and updated prior to each major decision point and periodically as necessary to reflect actual experience and increasing knowledge (e.g. knowledge gained from scientific research), with account taken of operational aspects that are relevant for long term safety. Following commencement of facility operation, revisions or updates to the safety case and supporting assessment should be conducted if significant changes are identified in operational practices, waste forms, design, etc."
— Paragraph 7.13: "The documentation of the safety case should be updated periodically in accordance with a systematic plan. The operatorshould implement proper controls over the process for approval of documentation of the safety case and over updates to the set of data and parameter values, models, scenarios and computer codes on which the safety case is based and that are used in safety assessment. Documents should be made subject to formal review processes only when they have reached the necessary maturity."
— Paragraph 7.23: "A principal function of the safety case is in the licence application and approval process. The regulatory body may require that the safety case be revised at various stages in the licensing process, including for approval to construct, operate and close the disposal facility, and whenever there are significant changes in the state of the disposal facility. The safety case should also be updated periodically to reflect new information acquired according to regulatory requirements."

The establishment of a legally based, independent, fully resourced and technically competent regulatory body is set out in Principle 2 of IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [19]. This principle is reinforced and further elaborated in IAEA Safety Standards Series Nos GSR Part 1, Governmental, Legal and Regulatory Framework for Safety [20], and GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [21]. GSG-13 [17] provides further specific recommendations for core regulatory functions and the associated processes used to implement the functions of the regulatory body.

3.3.2. Other international publications

The European Pilot Study on the Regulatory Review of a Safety Case for Geologic Disposal of Radioactive Waste – EC 2016 [15] includes a number of conclusions and recommendations relevant for regulatory reviews of safety cases for near surface disposal facilities. Although the Pilot Study [15] was directed at geological disposal, many of the concepts and ideas in the study are relevant for the current publication. That study serves as a key reference for a number of new ideas elaborated in the current publication. Some of the key conclusions from the Pilot Study [15] include:

— The regulatory process evaluates systematically all the elements of safety and its assessment. Interactions between the regulatory body and the operating organization need to take place from the earliest stages in the development of a disposal facility, even if initially the role of the regulatory body is less formal and its decisions or opinions may not be legally enforceable.
— The regulatory process requires the operating organization to compile and present all safety arguments and the accompanying evidence, particularly where key decisions relating to progressing to the next phase of development have to be made.
— The safety strategy sets out the high level approach for achieving safe disposal including the basis for an overall management system, a siting, design and implementation approach, and a safety assessment methodology. The safety strategy needs to be established from the beginning of the project.
— Elements of the safety assessment supporting the safety case may be distinguished between those related to assessment of the robustness and performance of the site and engineering of the facility; and assessment of impacts to people and the environment.
— The safety case has to include an assessment of these individual elements and an integrated assessment of the overall disposal system. The manner and extent to which these elements are assessed during the process of developing and implementing the facility will vary with the stage reached.
— A systematic approach to managing uncertainties is key in demonstrating confidence in the safety of a disposal facility.

The concept of safety functions (see SSR-5 [5]) as a complement to the analysis of FEPs has also been discussed more frequently over the last decade. Clear discussions of safety functions can help reviewers to understand the roles of different features of the system for safety and can also be a valuable communication tool with interested parties.

A report from the Western European Nuclear Regulators Association on radioactive waste disposal facilities safety reference levels [22] identified some specific considerations for periodic safety reviews that provide useful perspective. Taking into account modifications to the structures, systems and components and layout of the facility, to the procedures, and to the organization, and lessons learnt from research and development, monitoring, maintenance, testing, inspection and ageing management programmes, the periodic safety review, as a minimum, needs to achieve the following:

— Review and analyse the operational experience accumulated with equipment, structures, systems and components, including their maintenance, inspection and control; any operational occurrences or accidents that have happened, their root cause analysis and the corrective actions taken; and any modifications of the facility, of the operational procedures and of the organization.

- Review the waste acceptance criteria, taking into account the current state of knowledge and experience in physico-chemical and radiological characterization; review the waste acceptance process, including how waste production is controlled and how compliance with waste acceptance criteria is confirmed; and assess the overall impact on safety of deviating waste accepted for disposal.
- Review the operating experience in radiological protection aspects for workers and the public, including the control of emissions/release/discharges and the assessment of the radiological impact on the environment.
- Review the knowledge and experience of aspects affecting post-closure safety, including an analysis of the performance and potential evolution of barriers, the site and the biosphere. Review the assumptions made in the safety case to confirm that they are still valid.
- Review compliance with current regulatory requirements (national and international):
  - Identify any significant deviations from applicable current standards and good practice and evaluate their significance for safety;
  - Identify any conflicting requirements between different regulatory regimes.
- Review whether the objectives for operation, closure and post-closure remain achievable.

The report of the Western European Nuclear Regulators Association [22] also identifies some specific safety reference levels that address periodic reviews and evaluations of changes over the lifetime of a disposal facility:

- DI-97: "The licensee shall update the safety case to reflect current knowledge and submit it to the regulatory body:
  - in support of applications for major regulatory decisions;
  - as a result of major changes relevant to safety (e.g. in basic assumptions);
  - at least at regular (periodic) intervals as defined in the national legal and regulatory framework".
- DI-98: "The licensee shall update the safety case to reflect as a minimum:
  - Changes to regulatory requirements and standards;
  - Results from surveillance programs;
  - Changes to the radioactive waste inventory to be disposed of;
  - Results from analysis of operational occurrences and accidents;
  - Results of the periodic safety reviews".

3.4. EXPERIENCES AND INSIGHTS

3.4.1. Regulatory functions and processes

This section identifies key ideas from IAEA guidance documents that can be consulted for additional information when developing the regulatory functions and processes as applied to review of the safety case and safety assessments for near surface disposal facilities. Reports from the European Pilot Study – EC 2016 [15] also include specific recommendations. Emphasis in Ref. [15] is placed on administrative considerations (e.g. clearly defined roles and responsibilities, communication plans, documentation expectations, graded approach) because these considerations are critical for a successful programme. Confidence in an otherwise robust and effective regulatory review process can be compromised by misunderstandings resulting from unclear responsibilities or expectations.

3.4.1.1. *Roles and responsibilities*

Planning, development, operation and oversight of a disposal facility can involve a large number of organizations. There can be multiple government, regulatory and operational organizations with roles to be considered. Thus, it is necessary to clearly identify the roles and responsibilities of all organizations involved in the regulation and implementation of the disposal facility from the inception of the process to develop a disposal facility. SSR-5 [5], Requirements 1–3 and the supporting text state the requirements for the responsibilities of the government, regulatory body and operating organization, respectively. It is also important to specify when the formal regulatory roles begin in the process (e.g. at the concept, siting or design stage) and when the roles change. GSG-13 [17] provides additional details to be considered when establishing roles and responsibilities.

Although there is guidance to establish the roles of the three main types of organization (i.e. government, regulatory body, operating organization), the situation is often more complicated with multiple organizations involved in each of the three functions. For example, governmental organizations for the military, industry, energy, health or indigenous populations may all have some role related to radioactive waste. There may also be different regulatory organizations for nuclear safety, environmental protection, military and other areas, and national, regional and/or local regulatory bodies that could have a role in radioactive waste disposal. For implementation and operation, there may be different organizations responsible for development and planning, design, construction, operation, closure and post-closure for the disposal facility as well as a variety of waste generators and treatment facilities that could send waste to the facility. It is thus important to clearly identify early in the process the roles and responsibilities related to reviews of the safety assessment and safety case for each of the governmental organizations and regulatory bodies involved.

There will be challenges associated with obtaining the necessary expertise for a review, while also maintaining a level of independence for the reviewers. It is often the case that people familiar with a project (even if they are not directly participating), or with radioactive waste management in general, will be those that are most qualified to review.

The regulatory authority may develop a regulatory strategy for the facility, providing guidance on how and when compliance with the regulations, technical and environmental conditions and the authorization conditions will be reviewed, and the conditions that may require re-evaluation of safety. Situations that require or do not require formal regulatory review would also be identified in the strategy. There is also a need to consider non-safety related conditions that might impact waste acceptance.

3.4.1.2. *Communication*

Communication is a critical element of the regulatory process. IAEA Safety Standards No. GSG-6, Communication and Consultation with Interested Parties by the Regulatory Body [23], provides recommendations on communication and consultation with interested parties. For a disposal facility, where development and operations can last for decades, requirements and their basis need to be clearly communicated with interested parties from the inception of the lifetime to create an environment where everyone understands the objectives and the basis for decisions in the future. Communication plans can be used to ensure that interested parties are consulted and clearly informed regarding when and how they will be involved in reviews during the lifetime.

National policy, strategy or regulations need to specify the role of interested parties and clearly define requirements for when and how they will be involved in the process. Reporting requirements can also be identified, including plans for formal regulatory reviews and the timing of public meetings and opportunities for public reviews. Clearly identifying and agreeing upon these approaches at the beginning of the process can help to avoid miscommunication or misunderstandings during the lifetime.

The overall communication process related to the safety case for near surface disposal facilities is discussed in more detail in Section 5.

3.4.1.3. Graded approach

Section 2 of GSG-13 [17] provides recommendations for implementation of a graded approach to regulatory functions and processes. A graded approach is used to establish a level of effort recognizing national circumstances and commensurate with the risks associated with facilities and activities. Applying a graded approach is also appropriate as a programme matures during the lifetime of a disposal facility. At the early stages, when less information is available, safety assessment approaches and associated reviews may be quite simple. As the facility evolves and more information about the wastes, site, facility design and operation plans become available, the level of detail for the safety assessment is also expected to increase.

The graded approach also applies to the significance of the decision being made. Requirement 14 of SSR-5 [5] addresses application of the graded approach to documentation:

> "The safety case and supporting safety assessment for a disposal facility shall be documented to a level of detail and quality sufficient to inform and support the decision to be made at each step and to allow for independent review of the safety case and supporting safety assessment."

For example, the regulatory review and safety assessment would be expected to be relatively rigorous for the decision to start operations because this is a key safety related decision.

3.4.1.4. Requirements, criteria and guidance

GSG-13 [17] emphasizes that provision of clear regulatory requirements, criteria and guidance on the safety of waste disposal is important, both to the development of safety assessments and to their review. Clear requirements and criteria assist the operating organization of the safety assessment to establish an accurate assessment context and to focus on the key regulatory issues when developing the safety assessment. In turn, this helps to ensure that the regulatory body receives a safety assessment that is well suited to the process of regulatory review and will enable informed regulatory decision making.

The regulatory body may also establish detailed technical and environmental criteria and provide guidance on how the high level concepts and principles could be met. An example technical criterion is the need to provide safety by use of an integrated system of multiple barriers. An example of environmental criterion is a limit on allowable concentrations of contaminants in groundwater. The safety assessment needs to demonstrate that all relevant principles, requirements and criteria have been considered.

It is also noted in GSG-13 [17] that it may be appropriate for the regulatory authority to develop guidance documents that detail their expectations for the level of information provided at each stage of the development of a facility. These documents would provide an appropriate level of detail as to what information is needed for the authority to assess compliance with the appropriate regulations, and technical and environmental criteria. By providing a clear expectation, these documents can benefit all parties involved in a review: the regulatory authority itself, the operating organization, and all other interested parties. In development of these documents, the regulatory authority may identify areas of regulatory uncertainty that can be addressed by the authority prior to receiving a licence application. For countries with multiple regulatory authorities, these guidance documents may be used to assign areas of responsibility for the reviews.

The use of regulatory acceptance criteria allows the reviewer to decide on whether the safety assessment documents meet minimal requirements. Regulatory acceptance criteria applied in a first screening check may cover aspects regarding the form and content of the presented documents before the reviewer undertakes a detailed evaluation. This practice may streamline the initial review process by avoiding a possible first rejection or iterative step that may be caused by the lack of formal demands and/or essential constituents of the documentation. This aspect is of value for both the reviewer and the operating organization. The safety assessment results ought to be consistent with the regulatory limits. Further objectives of an initial check could be to browse the documents to determine for example whether:

- The purpose of the safety assessment is clearly defined in the objective;
- The appropriate end points and time frames are chosen properly;
- The described disposal system covers the relevant parts;
- The applied methodology is described.

The pros and cons of prescriptive and non-prescriptive requirements bear consideration. In prescriptive approaches, regulations may specify certain aspects, such as scenarios that have to be considered by the operating organization, the length of the period to be considered in safety assessment, and the treatment of human intrusion. In addition, regulations might include criteria or guidance on details of assessment methodology, such as the scenarios or potentially exposed groups to be considered, or the use of particular approaches for optimization. In non-prescriptive approaches, the regulatory body just makes it clear that it is the responsibility of the operating organization to identify which scenarios need to be considered and to justify its choice of assessment timescales.

Non-prescriptive requirements have the benefit of providing flexibility to address conditions specific to a given set of waste streams, site conditions, design and operating conditions. Many countries use such approaches. However, such non-prescriptive requirements leave uncertainty regarding regulatory expectations and the need for more interpretation during regulatory reviews. Prescriptive requirements have the benefit of a clearer path to authorization, but might limit flexibility to account for facility specific conditions and result in unintended effects. For example, in the United States of America, prescriptive waste treatment and disposal facility design standards are used for disposal of waste with non-radioactive, hazardous constituents.

3.4.1.5. Regulatory controls and conditions

The safety case, safety assessment and the associated licence conditions determine, to a large extent, some of the principal controls and requirements on the disposal facility. For example, in establishing limits, controls and conditions, including waste acceptance criteria, for the disposal facility, safety assessment is used to determine, as appropriate, requirements for waste packages and their radionuclide contents, both for individual packages and for the site in total. The safety assessment is used in evaluating potential exposure pathways and in establishing and reviewing the site characterization and environmental monitoring programmes for the facility and the surrounding area. The safety assessment is based on the design or designs actually used or proposed for the disposal facility and the management of the site through the operational phase and the period of active institutional control, if established, after its closure.

Authorization conditions relate to the safety case as a whole and can be of several kinds and can derive from several sources, and include:

- Controls that ensure the disposal facility is designed, constructed, operated and closed as assumed in the safety case;
- Inventory controls or waste acceptance criteria;
- Discharge limitations during the operational period;
- Quality assurance requirements (e.g. governing the maintenance of appropriate records);
- Site characterization requirements;
- Facility monitoring requirements;
- Research and development requirements;
- Safety improvement programmes, including any justified interventions (in the case of existing facilities);
- Periodic resubmissions of the safety case with updated information.

The regulatory review determines whether the safety case provides sufficient information to establish conditions of authorization. Such reviews occur at multiple stages in the lifetime of the facility. For each major decision, conditions of authorization have to be written in sufficient detail and clarity to allow determination of compliance. Examples of the linkage between safety case reviews and the authorization process is discussed in Ref. [24].

Regulatory reviews of post-closure safety assessments of disposal facilities may also influence authorization conditions on existing or planned predisposal waste management facilities. For example, such conditions may relate to:

- Segregation and sorting requirements;
- Waste characterization requirements;
- Waste packaging requirements;
- Waste conditioning requirements.

These conditions might be included in the regulatory authorization appropriate to the relevant predisposal waste management facility (e.g. sorting facility, characterization facility, packaging facility, grouting facility, storage facility).

3.4.2. Regulatory review of the safety case through the life of a near surface disposal facility

Disposal facilities are developed in a number of phases and the safety case supports the decision making process for moving from one phase to the next. Elements of the safety assessments supporting the safety case can be separated into those related to: feasibility, the performance of components of the site and facility; safety assessments of impact to people and the environment, and assessments of the management system. The safety case includes both these individual elements and an integrated overall understanding of the safety of the disposal system. Appendix A.1 contains information on technical aspects of regulatory reviews of safety cases.

Even though the considerations for the regulatory reviews will be applicable throughout the facility lifetime, the manner and extent to which these elements are assessed during the process of developing, operating and closing the facility will vary with the phase reached.

The IAEA PRISM and PRISMA [4] projects considered the role of the safety case in supporting decision making during the lifetime of a disposal facility (see Fig. 3). Examples of decisions at each stage of the lifetime from the PRISM and PRISMA projects are provided in Table 1 of TECDOC-1814 [4]. Note that older facilities might not have followed this step by step process. In addition, Member States might have different authorization steps, which might or might not be associated with some form of licensing. In fact, some countries include a licensing step prior to construction, which is a significant decision for the implementation of a new facility. Appendix A.2 of the current publication provides additional information regarding important considerations for regulatory reviews and during the different stages defined in the PRISM [4] report.

Regulatory reviews of the safety case and safety assessment are closely linked to each decision point and will be an important factor to build confidence in each decision. Requirement 12 of SSR-5 [5] emphasizes the expectations for the safety assessment and safety case during the lifetime, stating:

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

The safety case and safety assessment will evolve throughout the lifetime of the facility as new information is obtained. As introduced in Section 3.3.1, the regulatory review approach needs to be implemented in a graded manner.

SSG-29 [9], para. 5.11 provides perspective for a graded approach and the expected level of detail:

> "The level of detail required in the safety case for any particular decision step has to be decided in consultation with, and subject to the approval of, the regulatory body [5]. In any case, the operating organization should develop the safety case to a level of detail appropriate to demonstrate clearly the safety of the disposal facility."

Table 1 of SSG-29 [9] provides a general roadmap to the expectations of a safety assessment at different stages in the lifetime, which allows to capture the changing information and bases for a safety assessment that will influence the level of detail in a review. The European Pilot Study – EC 2016 [15] also includes relevant recommendations on the subject.

At the beginning of the lifetime, the regulatory body will need to effectively communicate at which stages formal reviews are planned and the expected level of information for each review. Government, operating organizations and interested parties all need to be informed from the beginning to identify their roles in each review and to maintain proper and consistent expectations regarding the level of detail available for each formal review. At these early stages, the regulatory body might have a more formal role in, for example, representation on advisory bodies and providing input to legislation. As the project progresses, the regulatory body will be increasingly called upon to review the safety case.

A process can also be identified to re-evaluate the roles as the lifetime progresses. The regulatory body will provide guidance and recommendations to the operating organization, and it may be called upon to advise government and interact with other interested parties. Much of this will be concerned with the structure and content of the safety case.

The review process needs to be planned and managed since the early stages of the facility lifetime. SSG-29 [9] includes specific guidance for the conduct of regulatory reviews. IAEA GSG-3 [16] also includes a number of recommendations for regulatory reviews of a predisposal safety case, including a template for a regulatory review report for such facilities. Appendix A.3 provides more information on the overall management of the review process.

While communications with interested parties need to be continuous throughout the process, the level of engagement of interested parties will change over the lifetime. Decisions have to be taken about the role of interested parties at different stages and these decisions need to be communicated from the outset to ensure the roles are understood.

During early stages of the lifetime, before site specific designs are available, there needs to be some caution regarding interpretation of detailed post-closure safety assessment using uncertain or generic datasets. The regulatory body can anticipate that inputs and assumptions will likely change and review reporting needs to reflect that expectation. It is important as a result of the communication strategy for the public to understand the iterative nature of the process.

Also, from an early stage, the regulatory body will need assurance that the operating organization will allocate and commit appropriate resources to the project. The regulatory body also needs to define and implement an appropriate internal plan to ensure allocation of sufficient resources for the review of the safety case at all the stages of the development of the disposal facility. In particular, the regulatory body will need to establish and develop its resources and identify the need for research and development to be conducted in support of its expertise and ensure that the results are available in due time. The regulatory review is usually a resource intense exercise covering a wide range of disciplines and expertise. However, the resources available to regulatory authorities in different countries vary widely according to the scale of national nuclear programmes. In many countries with small nuclear programmes or limited uses of radioactive material, the number of regulatory staff that can be dedicated to the review of a safety assessment for a particular waste disposal facility is low. It is not uncommon for regulatory organizations to rely significantly on a single individual to deal with a particular facility over several years or more.

In the advanced phases of the project, the regulatory body will have to make decisions and go through defined formal legal processes. Such decisions involve granting an authorization for the operating organization to proceed to the next stage of facility development. The regulatory body will establish and issue any necessary conditions of the authorization, for example, in terms of having to construct the facility in accordance with the design and materials assessed in the safety case, or in terms of specific limits on the waste inventory that can be disposed.

Multiple reviews of the safety case and safety assessment will be conducted over the lifetime of a disposal facility. Paragraph 4.13 of SSG-23 [6] addresses the timing of major reviews as follows:

> "The safety case and supporting safety assessment should be reviewed and updated prior to each major decision point and periodically as necessary to reflect actual experience and increasing knowledge (e.g. knowledge gained from scientific research), with account taken of operational aspects that are relevant for long term safety."

A major review could also occur prior to closure and the transition to the post-closure period of active institutional control. Such major reviews will involve the most significant efforts and a need for coordination potentially across multiple governmental agencies, regulatory bodies and the operating organization. External peer reviews may also be conducted as part of the major reviews.

Paragraph 1.8 of GSR Part 4 (Rev. 1) [7] states (footnotes omitted):

> "Stages in the lifetime of a facility or activity for which a safety assessment is carried out, updated and used by the designers, the operating organization and the regulatory body include:
>
> (a) Site evaluation for the facility or activity;
> (b) Development of the design;
> (c) Construction of the facility or implementation of the activity;
> (d) Commissioning of the facility or activity;
> (e) Commencement of operation of the facility or conduct of the activity;
> (f) Normal operation of the facility or normal conduct of the activity;
> (g) Modification of the design or operation;
> (h) Periodic safety reviews;
> (i) Life extension of the facility beyond its original design life;
> (j) Changes in ownership or management of the facility;
> (k) Decommissioning and dismantling of the facility;
> (l) Closure of a disposal facility for radioactive waste, and the post-closure phase;
> (m) Remediation of a site and release from regulatory control."

As suggested by this list, the safety case and the safety assessments will be continually evolving over the different stages in the lifetime, and in some cases, within individual stages of the lifetime. Similarly there is an expectation of a need for a series of reviews.

Figure 6 illustrates a high level perspective of considerations for regulatory oversight and regulatory dialogue as a facility progresses through its lifetime. The actual stages may vary in Member States.

3.4.3. Regulatory review of changes to the safety case

3.4.3.1. Changes to the safety case

As discussed in the above, the development of a disposal facility is a dynamic process involving changes throughout the stages of the lifetime of the disposal facility as well as changes within each stage. The initial safety case is often developed based on limited information and there will be many uncertainties. During construction and operation of the facility, new information and knowledge will be available which improve scientific understanding of system and phenomena.

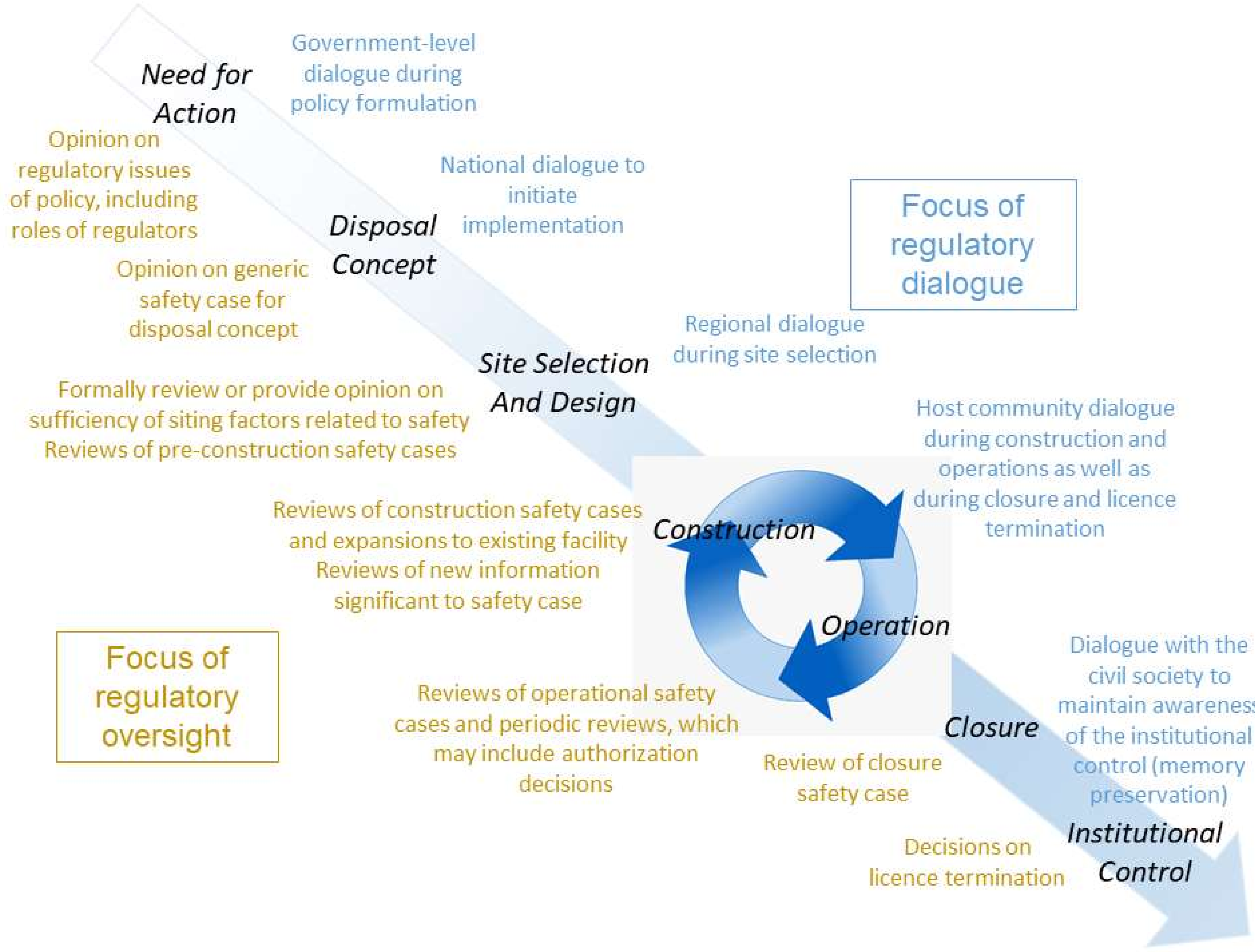

FIG. 6. Examples of regulatory body roles and dialogue during the lifetime of a disposal facility (courtesy of G. Thomson, Environment Agency and A. de Hoyos, Institut de radioprotection et de sûreté nucléaire).

