SAFETY CASE: AN INTERNATIONAL PERSPECTIVE

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Abstract. In recent years, it has become more and more evident that repository development will involve a number of stages punctuated by interdependent decisions on whether and how to move to the next stage. These decisions require a clear and traceable presentation of technical arguments that will help in giving confidence in the feasibility and safety of the proposed concept. The depth of understanding and technical information available to support decisions will vary from step to step. A safety case is a key item to support the decision to move to the next stage in repository development. Progress is noted, in the past decade, in the performance and safety assessment areas, particularly in the methodologies for repository system analysis. Progress is also observed regarding the understanding of the natural system and its characterisation, treatment of uncertainties, and modelling. Some areas are under active development, e.g. the area of scenario development and analysis. Finally, to increase confidence, rigorous quality assurance procedures need to be implemented, as well as the factoring of the contribution of R&D in underground research laboratories. The paper summarises the lessons learnt within relevant NEA initiatives as they evolved over the course of a decade and now allow a comprehensive view of what constitutes a safety case.

1. INTRODUCTION

Implementing and regulatory organisations in many of the OECD/NEA member countries are involved in the investigation and resolution of issues associated with long-term safety of underground repositories for radioactive waste.

In every national radioactive waste management programme, it is recognized that an appropriate level of confidence in the achievability of long-term safety should accompany the decision at each stage of a step-wise repository development. The current level of technical confidence should be illustrated and argued in a safety case. A safety case should also argue the possibility of reducing the current level of uncertainty in the next development phases.

The concept of a "safety case" has been progressively clarified in a series of initiatives that the NEA has had in the past decade, and which culminated with the publication of the NEA confidence document [NEA 1999] and the latest IPAG exercise [NEA 2001].

> "*Safety Case: A Safety Case is a collection of arguments at a given stage of repository development, in support of the long-term safety of the repository. A Safety Case comprises the findings of a safety assessment and a statement of confidence in these findings. It should acknowledge the existence of any unresolved issues and provide guidance for work to resolve these issues in future development stages.*"
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> "*Safety Assessment: is the evaluation of long-term performance of compliance with acceptance guidelines and of confidence in the Safety indicators by the assessment results.*"
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> "*Performance Assessment: the analysis of the performance of the system concept, with the aim of developing confidence that the system will (or can be designed to) perform within acceptable bounds.*"

Over the years, insights were obtained from the activities of the working group IPAG, from reviews of national safety studies, from the confidence document, topical sessions within the past PAAG and SEDE groups, plus from the cumulative knowledge of the IGSC. The findings of the various relevant initiatives are reviewed hereafter.

2. FEEDBACK FROM THE THREE IPAG PHASES

The IPAG initiative started in 1994 with the aim to provide an international platform to examine the overall status of Safety Cases and their supporting Integrated Performance Assessment (IPA) studies. The work has been carried out in three phases. IPAG-1 from 1995 to 1996, aimed to examine completed IPA studies as a practical body of evidence that would indicate the current status[1] of PA. IPAG-2 from 1997 to 1998 was carried out in order to examine the experience of peer reviews of IPAs, and especially reviews performed in support of regulatory assessment, from both the implementer and regulator points of view[2]. IPAG-3 has been carried out mainly between June 1999 and November 2000. It focused on the evaluation of the state-of-the-art for obtaining, presenting and demonstrating confidence in long-term safety and, made recommendations on future directions and initiatives for improving confidence[3].

The increase in the number of national organisations (e.g. from ten during IPAG-1 to 20 in IPAG-3) participating in these exercises stresses the importance of the Safety Case. The findings, such as compilations of questions and answers and the achievements of discussions during the successive IPAG exercises, constitute a relevant database of national Safety Cases.

2.1. IPAG 1: "Lessons learnt from ten performance assessment studies"

On the basis of the examination of ten PA studies, the IPAG-1 group identified several areas in which significant advances in methods and applications, and prospects for specific improvements were observed.

Traceability[4] and *Transparency*[5] were considered as relevant issues in PA even though they consume time and resources. Some guidance on methods for promoting transparency is given such as the presentation of assumptions and their basis, modelling accurately, data used and their sources, explanation of the results and points of weakness.

