Two decades of Safety Case Development: An IGSC

20th anniversary

Brochure

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Foreword from the Director-General, Nuclear Energy Agency

Nuclear energy is the largest source of non-carbon-emitting electricity generation in OECD countries and the second-largest globally after hydroelectric generation. As such, it plays a significant role in enabling the transition to a cost-effective, reliable, and low-carbon electricity infrastructure. This role can expand in the future around the world, particularly as new technologies come to market. As the future comes into focus, it is clear that all countries must demonstrate their ability to safely and responsibly manage high-level radioactive waste and spent fuel from nuclear energy plants.

There has been a long discussion in many countries regarding the management and disposal of high-level waste and the NEA has played a vital role in providing factual information to support these discussions. In this context, the work of the NEA Integration Group for the Safety Case (IGSC) has been extremely important and impactful. In its 20-year history, the IGSC has been the most important and effective international platform for developing relevant methodologies to develop and integrate scientific information and engineering approaches to underpin geological disposal. It has been at the heart of the global scientific consensus that deep geological repositories are a safe and effective approach for the disposal of high-level wastes and spent fuel. Moreover, the collaboration between IGSC and other NEA groups has fostered the discussions on regulatory matters, stakeholder engagement and information management in deep geological repositories.

The IGSC's 20 years of successful and vital work represents a tremendous accomplishment by the international community. I congratulate the many experts and participants who have contributed to the IGSC during the last two decades. I also gratefully acknowledge the four IGSC Chairs – Abraham E. van Luik (United States Department of Energy, 2000-2004), Hiroyuki Umeki (Nuclear Waste Management Organization of Japan, 2005-2010), Klaus-Jürgen Röhlig (TU-Clausthal, Germany, 2011-2015) and Lucy Bailey (Radioactive Waste Management, United Kingdom, 2016-present) – for leading this group and successfully building confidence and reaching scientific consensuses that have established a sound and durable basies for the safe disposal of nuclear waste.

While we celebrate the last 20 years, we recognise that more work remains ahead as more and more countries apply the work of the IGSC to move forward with the implementation of high-level waste disposal facilities. The NEA will continue to support its member countries in the development of the safety case for various disposal facilities and to further optimise the regulatory, environmental, societal and economic aspects of radioactive waste management and disposal.

William D. Magwood, IV

Director-General,
Nuclear Energy Agency

Feedback from

The IGSC allows us to gather information, share perspectives and maintain/expand our global expert network. The topical sessions (e.g. on the geological information needed for safety case at different stages; criticality) have also provided us the opportunity to present our activities and learn about other research programmes and activities (from implementers and regulators), and different manners of dealing with important issues that will come up in our situation, during the pre-licensing and later phases. This is a clear forum for sharing best practices, based on experiences (and "lessons learnt").

Ms Julie Brown,
Canadian Nuclear Safety Commission (CNSC), Canada

We consider the involvement of senior experts from countries with active disposal programmes as a strength of the IGSC. It stimulates collaboration and provides information on the state of science and technology. A great value of the IGSC is the in-depth investigation of selected topics including multiple international views, either in the framework of IGSC projects or through annual topical sessions. This requires that specialised experts are present.

Mr Ulrich Noseck,
Global Research for Safety (GRS), Germany

The value of the IGSC is to provide an internationally unique forum in which the safety case of DGRs is continuously discussed in an integrated fashion in order to increase its confidence by taking into account the state-of-the-art scientific and technical knowledge and evolving socio-political conditions. The "continuity" of such an activity can serve to develop new approaches and methodologies to make the safety case more convincing and robust, which is inevitable and invaluable for all member countries aiming at geological disposal stepwise to confirm if the planned repository is technically reliable and socially acceptable through the long implementation process of the project. The IGSC is also contributing to foster a "generalist" for geological disposal who can overview all important elements of the safety case by transferring its accumulated intellectual legacy/knowledge to the next generations.

Mr Tetsuo Fujiyama,
Nuclear Waste Management Organization of Japan (NUMO), Japan

member countries

On behalf of SSM and Swedish colleagues, I would like to express our sincere appreciation and support of the work of IGSC and the paper commemorating IGSC's 20th anniversary. SSM has been an active member of the IGSC since the very beginning. The work of this group has been of the utmost importance for SSM and its predecessors in understanding the technical and scientific aspects and in regulating the development of a Swedish safety case for spent fuel disposal. The IGSC has provided an excellent forum for the sharing of experiences with colleagues from other organisations representing the waste programmes of different countries, and in building a long-standing network for dialogue between regulators, implementers and academia.

Mr Johan Anderberg,
Swedish Radiation Safety Authority (SSM), Sweden

ENSI appreciates the technical discussions and the products of the subgroups of RWMC (e.g. IGSC, EGOS, Clay Club). The products are used for example for safety reviews in the site selection process and waste management programme to verify the state of the art. In addition, ENSI appreciates the detailed technical discussions on specific topics at the topical sessions. The detailed exchange on specific topics between implementers, regulators and research institutes is very valuable and unique at international level. The experiences from countries with advanced waste management programmes are very valuable.

Ms Ann-Kathrin Leuz,
Swiss Federal Nuclear Safety Inspectorate (ENSI), Switzerland

The greatest achievements provided by the IGSC are the group inputs to the safety case of individual countries that are at the advanced stages of repository development. The working groups tackle the technical gaps that must be addressed in order to meet the needs of member countries. The IGSC bridges the gaps between repository safety and social acceptance. It's a forum with diverse perspectives for regulators and implementers to interact and openly discuss both technical and regulatory issues.

Mr Tom Peake,
US Environmental Protection Agency (EPA), United States

Purpose of the brochure

The Integration Group for the Safety Case (IGSC) was established in 2000 by the OECD Nuclear Energy Agency (NEA) Radioactive Waste Management Committee (RWMC) in recognition of the need for continued progress on the basis for developing, reviewing and updating safety cases for geological repositories. For two decades, the IGSC has taken a leading role in identifying, documenting and evaluating emerging issues and trends, and in establishing consensus on good practices in the development of the safety case. The IGSC has also shown how it is possible to adapt the concept of the safety case in line with the needs, challenges and progress of national programmes at different stages of development. The work of the IGSC has in turn been particularly informed by developments in countries such as Finland, France, Sweden, Switzerland and the United States, which have moved from conceptual safety case studies to various stages of site-specific safety cases for geological repositories, with a new repository in Finland now under construction.

The principal aim of this brochure is to reflect on 20 years of IGSC work in order to trace the evolution of the concept of the safety case overall and as a tool for programme integration, for regulatory decision-making at major project stages, for knowledge transmission and wider communication, and for prioritisation of research, site evaluation and repository design. In the process, this brochure highlights the role and contribution of key IGSC activities and reports, and identifies remaining challenges in these areas.

This brochure is targeted at all IGSC stakeholders, including waste management organisations, regulators and the wider technical community involved or interested in safety case development for geological repositories.

The NEA Integration Group for the Safety Case (IGSC) organised a symposium on the "Current Understanding and Future Direction for the Geological Disposal of Radioactive Waste" on 10-11 October 2018 in Rotterdam, the Netherlands, hosted by COVRA and held in co-operation with the International Atomic Energy Agency (IAEA) and the European Commission (EC).

Acknowledgements

This brochure is an initiative of the NEA IGSC Secretariat and the IGSC core group. It was developed collaboratively by Manuel Capouet (Ondraf/Niras, Belgium), Paul Smith (Safety Assessment Management, Switzerland), Lucy Bailey (RWM, United Kingdom), Klaus Röhlig (TU-Clausthal, Germany), Miguel Cuñado (Enresa, Spain), Slimane Doudou (Galson Sciences Ltd, United Kingdom), Daniel Galson (Galson Sciences Ltd, United Kingdom), Jinfeng Li (NEA IGSC Secretariat), and Ichiro Otsuka (NRA, Japan, former NEA IGSC Secretariat). The authors would like to thank the reviewers for their careful reading and their insightful comments and suggestions.

The IGSC Core Group and Secretariat are dedicating this brochure to two key members of the IGSC who sadly died in March of this 2020 anniversary year: Jürg Schneider (Nagra, Switzerland) and Alan Hooper (RWM, United Kingdom). Jürg and Alan both made substantial technical contributions to the IGSC over its 20 year history. Alan was a founding member of the IGSC in 2000. Despite fighting an aggressive disease, Jürg was fully active in the IGSC right up to the last safety case symposium in 2018. Alan and Jürg were also both greatly respected and loved by their colleagues for their energy, optimism and positive approach to life. The IGSC has lost two wonderful colleagues and friends and our thoughts are with their families.

The NEA Integration Group for the Safety Case (IGSC) held its annual meeting on 8-10 October 2019 to discuss its ongoing and future activities in relation to developing safety cases for geological disposal of radioactive waste.

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Executive summary

The modern concept of "safety case" was introduced in radioactive waste disposal in the 1990s by the NEA Expert Group on Integrated Performance Assessment (IPAG) working under the Performance Assessment Advisory Group (PAAG). Since then, the concept has been further developed by the NEA through the work of the Integration Group for the Safety Case (IGSC), as well as by national programmes, and has now been adopted internationally by the radioactive waste management community. Since 2006, the safety case has formed a central pillar of the International Atomic Energy Agency (IAEA) Safety Standards for the geological disposal of radioactive waste.

In its 2014 brochure, the NEA defines the "long-term safety case" for geological disposal of radioactive waste as "the synthesis of evidence, analyses and arguments to affirm that a repository will be radiologically safe without human intervention after repository closure". More specific definitions and requirements may be adopted in certain countries by the competent authorities depending on the national context and status of the repository programme.

The IGSC has contributed to and documented the evolution of the structure and content of safety cases and the methodologies used to assess safety as repository programmes have progressed. The IGSC provides a platform for dialogue and continued interaction between the representatives of regulatory agencies and implementing organisations at the international level. The IGSC accomplishes its work through a variety of mechanisms, including plenary meetings, technical workshop and joint projects. As a result, a number of key publications have been produced. The present report reflects on 20 years of IGSC work, tracing the evolution of the safety case concept and its use as a tool for programme integration, for regulatory decision-making at major project stages, for knowledge transmission and wider communication, and for prioritisation of research, site evaluation and repository design.

A broad vision of the objectives of the safety case and its role in the decision-making and licensing process was set out in the NEA report *Confidence in the Long-term Safety of Deep Geological Repositories* (NEA, 1999). This report explains how the safety case builds confidence to make decisions; for example, through safety arguments related to the robustness of the safety concept and the use of multiple lines of reasoning in addition to more traditional dose and risk evaluations. The 1999 NEA report also emphasises the need for quality and reliability of the assessment basis and of the assessment itself and stresses the iterative nature of the development of the safety case, including the feedback provided for research and development (R&D) to strengthen future iterations of the safety case.

The 2004 NEA Safety Case Brochure, "Post-Closure Safety Case for Geological Repositories: Nature and Purpose", built further on these themes, noting that the safety case team should see themselves as analogous to lawyers using a range of arguments to provide reasonable assurance that the repository will evolve safely. The brochure also elaborated on principles underlying the safety case, such as the precautionary principle, as well as some of the major components of the safety case – safety strategy, assessment basis and safety assessment. Safety assessment was defined as "the process of systematically analysing the hazards associated with the facility and the ability of the site and designs to provide the safety functions and meet technical requirements" (NEA, 2004a). Subsequent work of the IGSC has further clarified the link between the safety assessment and the safety case. In the 2004 brochure the group developed this further by stating that "…the outcomes of the safety assessment are now seen as lines of argument, which are accompanied by additional considerations in order to build confidence in repository safety" (NEA, 2004a). The IGSC has also examined and documented the methods used in safety assessments, stressing, among other things, the importance of quality assurance and regulatory context.

Many of the activities of the IGSC over the last two decades have focused on clarifying the nature of the multiple lines of evidence within the safety case and providing specific examples of their use. Multiple lines of evidence, which may include, for example, performance and safety indicators in addition to dose and risk and the use of natural and archaeological analogues, are seen as a way of increasing the robustness of the safety case. In the broad view of safety assessment and the safety case implied by multiple lines of evidence, the work of geoscientists and other scientific and engineering specialists supports the basis for quantitative estimates of dose and risk, and provides direct input to the safety case.

When the IGSC was established, its primary focus was long-term safety, and the term "safety case" within the scope of interest of the IGSC was limited to consideration of the safety of a completed, sealed, slowly evolving repository over extremely long timescales and the associated technical underpinning work. This is where the main challenge in evaluating and demonstrating safety was considered to lie, because during the construction and operational phases, although specific safety cases are still required, there is significant experience of constructing similar-sized underground workings and of handling radioactive materials in operational nuclear plant and storage facilities. In addition, during the construction and operational periods, there is a potential for mitigation, and uncertainties are better understood – so safety case approaches differ. However, the IGSC has broadened its interests in recent years to include lines of evidence related to technical feasibility and operational safety and their integration with post-closure safety considerations. It has long been recognised that the "initial state" of the repository at the time of closure, including potential deviations, needs to be well understood as it is a boundary condition for the long-term evolution of the repository.