Paragraph 4.13 of SSG-23 [6] highlights expectations of changes during the operational phase, stating that: "Following commencement of facility operation, revisions or updates to the safety case and supporting assessment should be conducted if significant changes are identified in operational practices, waste forms, design, etc." Changes to inputs for the safety assessment are also expected during the design and construction phases as new information is obtained, design changes are made, and to reflect as built conditions.

The report of the Western European Nuclear Regulators Association [22] provides some specific suggestions for periodic safety reviews. Some specific examples of changes that can occur include:

- Facility design:
  - Disposal capacity;
  - Design of engineered cover;
  - Expanded footprint of facility;
  - New disposal units;
  - Concrete composition (e.g. use of self compacting concrete, chemical properties).
- Waste package:
  - New types of container (e.g. fiber reinforced concrete instead of reinforced concrete, stainless steel).
- Waste form, matrix, treatment or conditioning process:
  - New types of waste matrix (e.g. molten solidified waste, high pressure compacted waste, bituminous waste, grout designed to sorb key radionuclides);
  - New solidification materials (i.e. geopolymer, plastic);
  - Changes to the WAC (e.g. specific and less stringent waste acceptance criteria for certain waste streams);
- Unexpected monitoring data:
  - Groundwater condition which will indicate a potential concern for the long term integrity of the engineered barrier system system;
  - Unexpected leakage of radionuclide;
  - Changes in water chemistry suggesting potential concern.
- Unexpected waste disposal:
  - Identification of non-approved waste after disposal (outside WAC limitations).
- Natural phenomena not considered in safety case:
  - Flooding;
  - Tsunami;
  - Tornado;
  - Volcano activities;
  - Increased precipitation.
- New research results:
  - Long term degradation phenomena of engineered barrier system component;
  - Better knowledge of sorption values;
  - Improved characterization of subsurface properties.
- New site characterization:
  - Unexpected geological features found during construction;
  - Better knowledge of hydrogeology after additional measurements.
- Change in operational lifetime:
  - Extending operational period;

  - Change in timing of cover installation.
- Need to accept waste from other facility:
  - Unplanned type of waste (i.e. mixed waste);
  - New kinds of waste due to new facilities (e.g. new types of research reactors);
- Changes in regulatory framework.

3.4.3.2. Possible approach for addressing changes to the safety case as a regulator

It will be important to establish the regulatory processes to address changes starting in the early stages of the project. The level of engagement of multiple regulatory bodies and the public would need to be specified depending on the extent of the changes. For example, which reviews would require involvement of multiple regulatory bodies? When does the public participate in a review, observe a review or simply receive reports documenting a review? Change control processes play an important role to document the activities associated with these evaluations and updates, and the changes made.

The regulatory body needs to have confidence in the change control process established by the operating organization. The change control process needs to include clear procedures to ensure appropriate reporting of changes to the regulatory body. There may also be changes that are relatively insignificant and/or bounded by the range of conditions considered in the safety assessment. In those cases, it is reasonable to consider allowing internal operating organization review processes, with reporting to the regulatory body as appropriate. Some considerations for the change control process could include:

- Changes that cannot be made without prior agreement or acceptance by the regulatory body.
- Changes that are notified in advance to the regulatory body, which will have a time limited period to accept or reject them; if not the operating organization can implement them.
- Types of changes which are reported to the regulatory body that the operating organization will implement unless the regulatory body specifically requests to review them beforehand.
- Types of changes that have to be reported to the regulatory body (e.g. in annual reports), but that the operating organization will implement without a need for regulatory review.

Changes of varying levels of significance will occur. It will be important to consider how the accumulation of changes might impact the safety case and safety assessment. It is possible that a number of individual changes that are apparently insignificant when considered independently become significant when considered together. Documentation of changes is critical, because it is a major undertaking to produce a safety assessment and safety case. It is not reasonable to change the main documentation for each change. Thus, a documentation system, separate from the key reports, is needed to report and track the changes.

Some examples of factors to consider for review of a specific change include:

- Initial discussion on the change between operating organization and regulatory body with the purpose to:
  - Assess the high level acceptability of the change (e.g. quick determination that the change is acceptable or not to regulatory body or if it might be acceptable after further evaluation);

- Discuss the need to adapt the licence;
- Determine if immediate communication to the public is needed or can be documented as part of routine planned reporting (e.g. unexpected monitoring results, WAC changes);
- Agree on time frames for the change and modifications of the safety case, whichparts of the safety case need to be adapted prior to implementation of the change (e.g. WAC, design requirements), which parts can be updated later (and which delays can be accepted).

— Documents by the operating organization to:
  - Explain the change in detail with, if necessary, a partial safety assessment;
  - Indicate the specific parts of the safety case to be modified.
— Formal question and answer process up to approval.
— Implementation of the change and modification of the safety case.

3.5. CONCLUSIONS AND RECOMMENDATIONS

Regulatory bodies need to prepare for reviews of safety cases. Reviews will be needed throughout the lifetime of a near surface disposal facility. Regulatory bodies need to develop appropriate regulations and guidance, and to have and implement specific review plans. They also need suitably qualified staff to maintain the capability to conduct reviews. The focus of individual safety case reviews will evolve through the lifetime of the facility and as changes to the safety case and the facilities and activities occur.

The regulatory working group of the Forum on the Safety of Near Surface Disposal provided more details and insights on regulatory review of safety cases and related aspects to complement existing safety standards, and as such was a successful training activity, especially for less experienced regulatory bodies.

4. EXPERIENCES OF POST-CLOSURE SAFETY ASSESSMENT FOR NEAR SURFACE DISPOSAL FACILITIES

4.1. BACKGROUND

Safety assessment is the assessment of all aspects of a practice that are relevant to protection and safety; for an authorized facility, this includes siting, design and operation of the facility [11]. For a near surface disposal facility, safety assessment provides an analysis of the performance of the entire disposal system and its impact, where the performance measure is the radiological impact or some other global measure of the impact on safety. Safety assessment is the systematic process that is carried out throughout the design process and throughout the lifetime of the facility to ensure that all the relevant safety requirements are met by the proposed or actual design [11].

Safety assessment will normally include risk assessment [11] and may include probabilistic safety assessment. Risk assessment is the overall process of systematically identifying, estimating, analysing and evaluating risk for the purpose of informing priorities, developing or comparing courses of action, and informing decision making [11]. Risk assessment will normally include consequence assessment, together with some assessment of the probability of those consequences arising [11].

Requirement 23 of GSR Part 4 (Rev. 1) [7] states:

> "The results of the safety assessment shall be used to specify the programme for maintenance, surveillance and inspection; to specify the procedures to be put in place for all operational activities significant to safety and for responding to anticipated operational occurrences and accidents; to specify the necessary competences for the staff involved in the facility or activity; and to make decisions in an integrated, risk informed approach."

Considerations on integrated risk informed decision making are provided in TECDOC-1909 [25].

For radioactive waste disposal, attention is often focused on post-closure safety assessment because this period is unique to disposal facilities (c.f. reactors and predisposal waste management facilities), because impacts to people and the environment could potentially occur long after the facility is closed and regulatory control has ceased, and because the assessment of operational safety is relatively simpler and straightforward.

The *de facto* standard methodology for post-closure safety assessment developed beginning in the late 1970s through the early 1990s [26, 27], and was based largely on the 'FEPs approach', where the term 'FEPs' refers to features, events and processes that could directly or indirectly influence the disposal system and affect the migration of radionuclides released from the disposed waste. The development continued in several countries in parallel and later benefitted from the work of the Joint SKI/SKB Scenario Development Project [28], the NEA Working Group on the Identification and Selection of Scenarios for Performance Assessment of Radioactive Waste Disposal [29] and others.

Building on these studies, the IAEA ISAM project [2], proposed a standard methodology for safety assessment for near surface facilities (see Fig. 7 below) that included an approach for moving from a list of FEPs to a set of justified scenarios. ISAM also introduced new concepts such as the use of safety functions in communicating post-closure safety assessment results. Since it was published, the ISAM methodology, has become the international standard for post-closure safety assessment of near surface radioactive waste disposal facilities. It has been used widely around the world and it has also provided an input for safety standards and for other publications by the IAEA, the NEA and others.

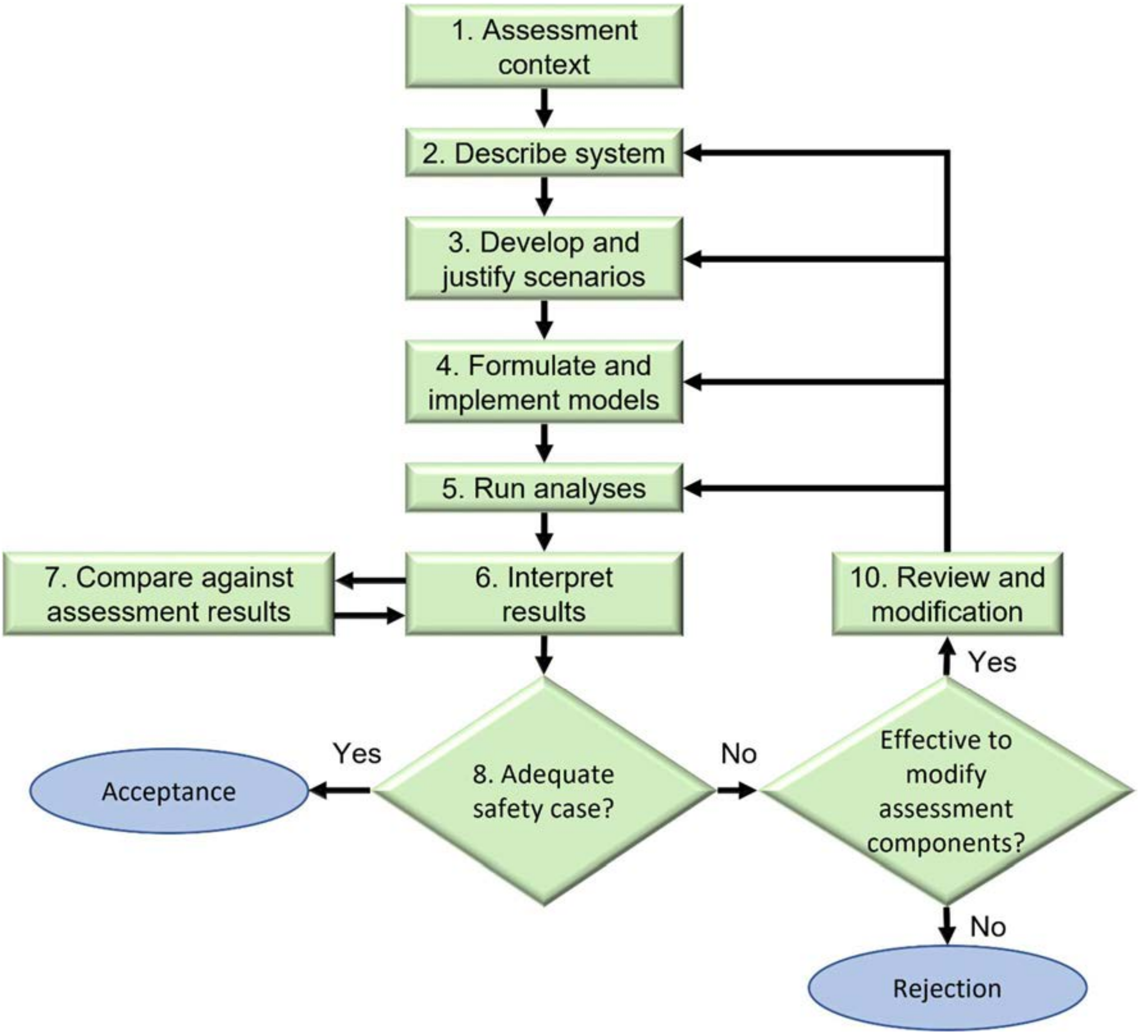

FIG. 7. The ISAM methodology for post-closure safety assessment (reproduced from Ref. [2]).

As the IAEA began developing the concept of the safety case, it became obvious that the ISAM methodology needed revision. The most obvious issue was Step 8 in Fig. 7. This step asks whether or not the safety case, not the safety assessment, is adequate. However, such a question cannot be answered as the safety assessment is only part of the safety case. Later in SSG-23 [6], the IAEA incorporated the safety assessment within the framework of the safety case (see Fig. 2).

4.2. OBJECTIVES AND APPROACH

Working Group 3 had the objective of reflecting on experiences in post-closure safety assessment for near surface disposal facilities and the use of the available safety assessment methodologies. The working group chose to evaluate a few components of the safety case, including the assessment context, the system description, and management of uncertainty (see Fig. 2). The working group's approach was to present and discuss recent examples and experiences of undertaking and using post-closure safety assessments for near surface disposal facilities.

Feedback from the members of Working Group 3 of the Forum on the Safety of Near Surface Disposal shows that although the ISAM methodology is a simplified representation of safety assessment, it is still an efficient tool and is in widespread use around the world. However, some consider that the available descriptions of the methodology are too general on various points to be easily understandable. In addition, since the ISAM methodology was published, there have been various developments in thinking on topics including safety functions, scenario development, and climate change that could now be taken into account.

Consequently, to reflect the experience from forum participants and to help users of the approach in their post-closure safety assessment studies, Working Group 3 reviewed the available information, publications, methods and approaches on post-closure safety assessment and identify areas where the existing materials might be updated in order to improve of the ISAM methodology.

The review conducted by Working Group 3 focused on component D, safety assessment, in the structure of the safety case illustrated in Fig. 2. Working Group 3 first discussed their experiences and identified the difficulties most often faced by the participants. Next the participants examined how post-closure safety assessment is addressed in different relevant publications (safety standards and others). From these exchanges of experiences and reviews, the working group was able to identify and highlight good practices and make proposals for the updating of post-closure safety assessment methodologies.

4.3. EXISTING REQUIREMENTS AND GUIDANCE

The members of Working Group 3 reviewed the treatment of post-closure safety assessment in the following publications:

— TECDOC-1380 [8]. This publication describes the application of the methodology developed in the ISAM coordinated research project for the purpose of deriving radioactivity limits for low and intermediate level waste disposal in near surface disposal facilities and provides illustrative values that can be used for reference purposes, for example at the preliminary planning stage of a disposal facility development.

— ISAM [2]. This publication covers the results of the coordinated research project on the ISAM project organized by the IAEA to improve and harmonize approaches to safety assessment and resulted in the development of the ISAM project methodology. The ISAM project involved the review and enhancement of post-closure safety assessment methodologies for both existing and proposed near surface radioactive waste disposal facilities. The main objectives of the project were to: (a) provide a critical evaluation of the approaches and tools used in the post-closure safety assessment of proposed and existing near surface radioactive waste disposal facilities; (b) enhance the approaches and tools used; (c) build confidence in the approaches and tools used. In order to help achieve these objectives, the ISAM project paid particular attention to discussing, agreeing and setting down a safety assessment methodology. The ISAM project focused primarily on developing a consensus on the methodological aspects of safety assessment, but also gave considerable attention to illustrating the application of the methodology to three main types of disposal facilities (vault, RADON and borehole type disposal facilities).

— SSR-5 [5]. This publication establishes requirements applicable to all types of radioactive waste disposal facility. It is linked to the fundamental safety principles and applies to all disposal options and it establishes a set of strategic requirements that are required to be met before facilities are developed. Consideration is also given to the safety of existing facilities developed prior to the establishment of present day standards. The requirements are complemented by safety guides that provide guidance on good practices for meeting the requirements for different types of waste disposal facility.

— SSG-23 [6]. This Safety Guide redefined the safety assessment to fit within the safety case (see Fig. 2) and provides guidance and recommendations on meeting the safety requirements in respect of the safety case and supporting safety assessment for the disposal of radioactive waste. The safety case and supporting safety assessment provide the basis for demonstration of safety and for authorization of radioactive waste disposal facilities, and assist and guide decisions such as siting, design and operations. The safety case is also the main basis on which dialogue with interested parties is conducted and on which confidence in the safety of the disposal facility is developed. SSG-23 [6] is relevant for operating organizations preparing the safety case as well as for the regulatory body responsible for developing the regulations and regulatory guidance that determine the basis and scope of the safety case, and for reviewing the safety case.
— SSG-29 [9]. This Safety Guide provides recommendations on how to meet safety requirements on the near surface disposal of radioactive waste. The Safety Guide provides recommendations on the development, operation, closure and regulatory control of near surface disposal facilities, which are suitable for the disposal of very low level waste and low level waste. The Safety Guide provides recommendations on a range of disposal methods, including the emplacement of solid radioactive waste in earthen trenches, in above ground engineered structures, in engineered structures just below the ground surface and in rock caverns, silos and tunnels excavated at depths of up to a few tens of metres underground. SSG-29 [9] is intended for use by those involved with policy development for, regulatory control of, and the development and operation of near surface disposal facilities.
— PRISM and PRISMA [4]. This publication arises from the results of two projects to assist Member States in understanding and developing safety cases for near surface radioactive waste disposal facilities. The objective of the publication is to give detailed information on the contents of safety cases for radioactive waste disposal and the types of arguments that may be included. It is written for technical experts preparing a safety case, and decision makers in the regulatory body and government. The publication 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 that might be included in a safety case for each of two hypothetical radioactive waste disposal facilities.

4.4. EXPERIENCES AND INSIGHTS

4.3.1. General insights on post-closure safety assessment

Initial working group discussions identified and discussed the following topics which were regarded as areas of relative difficulty, particularly for new safety assessors. Working Group 3 then held more detailed discussions on two of these topics (for specific waste types and scenario generation, see Section 4.4 below):

— **Assessment of radiological and non-radiological impacts**. One of the observed developments in regulations is the progressive integration of non-radiological impacts of waste disposal in post-closure safety assessment. However, the methodologies for evaluating radiological and non-radiological impacts may differ significantly (e.g. the concept of evaluation dose for a disposal facility as compared with the concept of evaluating chemical toxicity in terms of apparent effects or concentrations in air). This topic addresses the question of how to evaluate and compare potential post-closure non-radiological and radiological impacts so that the results can be used in good decision making (see the discussions on decision making by Working Group 1 in Section 2).

- **Revising safety assessments**. Safety assessments need to be updated to take account of new information and changes and planned improvements at a disposal facility, and results from revised assessments used in decision making (e.g. on facility design, waste acceptance). Changes can be caused by many things (e.g. worse than expected geology, poorer than planned vault construction and performance) and some of these can call into question the safety of the waste disposals. Revision of the safety assessment will also lead to changes to the safety case and these changes can be quite difficult to communicate — for example, if the new information leads to restrictions that did not exist before, or if previous restrictions are relaxed.
- **How to apply the graded approach in post-closure safety assessment for waste disposal**. Assessing and making decisions on the safety of disposal facilities often involves addressing optimization and the as low as reasonably achievable principle. Improving knowledge and developing more complex models may be very expensive and a balance has to be found when deciding where to expend resources. This topic is therefore related to clarifying how to select what needs to be taken into account in post-closure safety assessment and examining how to define the necessary research (for more important and less important topics).
- **Specific waste types**. Generally, the design of a disposal facility and system is based on the waste type that makes up the largest part of the inventory for disposal (in volume or activity terms). But the management of specific waste types, for example, having different physical or chemical properties or non-standard waste packages, may necessitate further analysis.
- **Fulfilling safety functions in the longer term**. Safety functions are often linked to requirements in the design of certain physical features (e.g. the waste package or engineered barriers). Safety demonstrations often assume the possibility of monitoring the effectiveness of safety functions and sometimes assume the possibility to re-establish them. In the post-closure phase, however, human intervention to re-establish the safety of a disposal facility cannot be assumed to be possible. This topic therefore relates to the question of how long the components of the disposal system will fulfil their safety functions.
- **Dealing with long term changes**. Many assumptions in post-closure safety assessment (e.g. regarding climate, human habits or hydrogeology) are based on present day knowledge and information. The post-closure safety assessment, however, has to deal with very long timescales over which there may be significant changes. Working Group 3 noted that it could be sensible to take account of the probability of various changes to the disposal system and make links to recent work on the effects of climate change (see, e.g. Refs [30, 31]).
- **Proper interpretation and use of post-closure safety assessment calculations**. Working Group 3 noted that the rationale for assessments made for different scenarios is not always clear. This confusion relates, among other things, to the degree of conservatism and realism in the different scenarios.
- **Methods for addressing and managing uncertainties**. The feedback of participants was that uncertainties management and sensitivity analysis are not addressed in sufficient detail in the international standards.
- **Management of long lived radionuclides**. Near surface disposal facilities are generally designed for very low level and low level waste containing predominantly short lived radionuclides. The working group participants noted that even these waste classes contain

some long lived radionuclides and that the long lived radionuclides can have a significant effect on disposal system design and waste acceptance.

— **Choice of radionuclides for inclusion in safety assessment**. Safety assessments are based on models of the disposal system which provide simplified representations of reality. Some level of simplification is inevitable as, for example, the data available will be incomplete at some level of detail, and the models are discretized in space and time. This topic is about how to choose which radionuclides need to be considered in post-closure safety assessments in order to simplify calculations without missing radionuclides or their daughters that might be important to dose or risk.
— **Understanding and representing the performance of engineer barriers in post-closure safety assessment**. Working group participants noted the difficulty of understanding and representing in post-closure safety assessments the progressive evolution and/or degradation and long term performance of engineered barriers and their materials (e.g. steel, concrete, clay).
— **Scenario generation**. There is now significant experience of applying the ISAM methodology for scenario development in a range of safety assessments and safety cases. However, best practice in scenario development has evolved since the original ISAM report was published and the various IAEA guidance documents do not yet reflect these developments. Perhaps the most important of these development is the use of safety functions to describe how the disposal system provides safety, and this is not reflected in the current guidance.

4.3.2. Detailed insights on post-closure safety assessment

4.3.2.1. Compatibility between specific waste types and the type of disposal facility

Working Group 3 was concerned with avoiding situations in which specific waste types might not appear to meet WAC and become waste with no agreed disposal route (so-called 'orphan wastes'). Potential solutions in such cases might be, for example, to change the waste packaging and/or to improve the realism and/or the level of detail in post-closure safety assessment models and put the safety assessment within a broader decision based framework [32].

Near surface disposal facilities often have two types of limits — limits on the overall capacity of the disposal facility to receive waste and radionuclides and, on a smaller scale, limits on the concentration of radionuclides in a waste package. How these limits at different scales are used for setting detailed WAC at a package level can cause problems if not set appropriately. The following experiences were discussed:

— At the Dounreay site in Scotland, United Kingdom, the permit (authorization) is being re-examined because the original safety case did not indicate that there was sufficient capacity for a specific radionuclide. The operating organization would need to revise the safety case (e.g. by collecing more information and making more realistic, less conservative assumptions) in order for the WAC to be revised, thus allowing these disposals.
— In Spain the strategy to address a similar problem might be to manage the waste in a different way rather than change the WAC for the disposal facility. It might be possible to reinforce the engineered barriers to give improved performance and thereby enhance the capacity of the disposal facility. Improvements in the characterization of the waste can often also allow more waste to be disposed of by avoiding assumptions that waste contains more radioactivity that it actually does.

- The Low Level Waste Repository (LLWR) in the United Kingdom has a system to address exceptional waste so that such waste can be accepted by the disposal facility as long as the limits on the overall capacity of the disposal facility and the limits on the capacity of individual disposal vaults can still be met. This allows package limits to be overridden in these circumstances. The capacity of a disposal facility may change with time due to more information becoming available, either on the site or on the proposed inventory of waste for disposal. The process needs to recognize that the updating of the post-closure safety assessment over the lifetime of the disposal facility can present challenges in ensuring that no orphan wastes are created that cannot be disposed of. The updating of the safety case offers opportunities to revise the capacity of the facility, but can also lead to reduced capacity if less favourable conditions are discovered.
- In the Republic of Korea the limits on the capacity of the disposal facility have been modified to address changes in the waste inventory due to new waste streams and because of waste heterogeneity. Previous highly conservative assumptions in the post-closure safety assessment have been addressed, particularly by taking account of waste form performance to allow the capacity of the facility to be increased.

4.3.2.2. Relevant experiences on using the ISAM methodology

There is therefore a need to update the ISAM methodology (and documents that draw on it) to reflect this practical experience taking due account of developments documented by other related projects (see e.g. the NEA Scenarios Workshop report [33], the NEA Methods in Safety Assessment (MeSA) report [34], the NEA FEPs list [35], and outputs from the IAEA's Modelling and Data for Radiological Impact Assessments (MODARIA II) [31] and International Project on Human Intrusion in the Context of Disposal of Radioactive Waste (HIDRA) [36] projects.

(1) Assessment context

The context for a safety assessment (Step 1 in Fig. 7) determines the level of detail needed in the system description, and can influence aspects such as the number of scenarios. Recent safety case and safety assessment flow diagrams place the assessment context in different places within the overall methodology [34]. The assessment context that needs to be specified relates to the reasons why the safety assessment calculations need to be done i.e. the specific question being asked of the calculations.