According to the Safety Assessment report, participants agreed that a universal plan of contents couldn't be recommended. However, as said before and taking account of the need to promote transparency in PA documents, a set of fourteen elements (or topics) that should be addressed in a safety assessment report was proposed:

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[1] IPAG-1: Lessons Learnt from Ten Performance Assessment Studies, OECD/NEA 1997 report [NEA, 1997].
[2] IPAG-2: Regulatory Reviews of Assessments of Deep Geological Repositories, OECD/NEA 2000 report [NEA, 2000-a].
[3] IPAG-3: Approaches and arguments to establish and communicate confidence in safety and the overall results of IPAs, OECD/NEA report (to be published).
[4] By traceability, it was understood as an unambiguous and complete record of the decisions and assumptions made, and of the models and data used in arriving at a given set of results.
[5] By transparency, it was understood as the PA record to be written in such a way that its readers can gain a clear picture, of what has been done, what the results are and why they are as they are.

Program context	Historical perspective, regulatory context, brief description of the waste disposal concept
Regulatory criteria	Criteria or guidance, quantitative and qualitative
Objectives and scope of the assessment	Related to the programme context
Description of the system at the conceptual level	Required level of safety e.g. multi barrier concept, safety functions
Statement of the constraints	Long time scale, uncertainties.
Approach to safety assessment	Treatment of uncertainties, models using, traceability...
Detailed description of the disposal system	Waste form, EBS, site characteristics
Interpretation and elicitation of databases	Methods description, use of expert to elicit data
Scenario development	Methodology, description, assumptions, justification
Description of models	Conceptual and mathematical, spatial and temporal, assumptions
Results and interpretation	For individual subsystems and total system, sensitivity uncertainties.
Confidence in key arguments	Key processes, model, data and assumptions revisited and their basis examined
Compliance with regulatory criteria	Overall compliance with regulatory criteria
Conclusions	Indication of areas in which further development is required, which goals have been reached

IPAG 1 participants also revealed the different vocabularies to be clarified such as Performance Assessment/Analysis, Safety Assessment/Analysis/Case and agreed there was no available definition, but an interpretation might be given within the safety study.

IPAG-1 participants pointed out the potential long-term stability uncertainties as far as the geosphere as a key component of the multi-barrier system is concerned. They recommended coordination between site characterisation and design such as an explanation of the basis for selecting geosphere functions to be taken into account and to be discarded in PA calculations.

Moreover, PAs should address the issues of uncertainties (on scenarios, models and parameters) and completeness in the context of the safety arguments and relevant characteristics of the specific disposal system. Finally, natural analogues were seen as a component of the confidence-building process as they support the understanding of key processes regarding the different components of the multibarrier system and provide evidence that no unexpected processes or phenomena have been present or active.

2.2. IPAG 2: Regulatory reviews of assessments of deep repositories

The IPAG-2 study compared international experiences of peer reviews of IPAs and, especially reviews performed in support of regulatory assessments from both implementers and regulators points of view. The findings on four topics are summarized hereafter:

As far as the conduct of review is concerned, it was observed that the dialogue, and moreover making records and stable documentation from this dialogue, is important and of benefit both for regulators and implementers and enhances the overall credibility of the step-wise process through which implementer and regulator should establish a structured framework for PAs and reviews early in a repository programme. The implementer has to produce a complete analysis of repository safety; thus independent assessments or calculations by regulators can

be beneficial for the reviews. Regulatory guidance should clearly state the requirements and be flexible in order to avoid frequent updates.

Concerning the Safety Case, the necessary integration of site investigation and design development in the PAs was pointed up, focusing on the intrinsic safety of the disposal system and not only on the calculations used to demonstrate safety. Multiple lines of reasoning such as natural analogues and paleohydrogeology might help in this objective and variety of techniques and approaches could be used in a complementary manner, e.g., probabilistic versus deterministic calculations. In addition, qualitative "soft" and quantitative "hard" information should be considered as complementary arguments and as already indicated in the IPAG-1 report; consideration should be given to increasing their value in the decision-making process. At the end, the multi-barrier system was confirmed as the key element for long-term safety and further work is needed to describe what is specific to a deep geological disposal system. Implementers clearly need also to be explicit in their interpretation of the multi-barrier concept.