The work of the IGSC has highlighted and addressed several key features and activities in the development of the safety case, along with their associated challenges. These include:

1. **Integration.** As the range and depth of information contributing to the safety case increases, so does the need to carry out integration of this information in a structured manner. Integration requires interdisciplinary collaborative working and the pooling of knowledge and experience from safety assessors and subject-matter experts (scientists and engineers involved in R&D studies, and in repository site characterisation and design) and is crucial to the development of the safety case, The IGSC has contributed to integration of information on specific, detailed topics (e.g. the sources and the transport of gases in a disposal system, the evolution of cementitious materials in the Engineered Barrier System [EBS] of a disposal system), as well as on broader topics, such as geoscience, the engineered barriers and, at the highest level, integration in an overall "system concept" that presents a clear understanding of how the overall system is expected to provide safety as it evolves. Making a safety case is about integrating knowledge. Tools to facilitate integration have been and are being developed in several IGSC projects.
2. **Safety functions.** The system of multiple engineered and natural barriers, working in tandem, is key to implementation of the defence-in-depth principle that underpins safety. The concept of barrier "safety functions" is playing an increasing role in many national programmes in response to challenges associated with demonstrating and communicating long-term safety and its link to design, such as in the definition of performance targets for barrier components and their design specification. Safety functions are also informing the development of R&D programmes.
3. **Handling of uncertainty.** This has been a common theme and challenge featuring in most IGSC activities. It has long been recognised that an important aim of a safety case is to demonstrate that all credible futures are acceptable according to regulatory requirements, not to "predict the future". There will always be some residual uncertainty, and the challenge is to show that any that could call the safety case into question can be avoided, mitigated or reduced at least to the extent needed to justify a positive decision to proceed to the next programme phase.
4. **Scenario development.** This has been the subject of two dedicated workshops (a 1999 workshop organised by the Performance Assessment Advisory Group (PAAG) and a 2015 workshop organised by the IGSC) and has also featured prominently in several other IGSC workshops, projects and publications. Identified trends include a tendency to describe scenario development as having both "top-down" and "bottom-up" aspects, the increasingly widespread use of safety functions in scenario development and the recognition of the wide range of roles scenarios can play in a disposal programme.
5. **Knowledge management.** Managing the ever-increasing amounts of information and knowledge across a project lifetime spanning multiple generations is a challenge faced by all repository programmes. The IGSC has identified a variety of tools that can be used to structure and thus better manage and transfer this knowledge; and has examined the issues around using metadata within national programmes. It has also identified the need to keep the safety case consistent with evolving and expanding requirements, design specifications and data changes (termed "configuration management" by some programmes). Configuration management becomes increasingly challenging as the safety case becomes more complex and different parts of the safety case may be updated at different times. Programmes in the implementation and operational phase involve more actors, who may be geographically distant, and require increasingly fast adaptation to changes. On a later time horizon, the challenge of transmitting information beyond closure of the repository has been examined with the aim of supporting the capacity of future members of society to make their own informed decisions regarding a radioactive waste repository after closure and of reducing the likelihood of inadvertent human intrusion.

The IGSC has also worked to clarify regulatory requirements and expectations in relation to the safety case, identify trends in the development of regulations (e.g. in relation to safety indicators complementary to dose and risk and to the use of stylised scenarios), identify measures that promote confidence in legal and regulatory frameworks, and clarify the interactions between regulations and the safety case, which are often developed concurrently in the initial stages of a programme. Best practice in disposal system development is based on application of an iterative and adaptive approach that ensures that new information is incorporated in the design and into the safety case, both of which are subject to internal and external (regulatory) scrutiny at all major decision points.

As part of defining best practice, a broad view of optimisation has emerged within the IGSC in which optimisation accounts not only for safety requirements, but also factors such as use of resources and social expectations, and is viewed as a process that contributes to building confidence in the safety case. The overall aim of optimisation is to achieve a disposal system that is safe during both the operational and post-closure periods, is technically feasible and affordable taking into account the socio-economic context, and meets stakeholder and regulatory requirements. Optimisation requires communication and the development of a common understanding among experts involved in the disposal programme, as well as with regulators and stakeholders.

The increased demands on both implementers and regulators in terms of human resources, activities to ensure quality assurance, and additional requirements on information management systems and management plans for construction work have been noted as particularly challenging as programmes advance.

The 1999 NEA report laid the foundations of a holistic approach to the safety case for radioactive waste disposal. For two decades, the safety case has evolved from a set of compiled reports to an integrated and systemic demonstration of safety. The IGSC has now become increasingly conscious of the need to broaden this holistic vision further and to tackle additional themes relevant to the safety case.

One prominent challenge is illustrated by the recent collaborative work with the NEA Forum on Stakeholder Confidence (FSC). Communication with stakeholders is an essential part of safety case development, and that communication requires several levels of documentation targeted at different audiences. From 2014 onwards, the IGSC has been explicitly addressing the issue of safety case communication and stakeholder interaction, leading to the publication of a report in 2017 and to increased collaboration with the FSC, including a joint workshop on safety case communication in 2017 and a further planned joint workshop in 2021.

In the future, the IGSC foresees interactions with other expert communities to exchange knowledge and experience on issues related to the operation of nuclear facilities and on waste characterisation. The former is important because of the interplay between operational safety considerations and post-closure safety; the latter is important because a deeper understanding of waste characteristics has the potential to reduce uncertainties in the safety case significantly.

1. Introduction

1.1 Geological disposal and the safety case

Radioactive waste is produced in all phases of the nuclear fuel cycle and from the use of radioactive materials in industry, medicine, defence and research. Higher activity radioactive wastes, such as spent nuclear fuel and high-level waste from fuel reprocessing, can be hazardous for hundreds of thousands of years. Disposing of radioactive waste in engineered facilities or repositories located deep underground in suitable geological formations is being pursued worldwide as the preferred option. The concept of geological disposal takes advantage of the favourable characteristics of both the local geological environment and engineered materials to isolate and contain radioactive waste for the required timescales.

The repository must be shown to protect humans and the environment both in the short and long term. The safety of a disposal system is evaluated and documented in a "safety case" that supports decision-making at each stage of repository development. It presents the underlying evidence for safety and quality of the methods by which safety is assessed. It aims to promote confidence in the quality of scientific and management processes, as well as in the results of analyses.

The modern concept of "safety case" was introduced in radioactive waste disposal in the 1990s by the NEA Expert Group on Integrated Performance Assessment (IPAG), working under the auspices of the NEA Performance Assessment Advisory Group (PAAG). Since then, the concept has been further developed by the NEA as well as in national programmes, as evidenced in the 1999 NEA report *Confidence in the Long-term Safety of Deep Geological Repositories* (NEA, 1999), in the "Safety Case Brochures" (NEA, 2004a; NEA, 2013a), and in a series of symposia (NEA, 2008; NEA, 2014a; NEA, Forthcoming).

In "The Long-term Safety Case for Geological Disposal of Radioactive Waste: Its Concept and Continuing Evolution" (NEA, 2014b), a long-term safety case for geological disposal of radioactive waste is defined as: "the synthesis of evidence, analyses and arguments to affirm that a repository will be radiologically safe without human intervention after repository closure. A long-term safety case is continually developed and examined at specific points in the stepwise process of repository development and is part of the documentation that is needed for a legal permit to further develop a repository project further". The report also states that: "A long-term safety case is typically prepared also to help in reviewing the current status of a project, to test the methods used in safety assessment, or to help prioritise the R&D programme. The safety case serves as a platform for discussions between the implementer and the regulatory authorities, as well as with experts and other stakeholders."

The NEA Expert Group on Operational Safety (EGOS) held its annual meeting on 7 October 2019 to discuss operational safety and the long-term safety of geological disposal of radioactive waste.

The NEA definition of the term "safety case" given here is generic and aims to cover a variety of situations. Some national programmes and the competent authorities may choose to adopt specific definitions and requirements, depending on the national context and the stage reached by the programme.

When the IGSC was established, its primary focus was on long-term safety, and the term "safety case" as defined by the IGSC was limited to consideration of the safety of a completed, sealed, slowly evolving repository over extremely long timescales and the associated technical underpinning work. This is where the main challenge in evaluating and demonstrating safety was considered to lie. However, as projects move towards licensing and implementation, aspects of constructability, mining safety and operational safety (during underground transportation and emplacement) take on increasing prominence and are addressed either separately or in a single safety case submission. A definition of the safety case in relation to safety assessment and design aspects is given in Box 1 of this brochure.

1.2 IGSC origins and mission

The Integration Group for the Safety Case (IGSC) was established in 2000 by the NEA Radioactive Waste Management Committee (RWMC) in recognition of the need for continued progress in the area of repository development, and especially in the area of developing safety cases (NEA, 2000a).

The IGSC combines the work of two former NEA technical groups, the Performance Assessment Advisory Group (PAAG) and its sister group, the NEA Co-ordinating Group on Site Evaluation and Design of Experiments for Radioactive Waste (SEDE) (NEA, 2000b). However, the IGSC is not a mere joining together of the two predecessor groups; its mission is to establish, integrate, and document the technical and scientific basis for developing and reviewing safety cases for geological repositories, which should serve as platforms for dialogue among technical experts and as a tool for decision-making (NEA, 2015a). The IGSC is the main technical advisory body to the RWMC on geological disposal of radioactive waste.

Over the last 20 years, the IGSC has fostered consensus on good practice and has encouraged the development of innovative and advanced approaches. The safety case concept has now been adopted internationally by the radioactive waste management community. By promoting the exchange of national experience in evaluating and implementing geological repositories, the IGSC has captured valuable insights covering all methodological and technical aspects of the safety case. The IGSC co-ordinates with other NEA committees and working parties on radioactive waste to integrate multidisciplinary aspects of waste disposal programmes, including technical, legal, regulatory and societal aspects (NEA, 2000a).

Clay Club 26th Meeting, 21-22 September 2016 in Paris, France.

Salt Club 8th Meeting, 7 September 2018 in Hanover, Germany.

The activities and priorities of the IGSC cover the following main themes:

- **What do we know? –** The technical and scientific basis for the understanding of the disposal system behaviour, including an assessment of uncertainty (i.e. what we do not know). Examples include the performance of engineered barriers (EC, 2010), geoscientific evidence as a basis for the safety case (NEA, 2010), and the sources and transport of gases in a disposal system (NEA, 2015b).
- **How do we use what we know to demonstrate safety? –** Assessment strategies, tools and methodologies for integrating and processing what we know in a way that allows well-founded conclusions regarding both long-term and operational safety, while acknowledging any remaining uncertainty. Examples include feature, event and process (FEP) databases, scenario development methodologies, and deterministic and probabilistic approaches to assessment and uncertainty analysis (NEA, 2016; NEA, 2019a).
- **How do we achieve safety in practice? –** Design and implementation of repositories, including the development of the required technology for ensuring operational and long-term safety. Illustrative examples include the NEA project on the Engineered Barrier System (EC, 2010) and the work of the Expert Group on Operational Safety (EGOS).
- **How do we present information and build confidence in safety? –** Presentation of safety cases to stakeholders in a way that effectively communicates and builds confidence in safety, including not only the technical aspects of safety, but also organisational structures and the legal and regulatory framework. Examples include the IGSC initiative on "Communication on the Safety Case for a Deep Geological Repository" (NEA, 2017) and the recent collaboration with the NEA Forum on Stakeholder Confidence (FSC).

1.3 IGSC operation

The IGSC comprises senior technical specialists and managers from national waste management organisations (WMOs), regulatory agencies, and research and technical support organisations. The diversity of its member affiliations is one of the IGSC's strengths.

The IGSC provides a platform for dialogue and continued interaction between the representatives of regulatory agencies and WMOs at international level. Organisations with R&D responsibilities are an important third party to this interaction, both in their capacity as providers of technical services to regulatory agencies and WMOs, and as they constitute a further link to the international technical community (NEA, 1999).

The IGSC accomplishes its work through a variety of mechanisms (NEA, 2015a) including:

- Annual plenary meetings with in-depth discussions of emerging issues and trends. These meetings include topical sessions that aim at sharing views on the treatment of a specific aspect of the safety case as well as exchanges concerning recent developments in member countries. Topical sessions have proved particularly important in capturing key messages and information in the forefront of safety case development. IAEA and European Commission (EC) representatives are invited to IGSC plenary meetings to facilitate international collaboration.
- Technical workshops to explore key safety case topics in detail.
- Studies and joint projects that are backed by the collective expertise of the participating organisations.
- National programme safety case peer reviews by IGSC participating organisations, in some cases supported by experts from consultancy and research/academic organisations. Taking advantage of its expertise, the IGSC is the major contributor to NEA peer reviews of deep geological disposal programmes (see NEA, 2005), with IGSC members providing the core of many peer review teams. These regular peer reviews have provided valuable assistance to national programmes and, at the same time, fostered joint understanding of major topics of the safety case.
- Safety case symposia, held every 5-6 years to share experience on major safety case developments. The symposia attract a wide audience from national and international organisations involved in radioactive waste management, academia and stakeholders (see e.g. NEA, 2008, NEA, 2014a, NEA, Forthcoming).

The outcomes of IGSC activities are documented in publicly available technical reports, information flyers and databases (see Timeline in Figure 1).

To help accomplish its activities, the IGSC is supported by several subgroups carrying out tasks on specific topics. Three of these subgroups focus on the feasibility of repositories in three different generic host rock types. These are the Clay Club, Salt Club and Crystalline Club, which are concerned with argillaceous, salt, and crystalline rock formations, respectively. They each promote the exchange of scientific evidence and information concerning the feasibility and safety of geological disposal of radioactive waste in the respective rock types and carry out research studies on topics of common interest to the organisations within each club. A fourth subgroup, the Expert Group on Operational Safety (EGOS), deals with the operational safety of geological repositories. It aims to share technical, regulatory and stakeholder experience with regard to operational safety, and to identify operational hazards in a repository using experience gained from the operation of nuclear facilities, mines and other relevant engineering projects from outside the nuclear industry.