It is important to know the purpose of the request for safety assessment calculations, and within a safety case, multiple questions may be asked that would necessitate different calculations. There might not, therefore, be a single assessment model, but a family of related models. Understanding how the results of a calculation will be used in decision making can also be an important part of the assessment context.

(2) System description

The system description (Step 2 in Fig. 7) is a phenomenological description at a level appropriate for carrying out the safety assessment calculations. To create the system description, scientists working with safety assessors and engineers need to ensure that the resulting description describes the characteristics of the system that are important for the assessment. This step, therefore, requires a multidisciplinary team — one person alone cannot undertake an assessment.

It is important that the specialists contributing to the system description have an appropriate overview of the whole system and of how the safety assessment process works so that they understand how their parts fit into the overall system. Interfaces between disciplines are important. Specialists need to talk to each other. It is necessary to establish boundary conditions and ensure that the description is internally consistent.

The system description needs to include how the system is expected to evolve with time, the processes to be considered and the uncertainties.

The safety strategy component of the safety case (component B in Fig. 2) influences the system description as this underpins much of the development of the safety functions which, in turn, help to define the important components for safety assessment and the properties and uncertainties that may be important for understanding safety.

(3) Scenario development

To generate scenarios (Step 3 in Fig. 7), all participants agreed that to consider ISAM is a good basis for safety assessment.

Amongst the working group, scenarios have been generated in different ways:

- For the near surface waste disposal facility at Dessel in Belgium, the post-closure safety assessment scenarios were based on an analysis of phenomenology.
- For the El Cabril near surface waste disposal facility in Spain and for near surface disposal facility in Lithuania, the post-closure safety assessment scenarios were developed following the ISAM methodology.
- For the Centre Stockage de l'Aube and the Centre Stockage de la Manche in France, scenarios were are generated on the basis of safety functions analysis.

Note that the safety functions as used in many modern safety cases are often more detailed than the high level safety functions of isolation and containment considered in the IAEA safety standards. These more detailed safety functions are often at the level of individual barriers which together contribute to the safety of the entire disposal system.

FEPs are not shown as an explicit input to the safety assessment in the ISAM methodology diagram (see Fig. 7), but maybe it would be sensible to do so in any update to the figure. Every Working Group 3 participant used FEPs in some way, and there was agreement that the efficient screening of FEPs is an important consideration.

More recent experience from Spain was also discussed. The safety assessments for the El Cabril disposal facility for very low level and low level radioactive waste were recently revised following the ISAM methodology. Those carrying out the analysis felt that they were only able to follow ISAM because they already had background in the screening of FEPs and development of scenarios; they would not have been able to do it based just on the ISAM report. The screening of FEPs was the most difficult part, in particular how to decide what to exclude and how to justify the decisions. Even though there are some relevant references in the literature (see, e.g. Ref. [26]), more guidance is needed on how to do this FEP screening.

One aspect that is missing from the current ISAM document is discussion of alternative FEP screening methodologies and their common features and differences. The ISAM examples are simply reports from the different programmes without a common template, and this is not always helpful for deciding how to tackle a new problem.

(4) Inadvertent human intrusion

The treatment of human intrusion in post-closure safety assessment varies between different countries and programmes according to the national legal and regulatory framework.

Some human intrusion scenarios for near surface disposal facilities are associated with a high probability of occurrence, while in other cases human intrusion scenarios are considered to be of low probability. The United Kingdom assumes for assessment purposes that human intrusion into a near surface disposal facility is a probable event after the end of active institutional control. The United States Department of Energy assumes effective institutional control in perpetuity so that the probability of human intrusion is low. Spain considers some human intrusion scenarios to have a high probability and thus treats their effects in the main reference scenario.

Some human intrusions could have short and longer term effects on the evolution of the site. For example, Belgium has assessed the immediate and derived effects of human intrusion in order to capture what this type of activity does to the evolution of the disposal system separately.

(5) Verification and validation of models

The ISAM methodology diagram (Fig. 7) does not show explicit steps on verification or validation of models; these are implicit within step 4 "Formulate and implement models". In the Russian Federation, the assessment model is calibrated taking account of data from monitoring of the subsurface during the operational period. In the United Kingdom and in France, the appropriateness of models is assessed by testing different representations of the disposal system and making comparisons between them.

(6) Treatment and management of uncertainties and sensitivity analysis

There is relatively little in the ISAM report [2] on the treatment of uncertainty, although much has been written elsewhere (see, e.g. Refs [16, 34, 37]). The coverage of the treatment of uncertainty in the PRISM and PRISMA report [4] is also quite limited and deals with what is to be done rather than how.

Experience in Belgium is to separate the treatment of uncertainties in the safety assessment from the management of uncertainties. Uncertainty management includes deciding which uncertainties you can treat in the assessment and which you cannot, and may need to be managed in other ways (e.g. through design). Working Group 3 participants felt that more guidance is needed on uncertainty management, but that this probably fits within the safety case rather than in the safety assessment.

In Canada, the Canadian Nuclear Safety Commission Regulatory Document REGDOC-2.11.1 [38], states the following:

> "An uncertainty analysis of the assessment results should be performed to identify the sources and significance of uncertainty. This analysis should distinguish between uncertainties arising from:
>
> — Input data or parameters;
> — Scenario assumptions;
> — The imprecision in the mathematical model;
> — The conceptual models".

Overall, the feedback from the participants is that, considering the importance of the topic, uncertainty analysis, sensitivity analysis, and uncertainty management are not well enough addressed in the existing international standards.

In addition to this, the ISAM methodology diagram (Fig. 7) could be upgraded to further emphasize sensitivity and uncertainty analysis.

4.4. CONCLUSIONS AND RECOMMENDATIONS

Working Group 3 considers that the ISAM methodology is still a good reference for the conduct of post-closure safety assessments. However, the group suggests the following to help safety assessors apply the methodology:

- Emphasize the importance of the assessment context in ensuring that the results of any modelling are used appropriately so that good decisions are made.
- Make the relationship between the system description and the assessment basis clear and consistent, and include the following:
  - A description of the state of knowledge taking account of developments in the scientific understanding;
  - The phenomenological basis (e.g. for, or based on, detailed process models);
  - Identification of safety functions for the components of the disposal system;
  - Time dependence and system evolution (e.g. evolution not only of the system geometry/features, but of engineered barriers, climatic and other conditions [30, 31]).
- Take account of current best practices in post-closure safety scenario development, for example that make use of safety functions.
- Provide a sound and appropriately detailed underpinning basis for assumptions (e.g. waste inventory, barrier degradation rates) in safety assessment calculations to avoid conservative assumptions.
- Include explicit and detailed information on the treatment of uncertainties and sensitivity analysis in post-closure safety assessment.
- Take account of waste heterogeneity as needed for assessing the acceptability of heterogeneous waste streams or waste streams with characteristics that are in some way unusual for the disposal facility.
- Have a process for managing waste that does not, on first evaluation, meet WAC.

5. COMMUNICATION OF THE SAFETY CASE FOR NEAR SURFACE DISPOSAL FACILITIES

5.1. BACKGROUND

The operating organizations of near surface disposal facilities have to develop a number of documents as part of the safety case, which serves as a central point for the collection of scientific, technical, administrative and managerial arguments and evidence in support of the safety of a disposal facility, and which covers the suitability of the site and the design, the construction and operation of the facility, the assessment of radiation risks and assurance of the adequacy and quality of all of the safety related work associated with the disposal facility.

The safety case also serves as a repository of identified uncertainties to be resolved in the research and development activities for the fulfilment of required safety of the near surface disposal. Besides the usual roles of the safety case, which includes the demonstration of safety used in the licensing process and the identification of unresolved questions to be further investigated, the safety case has to be communicated to various parties involved in the near surface disposal facility.

There are differences between Member States as to who the interested parties are in the case of the near surface disposal. The interested parties depend mainly on the national framework and authorization process of the near surface disposal facility and they need to be clearly identified. The parties are also evolving depending on the stage of the near surface disposal facility.

The basic roles and responsibilities are typically taken by the government in the early stages (e.g. national policies addressing a ‘need for action’ and ‘disposal concepts’) and again at later stages (i.e. at the ‘closure and active institutional control’ stage), by the regulatory body with the primary role in the authorization process, and by the operating organization in leading on safety during all of the waste management steps within the different stages (see Fig. 3 and Ref. [4]). Besides these official bodies, there may also be many other parties that are interested in the near surface disposal facility and that need to be involved through communication activities.

As can be deduced from GSG-6 [23], communication and consultation are strategic instruments that support all organizations in performing their functions. They enable the organizations to develop awareness of safety among interested parties. The establishment of regular communication and consultation with interested parties will contribute to more effective communication and will increase the trust between all involved.

There are some general recommendations to be applied with the aim of establishing and implementing a strategy for communication and consultation with interested parties. The regulatory body, together with any technical support organizations, has to demonstrate effective independence. The concepts of transparency and openness underlie the strategy for communication and consultation with interested parties, so it builds on the trust in competence and integrity. The basic elements are provision of information, proactive communication, willingness to listen and respond to a broad variety of concerns, involvement of at the earliest opportunities and documenting the outcomes of communication and consultation. The proper implementation the basic elements will ensure and further enhance the trust of the interested parties.

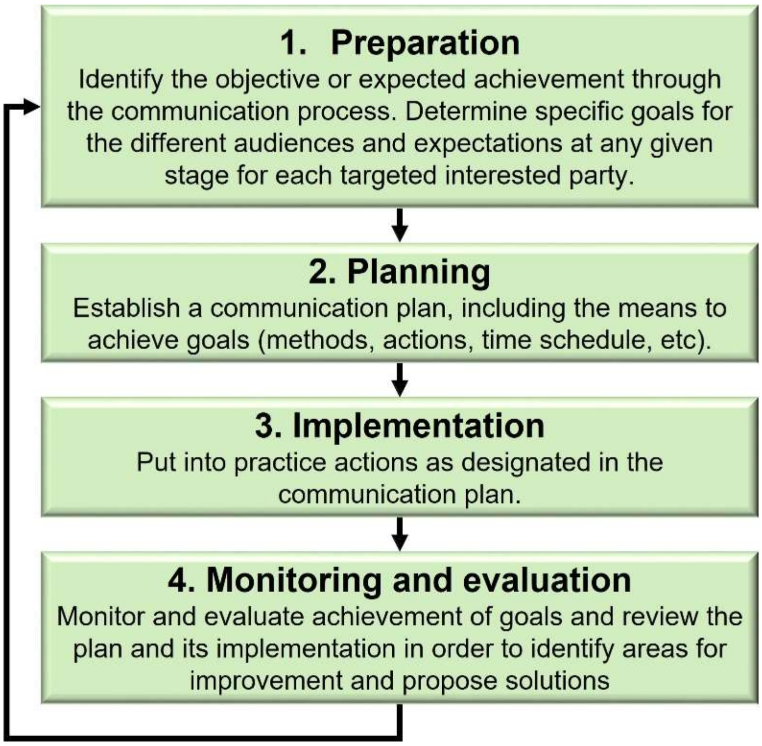

FIG. 8. Steps in the communication and consultation process (reproduced from GSG-6 [23]).

To ensure good communication and consultation with interested parties, appropriate arrangements have to be established and implemented by the responsible parties. It is advised to start the communication and consultation process early and continue the process throughout a series of steps, from identifying the objective of communication, development of a communication plan, through implementation of the plan, together with ongoing monitoring and evaluation to identify areas for improvement (Fig. 8). As the strategies and plan are often developed by different responsible entities, one important issue is the coordination amongst communication actors to ensure that the communication is well aligned. However, such coordination needs to be performed in such a manner not to jeopardize the independence of regulatory bodies.

The methods for communication and consultation need to be used in accordance with national framework. Any communications and consultations need to take into account the concerns and interests of interested parties. A near surface disposal facility is usually perceived by public as the facility with a potential risk for humans and environment it therefore receives a lot of attention, in particular during the decision making for site selection and the approval of construction. Many different methods have been developed for ensuring communication with interested parties regarding the near surface disposal facility; however it is important not to ‘blindly’ transfer approaches between sites. The working method needs to be adapted so that it is suited to the national framework. Communication plans need to be continuously improved to take into consideration other experiences at the national and international levels, feedback from interested parties, results of evaluations of previous communication activities, and evolving mechanisms and approaches to communication.

5.2. OBJECTIVES AND APPROACH

5.2.1. Objectives

The aim of the Working Group 4 on communication of the safety case for near surface disposal facilities was to address major issues on how to communicate the safety case and how to include different interested parties in an iterative process of communication. Interested parties can include regulatory organizations, the general public (including the host community), non-governmental organizations or any other stakeholder who has expressed an interest in the near surface disposal facility.

The specific Working Group 4 objectives were to identify:

- Approaches to coordinating the communication activities throughout disposal facility lifetime, including the agreed upon process between the operating organization and the regulatory body (from 'need for action' to 'licence termination', as presented in Fig. 3).
- Approaches to communicating technically and scientifically complex material (such as a safety case) to non-technical people which can include decision makers and members of the public.
- Approaches to addressing issues and concerns from interested parties during the process.
- Available communication resources (e.g. guides, reports or training material on communication).

The scope of Working Group 4 covered the whole lifetime of a near surface disposal facility.

5.2.2. Approach

The approach taken by Working Group 4 to analyse the issue of communicating the safety case for near surface disposal is illustrated in Fig. 9 and involved the following:

- Completing a literature review of existing requirements and other guidance;
- Describing the basics of communication;
- Discussingthe communication of the safety case with other Forum participants;
- Completing a questionnaire during the Forum to identify specific topics to be communicated regarding the safety case and challenges experienced in practice;
- Identifying specific topics in communicating the safety case for near surface disposal;
- Examining selected case studies from the radioactive waste management sector or relevant examples from other industries.

All activities were implemented to a certain level of intensity, despite COVID-19 restrictions, and the results are summarized in the following sections. During the second annual meeting of the Forum on the Safety of Near Surface Disposal, a questionnaire was developed, and this was distributed amongst Forum participants for completion. Joint discussion sessions were held with Forum participants to receive initial responses to the questionnaire and to discuss the issues raised. A template was developed to document the case studies and examples that are discussed and presented in subsequent sections or appendices.

FIG. 9. Working Group 4 approach.

5.3. EXISTING REQUIREMENTS AND GUIDANCE

Many IAEA safety standards, guidance and other reports address the communication and consultation of the nuclear activities and facilities.

5.3.1. Safety Fundamentals

Principle 2 of SF-1 [19] states:

> "The regulatory body must:
>
> ....
>
> — Set up appropriate means of informing parties in the vicinity of the facility, the public and other interested parties, and the information media about the safety aspects (including health and environmental aspects) of facilities and activities and about regulatory processes;
> — Consult parties in the vicinity of the facility, the public and other interested parties, as appropriate, in an open and inclusive process."

The public usually have incomplete knowledge and great deal of uncertainty regarding any issue involving nuclear and radiations safety. Public also expect to have access to information about safety and regulatory issue in order to form opinions and make fully informed decision. At the end the public expects to have fair and reasonable opportunities to provide their views and to influence the regulatory decision making processes.

5.3.2. General Safety Requirements

Paragraph 2.5 of GSR Part 1 [20]states:

> "The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:
>
> …….
>
> (5) Provision for the involvement of interested parties and for their input to decision making."

Requirement 36 of GSR Part 1 [20] states:

> "The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."

Further, para. 4.66 of GSR Part 1 [20] states:

> "The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication, and it shall hold meetings to inform interested parties and the public and for informing the decision making process. This communication shall include constructive liaison such as:
>
> (a) Communication with interested parties and the public on regulatory judgements and decisions;
> (b) Direct communication with governmental authorities at a high level when such communication is considered necessary for effectively performing the functions of the regulatory body;
> (c) Communication of such documents and opinions from private or public organizations or persons to the regulatory body as may be considered necessary and appropriate;
> (d) Communication on the requirements, judgements and decisions of the regulatory body, and on the bases for them, to the public;
> (e) Making information on incidents in facilities and activities, including accidents and abnormal events, and other information, as appropriate, available to authorized parties, governmental bodies, national and international organizations, and the public."

Thus the regulatory body has to consult with interested parties and the public in residing in the vicinity of authorized facilities and activities an open and inclusive process. Interested parties including the public have to have an opportunity to participate in the process for making significant regulatory decisions, subject to national legislation and international obligations, and results of these consultations have to be taken into consideration by the regulatory body in a transparent manner.

Regarding public consultation, the regulatory body in its public informational activities and consultation needs to set up appropriate means of informing interested parties, the public and the news and media (including social media) about the possible radiation risks associated with facilities and activities, the requirements for protection of people and the environment, and the decision making processes of the regulatory body. The level of awareness or knowledge basis often corresponds with the geographic local of the interested parties (i.e. communities closer to nuclear facilities are more informed) thus the communication mechanism or approach also needs to be considerate of the geographic location of the interested parties. The results of these communication activities need to be taken into consideration by the regulatory body in a transparent manner.

Requirement 5 of IAEA Safety Standards Series No GSR Part 2, Leadership and Management for Safety [39] and its associated paragraphs state:

> "Senior management shall ensure that appropriate interaction with interested parties takes place.
>
> 4.6. Senior management shall identify interested parties for their organization and shall define an appropriate strategy for interaction with them.
>
> 4.7. Senior management shall ensure that the processes and plans resulting from the strategy for interaction with interested parties include:
>
> (a) Appropriate means of communicating routinely and effectively with and informing interested parties with regard to radiation risks associated with the operation of facilities and the conduct of activities;
> (b) Appropriate means of timely and effective communication with interested parties in circumstances that have changed or that were unanticipated;
> (c) Appropriate means of dissemination to interested parties of necessary information relevant to safety;
> (d) Appropriate means of considering in decision making processes the concerns and expectations of interested parties in relation to safety."

Paragraph 2.30 of GSR Part 3 [21] states that "The regulatory body shall establish a regulatory system for protection and safety that includes … provision of information to, and consultation with, parties affected by its decisions and, as appropriate, the public and other interested parties."

Paragraph 5.9 of GSR Part 4 (Rev. 1)[7] states:

> "Since the safety assessment provides such an important input into the management system for facilities and activities, the processes by which it is produced shall be planned, organized, applied, audited and reviewed in a way that is in accordance with the graded approach. Consideration shall also be given to ways in which results and insights from the safety assessment may best be communicated to a wide range of interested parties, including the designers, the operating organization, the regulatory body and other professionals. Communication of the results from the safety assessment to interested parties shall be commensurate with the possible radiation risks arising from the facility or activity and the complexity of the models and tools used."

GSG-6 [23] provides recommendations on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). Communication and consultation are strategic instruments that support the regulatory body in performing its regulatory functions. They enable the regulatory body to make informed decisions and to develop awareness of safety among interested parties, thereby promoting safety culture. The establishment of regular communication and consultation with interested parties will contribute to more effective communication by the regulatory body in a possible nuclear or radiological emergency.

Further information on communication and consultation is available in Refs [40–46], however, so far, communication of the safety case has not been addressed in IAEA reports.

5.3.3. Other reports

There are many industry reports which address the communication challenges with respect to radioactive waste disposal and provide best practices for communications with interested parties. In addition to the IAEA publications referenced in the previous section, one such report includes the NEA Communication on the Safety Case for a Deep Geological Repository [47]. While the report is devoted to the topic of communication of the safety case for deep geological repository, its purpose is to collate the lessons and insights in order to guide ongoing stakeholder communication efforts by operating organizations and the regulatory body. It includes also reviews of a number of documents from the NEA and the European Commission, and several national communication activities.

As stated within the NEA report [47], the key principle is a two way communication with all interested parties, where the communication is oriented towards communicating 'with' rather than 'to'. This includes entering a dialogue and engaging with interested parties from the beginning of the process. Such an approach enables understanding of the issues from the stakeholder perspective and therefore helps to facilitate a successful communication outcome. As shown through past lessons cited in the NEA report [47], communication is an interactive process and can be a challenging task.

Key points from the NEA report [47] with respect to communication of the safety case for a radioactive waste disposal facility can be summarized as follows:

— When conveying complicated or technical information to the public in plain language, clear, accurate and accessible information that does not minimise or exaggerate issues has been found to be necessary and practical.
— When discussing technical issues with public stakeholders, an explanation of the national regulatory framework for ensuring safety should first be provided, giving an overview of defence-in-depth and emergency preparedness, in particular, to demonstrate the completeness of the regulatory process and build public confidence in the regulator's competency.
— It is important to provide the information on the decision making process for different stages of the potential radioactive waste disposal facility, with identification of responsible authorities and their roles, to point out the future decisions which may be taken and where interested parties can participate.
— It is recommended to explain how the radioactive waste disposal facility has been designed to be safe corresponding to the risk associated with the waste to be disposed.
— Material, describing technical concepts or issues, should be tailored to engage the audience and should take into account their education levels, interests and risk perceptions and preferred methods of reviewing information.
— Tools such as photos, diagrams, infographics and animations are effective in illustrating the complex, long term process of disposal facility evolution.

- In dealing with critical observations, it is important to understand the emotion behind the issue and recognize that interested parties may have a different concept or definition of risk than technical experts or regulators.
- When communicating about risk, being open about the inherent uncertainties and presenting information in an uncomplicated manner can help build the public's trust, as well as increase receptivity to understanding and discussing issues constructively.
- The use of indicators is one possible line of reasoning to provide additional assurance of repository performance. Engaging the public in developing the use of indicators and/or assisting non-technical audiences to understand the applications/interpretations of different indicators and monitoring of results could enable local communities to better appreciate the functions of the engineered barriers and the repository system.
- Monitoring, which may consist of qualitative and quantitative parameters, can be an effective means to address public concerns. Clear rules governing the planning and performance of monitoring as well as the sharing of the results will avoid a potential distrust in the information.
- As observed in many national programmes, considering the reversibility (of decisions) and the retrievability (of the emplaced waste) to add flexibility to the implementation process and robustness to the waste disposal system involves balancing safety, practicality and cost.
- The potential uses of natural analogues is discussed and the potential value of using analogues for public communication and confidence building. The visual appeal of some analogues (e.g. the longevity of Roman establishments or the burial mounds in North America) has led some countries to bring analogue information into their engagement with non-technical audiences.

Lastly, in the report it is recognized that effective communication with interested parties occurs when communication experts are integrated and involved, in addition to the technical experts improving their own communication skills. An essential starting point for communication is trust in the responsible organization which can be gained in the appropriate interactions.

5.4. EXPERIENCES AND INSIGHTS

During the Forum on the Safety of Near Surface Disposal, feedback from the Forum participants was gathered through the use of a questionnaire, presentation of case studies as well as general discussions with participants who have had experience in communication of a safety case. The Forum participants identified some general insights on the basics of communication, good communication practices as well as general communication issues and challenges. More specific topics related to the communication of safety case for near surface disposal included: communication strategies for the various stages of the evolving safety case, roles and responsibilities in safety case communication, coordination of communication among official parties, building trust and confidence with interested parties, communication with media, communication of complex or technical information, and effective communication mechanisms and approaches. The results are summarized below entirely on the basis of the information received from the Forum participants.

The Forum participants who answered the questionnaire are mainly representatives of regulatory bodies, operating organizations and several technical support organizations. The composition of the Forum changed over the years, and the participants might not have been a representative sample. Therefore the findings presented are just an illustration of various perspectives.

5.4.1. General insights

5.4.1.1. Basics of communication

For effective and efficient implementation of communications on a safety case for near surface disposal, it is best practice to establish a communication plan with ongoing monitoring and evaluation to identify areas for improvement. Each official organization involved in near surface disposal would have its own communication plan, but the core responsibility is with the operating organization. The communication plan is a key tool for properly addressing a general approach to the safety case communication and specific issues raised, and for efficient planning and use of the human and financial resources. In some Member States the regulatory body reviews the operating organization's communication plan.

There are several basic steps in the development of the communication plan for any activity, including the following:

- Identification of the communication objectives and goals;
- Consideration of background which includes the social climate, national framework and context in which the activities are taking place;
- Identification of interested parties and stakeholder mapping;
- Development of the key messages;
- Identification of communication mechanisms and approach, including establishment of communication tools;
- Development of the communication plan;
- Implementation of the communication plan;
- Ongoing monitoring and evaluation to identify areas for improvement;
- Update of the communication plan according to the evaluation results.

A communication plan for a near surface disposal safety case is a document explaining how to communicate with different interested parties about the safety case during the different stages of near surface disposal facility. First, the communication objectives and particular goals are clearly identified. The plan could include proactive communication on safety case and supporting documentation, as well as specifying the level of detail at which the communication is to be focused. The communications are likely implemented in social climates and legal frameworks specific to the state; therefore, the background and context in which activities will be performed should be considered, and a brief history of the relevant and related issues given. Also, it is important to point out the decision making process, the stakeholders or parties involved, the documentation developed as part of the safety case, and other circumstances.

For any communication plan, stakeholder mapping is essential and may be performed earlier in the process than implied in the sequencing of the steps above. It enables identification of the interested parties, their specific needs or concerns, and possible impacts or influences such as the ways in which they interact between themselves or in the process. Typical examples of target groups include formal and non-formal representatives who are or could be affected by the activity, such as authorities, politicians, media, local citizens, local representatives, opinion leaders, pressure groups, cross border countries, employees, scientists and specialists, and young people.

For each of the relevant target groups, as part of the stakeholder mapping, it is important to understand their knowledge and initial opinion or perspectives about the near surface disposal facility, as well as their attitudes and behaviour, so as to be able to communicate with them. It is necessary to recognize what is to be addressed, in the opinion of the target groups, in order to meet the goals of the project or communication activity. Also, it is of benefit to identify who could be allies or partners in the communication activity.

