Developing a joint safety case review framework: achievements within SITEX-II EC project

F. Bernier¹, J-P. Wouters¹, K. Mannaerts¹, M. Surkova¹, D. Pellegrini², M. Rocher², M. Tichauer², J. Miksova³, L. Nachmilner³, J. Mecke⁴, C. Castel⁵, P. Jansser⁶, N. Zeleznik⁷, Grupa Jacques⁸, G. Hériard-Dubreuil⁹, D. Ilett¹⁰, M. Sentis¹¹

¹ FANC, ² IRSN, ³ CV REZ, ⁴ CNSC, ⁵ ASN, ⁶ Bel V, ⁷ EIMV, ⁸ NRG, ⁹ MUTADIS, ¹⁰ EA, ¹¹ ENSI

Summary

The EC H2020 project SITEX-II (Sustainable network for Independent Technical EXpertise of radioactive waste disposal - Interactions and Implementation) has resulted in the establishment of a network to ensure sustainable capacity for developing and coordinating joint and harmonised activities related to the independent technical expertise function regarding the safety of deep geological repository of radioactive waste.

In workpackage WP2, entitled "Developing a joint review framework", a common understanding among regulators, Technical Support Organisations (TSOs) and Civil Society (CS) has been developed, on the interpretation and proper implementation of selected high-level safety requirements issued by international entities (EC directives, IAEA, ICRP, WENRA,...). Also, a guidance on reviewing the safety case has been developed.

This paper presents the main achievements of this work.

Introduction

The fulfilment of the safety requirements by Waste Management Organisations (WMOs) requires not only a clear formulation of regulatory expectations but also technical guidance explaining how these requirements can be met in practice and how their fulfilment should be substantiated in the safety demonstration (i.e. safety case).

In the framework of the SITEX-II project, four topics were discussed to share national experiences and prospective views on the interpretation and implementation of these safety requirements and/or recommendations: "Optimisation of protection", "Waste Acceptance Criteria", "Operational issues in regards with post-closure safety" and "Site characterization programme".

Discussions on the abovementioned topics were reported in position papers (SITEX-II, 2018a) providing a reference to national regulatory bodies supporting the development of their own technical guides and to WMOs when developing the safety case during its various phases. The first part of this paper highlights the key points of these position papers.

In addition, a technical guide on the review of a safety case describing the role of the regulatory body in the pré-licensing and licensing processes has been developed (SITEX-II, 2018b). It identifies the needs for an efficient review management system, describes the competences and expertise the regulatory body has to acquire for independent review,
points out the importance of the safety strategy and proposes a tool to analyse a safety case through the different key phases of the development of a deep geological repository (DGR). The second part of this paper gives a summary of this guidance.

**Position papers**

**Position paper on optimisation of radiological protection applied to the development and implementation of a DGR**

There are various uses of the word “optimisation” throughout international and national guidance. For the regulatory body, it is important to focus on the optimisation of protection as defined by ICRP (ICRP – 122, Weiss & al., 2013). There is therefore a need to discuss on the practical implementation of this principle.

The position paper points out the following key messages:

- The optimisation of protection is a stepwise and iterative process. It consists of the identification of safety criteria or attributes to select the optimal protective options. These criteria/attributes must allow the assessment of the safety benefits of the considered options in terms of performance and robustness. Common understanding and commitment to these criteria/attributes should be reached between all concerned organisations prior to the start of the options comparison exercise. Both operational and long term protection have to be optimised from early phases and across the full lifecycle of the DGR, and balanced as a whole. Optimisation of protection does not mean “minimisation” of radiological impacts as the best option is not necessarily the one with the lowest dose. The “optimum” is considered to be reached once the benefit in protection has become small with regard to the resources needed.

- Prevailing circumstances, which refers notably to non-technical aspects (social issues, resources, political context ...) can bound the optimisation process to various extents, such as by limiting the available options and/or by defining additional conditions (e.g. retrievability). However, prevailing circumstances may not unacceptably impair safety.

- A decision “to go-back” (i.e. undoing previous decisions/choices) should be the result of optimisation in the sense that the benefits of going back should be balanced with the risks and costs of going back.

