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Regulatory Review and Confidence Building in Post-Closure Safety Assessments and Safety Cases for Near Surface Disposal Facilities, IAEA ASAM Coordinated Research Project

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Abstract. The IAEA successfully concluded a Coordinated Research Program (CRP) called ISAM, which focussed on the development of an Improved Safety Assessment Methodology for near-surface radioactive waste disposal facilities (1997-2002). In November 2002, and as an extension of ISAM, the IAEA launched a new CRP called ASAM, designed to test the Application of the Safety Assessment Methodology by considering a range of near-surface disposal facilities. The ASAM work programme is being implemented by three application working groups and two cross-cutting working groups. The application working groups are testing the applicability of the ISAM methodology by assessing an existing disposal facility in Hungary, a copper mine in South Africa, and a hypothetical facility containing heterogenous wastes, such as disused sealed sources. The first cross-cutting working group is addressing a number of technical issues that are common to all near-surface disposal facilitiess, while the second group, the Regulatory Review Working Group (RRWG) is developing guidance on how to gain confidence in safety assessments and safety cases, and on how to conduct regulatory reviews of safety assessments. This paper provides a brief overview of the work being conducted by the Regulatory Review Working Group.

1. Background

For several decades, many countries have been developing near surface facilities for the disposal of low and short-lived intermediate radioactive waste. In line with the internationally agreed principles of radioactive waste management and the related safety standards, the safety of these facilities needs to be ensured during all stages of their lifetime, including the post-closure period. Formal methodologies for assessing the long-term safety of such facilities have been developed over the years, but inter-comparisons of these methodologies carried out by the IAEA have revealed a number of discrepancies between them. Consequently, in the period 1997 to 2000 the IAEA co-ordinated a research project entitled "Improving Long Term Safety Assessment Methodologies for Near Surface Radioactive Waste Disposal Facilities" (ISAM) [1]. The

objectives of the ISAM project were to provide a critical evaluation of the approaches and tools used in post-closure safety assessment for proposed and existing near-surface radioactive waste disposal facilities; enhance the approaches and tools used; and build confidence in the approaches and tools used.

As part of the ISAM project, a structured iterative and consistent safety assessment methodology was developed. This methodology is built around the following key components (Figure 1):

(a) Specification of the assessment context;
(b) Description of the radioactive waste disposal system;
(c) Development and justification of scenarios;
(d) Formulation and implementation of conceptual and mathematical models; and
(e) Analysis of results and building of confidence.

Although, the ISAM methodology has found widespread acceptance, the participants recognized the need to test further the applicability of the ISAM methodology using a range of practical, real-life situations. Building on the experience of the ISAM project, the IAEA launched, in 2002, a new coordinated research project entitled "Application of Safety Assessment Methodologies for Near-Surface Radioactive Waste Disposal Facilities" (ASAM) [2]. The overall objectives of the ASAM project are to explore practical application of the ISAM methodology to a range of proposed and exiting near surface disposal facilities for a number of purposes, such as development of design concepts, safety reassessment and upgrading of existing facilities; and to develop practical guidance to assist regulators, operators and other specialists reviewing safety assessments.

The ASAM project is coordinated through several meetings in which the focus, direction and outcome of the project are discussed and agreed. The work programme is being implemented by five working groups; three dealing with application of the ISAM safety assessment methodology to different waste types, and two cross-cutting working groups dealing with various common issues. The scope of each working group is as follows:

- Safety Reassessment - reassessing the safety of an existing disposal facility in Hungary;
- Disused Sealed Sources and Heterogeneous Waste - assessing the safety of disposing of disused sealed sources and other heterogeneous radioactive waste;
- Mining and Minerals Processing Waste - assessing the safety of disposal of mining and minerals processing waste and other waste with an enhanced content of naturally occurring radionuclides using a Copper mine in South Africa;
- Regulatory Review– Developing guidance on regulatory review of safety assessments and for the incorporation of safety assessment in the safety case;
- Common Aspects – considering specific aspects common to the application of safety assessment methodologies to all near surface disposal facilities, such as the assessment of disruptive events (e.g. human intrusion) .