The key messages about the near surface disposal facility and the related safety case need to be developed and conveyed to the interested parties. The messages will address the identified issues and concerns, but could also be in general supporting the communication activities of the project. One important issue is the language to be used which needs to be easily understandable and developed for the particular audience. This is not an easy task and the generalization of different processes and complexity of radioactive waste disposal necessitate a very deep understanding of the system and related processes.

The number and types of communication mechanisms (i.e. tools) that need to be developed depend on the message, audience, timing, resources, and legal and regulatory requirements. The communication mechanisms can include different events (e.g. seminars, conferences, meetings, fairs, open days), press conferences, brochures and reports, photos, diagrams, presentations, posters, newsletters, videos or any other recorded material, public information centres, the internet and social media. The communication mechanism needs to be carefully developed and used as needed. It is useful to develop a contact database of all interested parties to be used in the implementation of the communication plan however respecting any information or privacy protection regulations.

The communication plan, identifying the key communication activities, also includes the target time frame for key communication activities to occur in order to support the progress and evolution of stages in the near surface disposal facility. The coordination team for implementation of the communication plan will need to be specified and include the organization’s senior management when appropriate. The team should typically consist of relevant technical experts and communication staff. All those listed as having responsibilities with regard to implementation of the communication plan need to be aware that they are listed. The communication plan needs to address potential controversies and sensitive issues, pre-identified key interested parties, important timing elements, etc. Each challenge identified can then be linked to specific steps or mitigating activities. A list of frequently asked questions (FAQs) and their responses can be developed to anticipate questions raised by interested parties. These answers need to be easily understandable and made available in written form. The list of FAQs needs to be regularly reviewed and updated as required.

As part of the communication plan, approaches for monitoring and evaluating the effectiveness of the communication activities (i.e. lessons) can be developed in order to support continuous improvement of the communication plan. This may include requesting feedback surveys by the parties targeted by the communication activity. Based on the monitoring reports, the related actions could be agreed (such as unresolved questions, documents to be provided, needs for further communication) and also ways to improve and update the communication plan. The updates are developed depending on the intensity of the process, but in the most intensive stages, like site selection, probably on a yearly basis or more often.

More information can be found on the IAEA Nuclear Communicators’ Toolbox[1].

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[1] Available online at: https://www.iaea.org/resources/nuclear-communicators-toolbox

5.4.1.2. *Good communication practices*

Several good communication practices were identified through the experiences conveyed by Forum participants and include:

- Good communication skills, including listening to the interested parties, using non-verbal communication and being empathetic, clear, concise and confident during the discussion.
- Concerns and fears expressed by interested parties might not be rational so it might not be possible to address them with strictly factual arguments. The communicator needs to have an open mind to be prepared for any situation while always conveying respect to the interested parties.
- Effective communication requires building trust which means involving interested parties to the extent feasible and applicable. For example concerns from interested parties may be captured or represented through presentation of safety assessment scenarios (e.g. scenarios of public interest in Canadian surface disposal project) or even changing the disposal design (e.g. the inspection galleries in the Belgium surface disposal project).
- The communication activity and content need to be tailored to the interested parties, and regular effectiveness reviews of the communication approach completed as the interested parties and/or their concerns may evolve.
- The importance of the communicating with the general public ought never to be underestimated and there is a need to build an effective communication strategy.
- In performing the communication activities it is beneficial for different disciplines to be involved from all spectrums of natural and technical sciences, including individuals from the social sciences and humanities or independent roles which foster trust with the public (such as academia).
- When interested parties disagree on particular areas, acknowledging how the issue and concern has been dispositioned, or identifying the path forward for any outstanding issues, can demonstrate the integrity of the dialogue and that various perspectives have been considered.
- In public meetings such as open houses, it may be necessary to organize the meetings in smaller groups, such that all participants have the chance to express themselves without the presence of more vocal interested parties.
- Education and awareness initiatives, such as discussions on nuclear science, technology and radiation, within the school system can support establishing knowledge levels about radioactive waste management which will support communications later.
- Information needs to be very clear, understood by the public and delivered in a timely manner. The communication plan needs to identify a suitable channel of education and sharing information with the public. This would help to mitigate any misinformation or fears with respect to radioactive waste management.

5.4.1.3. *Communication issues and challenges*

Several more general issues and challenges with respect to communication of radioactive waste management and disposal include:

- Radioactive waste management and near surface disposal are often associated with other activities, such as the predisposal management of waste and remediation of areas after nuclear accidents or activities related to electricity policy and production including climate change. Therefore, when dealing with near surface disposal, other associated frames can impact the communication. It is often believed that the communication is trivial, but it often has profound effects on the acceptance of safety case and the disposal facility.

- It can be challenging to communicate with interested parties who are, in general, against nuclear energy thus also opposed to radioactive waste disposals. This can often impact the willingness to communicate in an open manner.
- During coordination between the various official organizations regulatory bodies need to maintain their independence from operating organizations as they represent the main authority with regard to nuclear, radiation and environmental safety.
- The need for clear policy on radioactive waste disposal in order to reach a long term decision and a stable national framework for the establishment of disposal facilities.

5.4.2. Specific communication topics for near surface disposal facilities

5.4.2.1. Communication strategies for various stages of the evolving safety case

The timing and level of engagement with interested parties will be dependent on the specific stage of safety case and disposal facility development. However, it is best practice to clarify the various communication strategies as early as possible in order to ensure communication activities are properly planned and implemented.

During the initial stage in the process (e.g. 'need for action' and 'disposal concept') the issues to be clarified in the communication strategy could be:

- Coordination of communication for near surface disposal facility on a national level.
- Communication on the purpose of the disposal project and consequence of 'do nothing'.
- Communication of the legal requirements and responsibilities of the interested parties involved.
- Communication of the process of establishing the disposal facility (including the iterative nature of the process).
- Role of the public in the establishment of the disposal facility (e.g. level of participation in the decision making process).

While this early stage usually does not involve a formal authorization, the regulatory body needs to be kept informed of all relevant developments and may have a formal obligation to advise the government as part of the communication.

The various stages of near surface disposal facilities imply different approaches to communicating the safety case outcomes reflective of the level of engagement from the interested parties. There was agreement from Forum participants that, with respect to communication, the most difficult stage of near surface disposal can be site selection. The lessons discussed included many cases of failed site selection, mainly due to public opposition. Thus, this seems to be the most important part in the communication process and needs to be carefully planned by the operating organization (or government depending on the national framework). The communication activities need to be prepared to cover broad topics from policy development, generation of radioactive waste, criteria for site selection, possible design of disposal, safety issues, licensing processes and decision making, and any other issue which arises in the first interactions with the public. Results of successful site selection also show that is important to establish flexible process in which the challenges can be successfully resolved.

While it is recognized that the development of a disposal facility for radioactive waste can take years, Forum participants expressed the view that the delays in the implementation of already announced activities (including according to adopted strategies and plans) might have a negative effect on the process of building trust and confidence with the interested parties.

5.4.2.2. Roles and responsibilities in safety case communication

There may be many different official parties within the near surface disposal 'establishment', including parliament, government, ministries, regulatory bodies, operating organization, technical support organizations, waste generators, local authorities, transportation companies and other companies within industry. Depending on the process, the official parties would be identified, and their roles defined, for example:

(a) Ministries: Establish legal infrastructure, make the law, set the policy;
(b) Regulator body/bodies: develop a strategy according to the given policy;
(c) Operating organization(s): develop a strategy according to the given policy.

All official parties are likely involved in the communication of the safety case at some point in the stages of near surface disposal facilities. While any particular role depends on the national framework, including the country specific approach to authorizations, based on the feedback of Forum participants the respective roles and responsibilities include:

— The government (which has primary role during 'need for action' and possibly 'disposal concept') is responsible for communicating the national framework and decision making process. The government may discharge this communication responsibility to the regulatory body.
— The operating organization (which is responsible for the development of the safety case) is primarily responsible for communication along with the regulatory body (which is responsible for the review and approval of the safety case and supporting safety assessment).
— The operating organization plays the more significant role in the communications with respect to the general public, municipalities, local groups and non-governmental organizations.
— The regulatory body plays a more significant role with rendering information to the parliament or other governmental and Member State bodies. Furthermore, the regulatory body and/or other State bodies are also obliged to provide information on the international level in order to fulfil the obligations under the conventions regulating access to environmental information and transparency.
— Engagement of experts within technical support organizations (especially in this collaborative/integrated industry) ensures the delivery of scientific and technical information supporting the safety case. The exchange of information is mandatory for the analysis and submission of the correct information to interested state authorities for decision making.
— Recognizing that communication is a mutually beneficial process, the public plays an important role in communication of the safety case, as the government and regulatory body could receive input from the public for the purposes of formulating strategy and policy positions and their clarification and/or amendment.

The communication strategy may also identify the speakers for particular topics. Specifically, during communication with interested parties, according to the scope of the questions, the appropriate responsible organization(s) need to be identified for the provisions of answers (e.g. operating organization, government). In general, each responsible organization responds to questions related to topic of their responsibilities. For example, the regulatory body responds to questions related to the legal and regulatory framework and requirements, review process and licensing. All the official parties responsible for communicating the safety case need to provide objective information to the interested parties (by using appropriate technical and legal terminology).

5.4.2.3. Coordination of communication among official parties

Coordination among the official parties responsible for communication needs to be agreed upon depending on the stage of safety case development. The main official parties — especially the operating organization and the regulatory body — need to develop and coordinate their respective communication plans as appropriate. It is important to have clear lines of communication among the official parties. Other examples cited by Forum participants include:

- The coordination between the regulatory body, the operating organization and technical support organizations during the communication process is important in order to find the most effective approach in order to gain trust of the interested parties including local communities.
- It is important to organize dialogue between the regulatory body and the operating organization starting from early in the preparation and development of the safety case for a near surface disposal facility. This needs to be accomplished in a formal and transparent way so that through the dialogue trust can be established between the organizations while maintaining the necessary independence (e.g. use of administrative protocols).
- One important aspect is also the coordination of reviews with multiple regulatory organizations that are involved in the review and decisions. Operating organizations need to communicate with the regulatory bodies, but these regulatory organizations also need to communicate with each other to understand better their particular role, and the documents, as for some authorities, near surface disposal is not a usual topic of their decisions.
- While it is accepted that the regulatory body needs to be independent, there is also value in technical discussions. This dialogue through the process can have the benefit of early identification of potential issues, or errors in interpretation of legislation and regulatory expectations. The regulatory body will still want to undertake detailed scrutiny on submission of the complete safety case, but early engagement, discussion and acceptance of approaches, which can be termed ‘process by agreement’ may aid communication between the operating organization and regulatory body.
- The coordination between the Member State authorities in the process of providing information according to the requirements of the Convention on Environmental Impact Assessment in a Transboundary Context.

Several effective mechanisms of coordination were identified through discussions at the Forum. These include the use of regular meetings to examine the issues, problems and need for harmonization of approaches. In many countries the regulatory body ensures that the regulation development is public and that all interested persons have the opportunity to raise questions and provide comments on the new legislation. It is found that such interactions are productive as they can bring a lot of inputs and clarify the meaning of the requirements.

Observed gaps in effective communication between waste producers, operating organizations and regulatory organizations were also identified by Forum participants. Of course, the independence of each organization needs to be respected, but there also needs to be open dialogue on technical issues of common concern. One example is the derivation of WAC by the operating organization. Updates to the criteria might take several iterations, preceded by intensive consultations. There is evidence that some WAC were defined without adequate communication with the waste producer beforehand, similar to situations regarding the design (disposal model or acceptable disposal package) for a disposal facility. Waste generators reported a general lack of communication which results in a lack of understanding of how the WAC are established or formulated, which can in turn result in non-compliant waste generation.

There are also challenges with communication of the safety case by technical support organizations or technical staff. The individual staff are specialist in very narrow fields and the general picture could be difficult to understand if not conveyed properly. Also, there can be enormous amounts of data utilized during the development of a safety case for near surface disposal, so understanding all of the details is challenging. Therefore, the information on safety case development has to be exchanged also within the organization using regular presentations, discussion of new concepts, like additional scenarios, models, uncertainties and related results. Use of assessment manuals that compile the approaches, assumptions and parameters to be used in assessments can be a useful means of consistency and communication among technical specialists, who often sit within different organizations. It is important to have clear data management and quality assurance/quality control processes, accessible and relevant to all staff contributing work to the safety case. This will include a documented approach for data elicitation, which may be needed in some assessments.

5.4.2.4. Building trust and confidence with interested parties

Although the risks associated with near surface disposal facilities are not high, interested parties (specifically the public) without or with knowledge of the practices of near surface disposal, will generally express some safety concerns. The public will want to know how such a facility within their community would impact them. Effective communication and trust or confidence building is key to public acceptance of any nuclear installation including a near surface disposal facility to be sited within a community.

The public are most likely to trust an independent regulatory organization with a transparent decision making process and a traceable track record which demonstrates this. Such trust can be the foundational block. It was the view of many Forum participants that an operating organization can build the trust or confidence of the public by demonstrating its full compliance with the requirements of the regulatory body.

Prior to the near surface disposal facility site selection, the operating organization needs to investigate the local community in order to understand them, and to engage with its opinion leaders and explain the purpose of the facility to them. It is very important to provide factual information to the public, including details related to the positive and negative effects associated with siting the facility within their community and the measures that have been or will be put in place to mitigate the negative effects.

It is good practice to hold meetings with representatives and opinion leaders at their convenience and choice of venue. The schedule and agenda for the meeting need to be made known to the general public in sufficient time for them to adequately prepare their questions. The operating organization and/or regulatory body can then work with the representatives and opinion leaders to engage the entire community.

It is essential that the regulatory body explains to the public its mandate, role and the requirements that the operating organization needs to meet in order to be granted any necessary licence (e.g. for site selection, construction or operation). An example of one regulatory organization's approach to communications is provided by Canada (see Section A–4 of the Annex). For trust/confidence building and transparency, it is useful for the regulatory body at each stage, to share its findings, recommendations and conclusions of the regulatory review of the safety assessment and case with the public.

Confidence building can be supported by recognized independent third parties, including academia or other trusted fields. Thus where trust or confidence in the regulatory body is questionable, or where it has been identified as good practice, the operating organization may fund an independent expert or body chosen by the public to review the safety assessment and/or safety case of the facility and advise them accordingly.

The Forum participants recognized the necessity for individuals undertaking communication activities to have specialized knowledge of the safety case. The experiences shared showed that the public are more likely to engage in a dialogue when the individuals from the official parties can provide prompt responses to the questions being asked. Thus, knowledge of the safety case is beneficial for effective communication and confidence building.

Technical experts involved in communication activities need to gain the necessary skills through communication training. There may be a lack of personnel qualified to communicate information on the safety case to the public, particularly with competence to overcome possible 'hot topics' or deal with prejudiced and intolerant attitudes. Training initiatives are needed in order to enhance the capacity and communication skill sets of technical staff to ensure that communications are effective.

Lastly, Forum participants had a variety of opinions related to whether full transparency is needed or even possible. Some participants were of the opinion that full transparency should be used as a tool to build trust among interested parties. The most common opinion was that transparency is important for the acceptability of the nuclear facilities and for building confidence between the official parties (i.e. government, regulatory organizations, operating organizations) and other interested parties. However, the protection of information of a security sensitive or proprietary nature needs to be respected.

5.4.2.5. Communication with media

An important aspect is how to communicate with the media on the safety case for a near surface disposal facility because the media can disseminate information widely and, in this way, impact the general opinion. Even one minor event improperly communicated can have a significant impact. For example, in Norway there was an incident involving the mismanagement of 5.5 litres of liquid radioactive waste from medicine; although it was corrected and reported to the authorities, the incident received a lot of attention in the media.

Building strong relations with the media is important in order to properly communicate the safety case outcomes. To build such strong relations, interactions with the media might need to be more frequent than only once a year as is the case in some programmes. Plans need to be developed to proactively establish contact with the media in order to build trust and develop ways of resolving difficult situations.

The Forum participants expressed the view that it is also appropriate to use the media as a platform to explain certain technical aspects of the safety case and send clear messages to the public. Information has to be provided openly and correctly, with questions answered in a concise and clear manner, and general issues can be discussed with the public to provide context (e.g. the activities leading to the production of radioactive waste that were beneficial to society). Furthermore, improving the relationship with the media can usefully include helping media representatives to better understand the technical aspects of the disposal projects and the special terminology used, with a view to discussing the safety case in an informed and objective way, based on information that is presented correctly and not taken out of context.

At the same time, the majority of the Forum participants also cautioned that there is a tendency for the media to select or highlight negative storylines over positive ones, and to publish inaccurate or misleading messages. In these cases, publication of corrective statements can be considered and pursued by the appropriate official party. In this respect, it is better to exchange information with media representatives who are neutral and are capable to evaluate the facts in an objective and professional manner. In view of what has been stated, it is important that communication with the media is undertaken by staff trained to do so.

5.4.2.6. Communication of complex or technical information

There is a lot of complex and technical information in the safety case for a near surface disposal facility that is relevant to communicate, taking into account the needs of different audiences and the level of their technical knowledge. With respect to communicating the complex or technical concepts of the safety case, as well as nuclear industry specific terminology in general, Forum participants provided the following experiences:

- The level of the audience’s technical knowledge needs to be taken into account. Otherwise interested parties may misunderstand the basis for the safety case and its importance and/or the limits and conditions on waste disposal derived from the safety case.A good approach is to recognize and communicate at the knowledge level of the audience.
- For many aspects of the safety case, the details are relevant to explain or communicate to the public. However, providing too much detail creates the risk of confusing the public and could generate new or increased concerns. The level of detail depends on the target audience and the relevance of the topic for communication. Where it is necessary to provide information on how the environment might be affected, a good approach to moderating concerns is to preface the discussion with an explanation of how defence in depth is intended to reduce the consequences of events impacting the environment.
- It can be difficult to communicate the uncertainties that are addressed in the safety case. The issue is very technical and scientists often have different opinions on the understanding of uncertainties. A good approach is to present the overall situation and to describe how uncertainties are being assessed and managed. Open and clear communication on this topic is important as it has the potential to impact interested parties’ confidence.
- The safety case for a near surface disposal facility will consider not only nuclear and radiological safety, but also non-radiological risks and other environmental impacts. Communication will need to account for different regulatory regimes and different audiences for these assessments
- It can be difficult to develop the safety case for several audiences. In principle, the safety case is intended for review by the regulatory body, and includes all the technical details, identified uncertainties and areas of further investigation. When the safety report becomes public, it could be misunderstood, especially as it points to the challenges which need to

be addressed in the future. It has been reported by Forum participants that some non-governmental organizations are abusing this transparency to stress the problems and present them as a lack of knowledge. It may therefore be useful to publish a 'plain language' synopsis type document for dissemination to the general public.

- Generally, it is good practice to explain how the facility has been designed to be safe corresponding to the risk associated with the waste to be disposed. This can be assisted by a clear presentation of the safety functions provided by the facility over time and how these are derived from the safety case and safety assessments. The communication of complex systems and ideas can also be supported by figures such as Fig. 10 to illustrate the safety functions.
- It is particularly important to communicate on site and disposal project specific features and on plans for the preservation of information and knowledge after closure of the disposal site.

The application of graded approach within the safety case for near surface disposal can support the determination of key messages or topics for emphasis during communication. For example, the hazardous lifetime of the waste to be disposed in a near surface disposal facility is typically orders of magnitude lower (hundreds of years to thousands of years) than the one associated with high level waste (hundreds of thousands years to millions of years). Therefore, the uncertainties associated with post-closure evolution of the disposal system, and the associated post-closure safety assessment scenarios might take secondary importance to the WAC and their verification. Thus the key messages developed will tend to focus on the short lived nature of the inventory and operational controls to ensure the waste inventory is controlled.

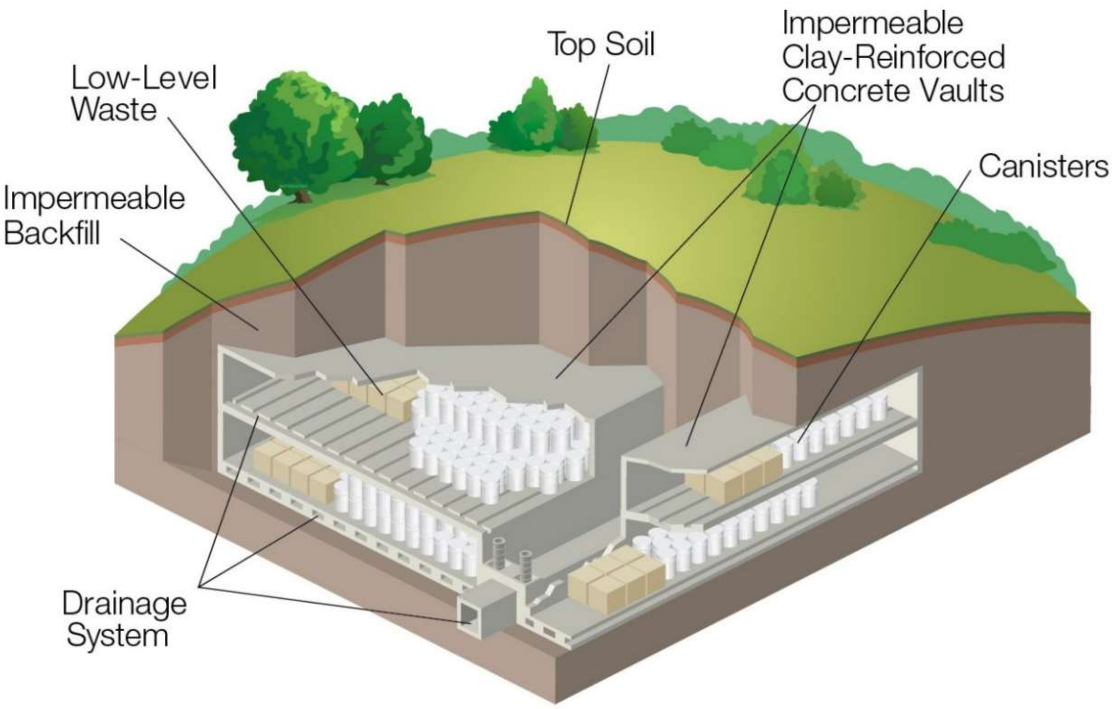

FIG. 10. Example illustration of near surface disposal of low level waste from an 'easy to read' Information Digest publication (reproduced from Ref. [48]).

5.4.2.7. *Effective communication mechanisms and approaches*

With respect to general communication mechanisms and approaches, several examples were identified by the Forum participants and can be summarized as follows:

- Submitting reports (including annual reports) to the parliament, government, the local authorities, international institutions and other bodies; providing information in response to oral or written parliamentary questions; coordinating stakeholder involvement and communication during the safety case development process.
- Taking part in workshops, conferences and other international forums to discuss environmental and safety issues in order to cover safety aspects, environmental monitoring and control, emergency preparedness and response and other relevant matters.
- Initiating, organizing and holding technical meetings, consultations, discussions and video conferences between the stakeholders (most often between the operating organization and the regulatory body).
- Ensuring access to information for the media, interest groups and non-governmental organizations through the communication channels; organizing 'tables of transparency'; holding public meetings, including in universities and schools; running public information campaigns.
- Communicating through formal publications, including on official websites, social media, press releases, newsletters, official letters and short messages.

Several mechanisms for communication of complex or technical information related to safety cases were also identified during the Forum. There was general agreement that the communication tools adopted need to be reflective of the target audiences, use clear and simple language, and include wherever possible figures and other visual aids. The following can support the communication approach:

(a) Using data (e.g. numbers, statistics, relations) to communicate when appropriate.
(b) Applying logic to support the communication. For instance, the use of nuclear energy and the nuclear applications generate waste that needs managing in a safe manner. There is an international consensus that employing the multibarrier approach to the design of a disposal facility according to the national legislative requirements, is the appropriate way to support safety and keep under control the associated risk to humans and the environment.
(c) Using pictures and infographics. Visual information, graphics or data visualization (such as the infographic in Fig. 11) can be used to present information quickly and clearly. Visual elements tend to be easier to understand and remember for the stakeholder.
(d) Using stories or analogues.
(e) Encouraging participation of all responsible bodies in the events.
(f) Using metaphors and analogies to support the communication.
(g) Finding ways to make it matter to the audience.
(h) Explaining concepts using details the audience already knows.
(i) Leaving out unnecessary details.

Social science research can also be a very valuable input for the communication of the safety case for near surface disposal. It can be used in many different ways in order to complement the findings of the technical and natural science research. Social science researchers like sociologists, psychologists and political scientists could help the operating organization to better design the material to be used in communication of the near surface disposal safety case and to fit the needs of the audience, to improve understanding of the perception, attitude and opinion of the audience by helping to create appropriate surveys or other evaluation methods, to find out the elements which are important to particular interested parties or to understand the social dynamics in the community.

5.4.3. Case studies

During the annual meetings of the Forum on the Safety of Near Surface Disposal several examples of communication of the safety case were presented. A template for describing Member State cases and providing examples of communication was developed and collected during the Forum. The template includes fields for a description of the context, the communication parties involved, the main messages to be conveyed and the target audiences. Further, the template focuses on the communication tools and materials used, results of communication, difficulties encountered and any lessons learned. The objective of this exercise is to obtain a description of cases and examples where:

- Communication with certain interested parties resulted in improved understanding of the safety case;
- Communication brought better understanding of the needs of the interested parties and there were lessons learned for better communication in the future.

Four case studies are given in the Annex. The first case study describes the communication of near surface disposal site selection phase in Cuba, the second provides an example of stakeholder communication for implementation of near surface disposal facility Environmental Safety Case in the United Kingdom, the third addresses stakeholder consultation on near surface disposal site selection in Pakistan, and the fourth case discusses the regulatory approach to consultation and engagement with indigenous groups in Canada.