In support of the above thesis on the traceability and transparency stressed in the IPAG 1 study, IPAG 2 also advised that IPAs prepared for licensing purposes be traceable, transparent, reproducible and publicly available. One aspect of developing traceability and understanding between the implementer and regulator is consistency of the methods and documentation structure and style. Other, non-technical stakeholders also review IPAs and have different needs with regard to traceability and transparency. An integration of their viewpoints is needed. At the end, NEA should explore in greater detail the approaches and techniques used for addressing the needs of public and other non-technical stakeholders in IPAs.

2.3. IPAG 3: Approaches and arguments to establish and communicate confidence in safety and the overall results of IPA's

In IPAG-3, the objectives were to evaluate the state-of-the-art for obtaining, presenting and demonstrating confidence in long-term safety, and make recommendations on future directions and initiatives for improving confidence. The IPAG-3 study mainly followed the work done on confidence building in 1999 in which the terms "Safety Case" and "IPA" are distinguished. The IPAG-3 study continued to make a distinction between these two terms. During IPAG-3 discussions, three main topics were developed for which some messages are summarized hereafter.

As already mentioned in the previous IPAG exercises, the long duration of the process reflects the complexity of the tasks and the desire to proceed by cautious steps due to technical issues and social acceptance.

These decisions may regard, for example, interim surface storage, siting and design, safety assessment, site characterisation, and the licensing of construction, operation and closure, sealing and post-closure monitoring that are taken throughout the development of a facility. Generally, the Safety Case is considered as one of the key bases and needs thus to be structured, technically argued, and supported with a clear link to the step-wise decision-making process and the level of confidence must reflect commitments at each relevant step. Based on answers provided by IPAG-3, key arguments were identified and categorized as presented below:

Confidence in the Proposed Disposal System	— Intrinsic robustness of the multi-barrier system — "What if?" scenarios and calculations — Comparisons with familiar examples and natural analogues
Confidence in the Data and Knowledge of the Disposal System	— Quality of the research programme and site investigations — Quality assurance procedures — Data from a variety of sources and methods of acquisition — Use of formal data-tracking techniques
Confidence in the Assessment Approach	— Logical, clear, systematic assessment approach — Assessment conducted within an auditable framework — Building understanding through an iterative approach — Independent peer review of approach
Confidence in the IPA Models	— Explaining why results are intuitive — Consideration of alternative conceptual models and modelling approaches – simple and complex — Testing of models against experiments and observations of nature — Model comparison exercises — Comparisons with natural analogues — Independent evidence such as paleohydrogeological information
Confidence in the Safety Case and the IPA Analyses	— Clear statements and justifications of assumptions — Demonstrate that assumptions are representative or conservative — Sensitivity studies — Clear strategy for managing and handling uncertainty — Multiple safety indicators — Multiple lines of reasoning
Confidence via Feedback to Design and Site Characterisation	— Support for any disposal concept design changes — Overall quality and safety of the disposal system

Uncertainty regarding phenomena and data over time scales such as the future course of events external to the repository or the long-term evolution of engineered materials were emphasized as an important issue in the Safety Case. Consequently, IPAG-3 raised the need for a clear strategy for dealing with these uncertainties that will be explained within the Safety Case and its supporting IPA. Generally, the higher the margins of safety in barrier performance, the less stringent are the demands on the precision of associated data. The quality of the Research and Development (e.g., site characterisation, properties of materials involved...), procedures, data and the use of these data are crucial and must be clearly stated in a dedicated section of the IPA's documentation.