Box 2 illustrates three examples of concepts and tools (FEPs, safety functions, knowledge structuring tools) where national programmes have learnt from each other by information sharing facilitated by the IGSC. National waste management organisations have developed programme-specific concepts and tools based on generic starting points, to meet their specific needs.

1.4 Structure of the brochure

Following this introduction, the brochure consists of seven sections:

Section 2 summarises the evolution of the safety case at a high level over the last 20 years, with reference to specific contributions of the IGSC.

Section 3 provides the IGSC's views of and contributions to the multiple lines of evidence required to construct a successful safety case.

Section 4 considers several issues key to development and maintenance of a successful safety case, identifying the importance of integration, the increasing use of safety functions, the treatment and management of uncertainty, and long-term knowledge management in safety case development.

Section 5 provides a regulatory perspective and summarises IGSC activities at the interface of implementation and regulation.

Section 6 identifies the importance of safety case communication and stakeholder engagement and summarises IGSC activities at the interface of safety case development and communication.

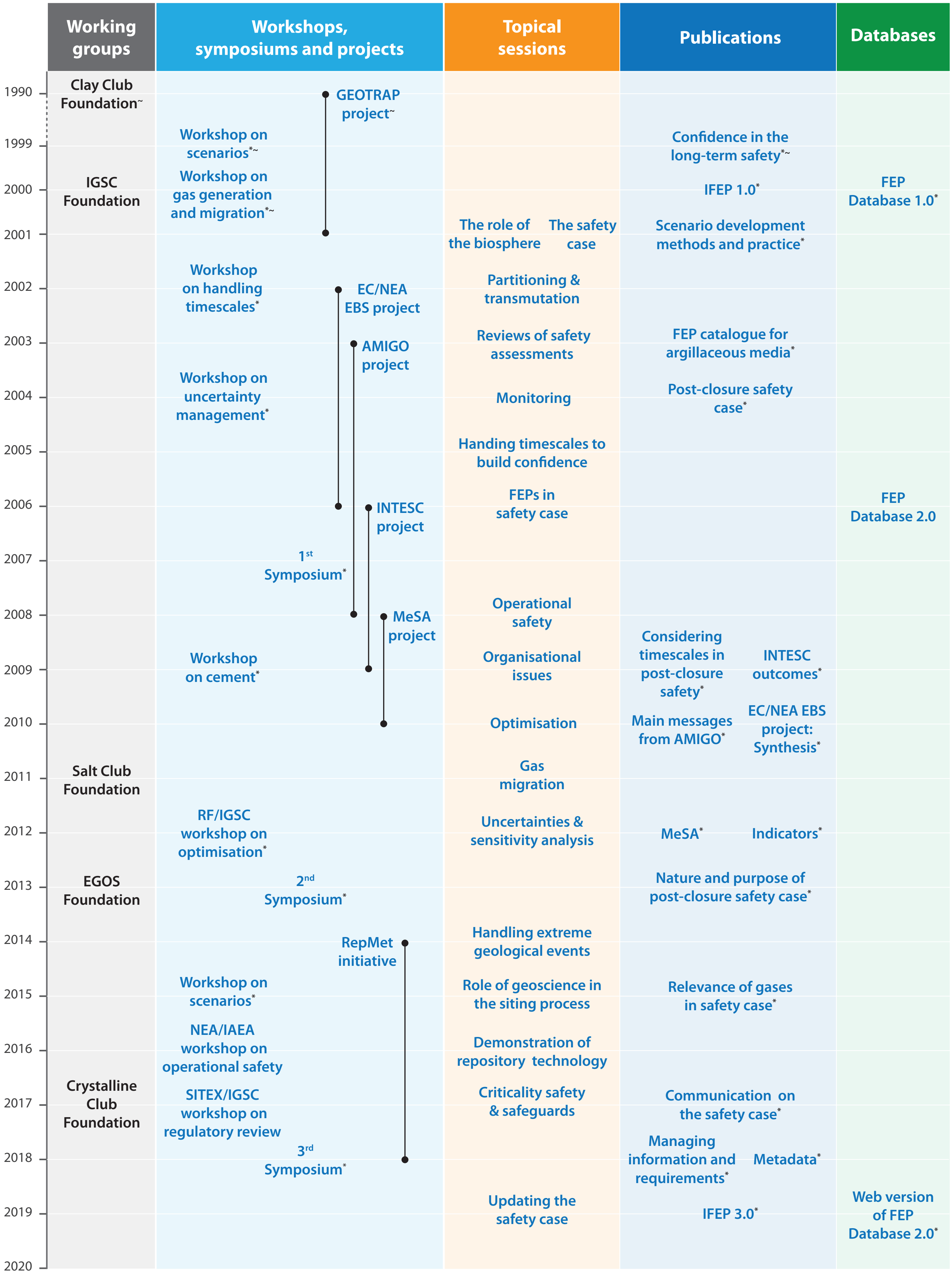
Section 7 summarises key messages from the work of the IGSC.

The final section provides a list of NEA IGSC and other publications cited in the brochure.

The acronyms used in the figure are defined as follows:

Organisations and working groups	EC	European Commission	IGSC	NEA Integration Group for the Safety Case
	EGOS	NEA Expert Group on Operational Safety	NEA	Nuclear Energy Agency
	FSC	NEA Forum on Stakeholder Confidence	RF	NEA Regulators' Forum
	IAEA	International Atomic Energy Agency		
NEA projects	AMIGO	Approaches and Methods for Integrating Geological Information in the Safety Case	MeSA	Methods for Safety Assessment for Geological Disposal Systems for Radioactive Waste
	GEOTRAP	Radionuclide Migration in Geologic, Heterogeneous Media	RepMet	Radioactive Waste Repository Metadata Management
	INTESC	International Experiences in Safety Cases for Geological Repositories	SITEX	Sustainable network of Independent Technical Expertise for Radioactive Waste Disposal
Other terms	EBS	Engineered Barrier System	FEP	Features, Events and Processes

Figure 1: Timeline of IGSC activities and selected publications



* Publications relating to these items are included in the References section.
~ Activity conducted by IGSC predecessor committees.

2. Evolution of the safety case structure over the last 20 years

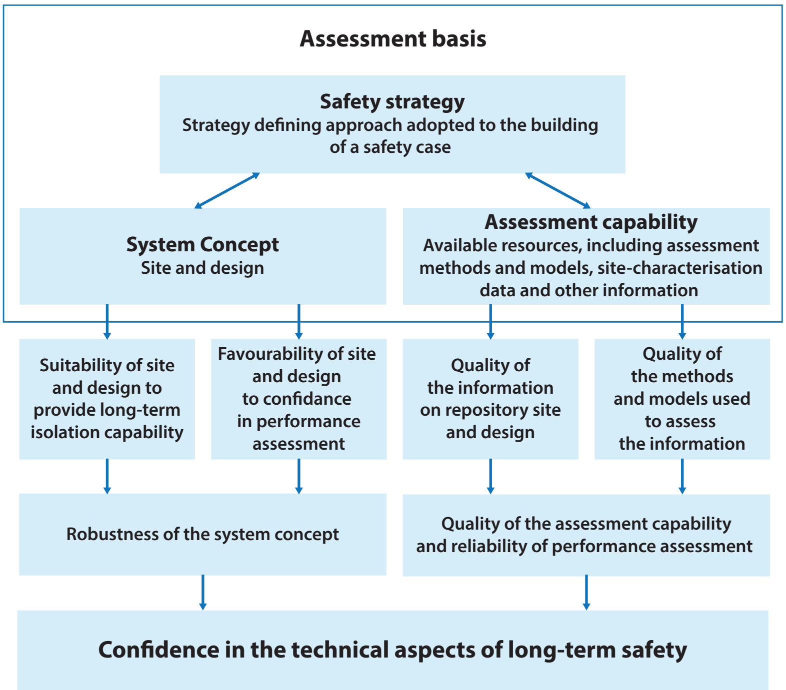
Numerous safety cases have been developed over the last 20 years to mark project milestones and to support national programme decisions on geological disposal of radioactive waste. These safety cases have focused on different types of repository host rock and have been compiled at different stages of repository development as well as under different societal and regulatory contexts. Review and exchange of views on these safety cases in the IGSC has helped identify and consolidate best practice in safety case development. The structure and content of safety cases and the methodologies used to assess safety have evolved as repository programmes have moved forward. The progress made has been captured in a number of reports. Significant IGSC documents have been informed by these developments and have helped shape the safety case concept over the last 20 years.

The NEA report, *Confidence in the Long-term Safety of Deep Geological Repositories*" (NEA, 1999), set out a broad vision of the objectives of the safety case and its role in the licensing process, emphasising that making a safety case for a repository is about building and demonstrating confidence in the safety of the proposed system. The safety case is described as a flexible tool that uses both quantitative and qualitative lines of reasoning to demonstrate confidence in the technical evaluation of safety in support of decision-making. The principle of "robustness" of the system concept (as defined in Section 4.1), quality of the assessment capability and reliability of safety assessment, are introduced as pivotal in the safety case (see Figure 5, in NEA, 1999). Robustness includes provision of additional lines of argument for safety, complementary to calculated safety indicators (such as dose and risk), which are an output of safety assessment models. Demonstration of quality and reliability strengthens confidence in the calculated safety indicators.

The 1999 NEA report also describes the role of the safety case within the repository development process. At each repository development stage, a safety case is compiled that uses the information and experience acquired at that stage. A viable repository project depends on confidence in long-term safety on the part of technical specialists in both implementing and regulatory organisations, and on the part of political decision makers and wider society. Decisions are taken both during and following the compilation of the safety case, based on an evaluation of confidence, including decisions regarding R&D aimed at enhancing the assessment basis for future iterations of the safety case. Such feedback loops are seen as reflecting a dynamic approach to confidence building, especially during the early stages of repository development.

Experience in several NEA member countries indicates that a repository development programme is most likely to succeed if it incorporates two main confidence-enhancing aspects in addition to the technical aspects of long-term safety described above. First, general agreement regarding the ethical, economic and political aspects of the appropriateness of the waste management option needs to be achieved. In this respect, stakeholder dialogue is crucial to building confidence in the safety of the concept. Second, confidence is needed in the organisational structures and legal and regulatory framework, with a repository development plan in which safety cases can be developed incrementally, providing key opportunities for interactions with regulators and other stakeholders. The 1999 NEA report stresses the importance of these two aspects.

Figure 2: The elements to be considered in the evaluation of confidence in long-term safety that complement calculated safety indicators such as dose and risk



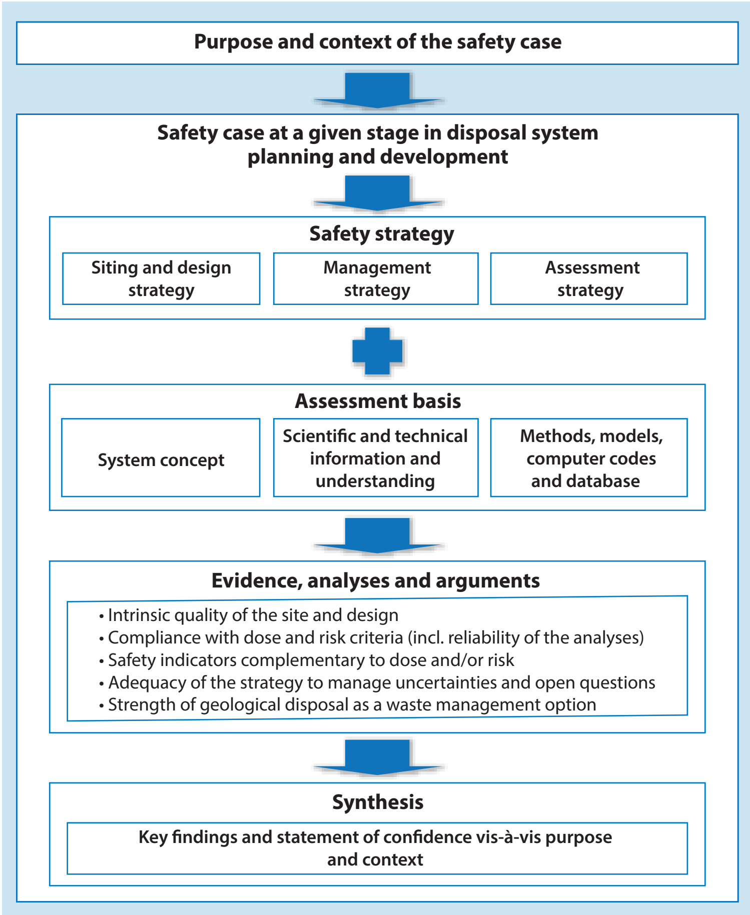
Source: NEA, 1999 (Figure 5).

Five years after the publication of the 1999 NEA report, and capitalising on the publication of several national safety cases during the intervening period, the IGSC issued the 2004 Safety Case Brochure, "Post-Closure Safety Case for Geological Repositories: Nature and Purpose" (NEA, 2004a). The essence of the safety case is well captured with the following statement: "The safety case may be seen as analogous, in some respects, to a legal case, in which multiple lines of evidence are produced, and… evaluated to allow a judgement to be reached". The safety case team should recognise the importance of making a case for repository safety using a range of arguments to provide assurance from a range of perspectives that the repository will evolve safely. The 2004 brochure further emphasises the concept of multiple lines of evidence as a means of developing confidence in the safety case findings; and represents a further departure from earlier approaches that tended to rely mainly on calculated safety indicators, especially dose or risk. Many of the activities of the IGSC over the last two decades have focused on clarifying the nature of these multiple lines of evidence and providing specific examples of their use (see Section 3).

