The 21st Meeting of the NEA Integration Group for the Safety Case (IGSC)
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Summary of the Topical Session on

"Considerations for Updating a Safety Case"

Chair: Tom Peake, US Environmental Protection Agency, United States
Chair: Doug Ilett, Environment Agency, United Kingdom
Rapporteur: Julie Brown, Canadian Nuclear Safety Commission, Canada

8.1 Introduction (Tom Peake, Doug Ilett)

Speakers in this session cover a broad range of safety case types; the object of this session is to explore why and when a safety case gets updated, with perspective from implementers and regulators. The question set for the Operator/Regulator duet portion of the session (talks 8.3, 8.4, 8.6, 8.7) is annex 1.

8.2 IAEA, GEOSAF III – "updating the safety case"

Andrey Guskov, IAEA

The initial goal of GEOSAF was to compare and harmonize approaches for geological disposal safety case development. GEOSAF II produced the initial illustration of the concept, consisting of a safety envelope, design target, and as built state, and focused on a pilot study for an operational facility. GEOSAF III looked at issues in mature safety cases, and continued with operational safety. A specific safety function must fall within the safety envelope, the design target lies within the safety envelope, the actual as built state needs to be demonstrated to lie within the design target; these concepts can be used to decide when and whether a safety case should be revised.

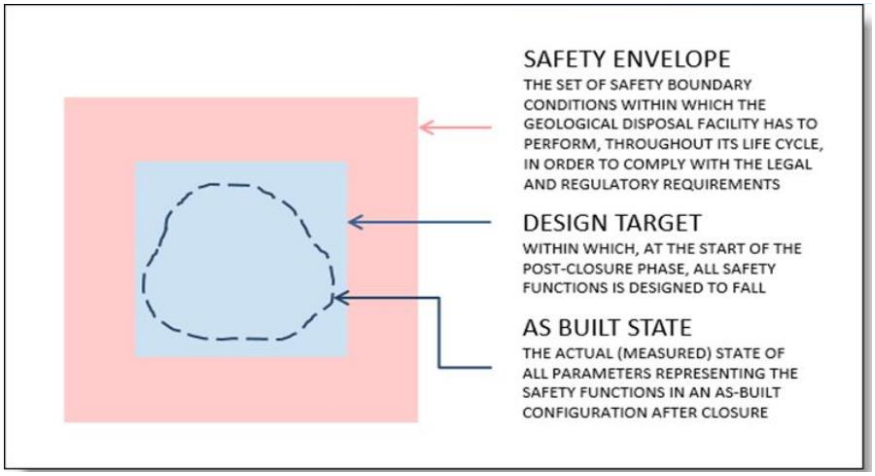

Figure 1: GEOSAF III approach. The state of the geological disposal facility is considered as a set of parameters that represent their safety functions. Those parameters include spatial configuration, physico-chemical, biological conditions…

By definition, the design target will evolve with the safety case, through licensed phases. The Finnish and Swedish safety cases were used as examples to develop systematic illustrations of design target, and how the safety envelope is set. Defining boundary conditions for a DGR may be, in part, qualitative.

Questions explored the relationship between design target and regulatory requirements – are they the same thing, can the relationship be defined?

Regulator – Operator duet 1: Canada, in site selection stage for a national DGR (question set in Annex1)

8.3 NWMO's considerations for updating a safety case

Mihaela Ion (NWMO, Canada)

An update on the NWMO's siting program provided context for the presentation.

- Currently, 5 communities remain in the site selection process, 3 in northern Ontario (crystalline) and 2 in southern Ontario (sedimentary).
- Drilling activities are underway in the Ignace area (northern Ontario).

The safety case basis

- Defined as the key safety attributes relevant for long-term DGR safety – geology, waste acceptance criteria, design elements etc.
- Iterative safety case approach being used based on a hypothetical site (called case studies)
- Approach is consistent with international guidance

A full safety case has not been developed yet. Instead, there have been updates to "case studies" to develop conceptual (partial) safety cases based on hypothetical sites. A planned safety case to be developed in 2020 will incorporate information from the boreholes being investigated in Ignace, followed by another in 2021/2022. The next one would then be developed for the licence application.

Case Studies (CS)		Issued
1CS, 2CS	Supported an Environmental Assessment	1990-1992
3CS	Updated repository design and site assumptions, method development	2004
4CS, 5CS	Used for discussion with CNSC (Canadian Regulator) on methodology	2012, 2013
6CS	First with current container concept	2017
7CS	First with multi-arm repository layout	2018

Figure 2: An overview of the seven case studies (CS) done in Canada to date.

NWMO is currently updating the R & D plan. This will also inform the plan for updating the safety case.

8.4 Canadian Considerations for the Regulatory Review of the Safety Case

Julie Brown (CNSC, Canada)

There are 2 current initiatives in Canada. One is the NWMO's project, the focus of presentation 8.3; currently in the pre-licensing stage as no site has been selected. Although site selection is not regulated in Canada, early regulatory involvement is necessary as best practice. A licence application for site preparation is currently expected in 2024.