- The regulatory body shall verify that the optimisation principle and associated requirements have been adequately implemented throughout the whole DGR development.

- The importance of protection against non-radioactive pollutants has been recognised. A balance should exist between protective measures against potential radioactive and non-radioactive impacts.

**Position paper on Waste Acceptance Criteria for DGR**

The position paper intends to cover the lifecycle of Waste Acceptance Criteria (WAC), including preliminary WAC and updating of WAC. The preliminary WAC may contain only generic criteria, i.e. might not contain every requirements related to a specific repository facility. In all cases, it is important that the waste is conditioned in a passively safe way so that they are suitable for safe storage, while ensuring as far as possible that they are also suitable for disposal so as to reduce any future need for re-conditioning or repackaging the waste.

The position paper points out the following key messages:
• Defining WAC is a stepwise iterative process, it shall be duly planned and adequate milestones identified prior at the start.

• Roles and responsibilities have to be precisely defined throughout the continuous and iterative process of defining WAC, allowing for thorough understanding of the criteria and their use by each interested party.

• Preliminary WAC should be available as soon as possible including the intention for minimizing the need for any future intervention. Their updating should be done through an iterative process carried out in parallel and in conjunction with the development of DGR design and safety assessment.

• Elaboration of preliminary WAC needs to take into account all the interdependent steps identified or assumed for the management of these wastes until final disposal, and their interdependencies.

• While defining limits and parameter values, particular attention should be focussed on how to practically check compliance of waste with these limits and values.

• Traceability of departures from WAC and non-conformity treatment is important and the lessons learned are a key task within the objective of continuous quality and safety demonstration improvement.

• WAC may include different parameters, eventually with different limit values to be checked at different steps in the management process of the waste.

**Position paper on site characterisation program for DGR**

Site characterization essentially begins at the earliest stage of the investigation of a site and is expected to become more intensive as the siting process progresses through to confirmation of the site. Even after site confirmation, site characterization activities will be required in the initial licensing phases and are normally expected to continue during the site preparation, construction and operational phases, in order to contribute further to an adequate baseline for future monitoring and to contribute to the confirmation of assumptions made in earlier safety cases and to reduce any residual uncertainty in the safety case.

The position paper points out the following key messages:

• Site characterizing activities could take place over decades. The data gathered in the preliminary stages may be used to support the initial licence application, forming part of the safety case and future iterations. The (prospective) licensee should demonstrate that the results of siting and characterization activities are accurate, comprehensive, reproducible, traceable and verifiable. Margins of errors need to be clearly identified in order to treat uncertainties properly. Therefore, site characteristic activities should be carried out under a robust management system.

• Regular dialogue with the regulator from the very beginning of the process is strongly encouraged to ensure that regulatory expectations and licensing requirements are clearly understood.

• The site characterization program should establish baseline conditions for the site and environment in its undisturbed condition (used as a reference for the monitoring); support the understanding of the normal evolution; identify any events and processes associated with the site that might disturb the normal evolution of the DGR system and support the understanding of the effect on safety of any features, events and processes associated with the DGR.
Position paper on operational issues with regards to post closure safety

For the expertise function, a challenge in the evaluation of DGR safety cases is to assess operational safety with regard to long term safety and vice versa. The IAEA GEOSAF (International Project on Demonstrating the Safety of Geological Disposal) definition of “safety envelope” has been adopted i.e. “values below which, at the start of the post-closure phase, the safety functions must fall in order to deliver post-closure safety)” (GEOSAF, 2013).

The position paper points out the following key messages:

• The design of the engineered barriers and the architecture result from an optimization process (including radiation protection) that considers both operational and long term safety.

• The performance of engineered barriers must be targeted to fulfil the requirements of operational safety and the requirements of long term safety. However, the long term performance of engineered barriers will be affected by the way they will be built and managed during the operational phase.

• The operational aspects of the safety case should show the strategy the (prospective) licensee uses for the final closure of the DGR. This strategy is deeply correlated with reversibility and flexibility where required.

• The management of ageing of equipment and structures should consider both operational and long term safety. In particular, it is of utmost importance to identify the components that need to be maintained (or replaced) accounting for their role in the long term safety.