This paper provides an overview of the work being carried out by the Regulatory Review Working Group and the progress achieved so far.

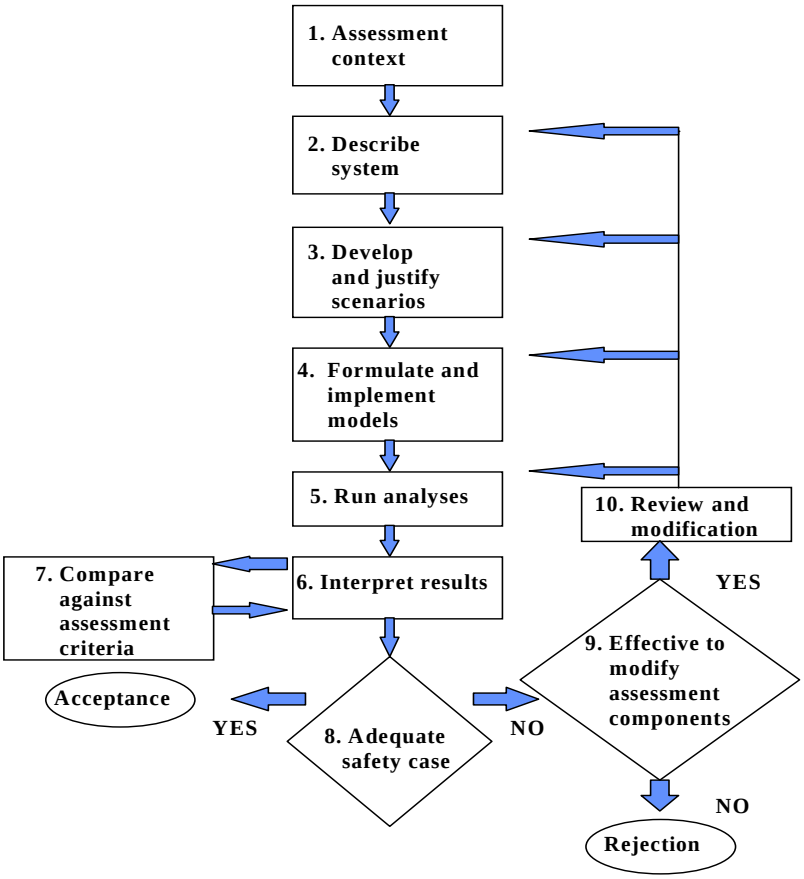

Figure 1. The ISAM Safety Assessment Methodology

2. The IAEA-ASAM Regulatory Review Working Group and its Objectives

The ASAM Regulatory Review Working Group is composed of approximately 21 regulators from 15 countries. The two main objectives of the RRWG are the development of a systematic regulatory review procedure for reviewing safety assessments and the development of guidance on how to document and gain confidence in safety cases for near-surface radioactive waste disposal facilities. The topics being considered in the context of these two objectives are presented in Sections 3 and 4 of this paper.

3. Guidance on Building Confidence in Safety Cases for Radioactive Waste Disposal Facilities

The concept of "safety case" has been analyzed and discussed extensively in the context of proposals for deep geological disposal of intermediate-level and high-level radioactive waste and spent fuel. Such analyses have been mainly conducted by groups such as the OECD Nuclear Energy Agency (NEA) Integration Group on the Safety Case (IGSC). However, the concept of the safety case for near-surface disposal facilities has not received the same level of consideration, despite the greater number and diversity of near-surface facilities and the wealth of available experience in developing, operating, upgrading and remediating these types of facilities.