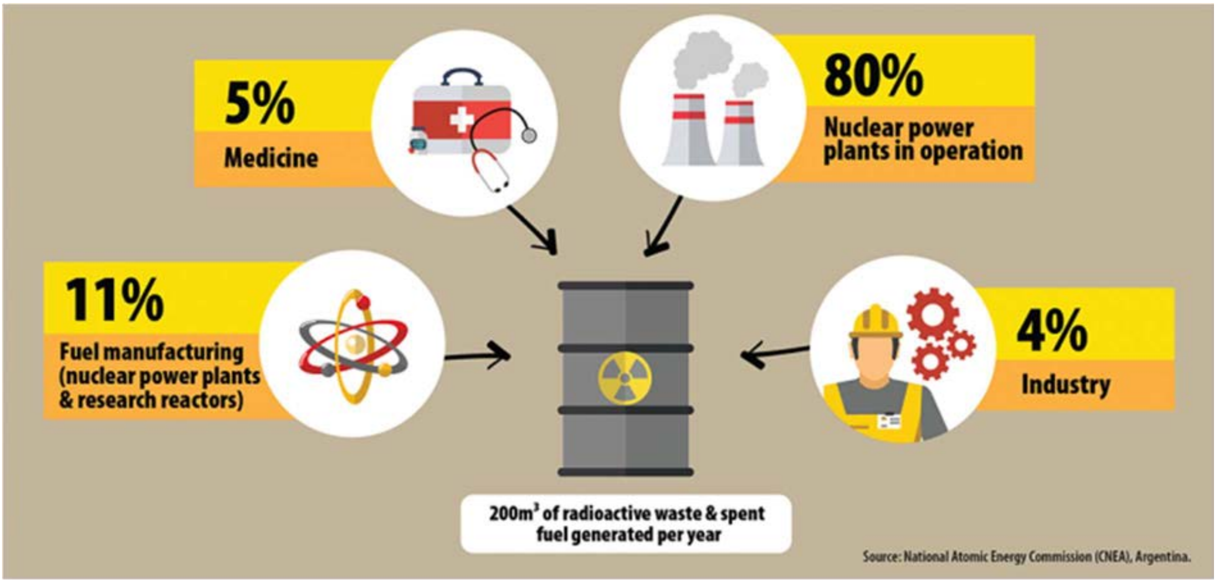

FIG. 11. Example of using graphic information to summarize radioactive waste streams in a country (reproduced from https://www.iaea.org/newscenter/news/seeking-a-solution-for-radioactive-waste-in-argentina).

5.5. CONCLUSIONS AND RECOMMENDATIONS

Overall, based on the collected case studies and examples, as well as the general discussions from the Forum, some common lessons learned can be deduced with a general value for communication of the safety case for near surface disposal:

- There is a need for clear national policy and strategy for disposal of radioactive waste and these need to be supported by appropriate communication strategies, and communication plans within each of the responsible organizations involved in the delivery of the national strategy.
- Effective and efficient communication of the safety case for near surface disposal is a continuous activity which has to be carefully planned and monitored.
- It is very important to identify and include in the communication plan all interested parties based on regular mapping in an iterative process as well as the appropriate communication actions suitable for the different parties, in particular for the local community involved in site selection.
- Optimal communication strategies and approaches are needed to ensure effective and efficient two way communication, recognizing the need for constant trust building with interested parties by all involved official organizations.
- Different interested parties might have different interests and communications needs.
- Safety case documentation needs to be accessible to all interested parties, using both web based options (including embedding hyperlinks and search functions to enable key information to be accessed easily) and alternative information provision for those in the audience unable or unwilling to access the internet.
- The communication plan needs regular review and modification to identify areas for imporovement, such as poorly understood concepts for which a different communication approach might be needed. This will ensure a sufficiently flexible process and can lead to a more robust understanding of the safety case.
- Develop the key ‘concept summaries’ into animations and infographics that can be embedded across multiple presentational formats (e.g. documentation, PowerPoint presentations).

6. FORUM OUTCOME

This publication results from the work of the Forum on the Safety of Near Surface Disposal during the period October 2017 to October 2023. During this period the Forum examined experiences and discussed best practices in:

- The use of the safety case in decision making on near surface disposal;
- Regulatory experiences and processes;
- Post-closure safety assessment;
- Communication of the safety case.

The Forum on the Safety of Near Surface Disposal has provided for many useful exchanges between Member States, and for the effective training of staff from many countries on the use of the safety case in decision making on near surface disposal.

Even though most countries follow IAEA requirements and guidance related to the safety of near surface disposal facilities, the discussions allowed identification of some differences in the application of the guidance in the different countries, as different national regulations apply.

The exchanges documented here may be helpful to people involved with safety cases and decision making on near surface disposal, and complement the safety requirements and safety guides available within the IAEA Safety Standards Series.

The Forum on the Safety of Near Surface Disposal is the only international forum for discussion on this topic and serves an important and valuable function.

APPENDIX
DETAILED INFORMATION ON REGULATORY REVIEW OF THE SAFETY CASE

A.1. TECHNICAL ASPECTS OF REGULATORY REVIEW OF SAFETY CASES FOR DISPOSAL FACILITIES

This section contains information on technical reviews of safety assessments and safety cases. The information here focuses on the review of post-closure safety assessments, but is likely to be equally relevant to an evaluation of safety during the operational period.

The primary objectives of regulatory reviews of safety assessments are:

- To determine whether the safety assessment demonstrates that the disposal facility complies with waste management principles and regulatory requirements, criteria and guidance.
- To determine whether the safety assessment has been conducted in an acceptable manner, is of sufficient quality, breadth and depth, and is fit for purpose.
- To contribute to regulatory decisions on whether to proceed with the next step in the authorization or licensing process for a disposal facility.
- To provide a means of determining appropriate authorization limits, conditions and controls on a disposal facility.

In order to assist with evaluating the safety case against the primary review objectives, it is common for a number of secondary objectives to be specified. These are likely to include an evaluation of whether the safety assessment:

- Is based on an appropriate assessment context and integrated with the overall approach for the safety case;
- Is sufficiently complete, given the status of the disposal programme and disposal facility.
- Is sufficiently transparent in its presentation of data and information;
- Is based on appropriate assumptions and contains adequate and traceable arguments supporting the adoption of those assumptions, including assessment scenarios, models and parameter values;
- Demonstrates an adequate understanding of the disposal system and contains a clear line of argument that supports a statement of safety;
- Clearly identifies the uncertainties associated with the understanding of the disposal system and the performance of the disposal facility and contains a clear statement of how uncertainties are managed;
- Has been conducted under a suitable quality assurance system.

Important topics associated with the conduct of safety assessments, and that will form part of the wider safety case include consideration of whether:

- Adequate information has been provided to justify that the radiological impacts of the disposal facility are as low as reasonably achievable, economic and social factors have been taken into account (‘optimization’), and that the site selection, facility design and safety assessment are based on science and engineering according to the state of the art.

- Adequate information has been provided to define an appropriate forward programme for improving the safety assessment, understanding of the disposal system, and control of the site.

- Adequate information has been provided to demonstrate the robustness of the disposal system. This includes demonstration of the robustness of individual barriers and their safety functions; evaluation of the defence in depth concept; verification that good engineering practices (demonstrability and feasibility) have been used; and demonstration that safety is achieved through passive means.

The regulatory process requires the operating organization to compile and present all safety arguments and the accompanying evidence, particularly where key decisions relating to progressing to the next phase of development are to be made. These arguments and supporting evidence can be presented in a variety of documented formats, and collectively they are referred to as the safety case.

The safety case sets out information on the design, construction and operational options considered and the key features on which safety relies. As a rule, it includes a programme of work to acquire enough knowledge to demonstrate the safety of the disposal system. Assessing the soundness of the considered options is essential to enable the project to move forward from one phase to the next.

The safety case will contain:

- The safety strategy, which sets out the high level approach for achieving safe disposal, including the siting and design approach, the strategy to manage the activities and the assessment methodology;
- The assessment basis, which sets out the information and analysis tools that support the safety assessment and describes the disposal system, the data and understanding relevant to the safety assessment and the methods, models and computer codes for analysing system performance and radiological impact;
- The safety assessment, which is the process of systematically analysing the hazards associated with the facility and the ability of the site, the host rock and the operational procedures to provide the safety functions and meet technical and safety requirements. The safety assessment also includes additional evidence and analyses for safety and for confidence in safety;
- The management system, which structures the overall approach for managing the activities conducted by the operating organization;
- A synthesis of all the available evidence, arguments and analyses and conclusions regarding the safety of the disposal and the level of confidence reached by the operating organization.

The safety case needs to demonstrate that all relevant data and information have been considered, all models have been tested adequately and a rational assessment procedure has been followed. It needs to include a verification of the consistency and completeness against regulatory expectations.

The regulatory review is generally performed against the regulatory expectations and acceptance criteria. A graded approach has to be applied depending on the complexity of a particular facility. SSG-23 [6] lists a number of secondary objectives for the review of the safety case and supporting safety assessment. Additional objectives to cover monitoring and surveillance and emergency preparedness are provided in GSG-3 [16]. Key factors for a regulatory body to consider during the evaluation of the safety case include verification that the safety case:

- Has been developed within an appropriate context;
- Is sufficiently complete, given the stage of development of the disposal facility;
- Is sufficiently transparent in its presentation of data and information;
- Has been prepared by competent personnel applying an approved management system;
- Has been subjected to independent peer review;
- Is based on appropriate assumptions, makes use of adequate assessment techniques and models, and contains satisfactory supporting arguments;
- Demonstrates an adequate understanding of the disposal system that includes identification and screening of hazards and related scenarios, such that all relevant safety functions and all potential safety concerns are addressed;
- Clearly describes how the identification, establishment, justification and optimization of limits, controls and conditions were performed;
- Clearly identifies the uncertainties associated with the understanding of the disposal system (as well as input data and models used) and the performance of the disposal facility;
- Provides an adequate assessment and supporting justification that any radiation exposure has been optimized and demonstrates that safety has been optimized to prevent accidents, appropriate protective measures have been identified, the consequences of accidents will be mitigated appropriately, and doses are as low as reasonably achievable throughout the lifetime of the facility;
- Includes adequate consideration of the justification and optimization of remedial measures for existing facilities, if applicable;
- Addresses all relevant factors of the management system to be applied for the siting, construction, commissioning, operation and closure of the disposal facility (e.g. internal and external audits, verification and validation, use of suitably qualified and experienced personnel, training, control of processes outsourced to subcontractors, action on conclusions and recommendations);
- Provides for adequate planning of emergency preparedness measures;
- Provides for adequate planning of surveillance and monitoring (maintenance) measures, and provides surveillance and monitoring data to show that design objectives have been achieved;
- Demonstrates that good conservative, proven design and engineering practices with adequate defense in depth have been used in developing the design of the facility;
- Provides for adequate recording of the data of the operation of the facility to maintain the knowledge and evaluate the operational experience, also for future generations;
- Defines a programme for future maintenance of the safety case, understanding the disposal system and institutional control of the site;
- Demonstrates that appropriate codes and standards have been applied to the design, manufacturing, construction, installation, commissioning, quality assurance, testing and inspection of structures, systems and components that are important to safety;
- Ensures that the reference accident considered in the design phase remains valid, and that adequate information on access control, physical security and surveillance is available;
- Takes into account changes in demography, if applicable.

In order to evaluate these issues, it is helpful to break down the review into a series of elements, against which more specific technical questions can be asked. For example, some basic content expectations can be identified:

- Safety case context:
  - Regulations identified and understanding demonstrated;
  - Level of detail appropriate for stage in disposal facility development.
- Development of the safety case:
  - Identifies appropriate understanding for the main phases of disposal facility development and timescales;
  - Clearly demonstrates and justifies how updated from any previous versions.
- Management of the safety case:
  - Appropriate quality assessment control system used;
  - Model quality assurance and procedures;
  - Data management quality assurance and procedures;
  - Management of contractors;
  - Staff competency;
  - Change control process.
- Documentation of the safety case and safety assessment:
  - Sufficient transparency in data;
  - Safety strategies documented and justified (claims, arguments, evidence);
  - Demonstration of defence in depth;
  - Satisfactory supporting arguments;
  - Appropriate assumptions.
- Understanding of the disposal system:
  - Waste inventory and waste form sufficiently understood — radioactivity, non-radioactive components, waste form, heterogeneity;
  - Hazards identified;
  - Engineering design described (e.g. containers, disposal facility, backfill, closure engineering);
  - Understanding of the site and its environs;
  - Exposure pathways understood;
  - Adequate conceptual model of the disposal facility;
  - Significant uncertainties (conceptual, scenario and parameter) identified, their potential impact understood and measures in place to manage them;
  - Items important for safety and safety functions clearly defined.
- The safety assessment:
  - Appropriate scenarios, including variants;
  - Appropriate source terms, activity concentration, assumed waste form, hazardous components, heterogeneity;
  - Understanding of evolution of the waste form with time;
  - Relevant pathways considered;
  - Relevant receptors assessed, humans and biota;
  - Appropriate models used (e.g. process, assessment and screening level);
  - Criticality;
  - Adequate demonstration of the linkage between the various models.
- Optimization:
  - Overall concept demonstrated to be the optimal solution;

- Components of the engineering design optimized;
- Doses and risks as low as reasonably practicable;
- Potential for accidents minimized, appropriate protective measures identified and mitigation measures for any consequences defined;
- Remedial measures for existing facilities justified and optimized, if required;
- Good engineering practices used.

— Operation and management of the site:
  - Key components of the management of the disposal system through all relevant phases identified;
  - Audit programme;
  - Confirmatory monitoring of consigned waste;
  - Monitoring and surveillance of the performance of the engineering and environmental discharges;
  - Planning for maintenance;
  - Planning for emergency preparedness;
  - Waste acceptance criteria defined, justified and met, consistent with the safety case;
  - Change control process defined, at what stage are changes sufficient to trigger an update to the safety case and/or WAC;
  - Identification, establishment, justification and optimization of limits, controls and conditions;
  - Forward programme for future development of the site (full lifetime) including relevant research and development;
  - Characteristics and properties of each component of the disposal system and their roles for safety functions described;
  - Impact of any modifications of the design clearly explained;
  - Incidents/occurrences and their corrective measures clearly recorded;
  - Emergency planning and response consistent with the design basis accidents demonstrated.

A.2. REGULATORY REVIEW THROUGHOUT THE LIFETIME OF THE FACILITY

This Appendix provides more detailed information on the roles of the regulatory body and communication activities throughout the lifetime of a disposal facility following the stages shown in Fig. 3.

A.2.1. Need for action

For a new facility, this stage involves a decision that new disposal capacity is needed. Such a decision will typically be taken at government level. This stage could also include identification of a need for a decision regarding a path forward for a historical disposal facility.

A.2.1.1. Government/regulatory body

There is generally no regulatory body involvement at this stage when developing a new disposal facility. However, one or more existing regulatory organizations may be involved in identifying hazards that suggest a need for action at an existing facility. This stage should include the start of discussions on the regulations that are needed and the path forward for establishing the regulatory bodies to develop and enforce the regulations. This stage is nevertheless important for regulators, because decisions at this time will have a lasting impact on the regulatory regime.

Considerations during this phase include:

- Identification of any existing regulatory organizations and applicable regulations, and of the need for new regulatory organizations and regulations. In cases with multiple regulatory organizations (which are common), it is essential to clearly identify the roles and responsibilities of each regulatory organization (especially when there may be local regulatory organizations in addition to national regulatory organizations).
- Specification of provisions to address changes in regulations, and changes in limits on waste streams, inter alia.
- Establishment of mechanisms to document the decision process and any justification of the basis for decisions. Such documentation also helps with public communication and establishing the baseline for the approach that was adopted.
- Description of expectations in accordance with the graded approach and how the regulatory role is expected to evolve over the lifetime.

A.2.1.2. Communication with interested parties

Communication at the government level will be important during the establishment of new organizations and their responsibilities and roles taking due account of any existing regulatory organizations.

Public consultation and communication channels also need to be defined and established. It will be important to set clear expectations regarding how the public will be involved in establishing regulations and in any reviews that are to be conducted. Specific information that can be communicated for reviews would include (some of these may be specified in the course of developing regulations):

- When reviews are planned to be conducted;
- The level of public involvement that is planned for different reviews and the duration of review and comment periods, especially when the public is involved;
- Plans for monitoring both by the operating organization and by the regulatory body;
- Plans for independent peer reviews.

A.2.2. Disposal concept

This stage of the lifetime involves more specific discussions regarding disposal concepts and the wastes to be managed. Regulatory organizations and regulations have to be put in place and regulatory organizations undertake reviews to support decisions about licensing that may affect disposal concepts. Regulatory organizations engage in discussions with the government, waste generators and interested parties.

A.2.2.1. Government/regulatory body

During this stage of the lifetime, the regulatory body will be establishing and implementing the regulatory framework to be applied and also may be involved in the review of the basis for selection of a disposal concept. Considerations for the regulatory body during this time, include:

- Evaluating the potential suitability of disposal concepts for all of the different waste types that need to be disposed of (e.g. surface disposal facilities to manage short lived waste), including reviews of safety cases, as applicable (informal or formal).

- Identifying requirements and objectives related to appropriate disposal concepts for specific wastes (general recommendations — at this time, it is important to avoid overly prescriptive specifications based on limited information).
- Verifying that all waste that needs to be managed has been identified in accordance with the national legal and regulatory framework and relevant international instruments (e.g. conventions). Also verifying that disposal routes have been identified for all waste types and/or identifying wastes that are not addressed by an identified disposal concept.
- Ensuring that both operational and post-closure safety are considered.

A.2.2.2. Communication with interested parties

Communication at this stage will include interactions with the government, waste generators, and interested parties as regulations are developed and disposal concepts are considered. Considerations for these communications include:

- Continuing public interaction to describe the waste to be managed and introduce the concepts being considered for disposal.
- Providing perspective regarding the widespread, successful and safe use of near surface disposal for LLW and other hazardous wastes around the world to help reassure interested parties and counter potential pressures to adopt geologic disposal for all wastes.
- Establishing regulatory communications protocols and consulting with the public on specifics regarding future engagement during the lifetime of the facility (e.g. key decision points for major reviews, planned public involvement in major and minor reviews).

A.2.3. Site selection and design

This stage of the lifetime is particularly critical for successful implementation of a disposal programme. Site selection and the development of a preliminary design are considered together to emphasize that the safety of a disposal facility depends on a combination of the site and the facility design (not one or the other). Siting has proven to be a challenging process in many Member States. Siting and the design process will need to be focused on the waste that is planned to be disposed of. Multiple designs may be adopted in a graded approach to address a variety of waste streams. There can be multiple decision points during this stage with regulatory reviews depending on Member State protocols.

The European Pilot Study [15] addresses some key considerations during this phase:

> "The conceptualization phase, during which an operating organization considers potential suitable sites and design options, establishes the safety strategy (approach to developing a disposal concept, approach to safety assessment and basis for the management system) and carries out preliminary assessments. Regulatory interaction at this stage could guide the operating organization on the likelihood of achieving the necessary demonstration of safety and could help the operating organization decide whether to commit resources to move to the next phase of the project."

Paragraph 1.9 of GSR Part 4 (Rev. 1) [7] emphasizes the need to consider non-radiological effects and effects on non-human biota during early assessments:

> "For many facilities and activities, environmental impact assessments and non-radiological risk assessments will be required before construction or implementation can commence. The assessment of these aspects will, in general, have many

commonalities with the safety assessment that is carried out to address associated radiation risks. These different assessments may be combined to save resources and to increase the credibility and acceptability of their results."

However, GSR Part 4 (Rev. 1) [7] states that it "does not establish requirements for such a combined assessment or make recommendations on how to assess non-radiological hazards."

A.2.3.1. Government/regulatory body

Regulatory considerations during site selection and facility design include:

- Possible approaches to site selection. In general there are two main 'end member' approaches: one involving regulatory establishment of exclusion criteria prior to site selection (prescriptive) and one involving regulatory validation of the site selected after a siting and safety case development process led by the operating organization (non-prescriptive). In the prescriptive approach, the regulatory body is involved in establishing exclusion criteria and design requirements. In the non-prescriptive approach, the regulatory body may prepare a review guide that documents its review process and describes the factors that will be considered in review. The approach in some countries falls between these two end members. Commonly regulatory organizations establish some requirements, but are careful to remain independent of the operating organization, and defer formal involvement until a safety case is provided for review.
- The overall performance of a disposal system is determined by a combination of site conditions, facility design, and waste forms. The establishment of siting exclusion criteria might therefore be overly restrictive if the facility design and waste form requirements are able to complement a non-optimal site.
- Higher level analyses (environmental impact assessments) can be used for an early indication of suitability of site and general design (public consultation). Such analyses are used to compare options and provide initial confidence in the expectation that a proposed site and design can be operated safely.
- Site selection often includes both safety case development and the conduct of environmental impact assessment for the regulatory body to consider.
- When considering alternative designs, specific options for waste streams and waste forms need to be considered, because waste form choices can have a significant influence on performance.
- The regulatory body may develop guidance regarding what level of detail will be reviewed for specific steps (main reports, annexes, supporting information).
- The regulatory body may approve different phases of design (depending on the regulatory body) or wait until a full safety case is provided prior to authorizing construction. A balance between giving an early approval and waiting for final approval through interim steps would need to be considered.
- Safety, security and safeguards conditions need to be considered for siting (this may involve different regulatory organizations).
- As the design process begins, change control needs to be established in order to manage aspects such as changes in the WAC, new waste streams, design modifications and changes to account for feedback from accidents. This is especially important after an initial safety case is developed. Change control is needed to continuously evaluate whether design changes could compromise assumptions in the safety case that might impact long term performance or compliance with regulatory requirements.

- The safety case has to be reviewed by the regulatory body at the site selection and design stage. Some countries also require WAC to be established, even if at this stage they are preliminary. The change control process needs to clearly describe how WAC can be updated in the future pending changes in wastes to be disposed.
- The change control process needs to identify the approach to review proposals for potential expansion of the facility in the future.

A.2.3.2. Communication with interested parties

During the siting and design phases processes for communicating with interested parties are established and implemented primarily by the operating organization. The regulatory body will also need to consider and establish how to involve public in its processes throughout the lifetime of the disposal facility. Factors identified during Forum discussions that might need to be considered as appropriate to the circumstances include:

- A partnership appraoch to communications (e.g. involving local communities) is sometimes established during this phase. The operating organization explains the factors relevant to siting and site selection and provides the basis for the selection made. The extent to which interested parties are involved in decision making on site selection can vary (e.g. from the provision of information to full collaborative inclusion). The regulatory body explains their processes and also answer questions from interested parties.
- Public consultation is often included in authorization and environmental impact assessment processes. Such consultations provide key documentation on the basis for moving forward and provides the opportunity for the public to identify areas of concern.
- Local planning commissions are often involved in decision making prior to construction (there are often other approvals in addition to those made by the national radiation safety regulatory body).
- Public input for the safety case that will be used as the basis for authorization and facility construction and development can help to gain support for the overall programme. The level of engagement in the authorization review is established by the regulatory body.
- Change control processes need to be clearly in place and communicated at this stage. It is important for the public and other regulators to understand that it is anticipated that there may be changes to facility design, facility capacity and other aspects,. and there is a formal regulatory process to consider such changes. The process also needs to address how new information (e.g. research, data) will be evaluated to ensure continued adequacy of the safety case.
- Baseline monitoring information is collected and results available to the public. The monitoring programme for the facility is also defined at this time. It is a good time to discuss background radiation levels and provide perspective regarding the disposal limits that are established versus doses that are routinely received by the public. This should help to place protectiveness of the disposal limits in better perspective.

A.2.4. Construction

The decision to begin construction of a disposal facility is a key milestone in its lifetime. Work efforts evolve from planning to physical activities associated with construction. Considerations for a regulatory body during construction tend to focus on inspections and quality controls, record keeping and reviews of new information that is obtained or changes to assumptions that were made in the safety assessment and safety case used to authorize construction.

The European Pilot Study [15] highlights considerations at the end of the construction phase leading to the second key milestone (approval for operations):

> "The construction (and application for operation) phase, during which the operating organization demonstrates that it has built the facility as planned in the safety case and in accordance with the conditions of the construction licence. Towards the end of this phase the operating organization will present its final approach for operation and a concept for closing the facility. In preparing for operation, the operating organization will need to demonstrate safety during operation and radiation protection of workers and members of the public."

A.2.4.1. Regulatory body

The regulatory body will focus on inspections and reviews of new site information and as built conditions compared to assumptions made for the safety assessment at the end of the design phase. Example considerations for a regulatory body during this phase include the following:

- There will likely be many differences from assumptions for site data and facility design made in the safety assessment before construction. An efficient process is needed for reporting of such changes.
- Clear stipulations are needed for reporting and reviews of new information about the site and changes to the design (i.e. key questions would be to assess if the change is significant enough to require formal regulatory review, what types of changes can be reviewed internally by the operating organization and simply reported to the regulatory body).
- The frequency of regulatory reviews for changes can be efficiently mitigated by including sensitivity and uncertainty analyses in a safety assessment to illustrate the range of acceptable values for input parameters. If new information is within the range considered in the approved safety assessment, a regulatory review might not be necessary.
- Results of the safety assessment (especially sensitivity and uncertainty analysis) can also be used to identify safety significant components and assumptions that need to be a focus of inspections and construction phase reviews. The results may also be used to identify specific laboratory or field studies to be conducted during the construction phase to confirm assumptions.
- Changes or new information may be within ranges considered in the safety assessment, but WAC may have been developed based on specific assumptions. WAC may need to be modified to reflect new information.
- All work on the safety case and on disposal facility development, operation and closure has to be conducted in accordance with an appropriate management systems, and this also applies to work by subcontractors and the regulatry body (e.g. during inspections).
- Independnet scientific experts can be used to support the evaluation of key data. Suitably qualified and experienced experts need to be identified that can be used for peer reviews in advance of the decision for operations. Peer reviews implemented during construction build confidence prior to a decision for operations.