The 2004 brochure elaborates on the major components of the safety case such as the assessment basis and the safety strategy, the latter receiving more prominence, being no longer defined as part of the assessment basis (compare Figure 2 and Figure 3), and being subdivided into a siting and design strategy, a management strategy and an assessment strategy.

View of main drift looking north towards station at 2,150 foot level.
US Department of Energy

Figure 3: An overview of the relationships between the different elements of a safety case – 2004 version



Source: NEA, 2004a (Figure 1).

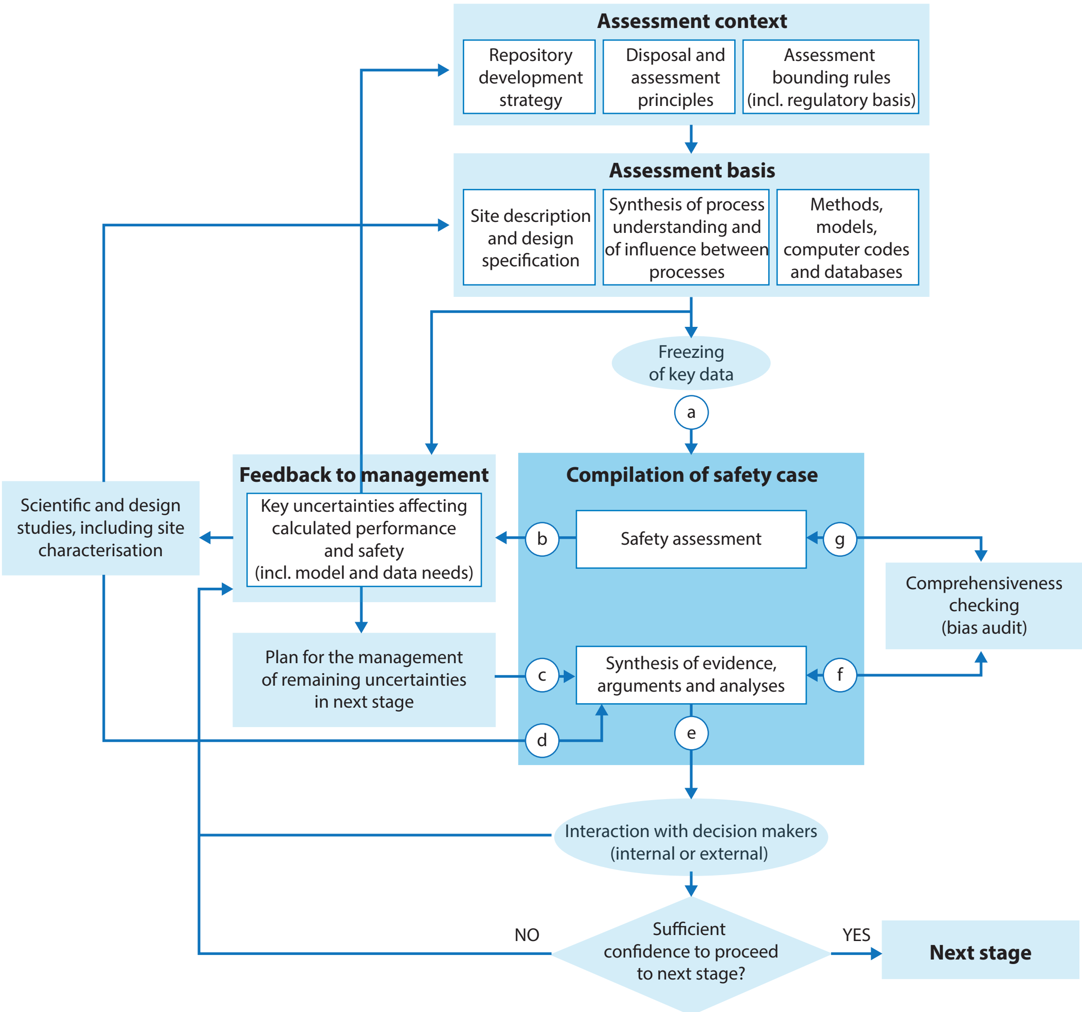
The brochure also discusses important principles such as flexibility, the precautionary" principle ("erring on the side of caution") and safety functions (see Section 4.2).

The key elements of the safety case were continuously developed during the IGSC's first decade, such as the central role of the safety assessment, the multiple lines of evidence (see Section 3), the understanding of the disposal system and its evolution, including design and feasibility aspects (see Section 4.1), the need for a management system, and the iterative development of knowledge and management/reduction in uncertainty (see Section 4.3) as the project progresses. As early as 2006, the IAEA recognised the safety case as a safety standard in the development of *geological disposal* (IAEA, 2006). The key pieces of the safety case were described in the superseding guidance *Disposal of Radioactive Waste: Specific Safety Requirements* (IAEA, 2011).

From 2008 to 2010, the IGSC organised a project on Methods for Safety Assessment for Geological Disposal Facilities for Radioactive Waste (MeSA) (NEA, 2012a). The aims of the MeSA project were to examine and document methods used in safety assessments for radioactive waste disposal repositories. Safety assessment was defined in the 2004 brochure as "the process of systematically analysing the hazards associated with the facility and the ability of the site and designs to provide the safety functions and meet technical requirements". MeSA cited a slightly revised definition and clarified the link between safety assessment and the safety case (see Box 1), stating that "the outcomes of the safety assessment are now seen as lines of argument, which are accompanied by others in order to build confidence in repository safety".

MeSA reinforced the understanding of the role of the different elements of the safety assessment and safety case and how they are iteratively connected (Figure 4). Let's note a few among these: the use of quality assurance processes such as completeness checking was emphasised. In this regard, the use of FEP databases such as the NEA Feature, Event and Process Database, for completeness checking was highlighted (see Box 2 on how IGSC members have contributed to and benefitted from the development of the FEP database). MeSA reiterated the importance of a clear and agreed repository development plan. A safety case should be forward-looking and point to the type and general schedule of upcoming activities and should describe how the new work will be used to confirm, reinforce or challenge the current safety case. The regulatory context was also stressed as a significant consideration.

Figure 4: A high-level generic safety case flowchart, showing the key elements and linkages



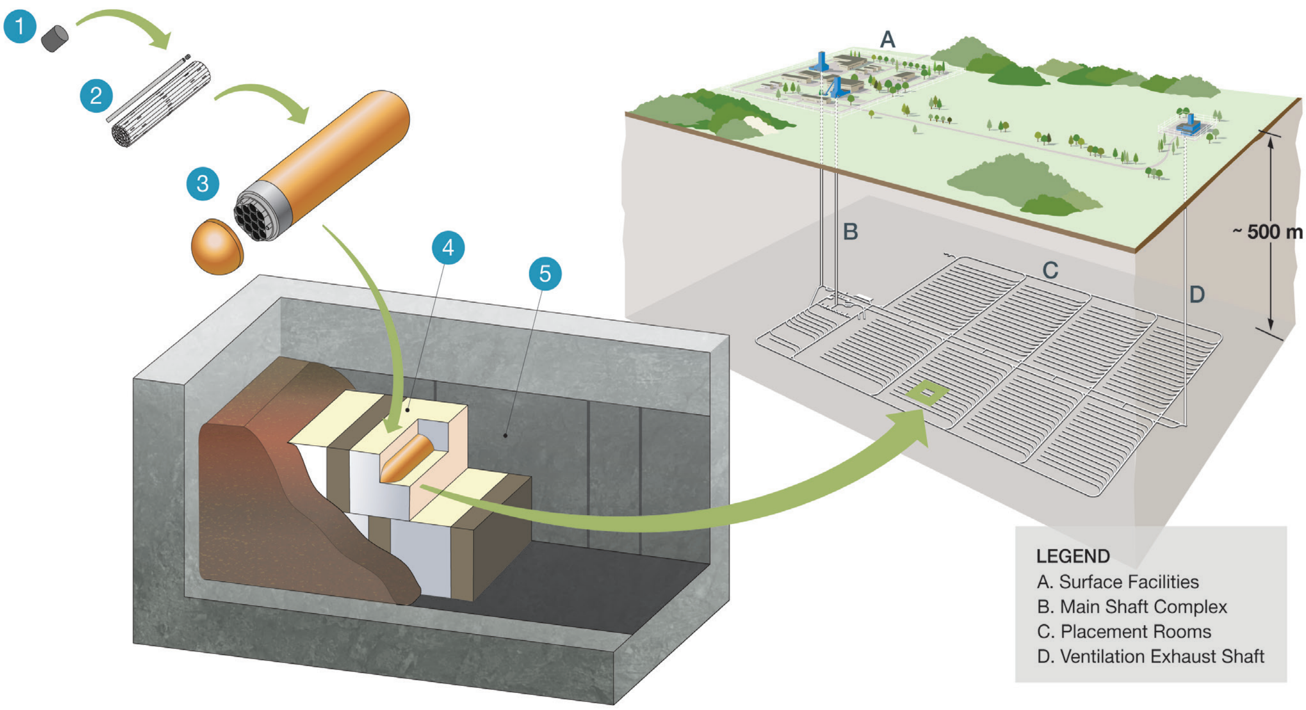
Note: The labels of the arrows aim at facilitating correspondence between this figure and Figure 5 on page 28.

Source: See NEA, 2012a (Figure 12.4) for a detailed description of the figure.

Box 1: Definition of the safety case and safety assessment as given in the MeSA project and how they are related

- Safety assessment is a systematic analysis of the hazards associated with geological disposal facility and the ability of the site and designs to provide the safety functions and meet technical requirements. The task involves developing an understanding of how, and under what circumstances, radionuclides might be released from a repository, how likely such releases are, and what would be the consequences of such releases to humans and the environment.
- The safety case is an integration of arguments and evidence that describe, quantify and substantiate the safety of the geological disposal facility and the associated level of confidence. In a safety case, the results of safety assessment – i.e. the calculated numerical results for safety indicators – are supplemented by a broader range of evidence that gives context to the conclusions or provides complementary safety arguments, either quantitative or qualitative. A safety case is the compilation of underlying evidence, models, designs and methods that give confidence in the quality of the scientific and institutional processes as well as the resulting information and analyses that support safety.

Note: excerpt from "Methods for Safety Assessment for Geological Disposal Facilities for Radioactive Waste: Outcomes of the NEA MeSA Initiative" (NEA, 2012).



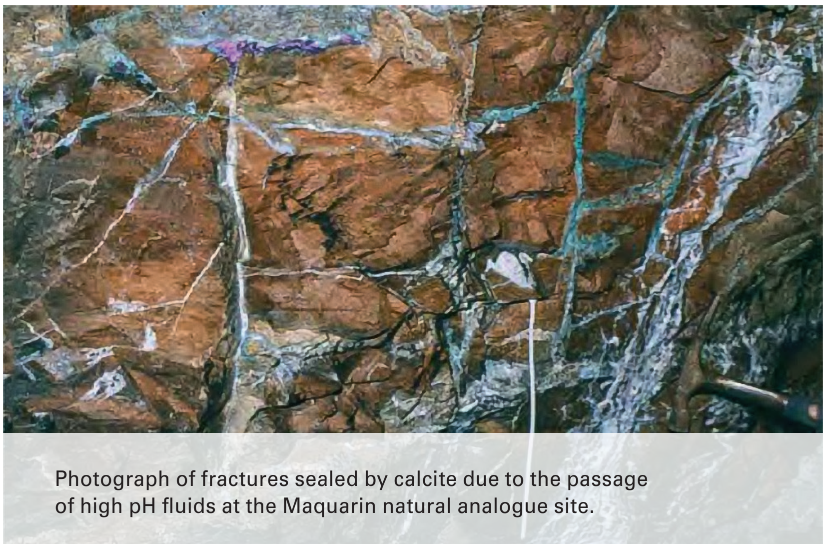
The five barriers to isolate disposed nuclear fuel from the environment.
Nuclear Waste Management Organization (NWMO), Canada

3. Multiple lines of evidence

In building a sound post-closure safety case and to help address challenges associated with the long timescales that need to be considered, multiple lines of evidence or arguments are used to provide complementary safety arguments to compensate for shortcomings in any single argument and increase the robustness of the safety case. Complementary types of evidence and arguments include the use of performance and safety indicators in addition to dose and risk. These complementary indicators are considered to avoid to some extent the difficulties faced in evaluating and interpreting doses and risks that may occur in the far future; and their use can also improve the understanding of the system to support the safety case (NEA, 2004a; NEA, 2012a). In addition, complementary indicators such as flux or concentration as well as indicators describing the hydraulic, chemical or mechanical status of barriers (e.g. state of stress or ionic strength) can give a more detailed picture of how the disposal system is performing. A comprehensive review of complementary indicators used in safety cases, including the reference values for safety indicators, is reported in the report, *Indicators in the Safety Case* (NEA,2012b).

The evaluation of safety and performance indicators is one of the key activities in the making of any safety case. Other lines of evidence can, however, also make a significant contribution. For example, elements within the assessment basis can be used to demonstrate the intrinsic quality, stability, and favourable characteristics of the repository site and of its design. This broader view of safety assessment and the safety case implies that the work of geoscientists and other scientific and engineering specialists not only supports the basis for dose and risk calculations, but also provides direct input to the safety case. This broader view of the safety case that extends beyond quantified safety impacts can have consequences for the ways in which programmes are organised.