Assembling a safety case for a near-surface disposal facility may pose considerable challenges because of the usual proximity of local populations, the susceptibility of near-surface facilities to disruptive events and erosion processes, the relatively high likelihood of human intrusion, and the wide range of situations that may need to be considered (e.g. development, expansion, reassessment, remediation, etc.). The objectives of the RRWG are to build on existing experience in the development of safety cases and to develop guidance on how to plan, document and build confidence in safety cases for near-surface disposal facilities. The guidance also considers relevant means of communicating key messages from such safety cases. The following sections provide an overview of the main topics considered in the safety case guidance document being developed by the RRWG.

3.1. Structure and Components of a Safety Case

It is more and more recognized that while safety assessments and their findings have traditionally constituted the foundation of a safety case, they should be put into a broader context with other factors and considerations that are relevant to the decision-making process and that are important for the stakeholders involved. In other words, the safety case should explain why the intended audience should have confidence in the acceptability of the disposal facility. In this context, the safety case should, therefore, present a collection of arguments in support of the long-term safety of a disposal facility, for example covering the following components:

- *A well documented and quality assured safety assessment, including discussions on how confidence was established at each stage of the assessment and in the overall safety assessment methodology, approach and findings. The safety assessment should, in particular, include a thorough treatment of uncertainty;*

- *A demonstration of confidence in the robustness of the disposal system. This implies the need for an in-depth and scientific understanding of the disposal system and of the reliability of the disposal facility engineering;*

- *A demonstration of confidence in the management framework and competence of the proponent/implementer, including demonstration that appropriate management structures and strategies are in place. Similar levels of confidence are required in the competence of the regulatory organisation;*

- *An identification of any unresolved issues and a demonstration of confidence in the ability of the program to resolve them;*

- *An adequate consideration of of alternative options and a clear rationale for the adoption of the proposed or selected waste management option; and*

- *An adequate demonstration that the safety case has been developed via a transparent process with appropriate stakeholder involvement .*

The safety case should be viewed as an open and flexible concept, or living document, which is used as a tool for demonstrating, promoting and communicating confidence in the long-term safety of a radioactive waste management facility. The development of a safety case, its content and structure are greatly influenced by country specific legislative and regulatory requirements, local concerns and could be achieved in different ways. Although many countries do not use the term "safety case" in a formal way, they follow processes that are compatible and, in essence, similar to the safety case concept.

The process of assembling a safety case is in most cases an interactive process that spreads over a long period of time. For this reason, the arguments included in the safety case may carry different weight and their importance and the level of scrutiny that they are subjected to by stakeholders may vary over time, depending on the development stage of the facility and the regulatory decision that is under consideration (e.g. early planning and stakeholders consultation stages, Environmental Assessment, licensing etc.).

3.2. ***Confidence in the Safety Case***

As mentioned earlier, the safety case is a tool for demonstrating confidence in the safety of a disposal facility by integrating safety assessment arguments with other relevant qualitative and quantitative arguments. Various stakeholders will have different interests and will tend to scrutinize the arguments that are more relevant to their areas of concerns. For example, technical reviewers may pay close attention to the safety assessment aspects while members of the general public may be more interested in the other more qualitative arguments. Waste producers may focus on disposal costs. Gaining confidence in the safety case requires that confidence is gained in each component of the safety case as described in the following sections.

3.2.1. Confidence in the Safety Assessment

The purpose of building confidence in the safety assessment is to provide readily understandable qualitative and quantitative evidence that all aspects of the safety assessment are based on sound scientific and technical principles and have been carried out in a systematic manner that is amenable to independent review. The guidance being developed by the RRWG concerning confidence in the safety assessment covers three aspects. The first aspect involves establishing an overall confidence in the safety assessment methodology, mainly from the perspective of structure, consistency and presentation. The second aspect involves establishing confidence by using different safety assessment approaches. The third aspect consists of gaining confidence in each stage of the safety assessment.