• Human factors should be integrated throughout the safety case, considering links between operational safety and long term safety. It is therefore important to ensure right from the design phase that the facility can provide compensating measures for such decline, i.e. a resilient design.

• Management system (including QA) and monitoring should allow checking continuously whether any event during operation may impact the facility and the safety envelope.

• The challenge for the regulatory body is to evaluate whether the safety case shows that (i) the safety envelope allows to reach the safety objective (ii) arguments and evidences allows to give confidence in reaching the safety envelope, (iii) a sound operational safety strategy has been developed taking into account peculiarities of the operational phase, such as concurrent activities (construction, nuclear operation, maintenance, partial closure...) and the specifics given by the context of a DGR (facility size, underground risks, monitoring...) and (iv) a capacity for resilience exists during the DGR lifespan, whatever the incidents, accidents, design and waste acceptance criteria changes that will occur before the DGR is finally closed.

Technical guide on the review of a safety case

Review through the different phases

As for all other nuclear facilities, the overall goal of the regulatory review of a safety case for a DGR for radioactive waste is to verify that the DGR will not cause unacceptable adverse impact on safety, human health and on the environment, now and in the future.

A project for DGR will extend over decades and will go through many development phases. The regulatory body has therefore a continuing role to review the Safety Case, which has to be regularly updated to remain an adequate basis for making decisions
throughout the DGR life cycle (Lemy and Bernier, 2013). The objective and the content of the regulatory review must be adapted to take into account the development phases of the DGR (i.e. conceptualization, siting, reference design, construction, operational, and post-closure). The regulatory decision-making process may involve more than one regulatory body and various stakeholders (public, interested parties ...).

At the end of each phase, the review of a safety case aims at determining whether it has been developed to an acceptable level in terms of quality and confidence in safety to move to the next phase of the project.

**Regulatory body involvement within the pre-licensing process**

During the pre-licensing phase, key elements for DGR developments providing the basis for all subsequent activities are established and important decisions are taken like the selection of the site. At the end of this phase, the applicant should be able to substantiate that the proposed design allows to reach the safety objective and that activities, covering all subsequent steps, may be carried out such that the safety is not compromised.

The pre-licensing phase is therefore crucial for the success of the disposal project. During this phase the regulatory body will develop and update the regulation and develop its own competences. It will also exchange with the prospective licensee to make clear the regulatory body’s expectations and to discuss the methodologies used to develop the safety case.

Early interactions with the regulatory body, prior to a formal licence being submitted, are essential. The regulatory body provides guidance and recommendation to the prospective licensee. If not already formalized, the process can be organized within the framework of a “service agreement” between the regulatory body and the prospective licensee. Much of this will be concerned with the objectives and targets to be reached at each step enabling to go forward the next step, the safety strategy, the management system, the methodological approaches to assess operational and post-closure safety and the content of the safety case. At some key decision steps, the regulatory body may be expected to make a preliminary review of pre-licensing documentation (e.g. R&D programme, preliminary assessment, safety case supporting the selection of the site ...) (WENRA, 2014).

The regulatory body may also have a more formal role in, for example, providing input to legislation (EPG report, 2016). The regulatory body may also be called upon to advise government and interact with other stakeholders.

The pre-licensing process should be understood by the parties concerned (IAEA SSG12, 2010) and milestones should be defined where they can judge the results achieved. The roles and responsibilities of each stakeholder have to be clear. The framework adopted should foster an open, transparent, fair and broadly participatory process (NEA, 2011) giving the public and civil society opportunities for early participation. This may include explaining the role of the regulator and future licensing process to potential host communities and members of the public.

However, the regulatory body should be very careful to maintain regulatory independence by not contributing to developing the concept and the design of the facility, and by making sure that the responsibility for the project is seen to lie with the prospective licensee (WENRA, 2014). With this regard, the regulator will need to establish and develop its resources and identify the need for its own independent research and development to be conducted in support of its expertise and ensure that the results are available in due time.