The Approaches and Methods for Integrating Geological Information in the Safety Case (AMIGO) project (NEA, 2010) highlighted that aspect. Geoscientific information can provide evidence of the intrinsic robustness of a site, including the stability and confinement capability of the geological environment, low rates of uplift and erosion, and absence of exploitable resources that may lead to human intrusion. The design of the facility itself, through the use of multiple barriers with various materials that do not interact with each other or with the host rock in an unfavourable manner, also strengthens the arguments made for its longterm safety, particularly if the barriers use well-known and widely available materials designed to minimise the likelihood of common-mode failure (NEA, 1999; NEA, 2012a).



Photograph of fractures sealed by calcite due to the passage of high pH fluids at the Maquarin natural analogue site.

Natural and archaeological analogues can build or lend support to understanding of key processes over long timescales, far beyond those achievable in the laboratory. They have been widely used in safety cases and can be particularly helpful when interacting with stakeholders (NEA, 2017).

Other (less common) lines of evidence have been used in some safety cases depending on the national context and programme stage. For example, the identification of "Reserve FEPs" (NEA, 2004a), defined as those FEPs that are omitted from safety assessment calculations because they are insufficiently understood, but are nonetheless confidently expected to contribute favourably to the performance of the barriers, demonstrates the existence of a safety margin beyond that indicated by the quantitative safety assessment. Such FEPs might include, for example, co-precipitation of radionuclides with minerals and sorption of radionuclides on corrosion products. It may be possible to include such FEPs in future safety assessment calculations if R&D resources are directed towards acquiring the necessary quantitative understanding.

At a management level, clear and transparent repository development plans and the application of quality assurance measures in the safety case strengthen arguments and promote confidence in the safety case (NEA, 2012a; NEA, 2013a). As shown in Figure 2, it was recognised in the 1999 NEA report that confidence in the technical aspects of long-term safety depends not only on the robustness of the system concept, but also on the quality of the assessment capability (including the assessment basis) and the assessment itself (NEA, 1999). Assuring quality of the assessment basis includes, for example, the testing and qualification of models and databases and the verification of computer codes. Aspects of quality assurance related to the assessment itself include audit checks, completeness checks and peer review. As programmes advance and safety cases become increasingly detailed and complex, the effort needed to provide adequate quality assurance also increases. It is challenging but essential to strike a reasonable and proportionate balance in allocating resources to quality assurance and to other aspects of safety case development, focusing quality assurance on the most important areas.

What has become more prominent in recent years (and is not shown in Figure 2) is the issue of how to show that the system itself is not only well designed and "robust", but can also be constructed as planned, without unacceptable deviations, through the implementation of quality control measures related to safe repository construction, operation and closure, as well as the application of waste acceptance criteria. Technical feasibility and operational safety receive increasing attention as a repository programme moves closer to licensing, and it has long been recognised that the "initial state" of the repository at the time of closure, including potential deviations during the repository construction and operational periods or during the manufacture of engineered components, needs to be well understood as it is a boundary condition for the long-term evolution of the repository. For example, the proceedings of the 2013 safety case symposium, *The Safety Case for Deep Geological Disposal of Radioactive Waste: 2013 State of the Art* (NEA, 2014a) mentions, as a key feature of SKB's assessment methodology, "the establishment of a quality assured initial state of the engineered components of the repository and of the site".

4. Key features and activities in the development of the safety case

4.1 Integration

The term "integration" is synonymous with the IGSC and appears in many contexts in its work. The safety case itself is seen as being about managing and integrating scientific and technical information. As for the management of uncertainty, safety assessment needs to be integrated within the management strategy (NEA, 2004a). Integration also features in the interdisciplinary collaborative working and the pooling of knowledge and experience from safety assessors and other subject-matter experts (geoscientists and other scientific and engineering specialists) needed for the development of an adequate range of evolution scenarios, and also to develop other lines of evidence for the safety case, as discussed in the previous section (the work of the IGSC on scenario development is discussed further in Section 4.4).

In the context of the development of the assessment basis, prior to carrying out a safety assessment, integration generally refers to the bringing together, or "synthesis", of various sources of information, for example:

- the features and structure of a geological barrier over a range of scales;
- the stability of repository system components;
- the nature and rates of certain processes;
- the frequency or likelihood of occurrence of rare events and their possible impact on the disposal system.

The topic of rare events is often seen as particularly challenging.

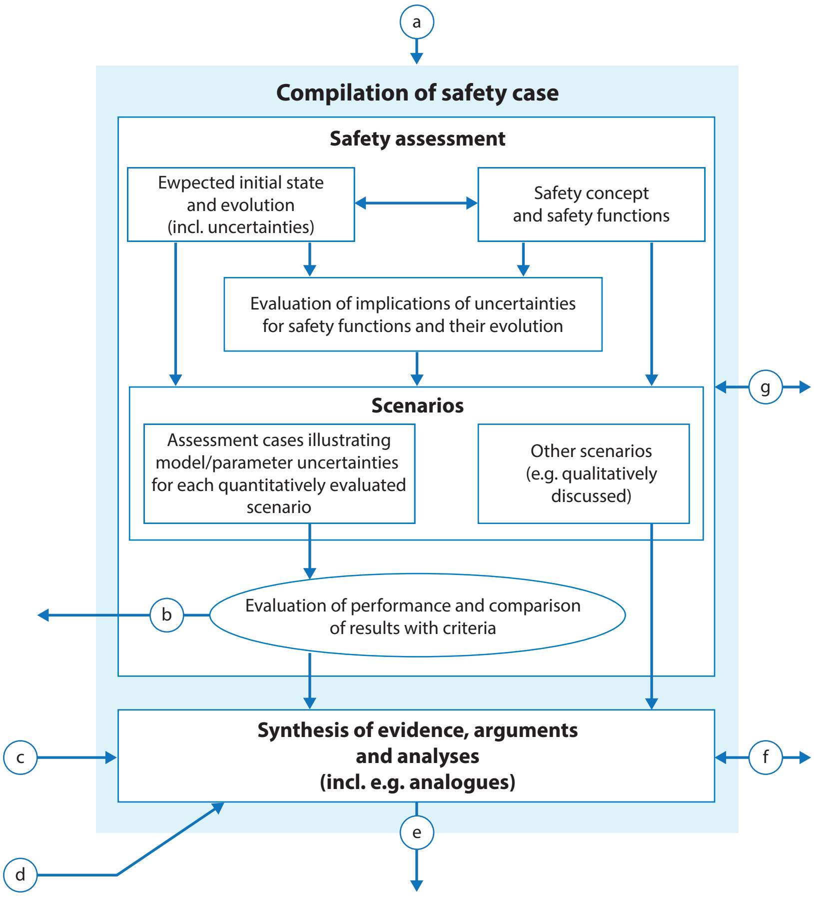
Overall, the aim of integration is to provide a coherent, consistent, logical, plausible and defensible description of the disposal system and its environment and evolution that adequately captures the various sources of uncertainty.

As the range and depth of information contributing to the safety case increases, so does the need to carry out integration in a structured manner. Integration may, for example, begin by bringing together information related to a single phenomenon or limited set of related phenomena. For example, the IGSC Position Paper on gas in post-closure safety cases, "Relevance of Gases in the Post-closure Safety Case for Radioactive Waste Management" (NEA, 2015b), is an integration of information and knowledge on that topic. Similarly, the IGSC workshop proceedings on cementitious materials, "Cementitious Materials in Safety Cases for Geological Repositories for Radioactive Waste: Role, Evolution and Interactions" (NEA, 2012c), integrated the information and knowledge on the role, evolution and interactions of these materials in geological repositories. Such syntheses correspond typically to the element "synthesis of process understanding" in the assessment basis, as depicted in Figure 4.

At a higher level, the integration carried out is wider in scope, with a prominent example being the geosynthesis or site descriptive model (SDM), which brings together all relevant geoscientific information to produce a single, conceptual model of the geosphere (see the discussion of AMIGO below).

At a still higher level, an overall "system concept" is developed, which may be defined as an integrated description of the expected initial state of the disposal system and of its expected evolution, including uncertainties in both of these (NEA, 2012a). As shown in Figure 5, the development of this integrated description of "expected initial state and evolution" is a first step in the safety assessment process, along with the development of a corresponding safety concept, which is a description of the roles of the natural and engineered barriers and the safety functions that these are expected to provide. The development of a system concept that demonstrates a clear understanding of how the system is expected to provide safety as it evolves and how the uncertainties pertaining to its evolution can be bounded, contributes directly to the multiple lines of evidence presented in the safety case. Implementing organisations have developed tools as a function of their needs to support the integrated description of the disposal system or a part of it. Examples of the variety and wealth of these tools can be found in Box 2.

Figure 5: Generic flowchart showing the main elements when compiling a safety case



Note: The labels of the arrows aim at facilitating correspondence between this figure and Figure 4 on page 22.

Source: See NEA, 2012a (Figure 12.5) for a detailed description of the figure.

Geoscience has received particular attention in the work of the IGSC in the context of the AMIGO project (NEA, 2010) and its predecessor, the Radionuclide Migration in Geologic, Heterogeneous Media, GEOTRAP (NEA, 2002), which ran from 1996 to 2001. The AMIGO project was initiated in response to a concern that insufficient use was being made of geoscientific information in safety cases, as well as to address the challenge of achieving effective co-ordination between geoscience programmes and safety assessment. It was noted in AMIGO that extensive experience over many years and via the work of many implementing and regulatory organisations has demonstrated that the use of an integrated multidisciplinary group, which includes both geoscience specialists and safety assessors, is an appropriate and effective method of synthesising geological information and developing confidence in an SDM or a "geosynthesis". A geosynthesis, or an SDM, may be seen as a qualitative and quantitative model of the geosphere that supplies the specialised information and data sets pertaining to the geosphere that are needed by the repository programme, not only for safety assessment, but also for repository implementation and for the design of the engineered barriers. Multidisciplinarity can also be taken to apply to other areas where integration is needed, including the properties and performance of the EBS (EC, 2010).

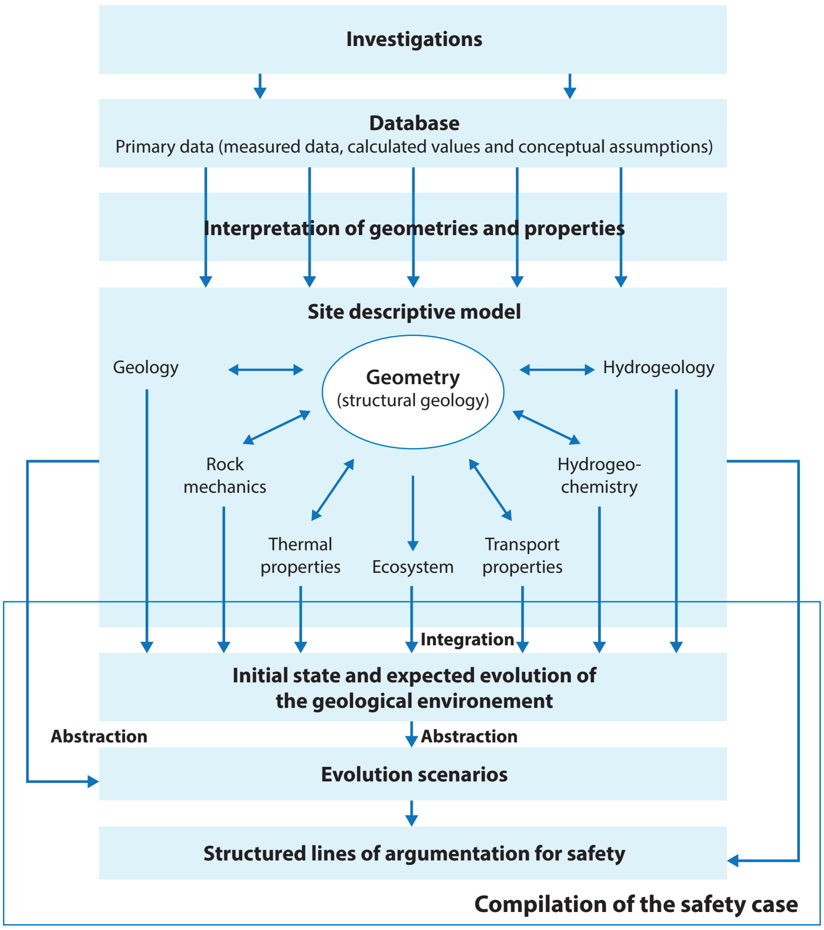
The AMIGO project concluded that concepts such as "geosynthesis" and "safety functions" (see Section 4.2) have provided useful mechanisms to prioritise and synthesise geoscientific information and to relate this information directly to the safety case. The scope of a geosynthesis is illustrated in Figure 6. Note that achieving a detailed description of a site and its long-term evolution may take several iterations of the safety case. To begin with, before a site is selected, a programme may use a generic site description based on high-level safety-relevant FEPs that allow the development of a provisional safety concept that can be refined as the programme proceeds.

Even where the host rock offers the potential of significant safety performance, a well-designed EBS that will fulfil multiple safety functions is an essential part of all repository concepts. The Joint EC/NEA EBS Project (EC, 2010) examined how to design, characterise, model and assess the performance of engineered barrier systems, as well as how to integrate these aspects within a safety case. With respect to integration, the conclusions of the project again emphasised the need for a continual and multidisciplinary process of iteration between detailed research and process modelling studies, safety assessment studies and engineering design studies. It was stated that "this process involves the simultaneous transfer downwards of high-level system requirements, and upwards of detailed materials and process understanding and performance assessment results, coupled with the periodic conduct of safety assessments, which integrate the various different types of information" (EC, 2010). The EBS Project noted the increasing use of requirement management systems for managing and recording design decisions, as well as the increased use of safety functions and related concepts.