Overall confidence in the safety assessment is increased when the assessment methodology is structured, transparent, traceable and compatible with international best practice. A test of traceability is that the regulators and other technical reviewers should be able to easily reproduce the assessment results, follow the logic and understand the assumptions used in the assessment. The assessment should provide a full description of the practical methods used in order to identify and reduce uncertainties, and should identify the assumptions and uncertainties that impact the most on safety. The safety assessment methodology, approach and results should be documented in such a way that the readers can gain a clear picture of what has been done, what the results are and why the results are what they are.

Confidence in the safety assessment results can be gained by using additional and complementary approaches to. These include:

- Use of multiple lines of reasoning through the use of complementary arguments based on different approaches and sources of evidence such as simple and direct approaches, natural analogues, expert judgment, international consensus etc.;
- Use of multiple safety indicators, which are alternative end points to complement dose and risk calculations;
- Use of a variety of assessment techniques such as probabilistic versus deterministic; simple versus complex approach; conservative versus realistic; and using qualitative versus quantitative information.
- Conduct of independent assessments by different groups of staff or organisations.
- Demonstration of implementation of a rigorous quality assurance system.

Guidance on how to achieve confidence in each stage of the safety assessment is being developed using the assessment stages involved in the ISAM methodology, which include: the assessment context; description of the system; development and justification of scenarios; formulation and implementation of models; analysis of the results (assessment findings); review and modification and subsequent iterations (see Figure 1).

3.2.2. Confidence in the Robustness of the Disposal System

The guidance provided under this section is very similar to that proposed for deep geological disposal but will be complemented with aspects that are specific to near-surface disposal facilities. Confidence in the robustness of the disposal system requires demonstrating that the system will continue to perform its expected overall safety function, regardless of likely possible perturbations that may occur in the future. The guidance makes the distinction between intrinsic and engineered robustness. Intrinsic robustness related to an appropriate choice of site (e.g., some sites can be expected to experience fewer perturbations from natural flooding or earthquakes than others). Engineered robustness might be demonstrated by describing special concepts and features that improve the resistance of engineered components to perturbations (e.g. multiple barriers, over-dimensioned components, redundant features etc.). The different aspects that are considered in the guidance document include:

- Confidence in the understanding of the site;
- Containment and isolation;
- Defence in depth, multiple barriers and multiple safety functions;
- Evolution with time of the safety function of the barriers;
- Test robustness of the system through “what if” scenarios;
- Confidence in the engineering and underlying science used to design the system;
- Use of best technology versus proven technology.

3.2.3. Confidence in the Management Framework

Implementers should demonstrate that they have in place all of the necessary management processes and systems required to assess, review and manage the disposal facility and related information throughout its life cycle and during the period of active institutional control. This demonstration may involve: the establishment or confirmation of plans for the provision of appropriate levels of funding for facility operation, safety assessment and research, an appropriate safety culture, appropriate procedures for dealing with records maintenance and organizational change, a commitment to open and transparent public involvement processes, appropriate quality systems and quality assurance plans etc. Regulatory organizations should also possess many of the same attributes in order to demonstrate credibility and engender trust. Confidence in the regulator and the regulatory process builds confidence in the safety of approved facilities. Examples of aspects considered in the guidance being developed include:

- Independent regulator with clear and consistent regulatory requirements and guidance documents;
- Stepwise decision-making process with well defined regulatory process and decision making points;
- Well established and documented regulatory review procedures based on consistent and transparent acceptance criteria;
- Adequacy of the management structure of both the implementer and the regulator;
- Competence and credibility of assessors and regulatory reviewers;
- Transparency and appropriate processes of public and stakeholder involvement;
- Consideration of international recommendations;

3.2.4. Communication with and Involvement of Stakeholders

Well designed and implemented programmes for stakeholder involvement in, and dialogue on, the safety case may be just as important to confidence building as the content of the safety assessment itself. The guidance provided under this section will build on the work of the NEA Forum for Stakeholder Confidence and other recent work in this area. It is the intention to illustrate the importance of successful stakeholder engagement processes by describing examples of both success and failure stories.