**Regulatory body involvement within the licensing process**

The licensing process includes generally construction, operational, and post-closure phases. At every successive licensing stage, the regulatory body will assure itself that the
licensee is achieving an adequate level of quality on safety-related aspects of the project and its implementation. The regulatory body will thoroughly review each aspect in the light of up-to-date information in order to decide whether to allow the licensee to move to the next step. All the information necessary to demonstrate the long-term safety fully and confidently may not be complete until a decision to close the facility is sought and it is subsequently confirmed that closure of the facility has been implemented appropriately.

**Regulatory body management system and expertise capacity building**

In order to fulfil its statutory obligations and to achieve and maintain, at all time, a high level of quality performance in regulating the safety of nuclear facilities and activities, the regulatory body has to develop, establish, implement, continuously evaluate and improve an effective and efficient integrated management system.

In order to ensure the quality and success of a regulatory review, the regulatory body should have personnel with expertise and hands-on experience in safety assessment of radioactive waste facilities and should have either in house expertise or should have access to specialists in all the necessary disciplines involved in such assessment. Independent R&D programme is important as well in order to gain the required expertise.

**Regulatory review of the Safety Strategy**

DGR are complex projects over long time scale. Sound management will require adopting a strategy for safety establishing the principles and approaches guiding how the safety objective will be achieved. The safety strategy is crucial for the whole development of a DGR for radioactive waste and its implementation. Safety strategy forms the foundation of the safety cases and serves as the basis for argumentation and justification. Therefore, it is very important that the regulatory body reviews the safety strategy from the very beginning of the project and that an ongoing dialogue on this issue is maintained. It will also be important to keep other stakeholders (including civil society) aware about the safety strategy and listen to their views. A sound safety strategy is indeed crucial to maintaining a broad consensus among involved stakeholders (EFG, 2016).

**Review grids**

Review grids have been developed (SIEX-II, 2018b) as a tool for guiding the review of the safety case through the different development/implementation phases. The review grids consist of a check-list of items to be reviewed in order to assist the reviewer. It is not a mandatory list since the database would have to be adapted for each country taking into account specificities of the national regulatory context. The review grid is an evolving tool.

Figure 1 presents an extraction of the review grid on the example of the monitoring. The review grid is divided into sections. Each relates to one specific component of the safety case as defined in the IAEA SSG-23 publication (IAEA SSG23, 2012): Safety Case context, Safety Strategy, System Description, Safety Assessment, Integration of Safety Arguments and Management System. In addition, the review grid includes specific sections related to Monitoring and Periodic Safety Review.
### Key Aspects of the SC (review & content)

<table>
<thead>
<tr>
<th>Monitoring</th>
<th>DI-049</th>
<th>Results of monitoring both within the disposal facility and in its environment</th>
<th>Verification that:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>• the regulatory requirements and license conditions are fulfilled;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• the disposal facility and system behaves and evolves as expected in the safety case;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• deviations from the expected behavior of the disposal are identified;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• key assumptions and models are confirmed.</td>
</tr>
</tbody>
</table>

**Figure 1: Review grids example**

Within each section, columns are describing the expected safety case content, the related WENRA SRLs (WENRA, 2014) and the verifications to be done by the regulatory body as a support of its review.

Other columns correspond to the pre-licensing and licensing phases. For each line the review grid specifies the status of the content of the safety case at these different phases: preliminary status asked for the related phase (P); first formal status asked for the related phase (F); Updates asked (U). An additional column “Generic” is marked with a cross (X) when a status can be given for all phases.

**Conclusion**

Four topics were selected within work package WP2 of the SITEX-II project to share national experiences and prospective views on the interpretation and implementation of these safety requirements and/or recommendations. The outcome of the discussions was reported in position papers providing a reference to national regulatory bodies and to WMOs.

The purpose of the WP2 was also to develop a guide on reviewing the safety case. The main objective of this workpackage aimed at completing the exchange of feedback on the regulatory review process throughout the development of the safety cases. Moreover, the review grids have been developed as an efficient tool to support the safety case review and will continue to be developed within the existing SITEX network.

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References

SITEX-II (2018a), “D2.1 - WP2.1 - Developing a joint review framework - Developing a common understanding on the interpretation and implementation of safety requirements”, [sitexproject.eu/index_2.html#deliverables](http://sitexproject.eu/index_2.html#deliverables)