4.2 Safety functions

A safety function is a description of the means by which a repository component (natural or engineered) contributes to safety. Safety functions, as well as related concepts such as "safety statements" and "pillars of safety", have been identified by, and have an increasingly prominent role in, many national programmes. They provide a way of showing that the principle of defence in depth has been followed. Adequate defence in depth has to be ensured by demonstrating that there are multiple safety functions and that the fulfilment of individual safety functions is robust.

Figure 6: Illustration of the development and components of a site descriptive model or "geosynthesis", and its use as a basis for scenario development and structured lines of arguments for the safety case



Source: NEA, 2010 (adapted from Figure 1).

Safety functions connect the system description to the safety objectives and provide a tool for structuring and prioritisation of R&D programmes. Safety functions are also used directly in safety assessment, e.g. through the development of "performance targets" or "safety function indicators" that indicate the conditions when the safety functions may be degraded or lost (see for example NEA, 2001). The 2007 symposium *Safety Cases for Deep Geological Disposal of Radioactive Waste: Where Do We Stand?* identified a "move in philosophy" to consideration of safety functions that embody key aspects of the performance of a geological disposal system, rather than simply multiple barriers per se, and noted that "…internal requirements can be developed that relate the ability of the disposal system to fulfil these functions, thus making more transparent the role of various components (and their synergies) in the disposal concept" (NEA, 2008). It was noted in the report, *Methods for Safety Assessment for Geological Disposal Facilities for Radioactive Waste: Outcomes of the NEA MeSA Initiative* (NEA, 2012a), that if safety functions are defined for system components, then it is necessary to introduce a method to evaluate whether the components fulfil their intended function. One such method is the definition of safety function indicators, with target values or numerical criteria assigned to these indicators in order either to allocate a certain performance, or to check and quantify the fulfilment of the safety function. Examples of the way the concept of safety functions has been adopted by national programmes and developed further to address the needs of their safety cases are given in Box 2.

4.3 Handling of uncertainty

Questions pre-dating the IGSC and still discussed today relate to the management and handling of uncertainty in the safety case: How much scientific work on a specific technical issue is needed before it is judged to be sufficient? How can we justify and communicate confidence despite the inevitability of some remaining uncertainty? What strategies are best for handling different sources of uncertainty?

All national programmes seek to achieve a robust repository concept, which involves siting and design strategies to reduce uncertainty, or to mitigate the adverse consequences of uncertain phenomena. There is general agreement, however, that complete certainty in the state of a repository as it evolves over time is neither achievable nor required in order to demonstrate that the repository will be safe. Rather, the safety case must instil confidence in its audience (the audience for the safety case is discussed in Section 6), and especially decision makers, that any situations, or 'scenarios', that could potentially pose a hazard to humans and the environment have been considered and are either impossible or are so unlikely and/or of such limited consequences that the associated risk to which they give rise is acceptable according to regulatory requirements. It is important to recognise that the aim of a robust safety case is not to 'predict the future', but to demonstrate that the range of credible futures is acceptable according to regulatory requirements.

The 1999 NEA report, which sets out the role of the safety case within the stepwise repository development process, points out that the degree of confidence needed for a positive decision to proceed from one programme stage to the next will vary, and generally increase, as the programme progresses, especially once the licensing stage has been reached. There will always be residual sources of uncertainty, but any that could call the safety case into question must be avoided, mitigated or reduced at least to the extent needed to justify a decision to proceed.

The 2013 NEA Safety Case Brochure, "The Nature and Purpose of the Post-closure Safety Cases for Geological Repositories" (NEA, 2013a), notes a high level of consensus on the sources of uncertainty in the safety case and on the ways to address them. Many of these are related to the long timescales over which safety needs to be assured. The approaches to handling timescales for geological disposal of radioactive waste are influenced by ethical principles, the evolution of the hazard over time, the uncertainty in the evolution of the disposal system (and how this uncertainty itself evolves) and the stability and predictability of the geological environment. The handling of uncertainty and other issues related to timescales in safety cases were the subject of numerous discussions within the IGSC in its first decade, culminating in the publication of a report, *Considering Timescales in the Post-closure Safety of Geological Disposal of Radioactive Waste* (NEA, 2009b). This report summarises uncertainties that arise from the long timescales over which the radioactive waste remains hazardous and how to address these in the safety case.

There is a well-established classification scheme for uncertainty that is used in safety assessment, which distinguishes:

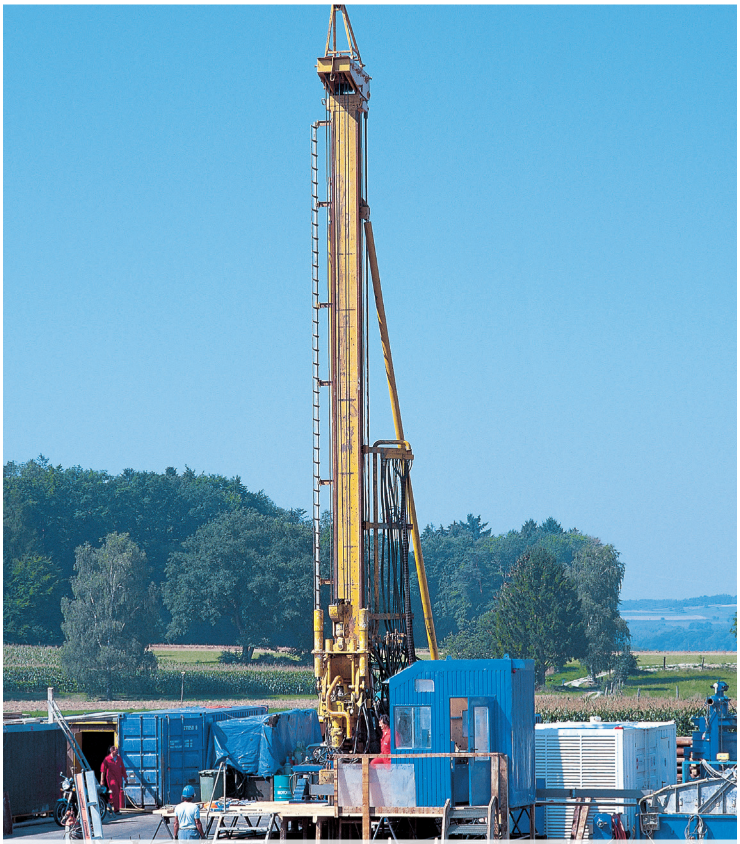
- scenario uncertainty;
- model uncertainty;
- data and parameter uncertainty (NEA, 2001; NEA, 2012b).

In this respect, a further distinction is made in some programmes between epistemic and aleatory uncertainty. Epistemic uncertainty is knowledge-related and in principle may be reduced with further effort. Aleatory uncertainty is system-related and random in nature and irreducible. Scenario uncertainty contains a larger element of aleatory uncertainty than the two other groups.

Following the MeSA project, the 2013 NEA Safety Case Brochure (NEA 2013a) noted that strategies for treating uncertainty within safety assessment were well established and fall into one or more of the following categories:

- Demonstrating that the uncertainty is irrelevant to the safety assessment;
- Bounding the uncertainty – for example, by making conservative assumptions;
- Addressing uncertainty explicitly using probabilistic and/or deterministic approaches and sensitivity analysis;
- Ruling out or excluding some uncertain events or processes – for example they may be ruled out on the basis of their very low probability or very low consequences;
- Using an agreed stylised approach to avoid addressing the uncertainty explicitly – for example biosphere uncertainties and uncertainties regarding future human behaviour.

Determining which sources of uncertainty must be either avoided or mitigated by siting and design measures, or reduced by site characterisation and R&D (e.g. by seeking multiple lines of evidence to support particular assumptions or parameter ranges; see Section 3), is a key role of safety assessment. The iterative link between the safety assessment and R&D, design and site characterisation programmes is an important aspect of developing confidence in the safety case.



Rig for the Benken borehole in the Zürcher Weinland, Switzerland.
Comet, provided courtesy of Nagra, Dieter Enz

It is not only the technical activities of the safety case that involve uncertainty, the context in which the safety case is developed may itself be uncertain. For example, national policies related to waste disposal, as well as legal and regulatory frameworks, may change over time. This type of uncertainty is potentially the most significant in a waste management programme, as a change in national policy can stop a repository development programme altogether. Effective communication of the safety case to all stakeholders may help mitigate this type of uncertainty.

A measure proposed to resolve a specific issue depends on the nature of the associated activity. Its relevance must be evaluated with respect to the programme stage and the objectives of the safety case at hand. Examples of risks and uncertainties affecting key activities/topics in safety case development and the measures that can be implemented to handle them at the level of the activity/topic itself, as well as at the overall programme level, are given in Table 1 (inspired from the examples of measures to enhance confidence building reported in *Confidence in the Long-term Safety of Deep Geological Repositories* (NEA, 1999).

Table 1: Examples of risks and sources of uncertainty affecting confidence in key activities or topics in safety case development and the measures to handle them at the level of the activity and at the overall programme level

Safety case activity/topic	Elements of confidence	Risks & sources of uncertainty	Possible activities to address risk/uncertainty (topic level)	Prioritisation of activities and additional management measures (programme level)
Assessment context	Desk studies show alternatives to geological disposal are less favourable.	Study becoming out-dated.	Literature monitoring & regular updates.	Activities authorised, since this is a recurrent question in societal debate: Report updates and publication of flyers to maintain visibility.
Safety strategy	A safety strategy has been designed based on the para-mount principles of robustness and conservatism.	The current safety strategy does not include treatment of feasibility, operational safety and monitoring aspects.	Update safety strategy taking into account strat-egies developed by more advanced programmes.	Update of the strategy to include feasi-bility aspects based on a generic design. Regulatory interactions for guidance on monitoring.
Initial state and evolution of the system	Thermal influence of the waste on the disposal system has been investigated using small-scale experiments and extended to relevant scales by modelling. The results do not undermine the safety concept.	The risk that thermal impact could be det-rimental to the safety is not totally ruled out because of uncertainty related to up-scaling.	Large-scale thermal exper-iment in the host rock.	Large-scale demonstrator is a priority because: 1. of the potential impact on the safety concept (and the programme); 2. it will guide design choices; 3. it will facilitate societal dialogue.
Initial state and evolution of the system	The degradation mechanisms of the waste form under repository conditions are well understood and the uncertainty range of the degradation rate is bounded.	Detailed mechanism of degradation is uncertain.	Process modelling to improve mechanistic understanding.	Future work placed on hold because improved understanding is considered to: 1. have limited effect on safety as shown by safety analysis; 2. be beyond the scope of the repository project; 3. be premature with respect to design development.
Safety Assessment	Safety assessment of the expected evolution scenario shows a safety margin with respect to regulatory require-ments.	Design optimisation with respect to cost/perfor-mance might reduce safety margin.	Analyse design variants with respect to cost and performance.	Analysis of design variants authorised, but need also to: 1. develop criteria to guide optimisation; 2. discuss optimisation approach with the regulator.
Quality Assurance	An effective system of record-keeping is developed so that decisions can be placed in a broad, historical context.	Risk of obsolescence of the knowledge manage-ment system.	Maintain the current knowledge management system or migrate to a new one.	Additional measure is to plan migration of the knowledge management system after the end of the programme phase.

4.4 Scenario development

The analysis of a sufficient set of scenarios for repository evolution in terms of their radiological consequences is seen as a key part of any safety assessment and safety case. The development of such scenarios has been the subject of two dedicated workshops, one organised by the Performance Assessment Advisory Group (PAAG) (NEA, 2001) and the other by the IGSC (NEA, 2016), and has also featured prominently in several other IGSC workshops, projects and publications, including MeSA (Section 5.3 of NEA, 2012a). Furthermore, in 2015, the IGSC organised a topical session entitled "Handling extreme geological events in safety cases during the post-closure phase", in which it was noted that there is a potential benefit to harmonising the treatment of scenarios involving extreme geological events between programmes (particularly neighbouring countries), including any assumptions and generic data used.

As early as 1992, an NEA Scenario Working Group (NEA, 1992) report defined scenario development as "the identification, broad description, and selection of alternative futures relevant to a reliable assessment of radioactive waste repository safety". According to the 2013 NEA Safety Case Brochure (NEA, 2013a), "a scenario, or more precisely evolution scenario is understood as a simplified description of a potential evolution of the repository system from a given initial state".

Regarding the methodology for scenario development, the 1999 NEA workshop identified two apparently distinct approaches:

- Top-down approaches, using, e.g. directed diagrams;
- Bottom-up identification and aggregation of FEPs, using, e.g. event trees and influence diagrams.

A move away from describing scenario development as a bottom-up process, with FEPs as its starting point, was noted at the 2007 symposium *Safety Cases for Deep Geological Disposal of Radioactive Waste: Where Do We Stand?* (NEA, 2008), where it was stated that "following the strong trend to build and use detailed system understanding, a number of recent safety assessments do not start any longer from an analysis of externally generated FEPs. Rather, 'scenarios' are generated internally to the project based on the scientific and technical knowledge base that the project has accumulated". In the same symposium, in the context of Nagra's approach in the Opalinus Clay project (Switzerland), it was noted that the FEP database was used primarily as "a 'book-keeping tool' to ensure phenomenological completeness of the assessment". Scenarios and calculation cases were derived from "a careful evaluation of the scientific basis, guided by a wide range of 'insight calculations' and sensitivity analyses". Similarly, in ANDRA's programme (France), alternative evolutions were described as the outcome of a "qualitative safety analysis entailing an integrated assessment of the impact of uncertainty on safety functions".