Moreover, IPAG-3 participants confirmed that the assessment and modelling approaches must also be clear, logical, continually improved through an iterative process, and submitted to independent peer reviews and accepted by stakeholders. For getting confidence in the modelling, one solution might consist of verification of numerical modelling by comparison with simple analytical models, solution of test problems and comparison of results from different methods used to resolve the same problems. Another solution involves participating in international model comparison exercises, using models to predict measurable parameters, comparison of results with natural analogues, and using paleohydrogeological data.

IPAG-3 participants recommended that a Safety Case should include a clearly developed "confidence statement", as proposed in NEA [1999], and that this should be given a prominent location within the documentation. The confidence statement should explain clearly how the assessment results compare with the appropriate regulatory criteria, and could

also make comparisons with levels of naturally occurring radiation and other everyday risks, to put the radiological risks arising from a repository into perspective.

Regarding the communication and presentation part of IPAG-3, the Safety Case is viewed as a starting point for related presentations, brochures, etc. to different stakeholders and for which their expectations must be understood. The presentation of a Safety Case must not underestimate the audience's technical sophistication so that the scientific community can be a participant in the societal decision-making process. Communicating a Safety Case will require multiple presentations because of the complexity of the integration process and the multitude of scientific and engineered disciplines. Flexibility needs to be maintained in consistency with audience's requests. Delivered messages must be clear and one 'main message' for a given iteration of a Safety Case should be recommended.

As a conclusion, the Safety Case is a management issue. Feedback to each relevant part of the Safety Case such as design and site characterisation can be possible if it is planned and managed at each relevant step of the repository development. As regards this last point, it is suggested that it is perhaps an area where further work could be done.

3. FEEDBACK FROM PEER REVIEWS AND CONFIDENCE DOCUMENT

Peer reviews are considered as a relevant activity of the RWMC division in the NEA. The peer reviews are both on methodologies and major R&D studies and to provide a decision-making basis for moving from one step to another. Peer Reviewers want to see more of a Safety Case than a Safety or Performance Assessment. Vis-à-vis a SA/PA, a Safety Case places the analyses and information in a decision-making context and shows strategic thinking and management strategy. They generally mention that the programme needs to be performed in a way that favours dialogue with stakeholders: technical community, regulators, and local community.

The previous peer reviews generally show that:

— Safety Assessments are just built around assessment capability and "regulatory requirement".
— The geology is normally well described, but more data are needed.
— Engineered barrier systems need to be emphasised in that they offer, at early stages, margins for optimisation and adaptation to the local environment.
— The role and use of experts is an important issue in building confidence.
— Less technical sections do exist but are not accessible to non-specialists. Lots of details exist with little rationale for choices/decisions, e.g., role of scenarios, role of biosphere representations, data.
— Lessons are being generated for subsequent assessments or repository development phases, but this feedback is not evident.
— Reasons for confidence in the analyses are interspersed in the documentation. No drawing together in conclusions on the quality of what was done and perspective on what more may be done.
— Common finding is thus that these studies have important limitations as tools for:

  - informing decisions on what to do next
  - dialogue amongst interested parties
  - arguing safety.

Typical problem areas are identified such as:

- Completeness of scenario analysis
- Consistency needs to be improved in assumptions, the level of detail, the vocabulary
- The transitory phase needs more attention
- Issues of traceability and transparency.

The NEA report on "Confidence in the Long-term Safety of Deep Geological Repositories" was published in 1999. It noted that a viable repository project depends on confidence in safety on the part not only of technical specialists in implementing and regulatory organisations and in the wider scientific community but also of political decision-makers and the general public. Various topics as described in the previous paragraphs are emphasised in this document, such as the step-wise process of deep geological repository development and the necessity to preserve credibility and confidence during the process. It is also mentioned that the Safety Case for a repository is carried out firstly by the implementer in a framework set by a number of practical and programme specific constraints. The articulation and contents of four main processes (see figure hereafter) that need to be achieved will permit safety to be argued and assessed by decision makers such as regulators, scientific bodies, and/or others:

(i) Establish an ASSESSMENT BASIS

– define a safety strategy that describes a suitable approach to the building of a safety case
– define the repository site and design (*system concept*)
– define the *assessment capability*