A.2.4.2. Communication with interested parties

The overall communication plan defined at the beginning of the facility lifetime will continue to be implemented. Updates could be made during this phase in accordance with the prescribed process outlined in the communication plan. Some specific actions to be taken in this phase include:

— Continue routine interactions with interested parties to reinforce transparency by sharing reporting of changes and new information and how that information is evaluated by the operating organization and the regulatory body.
— Identify and discuss safety significant components and key assumptions and share results of any studies that are conducted to build confidence that system will perform at least as well as planned.
— Describe how peer reviews will be used to supplement the regulatory review of a safety assessment prior to operations.
— Engage with the public in preparation for the safety assessment review and clearly describe the public's role in the review process.
— Reinforce the need to maintain independence between the operating organization and the regulatory body, but also the need to maintain communication to ensure review expectations are clear.

A.2.5. Licensing and operation

This phase is primarily oriented towards active disposal of waste. However, as noted in the European Pilot Project report [15], the operating organization may design and build new disposal units, and conduct interim or final closure activities for specific units. During this phase, the operating organization also develops an application for final closure of the facility, and prepares a plan for post-closure institutional controls, monitoring and surveillance. Towards the end of this phase the regulatory body will decide whether to grant a licence for the operating organization to close and seal the facility. When the operating licence is granted the operating organization proceeds to the next phase for closure of the facility. There could be multiple licensing activities during the operational phase (e.g. new units, closure of individual units, a significant new waste stream outside the operating envelope of the existing safety case).

A.2.5.1. Regulatory body

This phase requires a diverse set of activities for the regulatory body, spanning design and construction, operations and closure activities. As with the construction phase, inspections, quality control, record keeping and reviews of changes and new assessments will all be part of the regulatory body's duties. Thus, many of the considerations from the construction phase are also applicable here (see Section 3.4.4). A number of new considerations can be identified specific to this phase, related to ongoing operations and preparing for closure:

— The regulatory body can participate in operator readiness reviews to observe/inspect preparations for operations.
— Clear expectations are needed regarding updates to the safety case and when formal regulatory reviews are required (there can be a specific time frame, but the review can also be linked to what would be considered significant changes in assumptions or operations).
— Use of change control process to assess potential need for updates to the safety assessment and/or WAC to account for changes in waste streams, containers, disposal operations and closure concepts, inter alia.
— A cold (non-radiactive) testing phase may be included before a licence is issued.
— Conditions may be applied to the licence (e.g. frequency of formal reviews and/or updates to the safety case, required demonstrations for key assumptions).

- A special analysis to address a change can be initiated by the regulatory body or operating organization. This might be a supplement to the safety case which will not necessitate a full revision of the safety assessment.
- Waste characterization expectations, i.e. how the regulatory body inspects and confirms the characterization programme. The regulatory body will approve the characterization programme, including the frequency of destructive and non-destructive testing.
- Operational and post-closure safety need to be addressed in change control.
- Inclusion of routine audits of management systems, safety culture and procedures in inspections.
- Review by the regulatory body of results from confirmatory studies of covers, demonstrations, laboratory or field studies.
- Inspections for any interim covers or interim closure actions. Integration of final closure designs with plans for interim closure to avoid the need for rework.

A.2.5.2. Communication with interested parties

The communication plan will continue to be implemented. Updates could be made during this phase in accordance with the prescribed process outlined in the communication plan. Some considerations that are specific to this phase include:

- Continuation of routine local stakeholder meetings, but meetings could be more focused on topics related to potential changes in operations and specific closure plans.
- Specification of reporting requirements by the regulatory body. Some form of routine reporting by the operating organization to the regulatory body, with specified aspects reported to interested parties. This reporting could be done annually or, under specified conditions, some information (e.g. on accidents or significant unexpected changes) may be reported more frequently.
- The operatoring organization and regulatory body may publish operational reports on a routine basis (the content of these reports should be specified early in the process).
- For monitoring and surveillance activities, there is a need to recognize the difference between measurements that are compared directly to regulatory criteria, and other measurements that need some interpretation.
- Importance of recognizing the visibility of all information related to decisions and the need to include the basis for any decisions with that information for future reference (e.g. changes in waste packages, design, operations).
- Public meetings at release of safety case or during regulatory review to allow more details to be discussed in an open forum.
- Communication between the regulatory body and the operating organization regarding definition of conditions that could result in a need for a regulatory review and potentially a reassessment or review of the safety assessment.

A.2.6. Closure and institutional control

The closure and post-closure phases are a time of significant transition for the regulatory body and regulatory reviews. During closure, there will still be a need for inspections, change control and record keeping, but the frequency of changes will be expected to ramp down over time after the end of active operations. A safety assessment and safety case will need to be reviewed to authorize closure. This review phase will also involve consideration of operating organization documentation on plans for institutional controls and continuing monitoring and surveillance as required by the national legal and regulatory framework. After the final cover is installed, the regulatory body will typically need to confirm the as built conditions prior to authorizing a transition to post-closure institutional control.

A.2.6.1. Regulatory body

Some key considerations for the regulatory body during this stage of the lifetime include:

- Ensuring that the cover is installed consistent with safety case assumptions (e.g. timing and performance expectations). For example, if there is a delay in installing the cover, infiltration may be higher than assumed in the safety assessment during the delay. One approach to mitigating this is to consider a range of times for installation of the cover in the safety assessment.
- Regulatory review and authorization generally required for closure. In many cases, a new safety assessment and safety case may be required. However, if the facility has operated consistent with assumptions in the most recent safety assessment (e.g. in relation to waste streams, inventories, containers and operational assumptions), it may not be necessary to conduct a new safety assessment to support the closure decision.
- In some cases, there may be a regulatory authorization at the decision point to construct the cap and then a final authorization, based on the as built cap, for transition to institutional control. An authorization to construct a final cap could potentially occur for some disposal units during the operations phase.
- A key activity for the regulatory body will be confirmation of the actual closure conditions with a focus on safety significant assumptions in the safety assessment.
- Development of monitoring plans based on safety significant conditions from the safety assessment (e.g. aquifer monitoring focusing on mobile radionuclides).
- During the closure and post-closure phases, the regulatory body will continue to be expected to conduct periodic reviews of safety case with a primary focus on any new information from monitoring data and surveillance of the covers that would be a departure from assumptions in the safety assessment.
- Documentation of specific agreements and responsibilities if there is a transition in operating organization or regulatory body for the closure and institutional control phase.
- Consideration by the regulatory body of the benefits of a robust simpler cover as opposed to a complicated multilayer cover which may not last as long.

A.2.6.2. Communication with interested parties

Communication at this stage will place more emphasis on regulatory body activities to confirm that closure can be implemented consistent with assumptions in the safety assessment, and then to build confidence in the closure concept through routine reporting of monitoring data and any new information regarding the facility. Communication considerations for the regulatory body during this phase include:

- Visitor centres are used as a means to preserve memory of the facility and can serve as a location for access to records and reporting of results from ongoing monitoring and surveillance activities.
- If there is a transition in ownership, interested parties need to be informed about how roles and responsibilities and safety and security are being maintained.

— Clear description of monitoring expectations to interested parties, including an epxlanation that a safety assessment is not a prediction of what will occur, but a demonstration that doses or risks will be within acceptable ranges (generally less than some regulatory limit). Variability is expected in monitoring programmes and it is not unusual to obtain individual measurements that may not be consistent with the safety assessment. Communication of the process for evaluation of such results with more emphasis on seeking trends in time and space, and less emphasis on single point measurements that may not reflect overall performance of the facility.

A.2.7. Release from regulatory control

Prior to stopping any active institutional control by the operating organization, and releasing the site from regulatory control, assurance needs to be provided that the facility is safe and that the site can be released from such a control. Such assurance would be mainly based on the results of the safety assessment.

At the end of this active control phase, the facility could be released from nuclear regulatory control for unrestricted use, or responsibility could be transferred to another authority for non-radiological risks if that remains applicable, or to the government that would be in charge of passive institutional control.

A.3. MANAGING THE REVIEW PROCESS

Undertaking a safety assessment for a radioactive waste disposal facility is a multidisciplinary task that may necessitate the application of significant resources and expertise for multiple iterations of an assessment extending over decades. In order to perform an adequate and efficient regulatory review of such an assessment, it is important to have a clear vision, strategy and procedures for the review, and to have access to sufficient resources and expertise. All parties need a clear understanding of the process. SSG-29 [9] includes specific recommendations on the conduct of regulatory reviews, which are reflected in this Appendix. GSG-3 [16] also includes a number of recommendations for regulatory reviews of a predisposal safety case, including a template for a regulatory review report, that are relevant for this document.

A regulatory review will normally have four phases:

(1) An inception phase prior to receipt of any documents from the operating organization, in which initial planning for the review will be conducted. This will normally involve meetings with the operating organization to understand the extent of the information that will be provided.
(2) An initial review phase during which the regulatory body will make an initial evaluation of the submitted documents to assess the completeness of the assessment, for example by applying the formal acceptance criteria mentioned in Section 3.3, and the availability of supporting documents, and to make a preliminary identification of those issues that are most important to safety (e.g. in order to 'risk inform' the review). Evaluating the completeness of the assessment involves checking the assessment context against the submitted information and the regulatory body's expectations for the safety assessment.
(3) A main technical review phase comprising the bulk of the effort. This will include the development of detailed review comments and may include evaluation of additional information provided by the operating organization in response to comments. Detailed technical information relating to the conduct of this phase is provided in Section 3.4.

A completion phase in which the main conclusions of the review are identified and used to inform the decision making process. This phase is considered in more detail in Section 5.

There are several key attributes that may influence the quality and success of a regulatory review. These include:

- Independence of the regulatory review.
- Clear definition of regulatory requirements and expectations, including the criteria on which safety will be judged, and explanation of these requirements and expectations to the operating organization and other interested parties.
- Clear definition of the scope of the review and no undue influence of the review team by considerations that are outside the scope of the review. Any such considerations may be taken into account in a broader context by decision makers, together with the safety case review findings.
- Structure and traceability of the regulatory review process, with clearly defined roles and responsibilities and decision making steps.
- Conduct of the regulatory review with adequate resources and commensurate with the level of complexity of the safety assessment and the risks associated with the facility under consideration.
- Inclusion in the overall regulatory review process of a stakeholder consultation framework with well defined consultation steps, rules of procedure, and decision making.
- Documentation of the rationale for judgements as to whether or not the arguments presented in the safety assessments or safety case are adequately supported by the underlying science and technology, and whether those arguments are in accordance with regulatory requirements and expectations.

A.3.1. Review management

The management of a safety assessment review should be treated as a project, to which the standard principles of good project management apply. Depending on the scale of the review to be conducted, it may be necessary to establish a team of reviewers. Regulatory reviews may be conducted by the regulatory body with or without support from external organizations, but the results of the review have to be fully 'owned' by the regulatory body.

In some countries, review of a safety assessment is performed by several regulatory bodies independently according to their responsibilities (e.g. nuclear safety, radiation protection, environmental protection, health protection). Coordination between regulatory bodies may be necessary as there is a possibility for crossing issues resulting in different conclusions.

The review procedures applied will allow the regulatory body to demonstrate that the review of the safety assessment has been performed by competent people and recorded in a traceable and auditable manner. Project specific procedures might include structured approaches for demonstrating staff competence, for specifying responsibilities and tasks in the review, for documenting review comments, for recording the status of issue resolution, and for conflict resolution. Further procedures may be necessary if the review includes tasks such as audits or independent regulatory assessment calculations.

For each regulatory review, a review plan will be required to provide guidance on procedural and technical aspects of the review. Procedural guidance might include the means of documenting, exchanging and managing of the review findings. Technical guidance might include the review approaches and the criteria against which to judge specific aspects of the safety assessment. This document can therefore serve as a template from which a project specific plan can be developed. Examples of project specific review plans are included in Refs [49, 50].

The management of the review of a safety assessment could be undertaken by the regulatory body itself, or with an external support organization. In the latter case an appropriate agreement should be documented. Importantly, however, the regulatory body has to maintain ownership and responsibility for the results from the review.

Typically, a review project will be led by a project manager whose main responsibilities could include:

- Defining and communicating the objectives and scope of the review;
- Implementing appropriate quality assurance procedures and specifying any project specific requirements;
- Developing a review plan that identifies the review tasks and addresses other relevant topics;
- Assembling a review team with the necessary expertise and experience to undertake the review;
- Defining the project schedule and allocating resources for the conduct of project tasks;
- Identifying the responsibilities of review team members and ensuring that they receive adequate training and guidance in the review method;
- Coordinating the conduct of the review tasks and ensuring sufficient communication among review team members;
- Coordinating dialogue with the operating organization of the disposal facility, and with other interested parties;
- Reviewing and integrating documents generated during the project;
- Identifying early on during the review any areas of 'regulatory uncertainty';
- Arranging for approval of documents where required;
- Synthesizing and communicating review findings;
- Defining the necessary financial and human resources (where resources are limited, this will involve targeting reviews on high priority areas).

A.3.2. Review objectives and scope

The objectives and scope of the review have to be clearly defined as part of the inception phase and refined as necessary during the initial review phase. An important primary objective will normally be to evaluate the compliance of the safety assessment with applicable regulations and guidance.

The scope of the review may largely be dictated by legislation, regulatory responsibilities and regulatory guidance, but it may also need to be tailored according to the process to be followed, for example if different groups are conducting different parts of the review, or if the review is to be conducted in phases.

As stated in SSG-23 [6], when defining the objectives and scope of the review, relevant points to consider include:

- The important safety issues for the site.
- The extent of the safety information provided by the operating organization, and the resources available to the regulatory body.
- Whether the review will consider only radiological impacts on humans or will consider other impacts as well, for example impacts related to hazardous waste materials.
- Whether the review will consider impacts to the public, to workers, to non-human species and to the environment.
- Whether the review will consider the period during which the disposal facility is operational (i.e. only short term risks) or the period after facility closure (i.e. only long term risks) or both.
- What parts of the operating organization's documentation should be the focus of the review.
- The use to be made of the review results, for example whether they will be used as part of prelicensing dialogue with the operating organization, for facility licensing, or to establish conditions on an existing facility.
- The stage of the development of the project (e.g. environmental assessment, site preparation, construction, operation, closure, post-closure), which could affect the depth of review. For example, during site selection, very few design details will be available and therefore, detailed review of the design is not possible. In addition, if a series of reviews are being performed at the site (e.g. site selection followed by construction followed by operation licensing), areas where information has not substantially changed could rely mainly on the previous reviews.

A.3.3. Review team

The human resource needs for the review are generally identified during the inception phase and refined as necessary during the initial review phase.

Paragraph 8.13 of SSG-23 [6] states:

> "To the extent practicable, the regulatory review should possess the following characteristics:
>
> - The review team should possess a range of expertise appropriate to the review, including practical experience in areas that are most important to the particular safety case under review.
> - The review team should have experience in conducting reviews of relevant safety cases.
> - The review team should understand the context of the review to be conducted (e.g. they should have knowledge of the facility and of the regulations governing its authorization).
> - The review team should have a broad knowledge of waste management practices and programmes both nationally and in other States.
> - The review team should be made up of individuals whose findings will be viewed by interested parties as being credible.
> - The review team should be independent of the operator, and its members should not have had involvement in the development of the safety case to be reviewed or in any supporting work, and should not be directly involved in the management, financing or operation of the disposal facility."

The review team may need expertise in the following fields:

- National and international regulations, guidance and criteria for waste management and radiological protection;
- Safety assessment (e.g. scenario development and methods for the treatment of uncertainty, with a view to provide expertise on radiological and non-radiological hazards);
- The characteristics and sources of radioactive waste;
- Waste characterization, conditioning and packaging;
- Engineering and disposal facility design;
- Waste and facility degradation;
- Site characterization (e.g. geology, hydrology, hydrogeology, geochemistry, seismicity, geomorphology);
- Chemistry;
- Contaminant transport;
- Biology;
- Radiological protection;
- Climate change;
- The assessment of human actions;
- Mathematical modelling and computational methods;
- Internal hazards (e.g. fire, explosion, criticality);
- Human and organizational factors;
- Management system (e.g. quality assurance, quality control).

The in house technical resources available to regulatory bodies in different countries vary widely, and the establishment of a suitable review team often involves individuals and organizations outside the regulatory body. In some cases, review management could be transferred to an external support organization, but this does not mean that the responsibility for the review results and conclusions are transferred to the organizations outside the regulatory body. It is still the regulatory body that draws the final conclusions from the review.

Depending on the scope of the review and the composition of the review team, it may be appropriate to form groups of reviewers for the review of particular areas. This has an advantage that the review comments will represent more than the views of individual experts and, therefore, may be regarded as being more credible.

There are many possible ways of structuring a review team and, in deciding on an appropriate organizational scheme, it may be relevant to consider the following:

- The scope and schedule of the review, the size of the team, and the amount of information to be reviewed;
- The structure of, and the means of reporting, the safety assessment;
- The structure and content of the regulations and guidance;
- The physical parts of the disposal system (e.g. near field, far field, biosphere);
- Relevant scientific disciplines (e.g. hydrogeology, geochemistry).

Whatever organizational scheme is adopted, it is important that the responsibilities of each reviewer and each review group within the scheme are clearly defined, and that lines of communication and paths for the flow of information are specified clearly at the start of the review. This may involve allocating the regulatory criteria for assessment among the different parts of the review team and ensuring that there are mechanisms for sufficient interactions between the parts of the team.

For reviews of some facilities and safety assessments, it is important to manage the institutional knowledge of an issue or an overall review. Reviews can stretch over several years, and when the phased approval of siting, construction, operation and closure is considered, it becomes unlikely that the review team staff will remain the same over the entire review or set of reviews. Proper documentation of the review plan, intermediate and final results of reviews (including comments rejected as part of the process, comments provided to the operating organization , and comment resolution), and meeting summaries can assist in managing institutional knowledge. In addition, mentoring programmes between experienced staff and new staff, if possible, can be used to manage institutional knowledge.

A.3.4. Review schedule and resource allocation

The review schedule is generally defined as part of the inception phase, with a clear understanding of the process by all involved parties. The schedules need to include provisions for modifications and refinements as part of the initial review phase and, as necessary, periodically throughout the review process.

The review schedule will need to comply with any legal requirements or internal policy on review timescale, including requirements for periods for public comment or consultation. The schedule for review will also need to be tailored to the scope and objectives of the review. Typical timescales are from a few months to several years, depending on the extent of the safety assessment and the level of resources available for the review.

To manage the review, it will often be appropriate to establish internal project milestones for the completion of review tasks and the transfer of information between parts of the review team.

The ideal situation for the performance of the review is when all the necessary documentation (i.e. safety assessment reports, supporting evidence, results of measurements) is available for the initial phase of the review. However, in some cases, the initial review may identify significant gaps in the documentation. In these cases, there needs to be agreement on the programme for the provision of the safety assessment materials, and the planned schedule and resources for the regulatory review may need to be reconsidered. In the case of reviews conducted as part of formal licensing processes, the information making up the safety case and safety assessment has to be clearly identified.

Reviews of partial or incomplete assessments can be difficult because of delays in obtaining updated information from the operating organization, and because preliminary review conclusions based on one part of the assessment can be invalidated by new information. Multiple iterations of partial reviews before a complete assessment is available may be more resource intensive than a single review of a complete assessment, but is likely to lead to a complete assessment that is better aligned with regulatory needs for decision making. On the other hand, there is a risk with ‘rolling’ reviews that the regulatory review will not be transparent to interested parties, who could see the regulatory body as being too close to the operating organization. Review planning needs to consider such issues, to ensure that sufficient time and resources are available for review of the complete assessment, and that the review work is conducted as transparently as possible.

A.3.5. Regulatory dialogue with the operating organization during the review

During a review of a safety assessment, dialogue between the regulatory review team and the operating organization may be necessary for a variety of reasons. Early agreement on the timing and nature of official dialogue is recommended in order to avoid misunderstandings. Official dialogue needs to be carefully planned to maintain the independence between the regulatory body, operating organization and government.

It is a challenge to balance the need for routine communication for an efficient and effective process and the need to maintain the independence of the parties involved. The public and other interested parties should be informed about the nature of dialogue that will take place during a review and when external observers will be permitted. It will also be important to identify specific times when public briefings will be provided and public input will be accepted.

During the inception phase:

- The regulatory body and the operating organization discuss and agree on the objectives and scope of the assessment, including the assessment context;
- The regulatory body and the operating organization identify relevant regulatory requirements and define common understanding of assessment context and regulatory roles when different regulators are involved.;
- The regulatory body presents the management and planning of the review, including the way in which review comments will be addressed;
- Agreement is reached on involvement of interested parties in all aspects of the review process (this may also include other national or local regulators). For example, when the public will be allowed to formally comment, what parts of the review they can observe, and what parts of the review will be closed;
- Reporting protocols for the reviews are established, including when reports will be available to interested parties, including the public and other regulatory organizations.

During the initial review phase:

- The operating organization summarizes the structure of the assessment and the methods applied within the assessments, so that the review team can more easily conduct its review;
- The operating organization summarizes the results of the assessment, so that the review team can gain a ready appreciation of the key issues and uncertainties associated with the performance of the disposal facility;
- The regulatory body provides feedback from the initial review phase.

During the main review phase:

- The regulatory body presents preliminary review comments;
- The regulatory body and the operating organization identify any problematic issues and differences in opinions;
- The operating organization clarifies where and how issues are dealt with in its documentation, and identifies possible approaches to addressing issues identified during the review;
- The operating organization provides additional technical information (e.g. the results of new calculations).

During the completion phase:

— The regulatory body presents the main conclusions of the review, and the way in which the review results will be used in licensing and in establishing authorization conditions.

Dialogue can be facilitated through the use of commonly agreed formal procedures. For example, the exchange of information may be carried out via technical meetings between the review team and the operating organization, and by the provision of appropriate documentation. Participation of other interested parties in such meetings also needs to be specifically addressed before the review begins. Where meetings are used, it is important that appropriate records are kept and that the minutes of such meetings are agreed by the parties involved. The status and potential use of information in these records also needs to be agreed. Strategies for communication with other interested parties are addressed in GSG-6 [23].

A.3.6. Management of review comments and issue resolution

It is important to ensure traceable documentation of all review comments and assessments, and of the resolution of issues identified during safety assessment reviews. A range of tools exists to assist in the management of review comments. These tools are typically based around the use of standardized 'review and comment' or 'issue resolution' forms (see e.g. Ref. [51].

A typical issue resolution process is illustrated in Fig. 12. The following paragraphs provide general guidance on good practice for key steps in the process.

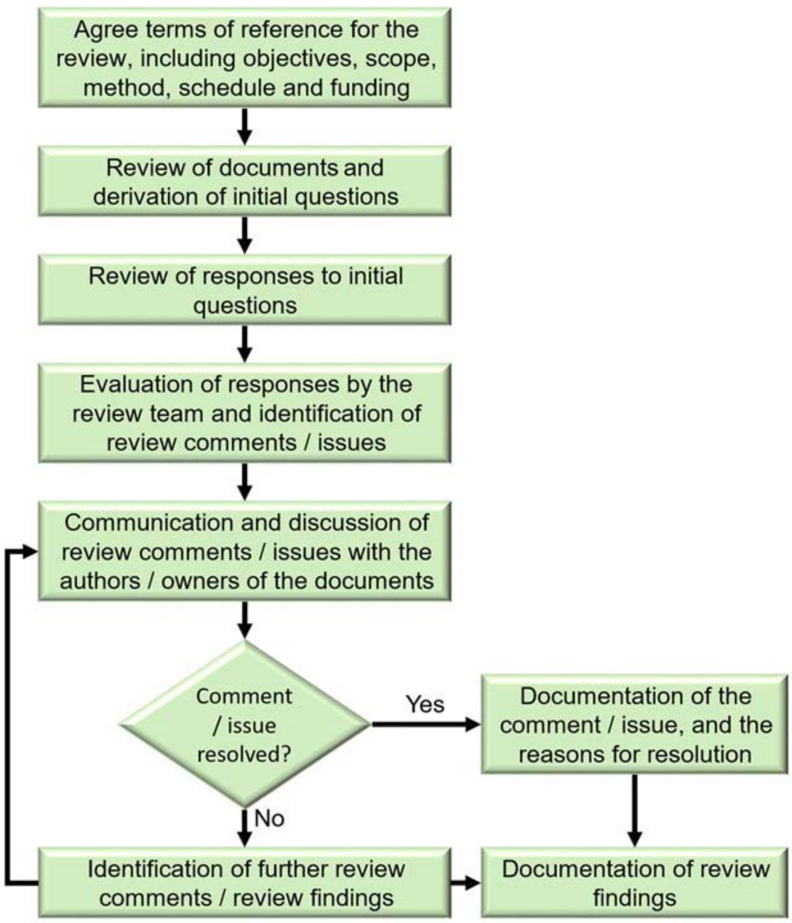

FIG. 12. Example of a review and comment resolution procedure.