The distinction between top-down and bottom-up approaches continued in the 2012 MeSA initiative, although some evolution of the meaning of these terms from the 1999 IGSC workshop is apparent. According to MeSA (NEA, 2012a), "in some assessments, scenarios are identified using a bottom-up approach that begins by assessing a range of external events or conditions (i.e. climate change scenario, intrusion scenario, initial defect scenarios) that may trigger changes in the disposal system or affect its performance. Other programmes structure the scenario definition using a top-down approach, i.e. identifying first the crucial safety functions and then focusing on what combination of conditions could jeopardise one or more safety functions". It was claimed that there is no conflict between these approaches and that they can be used in combination. In fact, in the summary of the outcomes of the initiative, it was questioned whether an exclusively bottom-up approach had ever been successfully implemented and suggested that assessors actually always begin from an integrated but preliminary conceptual understanding of system evolution and associated uncertainty, and use FEPs (together with interaction matrices, influence diagrams, etc.) to ensure that nothing is overlooked, i.e. for completeness checking. The 2015 scenario workshop (NEA, 2016) also suggested that the integration of top-down and bottom-up elements may in reality be a feature of all practical approaches to scenario development. Several attempts at such integration undertaken by national programmes were presented at the workshop. The workshop also identified the widespread use of safety functions in the formulation of scenarios as a key development and noted that various methods have been developed to analyse or assess the effects of detrimental FEPs and uncertainties on safety functions. It noted that, while there has been a substantial degree of international harmonisation in approaches to scenario development, differences in terminology and methodological details remain, in part due to differences in regulatory and programmatic context.

The main roles for scenario development within the safety case has long been seen as a means of structuring assessment calculations to demonstrate that safety criteria are met for all credible potential evolutions of the disposal system, and of communicating assessment outcomes. However, other roles have increasingly been recognised, including:

- developing and demonstrating system understanding;
- supporting the management of uncertainty within and between programme stages;
- integrating scientific and technical knowledge with a focus on its relevance to repository safety functions;
- providing an opportunity to optimise the system to increase the robustness of the safety case by identifying requirements on the engineered barriers;
- promoting multidisciplinary communication.

The value of "what-if" scenarios or cases investigating or demonstrating system robustness and illustrating the functioning of specific barriers is now widely recognised, as is the need for a separate handling (using stylised approaches) of future human actions and human intrusion. Scenarios are analysed using deterministic or probabilistic analysis techniques, which are seen as being mature, and are frequently used in combination, e.g. with parameter uncertainty treated probabilistically and alternative scenarios and/or model uncertainties assessed individually.

A clear trend was identified in MeSA towards the use of more sophisticated and realistic models, due to improved understanding of the phenomena and a greater inclusion of coupled processes due to increasing computational power; while noting that, no matter how complex, models remain abstractions of nature. It was also noted that there are different levels of abstraction corresponding to different categories of model, with mathematical models being abstractions of conceptual models and numerical models being abstractions of mathematical models. As indicated in Figure 6, the scenarios themselves may be seen as abstractions of the integrated understanding of the disposal system and its evolution. The 2015 IGSC scenario workshop defined scenario abstraction as the process of incorporating scientific knowledge relevant to a scenario into a model, taking into account the limits of and uncertainties in this knowledge, as well as the requirements related to the intended purpose of the model, and noted that the abstraction process generally involves a high degree of expert judgement.

4.5 Knowledge management

Information and knowledge increase as programmes move forward, and managing these effectively is crucial for keeping a long-running project on track. The IGSC has contributed to meeting this management challenge through the identification of a variety of tools that can be used to structure knowledge, as shown in Box 2, as well as through the Radioactive Waste Repository Metadata Management (RepMet) initiative, which was launched by the IGSC in 2014 (NEA, 2018a). RepMet analysed and investigated the application of metadata within national programmes for radioactive waste repositories. The initiative identified numerous benefits of using metadata within national programmes, including more structured management of information, meeting statutory requirements and ensuring that data quality is consistent with requirements. The initiative also noted that metadata have a role to play at all stages of the life cycle of a radioactive waste repository.

The IGSC has examined further the challenges of managing information and requirements in geological disposal programmes (NEA, 2018b). Requirements, designs and data, such as those from site and waste characterisation, evolve or expand as programmes develop. Many programmes have developed tools to relate their legal and regulatory requirements to the evidence and lines of argument of long-term safety within the safety case at the lowest technical level (e.g. the "argumentation model", the "safety statements").

When programmes move towards implementation, the issue of design requirements at the crossroad between engineering feasibility, operational and long-term safety becomes prominent. Some programmes identify "configuration management" as the process facilitating the orderly management of system information and system changes. Configuration management relates the high-level requirements to long-term performance targets (quantitative or qualitative) and design requirements and specifications. It includes the tools to manage and evaluate proposed changes to the system and to track and record the status of changes. Configuration management is challenging, particularly as the safety case becomes more complex and is updated in different parts at different times. As geological disposal programmes evolve, a greater awareness also develops of possible "as-built deviations" from the planned initial state, which may lead to different potential evolution scenarios (NEA, 2016).

The challenge of managing knowledge in the longer term, well after repository closure, was addressed by the NEA in its Preservation of Records, Knowledge and Memory (RK&M) Across Generations initiative, which was started in 2011 (NEA, 2019b). The initiative investigated how, through RK&M preservation, it may be possible to reduce the likelihood of inadvertent human intrusion into a repository and to support the capacities of future members of society to make their own informed decisions regarding a repository after closure.

5. Regulatory perspective

As noted in Section 1, the IGSC provides a platform for dialogue and interaction between the representatives of regulatory agencies and implementing organisations at the international level. Such dialogue is important as:

- The regulator needs to understand the concepts and strategy by which the implementer intends to demonstrate that a proposal is acceptable.
- The implementer needs to be fully aware of what is expected by the regulator at any given programme stage.

At the same time, it is essential for building trust in all organisations involved that regulators maintain their independence. This enables them to review safety cases developed by the implementer thoroughly and impartially. Such review may be supported by the regulator's own independent research and assessment.

The IGSC has organised or taken part in a number of symposia, workshops, seminars and projects that aim to foster such dialogue. In 2007, a specific aim of the symposium on *Safety Cases for Deep Geological Disposal of Radioactive Waste: Where Do We Stand?* (NEA, 2008) was to identify regulatory requirements and expectations on the safety case. In 2012, a joint workshop between the RWMC Regulators' Forum (RF) and the IGSC was held that addressed challenges to implementing organisations and regulators in "Preparing for Construction and Operation of Geological Repositories – Challenges to the Regulator and the Implementer" (NEA, 2013b). In the same year, the final report of the MeSA initiative explicitly discussed the regulatory perspective on a number of issues related to safety assessment (NEA, 2012a). More recently, in 2017, the IGSC took part in a joint seminar with SITEX[1] on regulatory review of safety cases for geological disposal.

The roles of the regulator regarding the safety case include development of regulations and guidance, reviewing of safety cases, and informing the government, implementers and stakeholders of their judgements. Timely fulfilment of these roles is essential to keep a repository development programme on track. This may be facilitated by allocating sufficient resources and by the building of staff competence, possibly including independent regulatory-led research (NEA, 2013b). It may also be facilitated by the elaboration of a detailed project plan, including the creation of a safety integration review team.

Best practice in disposal system development is based on application of an iterative and adaptive approach that ensures that new information is incorporated in the design and in the safety case, which are subject to internal and external (regulatory) scrutiny at all major decision points. It may be beneficial to engage with regulators early in the process of developing a safety case. Early engagement promotes mutual understanding regarding the repository development plan, the criteria to be fulfilled at each major project milestone, and the interpretation of national and international guidance. Not only do regulations provide a framework for the safety case, but, according to the final report of the MeSA initiative (NEA,2012a), the R&D supporting the safety case and practical experience in the field of safety assessment may, in some instances, feed back into the development of regulations. The concurrent development of regulations and the safety case itself might pose challenges to both parties (e.g. how to adapt a safety case with respect to updated regulations).

Issues impacting both implementers and regulators that have been identified by the IGSC as becoming more prominent as programmes advance include repository operational safety and reliability, increased demands on human resources, activities to ensure quality assurance, and the additional requirements on information management system and management plans for construction work (NEA, 2013b).

1 SITEX (Sustainable network of Independent Technical EXpertise for radioactive waste Disposal) was a project implemented within the 7th Framework Programme of the European Atomic Energy Community (Euratom). The project aimed to establish and develop expertise among technical safety experts and, through this, support independent regulatory reviews of the safety of geological disposal at national level.

The 1999 NEA report set out a number of measures to promote wider confidence in the legal and regulatory framework, including internal and external audits to ensure the technical competence and the adequacy of the management of the implementer and the regulator, as well as their independence, international harmonisation of regulations, and clear criteria by which an application is judged. However, the difficulty in harmonising national regulatory requirements has also been recognised, and consideration has been given to reasons for differences in the content and style of regulations, including the degree to which they are prescriptive or non-prescriptive (NEA, 2008; NEA, 2012b; NEA, 2016).

Regulatory perspectives on many of the challenges involved in developing the safety case have been addressed in the work of the IGSC, including the issue of assessment timescales and the overall time window covered by the safety case (NEA, 2009b), the use of complementary indicators (NEA, 2012b), and the development and analysis of scenarios (NEA, 2001; NEA, 2016), for each of which differences and similarities in approach between countries have been noted.

On the issue of assessment timescales, national regulations may provide guidance on the indicators or types of safety argument to be used within different time windows for safety, including indicators that are complementary to dose and risk. However, significant differences between national regulations remain concerning the degree to which the overall time window for the safety case is prescribed and the types of safety indicators, arguments or criteria that are applicable at different times. Other significant differences concern the regulatory positions on the time frames for monitoring, control and record-keeping (e.g. Table 4.2 in NEA, 2009b).

The development of safety indicators complementary to dose and risk, such as radionuclide concentrations and fluxes, has been driven mainly by concerns over the inherent uncertainty in estimating potential dose/risk to people in the far future, when climate and human behaviour may be radically different to today. Reference values for dose/risk are usually defined by the regulator, whereas reference values for complementary indicators other than dose or risk are, in most cases, the responsibility of the developer to propose and justify. There have, however, been suggestions in some IGSC discussions that further regulatory guidance on the use of complementary indicators would be desirable. For example, in *The Handling of Timescales in Assessing Post-closure Safety: Lessons Learnt from the April 2002 Workshop in Paris, France* (NEA, 2004c), it was stated that "the use of indicators complementary to dose and risk, their weighting in different time frames, as well as reference values for comparison, are issues that may well deserve further regulatory guidance" and in *Considering Timescales in the Post-closure Safety of Geological Disposal of Radioactive Waste* (NEA,2009b), it was noted that "the issue of how to evaluate compliance with requirements expressed in terms of qualitative indicators may need further consideration". A status report on indicators in the safety case was published by the IGSC in 2012, which noted an increasing recognition of complementary indicators within national regulations, and a requirement in several national regulations to place greater emphasis on complementary indicators in the far future, beyond the period when radiation exposure to humans can be reliably assessed, and especially after significant climate change (e.g. glaciation) may have occurred (NEA, 2012b).

Regarding the development and analysis of scenarios, there is consensus that regulatory guidance should be given for uncertainty that cannot be quantified and, in particular, for the formulation of stylised scenarios to represent the evolution of the surface environment, human society and future human actions. This will enable a proponent to defend its own stylised scenarios with well-founded arguments in a licensing procedure. Furthermore, the regulator may choose to limit the scope of the assessment to avoid undue emphasis on scenarios of lesser importance (NEA, 2001). Most regulators do not explicitly require or recommend a quantitative evaluation of the likelihood of scenarios and/or their associated FEPs, although likelihood estimates may nevertheless be called for where compliance criteria are expressed in terms of risk, and at least qualitative estimates are needed where scenarios are classified according to likelihood (NEA, 2016).

Overall, in line with the development of the concept of the safety case, regulators have increasingly come to expect the implementer not only to assess compliance with quantitative radiological criteria using scenarios that conservatively over-estimate potential impacts, but also to demonstrate that the behaviour and evolution of the disposal system are sufficiently well understood, with the help of further calculations that are more realistic (albeit with uncertainty). The latter may be used, for example, to quantify the expected or likely performance of the disposal system, to illustrate the extent of the margin present in the more cautious calculations, and to support decisions on repository optimisation (see below). Regulators also expect the implementer to inspire confidence in the results of its safety assessment. In this regard, assurance of data and assessment tool quality, appropriate quality management, and transparency and traceability of the assessment process are all considered essential (NEA, 2012a).

Optimisation of protection, as defined by the International Commission on Radiological Protection (ICRP), is regarded as a process to keep the magnitude of individual doses, the number of people exposed and the likelihood of potential exposure as low as reasonably achievable with economic and social factors being taken into account (ICRP, 2000). In the past decade, however, there has been a trend towards a broader view of optimisation as discussed in the more recent ICRP report on radiological protection in geological disposal (ICRP, 2013). This trend was also apparent at the joint RF/IGSC workshop in 2012 (NEA, 2013b), where it was noted that optimisation is a way of increasing the technical quality and robustness of the whole waste management process, such that not only long-term safety requirements are met, but other factors, such as operational safety, engineering feasibility and the efficient use of resources are taken into account.