(ii) Carry out a PERFORMANCE ASSESSMENT

– evaluate repository performance for the assessment cases
– assess compliance with acceptance guidelines
– carry out sensitivity analyses

(iii) EVALUATE CONFIDENCE in the calculated safety and modify, if necessary the assessment basis

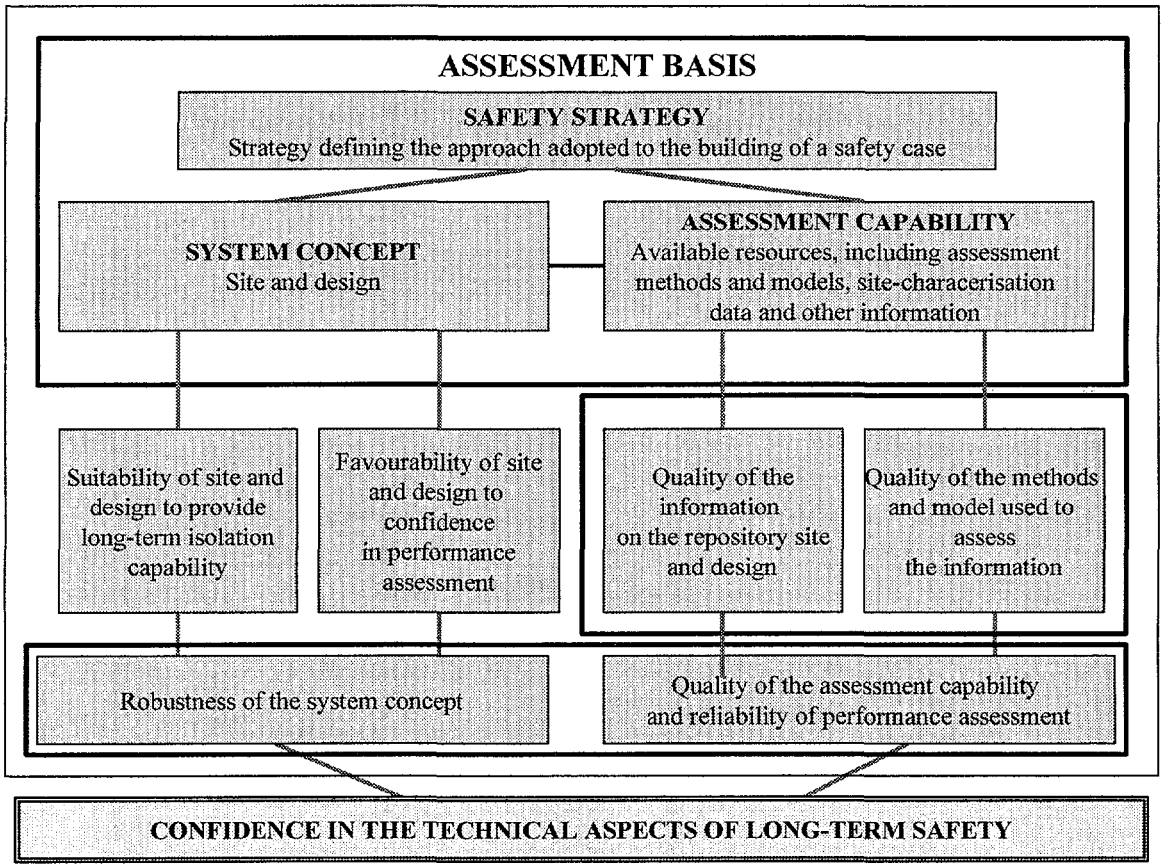
Steps (i), (ii) and (iii) define the safety assessment.

(iv) Compile a SAFETY CASE

– document the safety assessment
– state confidence in the safety indicated by the assessment and describe proposed way forward

Interact with decision makers and modify, if necessary, the assessment basis

The assessment basis is in fact the combination of the safety strategy, the system concept, and the assessment capability as described in the figure below:



To achieve safety, the confidence document raises the need to provide a conscious "safety first" approach that could be attempted regarding various possibilities such as:

- Through site and design choices, avoiding or forcing to low probability or consequences most phenomena that could be detrimental to safety
- A further characterisation and means to reduce uncertainty through R&D,
- Continuity of means and resources
- Avoiding over-reliance on any single safety provision
- Identified process for acquisition of technical knowledge and tools
- Internal guidelines showing a controlled, fit-for-purpose programme
- Periodic programme and quality reviews
- QA procedures to minimise likelihood of defects and errors
- Openness towards dealing with varied technical opinions (inside and outside programme).