A.3.6.1. Documentation of review comments

When documenting review comments and assessments it is good practice to ensure that:

- The approach taken in the safety assessment and the results of that approach are briefly summarized and specific references to the information are provided;
- Any significant comments and the justification for the comment are clearly stated using a standard format, and each comment is given a unique identifier for ease of cross reference;
- The relevance of the comment to safety, system understanding and/or control of the facility is noted;
- Recommendations regarding necessary actions to resolve the issues identified in the review comments are stated clearly, and a justification is provided for each recommendation.

A.3.6.2. Management of review comments within the review team

Individual reviewers or review groups might not be aware of the full range of information comprising the safety assessment or of other information relevant to disposal facility licensing. It is therefore important for the review manager to ensure that:

- Inconsistencies and duplication between comments made by different reviewers are resolved;
- The review team is kept informed of key results from all reviewers and review groups, and a project wide assessment of the relative significance of review comments is made.

Also, different reviewers might express conflicting opinions on issues. The project procedures need to include provision for dealing with conflicting opinions. After discussing the conflict among review team members and the project manager, if different opinions remain, then there are a number of possible approaches, depending on the nature and importance of the conflict. First, the project manager could determine a formal project position, and provide a single statement of project position to the operating organization, along with the rationale for the position. Second, the project manager could request further information from the operating organization to help resolve the conflict. Third, a neutral expert could mediate the discussion. In all cases, a record of the conflicting views needs to be retained in the formal project documentation.

A.3.6.3. Communicating comments to the operating organization

Final review comments will be communicated to the operating organization of the disposal facility. If there are many review comments, it can be helpful to assemble comments related to a particular topic within a review report that can be used to place the comments into the context of the whole review. The review report can also be used to convey the relative significance of the comments and recommendations within each topic. All documents for issue to the operating organization need to pass through the usual process for report approval.

It is good practice for there to be a single primary point of contact between the regulatory body and the operating organization and an agreed scheme of delegation governing communication between the review team members and the operating organization and its experts.

A.3.6.4. Resolving comments with the operating organization

As discussed previously, safety assessments will be conducted iteratively throughout the lifetime of a disposal facility development programme. The regulatory body will need to decide whether it would like a response to some or all review comments as part of the process of arriving at final review conclusions within an iteration, or whether a response to comments will only be requested subsequent to completion of the current review.

Problems sometimes arise from the difficulty of finding information that addresses particular regulatory concerns where the assessment documentation submitted is lengthy and poorly presented. The assessment documentation might also contain gaps or information that only inadequately addresses a regulatory concern. Where the operating organization can readily make available additional information that resolves a comment, this information can be considered by the regulatory body in its review. Further information could include more explanation, additional data, further calculations, further engineering or optimization analyses, or the results of literature reviews. Where a comment cannot readily be resolved, or has only been partially resolved, the comment is taken forward by the regulatory body to the review conclusions.

Meetings with other regulatory bodies and the operating organization may be necessary to resolve some cross cutting issues in cases when different regulatory bodies are involved.

Some comments may not be finally resolved until final delicensing or withdrawal of institutional controls over the facility. However, that there are unresolved comments does not need to keep the regulatory body from making decisions.

A.3.7. Addressing regulatory uncertainty

The review may highlight areas where there is uncertainty as to the appropriate regulatory response to an issue. For example:

- The regulations themselves may be open to interpretation (e.g. whether the regulation or an element of the regulation is applicable for a given purpose);
- The appropriate regulatory approach to the issue of human intrusion in assessments, including the consideration of intrusion and the period for which institutional controls can be relied upon;
- The choice of potentially exposed groups for consideration in the assessment.
- Whether impacts to non-human biota should be considered and, if so, how;
- Whether it could be acceptable to rely on dilution to achieve safety;
- The appropriate regulatory measure of safety when a probabilistic approach is considered and the impacts are presented as a distribution instead of point estimates.

If such uncertainties are identified as early as possible within the review, regulatory policy and technical positions can be established as part of the review process. In some cases, it may be necessary for the regulatory body to undertake studies to help inform the development of policy.

There may also be technical uncertainties for which additional information is needed to support a compliance decision. For example, the range of uncertainty for a safety significant assumption might lead to results that exceed performance requirements. In such cases, there may need to be licence conditions to conduct additional studies to reduce the uncertainty or to make changes to the design or operational practices to manage that uncertainty, such that it is no longer a concern. Uncertainties in assumptions can also be addressed via inspections and ongoing periodic safety reviews.

A.3.8. Reporting the findings of the review

The completion phase of the review will include the development of a final review report. There is no single correct way in which to organize such a report, and each report will inevitably need to be tailored to the review conducted. However, it is critical that all parties understand the plan and expectations for reporting from the regulatory review before the review begins. Higher level agreements regarding public involvement for each planned review may need to be established at the start of the overall facility lifetime. General information on what a regulatory body might include in such a report is provided below:

- Background to the review, including summary information on the site, the regulatory framework in which the review was conducted, purpose of the review, and approach to the review.
- Process of review: summary of the sequence of reviews and iterations.
- Key review findings concerning high level issues such as the safety approach, the assessment context, approach and results, the treatment of uncertainty (e.g. in scenarios, models or parameters), risk management and optimization, radiological capacity, appropriate limits and conditions, and the forward programme.
- Key review findings concerning the main technical areas of review, such as the characterization and modelling of waste inventory, engineering, geology, hydrogeology, chemistry, climate, biosphere, gas and human intrusion.
- Key review findings concerning compliance with the main regulatory criteria and guidance.
- List of unresolved issues or uncertainties.
- Conclusions of the review with regard to issues to be considered in licensing or authorization, such as further information to be provided by the operating organization, revised safety assessments, monitoring and other controls on the site, inventory restrictions, intervention and WAC.
- List of references, including reference to documents considered in the review, and underlying review reports that support the final review report.

In some cases, a description of the review team and the qualifications of the review team could be reported.

Regardless of the reporting format chosen, all comments need to be documented and archived. Information on the documentation of individual review findings is provided in Section 3.4.6.

Further information on communicating the results of the review to different audiences is provided in Section 5.

The initial development of a safety assessment for a disposal facility will typically take several years and the assessment will subsequently be refined during the lifetime of the facility (often a period of several decades). It is important, therefore, that steps are taken to manage the information exchanged during the review process, and to ensure that review results are transparent and traceable.

A.3.9. Making use of a risk informed approach

Failing to provide adequate resources for regulatory reviews may engender serious consequences. These include eroding public confidence in the regulatory body's decision and in its ability to ensure safety, decreasing the level of regulatory scrutiny, and delaying consideration of applications and proposals — delays that might penalize the operating organization. Another consequence is the potential for an increasing level of workload related to difficulties within regulatory organizations, which might lead to lower levels of vigilance.

Tailoring the scope of a review to those areas that are most important to safety is often referred to as taking risk informed approach, and even countries with large nuclear programmes have developed, or are developing, risk based or risk informed regulatory frameworks (see, e.g. Ref. [25]). To take a risk informed approach to a review, the following sources of information can be used:

— Information previously available to the regulatory body:
  - The results of previous regulatory reviews.
  - The results of any monitoring programmes.
— New information supplied by the operating organization as part of the safety assessment:
  - A synthesis of the approach to safety that identifies the key safety components.
  - Initial review by the regulatory body of the safety assessment to identify those issues that appear as the most important to long term safety.

While there is a body of experience in applying risk informed approaches when undertaking and prioritizing activities relating to regulatory compliance of operating nuclear power plants, there is relatively little experience in applying such methods to regulatory reviews of safety cases and safety assessments for radioactive waste disposal facilities. Potential difficulties arise because of:

— The very long time frames over which impacts have to be considered for post-closure safety assessments.
— The need to consider the details of the assumptions on which the assessment is based as well as the assessment results.
— The need for the regulatory body to make an independent determination of those aspects of the assessment that most influence safety.
— The possibility that such approaches may prevent the regulatory body from developing a sufficiently thorough, holistic understanding of the assessment of the facility.

A.3.10. Conducting a review with limited resources

Addressing the issue of limited resources is challenging. Proper review planning, including prior to receiving a document from the operating organization, is very important for focusing resources and conducting a successful review.

One of the main approaches to address the issue of limited resources is to use a risk informed approach as discussed above. The problem of limited resources can also be addressed to some extent by requesting the operating organization to produce a conservative assessment, based on the use of simplified scenarios and models. In this case, the operating organization may also be asked to demonstrate that there is only a low likelihood of impacts being greater than those calculated in the conservative assessment.

Difficulties related to resource limitation can also be addressed to some extent by organizing national and/or international reviews by credible individuals having recognized expertise in safety assessment. For example, the IAEA provides review services on request to national organizations. However, such reviews can never substitute the requirement for the national regulatory body to make its own decisions on safety based on its own reviews. The in house regulatory review can be based in part on the results of external reviews.

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ANNEX
CASE STUDIES ON COMMUNICATION OF THE SAFETY CASE FOR NEAR SURFACE DISPOSAL

A–1. CUBA: RADIOACTIVE WASTE DISPOSAL

In Cuba, radioactive waste come from the users of nuclear applications (e.g. in industry, research, medicine, and other activities like dismantling of small nuclear facilities). The national waste classification is in line with IAEA guidance and it is included in the nuclear regulatory framework. As yet, no national strategy for radioactive waste disposal has been defined or implemented.

The wastes from the applications of radioisotopes in medicine are mainly liquids and solid materials contaminated with short lived radionuclides and sealed sources used in radiotherapy and for sterilization of medical materials. Radioactive waste from industrial applications is generally spent sealed sources, which were used in level detection, quality control, smoke detection and non-destructive testing. The principal forms of waste generated by research institutes are miscellaneous liquids, trash, biological waste, scintillation vials, sealed sources and targets. Solid radioactive wastes are mainly produced during research works, cleaning and decontamination activities and they consist of rags, paper, cellulose, plastics, gloves, clothing, overshoes, etc. Laboratory materials such as cans, polyethylene bags and glass bottles also contribute to the solid waste inventory. Small quantities of non-compactable wastes are also collected and received for treatment. They include wood pieces, metal scrap, defective components and tools. There is no disposal facility available yet; the main practice is the storage for decay for the short lived radionuclides. The main problem for disposal are disused sealed sources.

The national policy about nuclear affairs has been established in Decree-Law No. 207 “About the use of nuclear energy” with the purpose to regulate the use of nuclear applications and to promote the use on nuclear energy. In the topic of radioactive waste, the national regulations take into account all the international accepted principles and requirements. Additionally, there are other technical documents (e.g. guidelines, procedures) that govern waste management activities (e.g. transport, storage). Resolution 35-2003 “Rules for the safe management of radioactive waste”, defines the responsibility and requirements for waste generators and managers. The waste generators assume principal responsibility for waste management, including the necessary funds to support all related activities. For radioactive waste management activities, the regulatory body is the National Nuclear Safety Centre (CNSN), and the Centre for Radiation Protection and Hygiene (CPHR), is the only licensed operating organization . The CPHR manages a centralized radioactive waste storage, conditioning and treatment facility and is responsible for all activities related to radioactive waste disposal in Cuba. Recently, the country became a Contracting Party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, and in 2018 the national report was presented.

The site selection process started in 1985 and finished in 2001, when the ‘site confirmation’ stage was reached. Under this process a site selection methodology was defined including a conceptual design for a centralized disposal facility (underground disposal chambers) and a final site was selected. The site is placed in the central part of the country, hosted in granodiorite rocks in a sparsely populated region.

Some features of the site selection process included:

— Graded approach (regional identification, screening process, site selection, site confirmation, etc.). During the process, 32 sites were evaluated including sedimentary formations, igneous rocks and salt domes.
— From regional scale (1:100 000) to detailed scale (1:5000).
— Site selection requirements relevant to decision support (according to national and international guidance, etc.).
— Several national studies and research were carried out (geological, hydrologic, climate, seismic, etc.).
— Initial conceptual designs were defined for disposal, near surface facility and storage facilities (for spent fuel). These designs were then modified according to the inventories update.
— A final site was selected for radioactive waste disposal (host rock: granodiorite formation).

Aspects which impacted the evolution of the safety case, during the site selection and conceptual design phase, as well as other related communication activities, included:

— New legislation: Nuclear Act, Environmental Act and related regulations, radiation protection decree, waste management decree law (establishing scope, requirements, stages, licence needs, new endpoints, etc.).
— Dramatic change in waste inventories when the nuclear power plant was closed in 1989 (only nuclear applications), modification to the original conceptual design (removed the nuclear power plant waste and the spent fuel storage).
— New ministry: Ministry of Science, Technology and Environment (CITMA), which issued new legislation and requirements (environmental act, environmental impact assessment, etc.). Additional safety assessment was carried out to evaluate the radiological impact to the environment (non-human species).
— During the site selection process, the need for future touristic developments changed the initial selected site from salt dome to igneous rock.
— On the basis of the previous results (cost analysis, funds availability, etc.) the disposal activities were delayed and the current interim storage facility for extended radioactive waste storage was upgraded.
— New design of disposal facility was evaluated: Preliminary safety assessment for borehole facility for disused sealed sources.

Official parties involved in the communication activities as well as their responsibilities are included in Table A–1 below. The identified interested parties or target audiences included:

— Regulatory body: National Nuclear Safety Centre (CNSN) to fulfil the regulatory requirements.
— Environmental regulatory body: Environmental Inspection and Control Centre (CICA) at the Office for Environmental Regulation and Nuclear Safety (ORASEN) to fulfil the regulatory requirements.
— Urban Planning Institute.
— Provincial and municipal governments (authorities and decision makers at the proposal site) to fulfil the regulatory requirements.
— Ministries: including those responsible for the environment, public health, mining and water resources, etc.

- Mineral resources management organization to assurance to fulfil the regulatory requirements and provide the authorization for site studies.
- Research institutions: seismology, geology, hydrogeology, climate/meteorology, underground facility design, transport, aviation, inter alia.
- Agency for Nuclear Energy and Advanced Technologies (AENTA).
- Defence organizations (e.g. national civil defence, Ministry of Defence).
- General public living near to the proposed site.

TABLE A–1. OFFICIAL PARTIES AND THEIR ROLE

Official Party	**Role**
Nuclear Energy Agency (AENTA), Environmental ministry (CITMA)	Coordinators and counterpart of the site selection process
Waste management operator (Until 1989, CTN was responsible for the radioactive waste disposal facility, it then moved to the CPHR)	Entity responsible for radioactive waste management, leader for the implementation of the safety case, it was in charge of the site selection process, safety assessment, conceptual design, etc.
Urban Planning Institute	Counterpart of site selection for urban developments (current and future socioeconomic impacts)
Meteorology institute	Definition of climatic events scenarios, provide meteorological information
Institute of geology and mining studies	Carried out several studies at the site: geological, geophysical, seismic, hydrological, hydrogeological, etc.
Transport ministry (terrestrial)	Evaluation of access to the site, design of roads to the disposal facility
Geography institute	Environmental baseline of the proposal site
Aviation institute	Information for accidental events scenarios (aircraft accident)
Environmental regulatory body (ORASEN/CICA)	Counterpart of site selection (environmental issues)
Nuclear regulatory body (National Nuclear Safety Centre (CNSN))	Counterpart of site selection (nuclear issues)
Project enterprise	Developed the conceptual design of the near surface facility
Energoproject	Information for accidental events scenarios (flooding event)
Mineral Resources Management Organization	Counterpart of site selection, provide the permit for the site studies
National Centre for Seismological Investigations	Information for natural events scenarios (earthquake studies)
Defence organizations (national civil defence, Ministry of Defence)	Counterpart of the site selection and provide information for extreme events scenarios
Ministry of Public Health	Counterpart of the site selection process
Provincial and municipal governments	Counterpart of the site selection process

Key messages were conveyed for the following topics:

- Technical and economic study for the site selection and design;
- Environmental impact assessment;
- Safety assessments reports (scope, goal, scenarios, models, results, etc.);
- Facilities conceptual design (drawings, budget, planned activities, etc.);
- Technical report of research results (geology, geophysics, seismology, hydrology and hydrogeology, topography, climate, etc.);
- Socioeconomics aspects of the site (populations, towns, main economic activities, etc.);
- Radioactive characteristics, inventories, etc.;
- Databases, records, field notebooks, etc.;
- Quality assurance programme;
- Environmental impact assessment (environmental baseline, ecology information, etc.);
- Thematic maps (geology, geophysics, hydrogeology, topography, etc.);
- Description of evaluated external events (natural and human);
- National and international regulations, etc.;
- Guidelines, methodologies, etc.;
- Official letters, communications to institutions, expert groups, council, etc.;
- Presentations, meetings reports, discussions, etc.;
- Bibliography reviews, international current status of disposal facilities and waste management activities.

Communication approaches included:

- Meetings in the headquarters of the regulatory bodies (environment and nuclear) and other related institutions during all the site selection process;
- Presentations in local places (lectures at the municipality museum) and provincial and municipal headquarters placed near the proposed site;
- Workshops on environmental and waste management topics including:
  - Site selection process and the site requirements (geology, hydrology, hydrogeology, seismology, climate, external events and socioeconomic factors),
  - Favourability of the proposed site.

The communication mechanisms and tools utilized included: technical reports, slides presentations, lectures and official letters (several of which are included in the bibliography to this publication).

Effectiveness and results of communication activities:

- Approval of the selected site (by the counterparts, regulatory bodies, etc).
- Changes and improvements in the safety assessment and in the safety case (conservative approach, etc).

The communication issues encountered, and how they were mitigated, are outlined in Table A–2 below.

TABLE A–2. COMMUNICATION ISSUE AND MITIGATION

Issue	Mitigation
Lack of knowledge among the target audiences about radioactive waste management and safety issues	Seminar/meetings/lectures/workshops focused on these aspects
Negative risk perception about nuclear/radioactive facilities	Conferences held, presented: for the site selection, safety assessments, environmental impact assessment, international status of waste management
Justification for site selection	Lectures/conference about the favourable characteristics of the proposed site and the site selection process. Results of safety assessments

Several lessons learned through this radioactive waste project included:

- Need to define a national strategy for disposal of radioactive waste (including actions, funds, etc.) to support all actions with the goal to complete the final waste management;
- Need to improve the information about radioactive waste management and safety topics for decision makers and the general public;
- Need to improve the current communications strategy, including broad public consultations;
- Enhancement of studies for site selection to complete the characterization of the proposed site (additional seismic (e.g. geophysics) and hydrogeological studies);
- Advantages of new designs (e.g. borehole) for disused sealed sources, which offer a more simple solution in comparison with the previous design (underground disposal facility).

Some useful references and available information on this case study are given in the Bibliography at the end of this publication.

A–2. UNITED KINGDOM: IMPLEMENTATION OF LOW LEVEL WASTE REPOSITORY LTD 2011 ENVIRONMENTAL SAFETY CASE

The Low Level Waste Repository (LLWR) is the United Kingdom’s principal facility for the disposal of solid low level radioactive waste. The LLWR is owned by the Nuclear Decommissioning Authority and operated on its behalf by the site licence company LLWR Ltd. LLWR Ltd is required by its permit to submit and maintain an environmental safety case (ESC) that demonstrates the safety of disposal now and in the future. The most recent ESC was submitted in 2011 [A–1] and we are currently undertaking a programme of work leading to the production of an updated ESC.

The primary audience for the 2011 ESC was the Environment Agency, the site’s environmental regulator. Secondary audiences included:

- Local policymakers, in particular the planning authority[2];
- Local community, in particular the villagers of Drigg;
- Waste generators and consignors;
- The wider scientific community.

[2] The LLWR is subject to local planning restrictions rather than national planning restrictions. This is why the key audiences are the local policymakers and public.

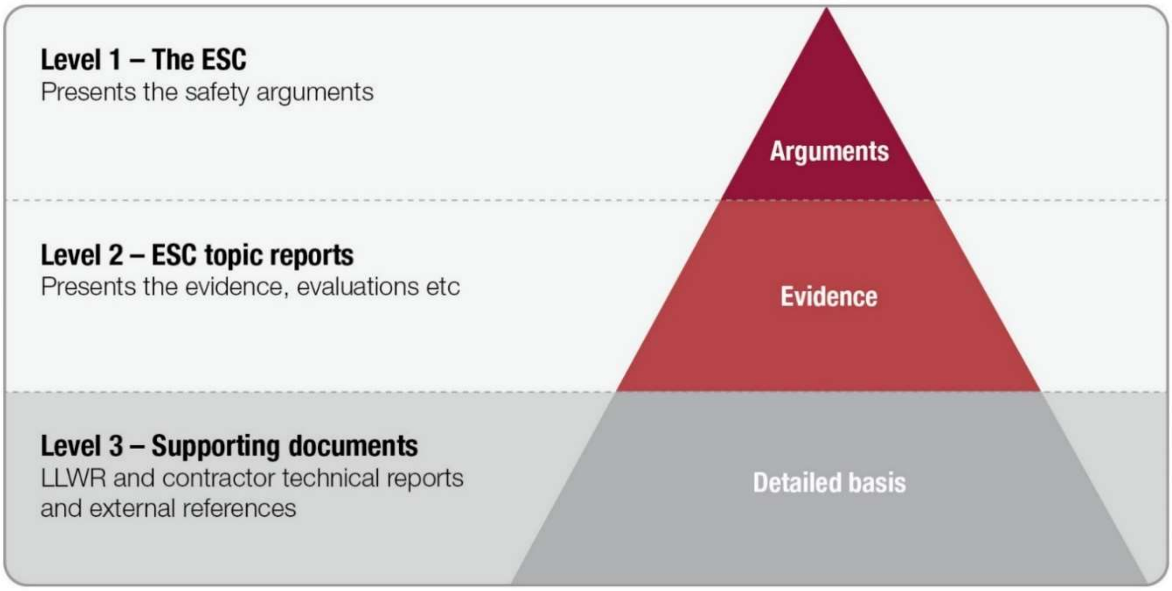

FIG. A–1. 2011 ESC document structure (reproduced from Ref. [A–1]).

The intent of the 2011 ESC was to demonstrate four overall messages:

- We have worked within a sound management framework and firm safety culture, while engaging in dialogue with stakeholders;
- We have characterized and established a sufficient understanding of the LLWR site and facility, and their evolution, relevant to its environmental safety;
- On which basis, we have carried out a comprehensive evaluation of options to arrive at an optimized site development plan for the LLWR;
- We have assessed the environmental safety of the site development plan, showing that impacts are appropriately low and consistent with regulatory guidance. Using our assessments, we have determined the radiological capacity of the facility and conditions under which waste may be safely accepted and disposed.

The primary presentational format, or communication approach, for the 2011 ESC was a set of paper documents, organized according to the hierarchy shown in Fig. A–1. Level 1 and 2 reports were produced with a common document template, and prepared to a consistent technical writing style.

In addition, the technical documents were supplemented with:

- Monthly meetings with lead Environment Agency inspectors during ESC development, to update on progress and agree key technical decisions.
- Presentations to Environment Agency assessors for each Level 2 document, reinforcing the message of the document and allowing for questions and answers.
- Press releases focusing on the key technical messages of the ESC.

The West Cumbria Site Stakeholder Group (WCSSG) was an important communication channel for the ESC. The WCSSG is an independent body whose role is to provide public scrutiny of the nuclear industry in West Cumbria. The public is invited to attend all meetings, and meetings are held in locations that are freely accessible to members of the public and press. A specific LLWR Working Group meeting is held quarterly at the nearby village hall. During the latter stages of development and following completion of the ESC, a number of presentations about the ESC were given by both ESC specialists and communications staff. ESC specialists were then available to answer questions from the public. LLWR Ltd. also wrote to potentially interested parties (including Greenpeace and other pressure groups) to ensure they held first hand information about the ESC.

A separate 'Non-Technical Summary' document was prepared alongside the ESC, which summarized the nature of the facility and the main safety arguments. This helped frame the discussions and presentations to the WCSSG.

The primary communication mechanism or tool for communicating the safety case was the main ESC documentation. This was posted online and also delivered by hand to key stakeholders in a bound portfolio. The documents are available at the national archive website.

The aim of an ESC is to 'make the case' that disposals are safe, which mostly involves conveying complex, technical information to technical experts. As such, specific attempts to enhance the communication of the ESC were focused on key concepts that, in the author's view, were difficult to understand and/or visualize for technical experts, and these were further developed into infographics with the help of an external graphics company. Examples are provided in Figs A–2 and A–3. These graphics were subsequently used within the presentations and display boards described in the preceding subsection.

LLWR Ltd. also produced and distributed leaflets describing the ESC and basic radiation science.

The communication strategy was successful in communicating to its primary target audience (the Environment Agency) in that it concluded that the ESC was adequate to support a permit application. In its review documentation, the Environment Agency stated that the presentation of the 2011 ESC was a significant improvement and found the documentation sufficient and comprehensive enough to complete its technical review. The subsequent permit application was subject to public consultation, for which the responses were broadly positive, particularly from local councils and community groups. The positive relations with the surrounding area were further demonstrated when planning permission for the construction of future vaults was awarded in 2016. The planning application was underpinned by the ESC and the initiatives described in the preceding subsection helped to remove any fear of the repository from within the local community.

Communication issues encountered for this project included:

- The Environment Agency's review of the ESC and subsequent permit application, took over four years, and 72 formal questions were submitted to LLWR during this period, as the Environment Agency felt the need to request further information beyond that presented. We believe this to be a symptom of the presentation of the ESC rather than the content.
- The Environment Agency's review process involved experts from a variety of backgrounds who each focused on a smaller subset of the ESC. This meant that many found it difficult to place their area of expertise within context. For example, a hydrogeologist reviewing the ESC hydrogeology report might have struggled to understand the context or consequences of the hydrogeology, as the remainder of the ESC was addressed to those with expertise in different disciplines.
- The 2011 ESC necessitated changes to waste acceptance criteria which were poorly understood or accepted by consignors.