The overall aim of optimisation is to achieve a disposal system that is safe during both the operational and post-closure periods, is technically feasible and affordable taking into account the socio-economic context, and that meets stakeholder and regulatory requirements. This broad view was reiterated in the 2013 NEA Safety Case Brochure, which emphasised that optimisation is a process that contributes to building confidence in the safety case by the demonstration of ongoing learning across the organisation (NEA, 2013a). Optimisation requires communication and the development of a common understanding among experts involved in the disposal programme, as well as with regulators and stakeholders. The safety case can provide a communication tool that can foster such a common understanding between these different parties.

Rather than re-examining past decisions, optimisation is seen as a forward-looking activity, continuing into the operational phase, in which decisions are taken based on the knowledge and understanding available at the time, and which focus on solutions that take advantage of any flexibility that remains available. A requirement for optimisation is incorporated in some form in many regulatory requirements. The role of the regulator is seen as being to set clear requirements that constrain the optimisation process.

6. Safety case communication and stakeholder interaction

Safety is of importance for all stakeholders involved in, or affected by, the development, licensing or hosting of a repository. Confidence in safety is an indispensable prerequisite for repository implementation. This was recognised early by the NEA, and it is worth noting that the first IGSC document on safety case methodology is entitled *Confidence in the Long-term Safety of Deep Geological Repositories* (NEA, 1999), cf. Section 1.1. The work of the IGSC was, and is, dedicated to the scientific, engineering and methodological fundamentals of the safety case; however, the IGSC is aware that communication of the safety case to stakeholders is an essential part of its development.

The term "stakeholder" describes anyone with a role to play or an interest in the process of deciding about radioactive waste management. This includes people with varying degrees of scientific and technical expertise, from specialists reviewing the safety case (e.g. on behalf of regulators) to interested lay people from potential hosting communities. Safety case communication (as any communication) needs to be focused on the intended audience. With such wide-ranging audiences, there need to be different levels of documentation targeted at different audiences. As an example, the French safety case "Dossier 2005" top-level documentation consists of:

- a 4-page leaflet for the general public (ANDRA, 2005a);
- a brochure for interested laypersons (ANDRA, 2005b);
- synthesis reports on disposal in argillite (ANDRA, 2005c) and granite (ANDRA, 2005d) formations aimed at decision makers.

At the next level of complexity, there are volumes on repository architecture and management, analysis of the repository evolution and safety assessment. These three volumes take a synthesising interdisciplinary perspective and in turn are based on five documents containing data available on different components of the disposal system, which in turn rely on numerous technical documents and scientific publications.

From 2014 onwards, the IGSC has been explicitly addressing safety case communication and stakeholder interaction in its work. A major milestone was the IGSC report, *Communication on the Safety Case for a Deep Geological Repository* (NEA, 2017), based on review of national and international examples of communication on safety-relevant issues and stakeholder interaction. The report dealt with two questions: i) what is the experience base concerning the effectiveness or non-effectiveness of different tools for communicating safety case results to an interested non-technical audience; and ii) how can communication based on this experience be improved and included as the safety case is developed? Major messages of the IGSC report include:

- Communication should be a two-way undertaking (communication "with" rather than "to" stakeholders).
- A communication plan and strategy should be developed that includes the identification of target audiences, the major messages to be communicated and the communication channels.
- The way messages are delivered needs to be tailored to the intended audience, but the communication should always be of one safety case, i.e. the messages have to be consistent.
- Openness, including openness about unresolved issues and uncertainties, is paramount.
- Building technical understanding and capacity within a potential host community can support communication.
- Implementers and regulators should both be involved in stakeholder outreach and dialogue, but independently.
- Communication with stakeholders can be improved by technical experts honing their communication skills (via training) and communication experts being integrated into the process.

The report was reviewed by the FSC, and the collaboration led to broader co-operation with the FSC. In particular, the IGSC and FSC held a joint workshop on safety case communication in 2017 and a joint topical session on "Managing Uncertainty in Siting and Implementation – Creating a Dialogue between Science and Society" in 2019. The key learning points emerging from the IGSC/FSC collaboration so far include:

- It is important to distinguish between risks (potential for harm) and uncertainties (lack of knowledge) in communicating about safety.
- Uncertainties should be addressed openly and competently.
- If stakeholders perceive that uncertainties are being downplayed, they will perceive that the uncertainty is a threat.
- Stakeholders want to receive information they can trust, in order to be guided in coming to their own decision (which may include a risk assessment based on the uncertainties). They want to be able to form their own view as to whether risks are acceptable and, where possible, to have some control in mitigating the risks.
- In order to trust technical information, stakeholders first need to trust the integrity of the information provider.
- Uncertainties should always be presented in a context that the stakeholder can relate to – some good examples of uncertainty communication include:
  - *Weather forecasts* – a probability of rain is presented, so that the audience can take informed decisions. The forecaster is generally trusted as an honest, independent information provider with no bias towards any particular outcome.
  - *Caesium in mushrooms (Finland)* – government communication concerning caesium present in forest mushrooms; which was stated as having no significant health impact, with the further advice that any risks could be reduced by cooking the mushrooms. This was regarded as a clear message also providing practical advice. Finnish people continue to enjoy their mushrooms (more so than had they been advised to cook all mushrooms).
  - *Life expectancy when critically ill* – doctors take care how to communicate (and some medical websites allow the user to specify the level of information they wish to receive), which may range between best and worst outcomes or a simple life expectancy – respecting the stakeholder's right to clear information, but also the fact they may not wish to know all the details.
- Not all uncertainties are the same – stakeholders may be willing to accept some uncertainties but not others; hence, it is important to understand stakeholder values and concerns. The more familiar an uncertainty, the more likely it is to be accepted (e.g. uncertainties regarding travel, weather, medical X-rays).
- Different generations can have different approaches to accepting uncertainty – it may be easier for younger people to accept uncertainty.

The intention is to continue the collaboration between the IGSC and FSC in order to strengthen the safety case as an instrument in the broader societal context. The next major collaborative event planned is a further joint workshop in October 2021.

Joint IGSC/FSC Workshop 2017.

7. Conclusions

The safety case has become a powerful and essential tool to support decision making at every stage of a geological disposal programme. Beyond its role as a demonstration of safety and technical feasibility, the safety case is also a platform for discussion both within a waste management organisation and with other parties. The safety case as a concept has turned out to be a valuable tool used by implementers as well as regulators, who both appreciate its strengths and its flexibility to be adapted to the specific features of any national programme. Internationally, the safety case has been incorporated in IAEA's Safety Standards, and some national regulatory requirements are formulated on the basis of the safety case concept.

The IGSC is the main technical advisory body to the RWMC on geological disposal of radioactive waste. It has shown itself throughout the last two decades to be an efficient instrument in developing the concept of the safety case and adapting it in line with the emerging issues faced by national programmes. Such issues now include those associated with the engineering and operational aspects of the licensing stage, as well as those associated with the early stages of a geological programme, including host rock selection and early interactions with stakeholders. The IGSC has operated as a neutral forum with the aim of sharing information concerning new developments, emerging issues and trends, innovative approaches, and lessons learnt (both favourable and unfavourable). Through this working format, the IGSC has provided a communication platform between national programmes at all stages of maturity and helped develop common views among these programmes, while preserving and explaining any remaining differences.

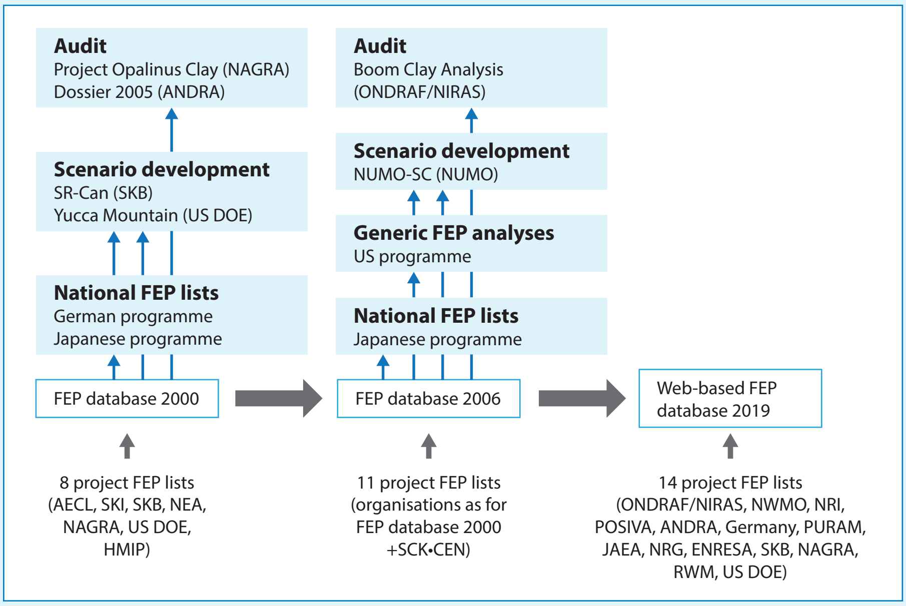
A landmark NEA report issued in 1999, *Confidence in the Long-term Safety of Deep Geological Repositories*, set out a holistic vision of the evolution of a geological disposal development programme and, in particular, of the safety case (NEA, 1999). Through two decades of information exchange, the IGSC has worked at moving from a view of the safety case centred on compiling reports, towards a far more integrated, systemic perspective. Safety case development has come to be seen as a structured process whereby science, engineering, safety assessment and quality assurance are brought together and integrated using well-designed strategies. This integration allows the derivation of multiple lines of evidence, to foster strengthened confidence in safety and feasibility. These two decades have seen important progress in the tools and concepts supporting integration, as well as their application in numerous national safety cases.

Increasingly, disposal projects are approaching or have reached the licensing stage, which has led to a further broadening of the holistic approach, with increased involvement of a range of stakeholders in the safety case, as evidenced by the recent and ongoing collaborations with the FSC. In the future, the IGSC will interact with other communities and groups, such as expert communities involved in existing nuclear facilities, sharing and developing expertise in engineering, waste characterisation, operational safety and safety case updates during facility operations.

The IFNEC Reliable Nuclear Fuel Services Working Group held a workshop on Approaches to Financing a Multinational Repository – Challenges and Alternate Approaches in Paris, France on 11 December 2018 (Technical visit to Bure URL on 10 December).

Box 2: Examples of topics on which IGSC members have exchanged knowledge and experience and learnt from each other

Over two decades, the IGSC has produced three NEA FEP databases/lists on the basis of specific FEP lists from national programmes and international projects. The NEA databases have in turn been used in national projects for audit, scenario development and FEP list development.

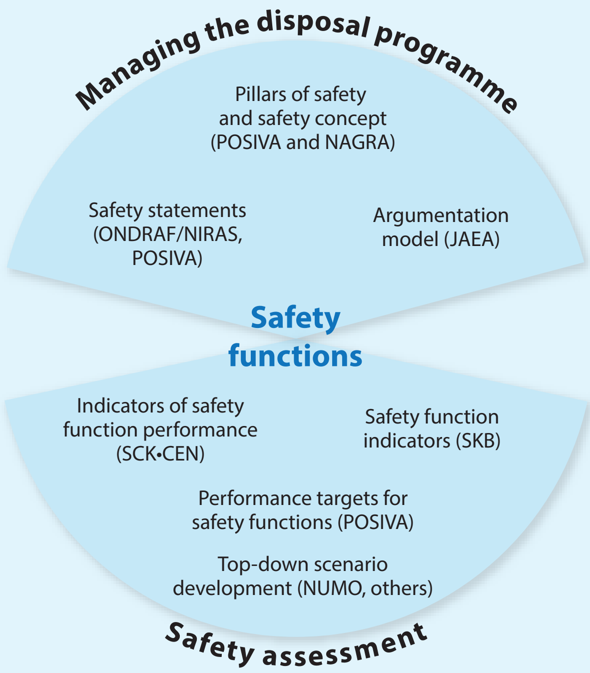


Below is a list of tools to support the development of system-specific understanding of processes and an integrated description of the initial state and subsequent evolution of a system as reported by the organisations in the MeSA project (adapted from Table 13.1 of NEA, 2012a).

Step/objective	Tool	Organisations
Developing system-specific understanding of processes and the interactions or influences between processes, including uncertainty.	System-specific FEP databases	All
	FEP interaction matrices	SKB, DBE/GRS/BGR, BFS, RWM, NUMO, JAEA, ENRESA
	Influence diagrams	NAGRA, NUMO, JAEA, ENRESA
	Process diagrams, influence tables	SKB
	Master directed diagram (MDD) (tree structure)	RWM
	Assessment model flowcharts (AMF)	SKB
Structuring description of initial state and subsequent evolution, including uncertainty.	Phenomenological analysis of the repository system (PARS)/"situations"	ANDRA
	Storyboards	ONDRAF/NIRAS, NUMO, NAGRA
	Timelines/subdivision of time frame	GRS, BFS, RWM, POSIVA, BGR, NRI
	Process reports	SKB
	Subdivision in space	BGR, RWM, POSIVA

Continued Box 2

Safety functions have been used in national programmes for different purposes in the safety case.



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Integration Group for the Safety Case (IGSC)

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The NEA Integration Group for the Safety Case (IGSC) has served as the most important and effective international platform for developing and integrating the science and engineering necessary to underpin geological disposal. Through its work, the IGSC has demonstrated that deep geological repositories are a safe and effective approach for the disposal of higher activity radioactive wastes and spent nuclear fuel. In its 20th anniversary year, the IGSC reflects on two decades of evolution of the safety case concept through nearly 20 key publications. The main topics addressed by the IGSC are safety assessment methodologies, constructing multiple lines of evidence, organisational and strategic issues, operational and feasibility aspects, regulatory requirements and stakeholder interactions. Together, these topics build confidence in the safety case.

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