4. Guidance on Regulatory Review of Safety Assessments for Radioactive Waste Disposal Facilities

Regulatory review plays an important role in safety case development. The conduct of a high-quality review enhances confidence in the credibility of the regulator, in the review findings and in any associated regulatory decisions made based on the safety assessment. The RRWG is developing a practical review procedure that covers the logical steps and activities typically undertaken by regulators when carrying out reviews of safety assessments. These include:

- The overall management of the review;
- Establishing the objectives and scope of the review;
- Establishing a review team;
- Establishing the review schedule and resource allocation;

- Dialogue with the proponent during the review;
- The management of review comments and issue resolution;
- Dealing with "regulatory uncertainty";
- Reporting the findings of the review;
- Conducting a review with limited resources.

A short summary of the 2 main topics considered in the guidance document is provided in the following sections.

4.1. Managing the Review Process

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 authority with or without support from external organizations, but the results of the review must be fully "owned" by the regulatory authority. The guidance being developed under this topic considers the main following aspects:

- Defining the objectives and scope of the review;
- Developing a review plan that identifies the review tasks and addresses other relevant topics listed here;
- Assembling a review team of competent personnel possessing the necessary expertise and experience to undertake the review;
- Defining the project schedule and allocating resources for the conduct of project tasks, including consideration of review conduct when resources are limited;
- Identifying the responsibilities of review team members and ensuring that they receive adequate training and guidance in the review method;
- Co-ordinating the conduct of the review tasks, and ensuring sufficient communication between review team members;
- Identifying early on during the review any areas of "regulatory uncertainty". An example of this type of uncertainty might relate to question of whether or how to apply new environmental protection standards when upgrading the safety of old disposal facilities.;
- Co-ordinating dialogue with the operator of the disposal facility, and with other stakeholders during the review process;
- Reviewing and integrating documents generated during the review process;
- Synthesis and communication of review findings.

The review procedures applied should allow the regulatory authority 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 documenting review comments, for specifying required competence, for specifying responsibilities and tasks in the review, 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 the review findings. Technical guidance might include the criteria against which to judge specific aspects of the safety assessment. The RRWG document may therefore serve as a template from which a project-specific plan can be developed. Examples of project-specific review plans include those developed for the Drigg low-level radioactive site in the UK [3] and for Yucca Mountain project in the USA [4].

4.2. Conducting the Review and Reporting Review Findings

This part of the RRWG guidance document identifies the main components of the safety assessment to be considered during the review. The procedure is illustrated for each of the steps within the ISAM assessment methodology, that is, the assessment context; the system description; the development and justification of scenarios; the formulation and implementation of models; and the analysis of results. For each step, the review procedure highlights the types of statements of confidence that the safety assessment should support, and lists appropriate questions that the reviewer should ask when conducting the review. Such questions are designed to help reviewers identify potential deficiencies in the safety assessment, but they should also help safety assessors to better document their safety assessment and thereby meet regulatory expectations.

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

- Is based on an appropriate assessment context;
- 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 arguments supporting the adoption of those assumptions, including assessment scenarios, models and parameter values;
- Demonstrates an adequate understanding of the disposal system;
- Clearly identifies the uncertainties associated with the understanding of the disposal system and the performance of the disposal facility;
- Includes an adequate consideration of optimisation and/or intervention;
- Has been conducted under a suitable quality assurance system;
- Defines an appropriate forward programme for improving the safety assessment, understanding of the disposal system, and control of the site.

5. Conclusions

The work of the ASAM Regulatory Review Working Group will provide practical tools and techniques aimed at improving the safety of near-surface radioactive waste disposal facilities. The regulatory review procedure will provide a consistent framework and approach for the review of safety assessments. The guidance on safety assessment review can be applied at a level of detail compatible with available resources. This is particularly important for countries with severely limited resources. The guidance on the safety case and confidence building should help in addressing the particular challenges associated with the development, upgrading and remediation of near-surface disposal facilities.

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