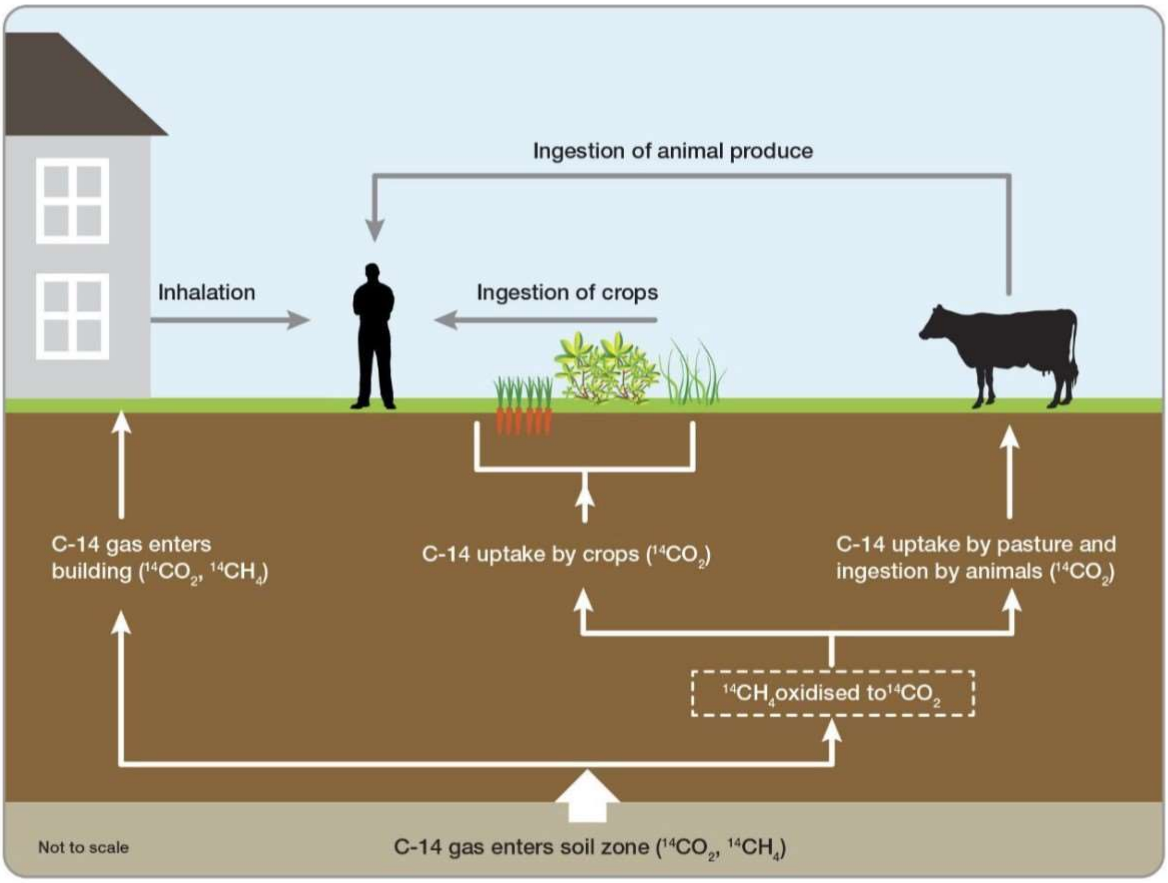

FIG. A–2. Example infographic to describe the exposure pathways for carbon-14 labelled gas (reproduced from Ref. [A–2]).

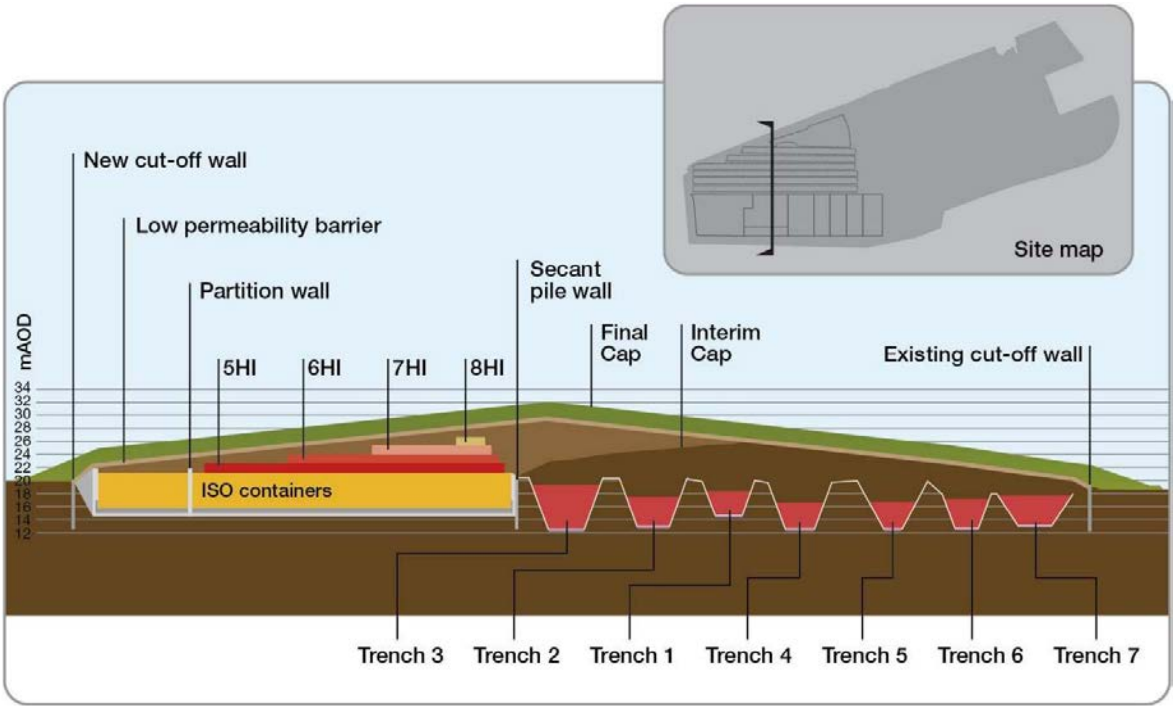

FIG. A–3. Example infographic to show the structure of the LLWR (reproduced from Ref. [A–1]).

LLWR Ltd. undertook a general review of ESC communication in 2018, focusing on the difficulties encountered for the 2011 ESC and with an aim to prepare an enhanced approach for the next major review of the ESC in 2021. The review included an external audit of the 2011 ESC with the remit to identify opportunities for improvement in all areas of communication, including writing style, presentation format, information flow, visual aids and communication media. This work is ongoing, but initiatives already identified include:

- Improving the accessibility and functionality of ESC documentation by transitioning to web based documentation, embedding hyperlinks and search functions to enable key information to be accessed easily.
- Identifying poorly understood concepts within the ESC through structured interviews and questionnaires with key audiences. Development of these key concept summaries into animations and infographics, able to be embedded across multiples presentational formats (e.g. documentation, PowerPoint presentations). We have identified a number of concepts to target in this way and have engaged an external contractor to develop communication tools for these concepts.
- Enhancing our approach to describing safety functions within the ESC as an explanatory tool.

Further, this case study can highlight an example of experience with communications and media. On 20 April 2014, The Guardian, a respected national newspaper, published an article with the headline "Cumbrian Nuclear Dump 'virtually certain' to be eroded by rising sea levels" and a by-line of "One million cubic metres of waste near Sellafield are housed at a site that was a mistake, admits Environment Agency". The article reports on a particular conclusion from the 2011 ESC [A–1] that the repository will begin to be eroded by the sea on a timescale of a few hundreds to thousands of years. The 2011 ESC demonstrated that even if the repository is eroded, the risk to the public is low and within risk guidance levels, and that construction of sea defences would be neither practicable nor optimal.

The article prompted some further local and national media coverage, which was rebutted by a number of television and newspaper appearances by senior LLWR staff to reinforce the safety messages from the ESC. In terms of communicating the ESC and the safety of the site, this episode contains two main lessons:

- In the nuclear industry, and particularly disposal of radioactive waste, there will always be those who seek to undermine and sensationalize. No matter how good your communications are, how well evidenced your arguments are, be prepared for negative media coverage in some form.
- To prepare for such coverage, it is advantageous to have an existing trusting relationship with key stakeholders, in particular the public who would be most easily swayed by such media coverage. In this example, many of our key local stakeholders, including the public, were already aware of the coastal erosion aspect thanks to our prior proactive communication. Of those who weren't, many were inclined to trust the rebuttal of the LLWR. In the nuclear industry it is often not enough to simply be 'correct'. LLWR Ltd has placed great emphasis on winning over the 'hearts and minds' of the local community. Because we cannot expect the general public to understand all of the underpinning of the safety arguments in the ESC, we need this relationship so that they trust our rebuttals of the negative media coverage.

Some useful references and available information on this case study are given in the bibliography at the end of this publication.

A–3. PAKISTAN: STAKEHOLDER CONSULTATION

There is a growing consensus that timely stakeholder involvement is a vital ingredient for effective environmental assessment, as it is for project planning, appraisal and development in general. The World Bank has found that public participation in environmental impact assessment (EIA) tends to improve project design, environmental soundness and social acceptability. Mwalyosi and Hughes identified a similar experience in Tanzania [A–3]. They found that EIAs that successfully involved a broad range of stakeholders tended to lead to more influential environmental assessment processes and, consequently, to development that delivered more environmental and social benefits. The participation of project stakeholders in planning, designing and implementation is now universally recognized as an integral part of the EIA.

This section provides summary details from the consultation meetings held with the stakeholders apart of the environmental and social soundness assessment process of a project in Pakistan.

Stakeholder definition

Stakeholders are the people or the group of people who are somehow directly or indirectly affected by a project, as well as those who may have interests in a project and/or the ability to influence its outcomes either positively or negatively. This includes those positively and negatively affected by the project.

Objective of stakeholder consultation

The overall objectives of the consultation with stakeholders are to get help, for the verification of environmental and social issues, besides technical ones, that have been presumed to arise and to identify those which are unknown or unique to the project. Public involvement, undertaken in a positive manner and supported by a real desire to use the information gained to improve the proposal, will lead to better outcomes, and lay the basis for ongoing positive relationships between the participants. The aims and objectives of a consultation process include:

- Informing the stakeholders about what type of project is proposed.
- Providing an opportunity for those otherwise not represented strongly, to present their views and values, therefore allowing more sensitive consideration of mitigation measures and tradeoffs.
- Providing those involved in planning the proposal with an opportunity to ensure that the benefits of the proposal are maximized and that no major impacts have been overlooked.
- Obtaining local and traditional knowledge (corrective and creative), before decision making.
- Increasing public confidence in the proponent, reviewers and decision makers.
- Providing better transparency and accountability in decision making.
- Reducing conflict through the early identification of contentious issues, and working through these to find acceptable solutions.
- Creating a sense of ownership of the proposal in the minds of the stakeholders.

TABLE A–3. OFFICIAL PARTIES, THEIR ROLE AND COMMUNICATION APPROACH

Official Party	Role	Communication Approach
Waste generator	Pre-disposal activities and preparation of waste acceptance criteria	Through meetings/visits/reports
Pakistan Nuclear Regulatory Authority (PNRA)	Regulation of nuclear installations in Pakistan	Licensing of the project/facility
Environmental Protection Agency (EPA)	Assessment of project's impact on environment through EIA process.	No objection certificate through EIA report and field visit
Local Administration		
Assistant Commissioner, Tehsil Lawa, District Chakwal	Assessment of project's impact on local area administration wise	No objection certificate through meetings/field visits/reports
Office of Divisional Forest Officer, Chakwal Forest Division,	Assessment of project's impact on nearby forests and national reserves	
Mines and Minerals Department, Subdivisional office Chakwal	Assessment of project's impact on natural resources in the vicinity of project area	
Local community	Project's impact on socioeconomic and sociocultural factors affecting the lives of local people	Focus group discussions, scoping meetings, public hearing called at or near the site through media
Environmental practitioners and experts		
Zoological Survey of Pakistan	Assessment of project's impact on fauna	Assessment of project's impact on fauna, flora and ambient air quality monitoring through field visits, instruments and publication of relevant technical report on the project area
Quaid-I-Azam University, Pakistan	Assessment of project's impact on flora	
WELCOS Lab, Lahore, Pakistan	Assessment of ambient air quality	

For the EIA studies of the project, a three step process is followed:

(1) Identification of main stakeholders of the project.
(2) Identification of stakes, concerns and expectation of local people/communities through surveys, focus group discussions and scoping meetings with local people/communities and administration.
(3) Identification of stakes and concerns raised by all stakeholders through a public hearing session that was then arranged in the vicinity of the project area.

Identification of stakeholders

Different types of stakeholders can contribute to the EIA process in different ways and, in most cases, inputs from a broad variety of stakeholders will complement the EIA process. It is advisable at the very beginning to draw up a list of stakeholders that are expected to be the focus of the project. Pakistan Atomic Energy Commission (PAEC) is the main stakeholder, operating organization and proponent of the project. PAEC is also the responsible authority for stakeholder engagements. The official parties (i.e. the main stakeholders) were identified and are listed in Table A–3 above.

In the second step as discussed in the previous section, a field survey and formal/informal meetings were carried out in the vicinity of the project area. For this purpose a process was prepared to access further concerns and expectations of local people and communities from the project.

TABLE A–4. DETAIL OF MEETINGS WITH LOCAL COMMUNITY

Meeting No.	Venue	Approx. distance from site (km)	No. of participants	Villages covered
01	Dhok Ali Khan, Tehsil Lawa, District Chakwal – Pakistan	12	12	03 (DhibbaKarsial, Dhurnaka, Dhok Ali Khan)
02	Dhok Ayub, Tehsil Lawa, District Chakwal – Pakistan	18	23	08 (Dhok Ayub, Dhok Deri, Dhok Hakim Khel, Dhok Miani, DhokGali, DhokKasura, DhokMehr Muhammad, DhokLakiKhel)

Consultation process

Focus group discussions

Consultation with locals and other relevant institutional stakeholders was carried out through focus group discussions and a scoping meeting. During the meeting, the following information was shared with the stakeholders:

- Name and purpose of the project.
- Reason for the selection of current location.
- Exact location of the project.
- Project execution process.
- Activities that will be performed at project.
- Socioeconomic benefits of the project including infrastructure development, plantation in the area, jobs opportunities, provision of standard education, health facilities, uplift of local market.
- Impacts of the project and its mitigations including noise, dust, increase in traffic, land use changes, flora and fauna (wildlife, birds).

The EIA team members visited the surrounding villages and two public meetings were held, in which around 35 people from 11 nearby villages participated. A summary of the meetings is provided in Table A–4.

An attempt was made to include local people of diverse age groups, educational backgrounds and professions, as shown in Fig. A–4.

The scoping meeting was carried out with representatives of local communities in collaboration with the district administration. Selected stakeholders who had been given some awareness of the project during focus group discussions were invited to this meeting and further details about the project were shared.

Public hearing

Environmental Protection Agency of Punjab, Pakistan, arranged a public hearing session in the vicinity of the project which was called through the media (i.e. local and national newspapers) and all stakeholders were welcomed to express their concerns and expectations from the project. EPA representatives described the project details to the public and after delivery of a presentation to the public by proponents, the floor was opened for questions and answers. The whole public hearing process was also streamed on Zoom so that those who could not come to the site could join the session online.

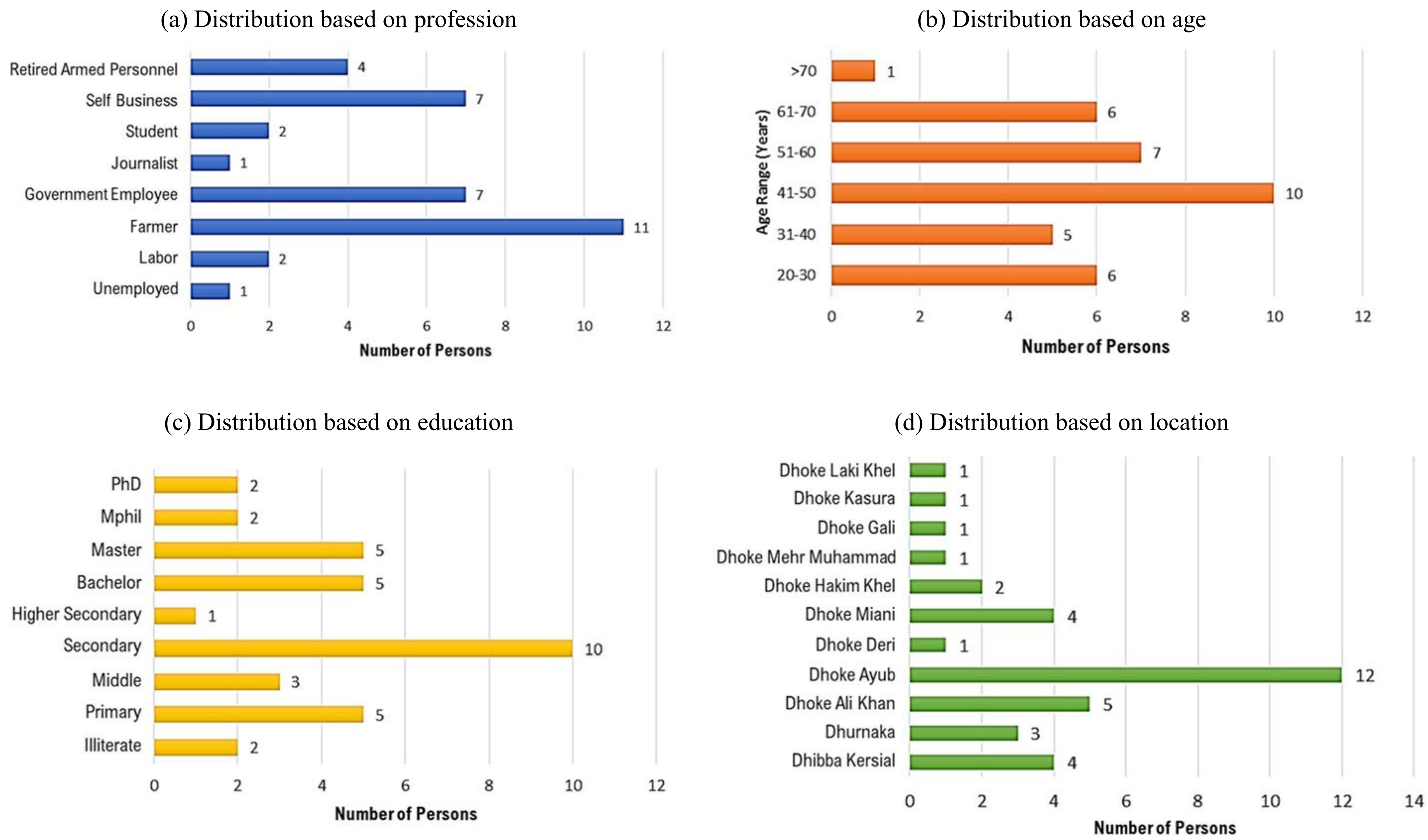

FIG. A–4. Demographic representation of the focus group by: (a) profession; (b) age; (c) education; and (d) location (courtesy of Musharraf H. Rizvi, PNRA).

Expectations of stakeholders

Communities, resident in the nearby villages were already aware of the project. Communities welcomed the plan and appreciated the initiatives taken by PAEC in identifying the current project site in the remote area of Dhok Miani, which has long remained an underdeveloped area. As the project would not directly affect them, the villagers generally did not have any apprehension or reservation about the project. They nevertheless viewed the project as one that would create employment opportunities and small business/trade opportunities for the local population. Stakeholders at the consultation meetings had the following expectations:

- Development of new educational institutes or upgrade of existing institutes.
- Provision of basic health facilities.
- Preference in jobs to local people.
- Tree plantation to conserve the natural beauty of the area.
- Infrastructure development, specifically road network.

A–4. CANADA: COMMUNICATION BY A REGULATORY BODY

The Canadian Nuclear Safety Commission (CNSC) is the regulatory body in Canada. The Commission consists of up to seven members, and act as an independent, quasi-tribunal and court of record. The Commission makes the licensing decisions. In making these decisions the Commission is supported by CNSC staff who provide expert research, analysis and opinion. The Commission uses public proceedings to get the information it needs to make decisions. At these proceedings, proponents, CNSC staff, interested parties and members of the general public may be present and can be heard.

CNSC staff communicate with many categories of interested parties with different levels of scientific and technological expertise: the Commission members, the proponents or licensees, indigenous nations and communities, the general public and interested parties who can obtain advice from their own experts. For a disposal facility such as a near surface disposal facility, the safety case is the main set of documents in support of the licence application. Communication from CNSC staff on the safety case to different interested parties usually follows the following main steps:

(1) CNSC staff communicates and clarifies the regulatory requirements and expectations on the safety case to the proponent or licensee.
(2) The proponent develops the safety case.
(3) CNSC staff review the safety case.
(4) The proponents revise the safety case to address CNSC staff review comments and findings.
(5) Steps 3 and 4 could be reiterated until CNSC staff is satisfied that all comments and concerns have been addressed.
(6) Based on the safety case and other documents, CNSC staff provide recommendations to the Commission, present the recommendations and address questions related to the recommendations from the Commission, indigenous nations and communities, the general public and interested parties.

Regulatory research is an important activity of CNSC staff. The results of the research provide independent science based support to staff's licensing recommendations and are taken into account in CNSC's requirements and guidance on safety case development. CNSC staff disseminate research results in peer reviewed journal publications and in publications and presentations at peer reviewed conferences.

In addition, CNSC staff conduct numerous outreach activities to share their regulatory role on the project, to communicate technical information of the project, and to listen to concerns of indigenous nations and communities, the general public and interested parties. Outreach activities can include visiting interested communities, hosting or attending in person workshops, as well as hosting remote webinars and technical information sessions.

Regulatory approach to indigenous consultation and engagement

In Canada, indigenous and treaty rights are protected under the Canadian Constitution, and the Government is legally required to meaningfully consult potentially affected indigenous nations and communities when making decisions that could impact them and their rights. In 2021, Canada passed the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) Act, which enshrines the principles of UNDRIP into Canadian law.

The CNSC, as Canada's nuclear regulatory body and an agent of the Government of Canada, is committed to going beyond the legal bare minimum for meeting the Duty to Consult as established by the Supreme Court of Canada. By providing funding, constant dialogue, formalized agreements and regular information sharing, the CNSC ensures that interested indigenous nations and communities have opportunities to participate throughout the regulatory lifetime, in order to ensure all issues and concerns are considered, and that information gathered, including indigenous knowledge, is used to inform the Commission's decisions.

The CNSC's Participant Funding Program, established in 2011, provides financial assistance to members of the public, environmental, non-governmental organizations and indigenous nations and communities to participate and provide information to the Commission through topic specific interventions related to environmental assessments and other licensing processes.

The CNSC has established several effective processes to support its duty to consult obligations. For the CNSC, collaboration includes further opening up the assessment and decision making processes to potentially impacted indigenous nations and communities. For example, the CNSC has signed multiple consultation agreements with indigenous nations and communities that create a framework for how the CNSC and the indigenous nation or community will be consulted and involved in the regulatory process. Examples include the collaborative drafting of key sections of CNSC staff's assessment reports and recommendations to the Commission, participation in technical review teams and rights impact assessment processes, and the incorporation of indigenous knowledge and traditional land use data.

These measures ensure that indigenous groups continue to be treated with respect and as another order of government that is directly involved in the CNSC's review and assessment process. This is a partnership approach that aims to achieve the principles outlined in UNDRIP, including addressing the concerns identified by indigenous nations and communities regarding nuclear projects, such as potential impacts on their rights, culture and way of life in a collaborative and ongoing way with the CNSC. These approaches are helping the CNSC to build trust and achieve positive, sustainable results.

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LIST OF ABBREVIATIONS

AENTA	Cuban Agency for Nuclear Energy and Advanced Technologies
ASAM	IAEA Application of Safety Assessment Methods project
CICA	Cuban environmental Inspection and Control Centre
CITMA	Cuban Ministry of Science, Technology and Environment
CNSC	Canadian Nuclear Safety Commission
CNSN	Canadian National Nuclear Safety Centre
CNSN	Cuban National Nuclear Safety Centre
CPHR	Canadian Centre for Radiation Protection and Hygiene
EIA	environmental impact assessment
EPA	Environmental Protection Agency
ESC	environmental safety case
FAQs	frequently asked questions
FEPs	features, events and processes
HIDRA	IAEA International Project on Human Intrusion in the Context of Disposal of Radioactive Waste project
ISAM	IAEA Safety Assessment Methodologies for Near Surface Disposal Facilities project
LLW	low level waste
LLWR	UK Low Level Waste Repository
MASC	Matrix of Arguments for a Safety Case
MeSA	OECD/NEA Methods in Safety Assessment project
MODARIA	IAEA Modelling and Data for Radiological Impact Assessments project
NSARS	IAEA Safety Assessment of Near Surface Radioactive Waste Disposal Facilities project
OECD/NEA	Nuclear Energy Agency of the Organisation for Economic Co-operation and Development
ORASEN	Cuban Office for Environmental Regulation and Nuclear Safety
PAEC	Pakistan Atomic Energy Commission

PNRA	Pakistan Nuclear Regulatory Authority
PRISM	IAEA PRactical Illustration of the use of the Safety case concept in the Management of near surface disposal project
PRISMA	IAEA PRactical Illustration of the use of the Safety case concept in the Management of near surface disposal - Application project
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples
WAC	waste acceptance criteria
WCSSG	West Cumbria Site Stakeholder Group

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