Achieving safety is not sufficient to get confidence in the safety case. One key task is to provide relevant arguments on the confidence in the safety. These arguments must be declared and described in the Safety Case A confidence statement should describe the strength of the arguments on which the findings of the safety assessment are based. For instance, in order to better support the confidence statement, it is important to offer commentaries on (i) the role of barriers and system functions, (ii) the identification and explanation of the assessment cases, (iii) the verification of the quality of tools, data, analyses, and the explanation that PA is for testing system performance.

4. FEEDBACK FROM IGSC EXCHANGES

From a variety of feedbacks, the Integration Group for the Safety Case [*IGSC*] considers that the Safety Case is one of the main work objectives of national programmes, which provides the rationale for doing work within the IGSC. Using the NEA confidence document as a starting point, the IGSC will continue work on the definition of process, components, methodology and means of ensuing consistency which are required to build a Safety Case. The IGSC has a role to develop common views on such key aspects of the Safety Case but should not be prescriptive. Since the beginning of the IGSC, two meetings were organised with topical sessions. The following major messages emerge from these exchanges:

— Multiple lines of reasoning should include additional safety measures and indicators.
— It is not possible to rigorously demonstrate compliance; the only realistic objective is to achieve adequate confidence.
— The way in which different bodies of scientific opinion are dealt with in the Safety Case is an important and outstanding issue.
— Whether, for example, operational safety is included in the Safety Case will depend on the particular circumstances of the Member countries.
— Development of the Safety Case involves mediation with society.
— We should take a common sense definition of the Safety Case and not make it more complicated than it needs to be.
— It is a presentation and linking of information and arguments on safety needed to support the decision-making process.
— Dependent on the programme-specific and regulatory context, the implications of retrievability may need to be dealt with in the safety case.

Different countries are at different stages and therefore opinions can be expected to vary on where the key issues remain.

5. CONCLUSION AND FUTURE WORK

The successive IPAG exercises have shown a clear evolution from a calculation (Performance Assessments) to integration (Safety Case) approach. The Safety Case is more than calculation results. It includes both qualitative and quantitative arguments and is not a science-only product.

At a technical level, the most important issue is how to manage dialogue with technical experts both in-house and outside. Communication with both technical and non-technical stakeholders is a priority goal for building confidence. A Safety Case should provide a well-documented safety assessment, including an evaluation of confidence in the calculated safety. It should describe the approaches adopted to achieve confidence and should include a formal *statement of confidence*. This last point corresponds to the fact that all relevant data and information, and their uncertainty, have been given consideration, all models have been tested adequately and a rational assessment procedure has been followed. Additionally, results need to be fully disclosed and subjected to QA and review procedures. The Safety Case is about managing and integrating technical and non-technical information. "Management" – "Safety culture" – "Strategy" – "Confidence" are key words in confidence building and for preparing a credible Safety Case.

The NEA Confidence Document and the IPAG-3 document are the culmination of a decade of efforts at the NEA in the area of development of the safety case. The IGSC is now the working party in charge expressly of developing all Safety-Case-related technical activities.

Aspects related to non-technical stakeholders will also be taken into account by the IGSC, but will also be reviewed by the NEA Forum on Stakeholder Confidence.

Consistent with the different initiatives carried out since 1990, one of the activities that will start under the NEA IGSC platform will concern the preparation of a booklet on the Safety Case. It will describe the issues connected to the Safety Case and the approaches available for satisfying the four elements of a Safety Case. It will not imply that all techniques and approaches be used in every safety case. Rather, it would provide a sense of the problems that exist and the range of techniques and approaches that can be used to formulate the Safety Case and develop and communicate confidence.