Information on regulatory perspective for updating a safety case comes from a different DGR project that has been through regulatory review, Ontario Power Generation (OPG) DGR for LILW.

- Context for updates to the safety case are informed by both the CNSC's regulatory framework, and the review of OPG DGR's licence application.

Four types of activities in the regulatory review include pre-licensing review of the proponent's early safety cases:

- Participation in international projects, preparation of regulatory documents to clarify regulatory expectations, and regulatory research.
- The regulatory review of the OPG-DGR project began in 2008 and culminated in 2014, and included the longest such public hearings in Canadian history. The review panel recommended the government to approve the project in 2015; the government has not yet made a decision.

With respect to repository development and related regulatory decisions – once licensed, compliance and verification activities would be ongoing through various licensing phases. This includes the ongoing evaluation of the licensee's safety case, commensurate with the activities being undertaken and the stage of the DGR, throughout the facility lifecycle.

8.5 Canadian duet – discussion

- Updates to the case studies (particularly the 6th and 7th) and whether there is any need to adapt a crystalline DGR concept with a new design?
    - The concept remains the same, but the layout would change. E.g. a multi-arm geometry for sedimentary host rock. There are also some minor changes to the methodology.
- How do you feel about statements in the regulator's presentation (8.4) about expectations for updating the regulator about (for example) changes to the safety case?
    - This is an expectation that would be met, especially as it is in line with how NPPs are regulated [in Canada]
- What do you mean the safety case was not "full"?
    - The case studies are used as a learning tool. They are not full because they did not use geological information relevant to a real site (using a hypothetical site). Regional information was used to constrain the geological information used, together with a conceptual design. Updates to the conceptual design are considered in updated case studies.
- What kind of review does the regulator do on the case studies?

    - In the pre-licensing stage, decisions to update the safety case are made by NWMO – the regulator would carry out a formal review upon request. Once licensed, updates would be based on regulatory requirements.
    - Safety case updates in licensing would be similar to what exists for the current nuclear industry.
- Do you address uncertainty and design targets (any link to GEOSAF III)
    - For some projects, far field and the link to the biosphere is not considered as part of the disposal facility; facility and system may not be synonymous
- What is the CNSC's hearing process - how does the commission work, what was the process for the OPG DGR?
    - The CNSC is headed by a Commission that functions a quasi-judicial tribunal. CNSC staff carry out their work separate from the Commission members, who make decisions based on evidence that is brought before them in a public forum (hearing), which can take place in the relevant community. The OPG DGR project was referred to a panel of experts, who took on the role of the commission.

Regulator – Operator duet II: Sweden, advanced national DGR program

8.6 Swedish Operator's considerations for updating a safety case

Allan Hedin (SKB, Sweden)

Allan Hedin provided an overview of the safety assessments of the KBS-3 concept that have been carried out to date. Note – in Sweden, safety assessments are close to the NEA definition of a safety case.

In the 1970 and early 80s, the KBS-1, KBS-2, and KBS-3 reports were used to establish the KBS-3 approach. Multiple safety assessments were carried out using this approach in the 1990s. The first main assessment took place in 2006 (SR-Can) using preliminary site data from two on-going site investigations and applying a new methodology based on safety functions. This was the preparatory step in supporting a licence application for the final repository in Sweden. The 2011 update (SR-Site) was based on the Forsmark site, using data from completed surface-based investigations. The PSAR is the basis for the (ongoing) construction licence application – planned for 2021.

Regulatory/legislative requirements drove many of the updates at particular points in time; SKB included new information for those required updates.

8.7 Swedish Regulator's considerations for updating a safety case

Bo Stromberg (SSM, Sweden)

Bo Stromberg presented a discussion of the safety case/safety assessment of both the planned spent fuel repository and the existing SFR facilities–material presented focused on long-term safety.

In Sweden the safety report should be updated continuously (this applies for any nuclear facility). By law, a safety case must be assessed every 10 years.

Experience is that in general, care is taken not to be prescriptive in the pre-licensing stage – with the regulator stating only observations and recommendations. During the licensing phase, regulators request clarifications and additional information. Post-licensing, the regulator must be able to determine that the facility fulfills all the regulatory requirements.

Reviewers of the safety case need a consistent approach, and a method to evaluate whether review comments have been incorporated. There is a tendency to focus reviews in subject matter areas, with a reliance on external experts – this leads to a risk of losing contact [with that expertise] if in-house knowledge is not built.

Stakeholders have a strong impact on the safety case review. For example: one research group criticized how corrosion issues were handled, and the Swedish court ruled that canister issue uncertainties that they identified were not accounted for.

8.8 Swedish duet – discussion

- With respect to implementer-regulator interaction in the pre-licensing phase, what is the basis for this platform?
    - The regulator has a formal role in the review of SKB's RD and D program
    - Regulator has formal mandate on site evaluation, to interact closely with SKB and follow site investigation progress
- Do safety case updates prompt updates to regulatory requirements?
    - This is the practice internally, but it is not formal (or laid out). The goal is not to become too prescriptive (in contrast with e.g. the U.S.)
    - Updates are done based on the outcomes of review
- With respect to the post-licensing stage, the implementer must manage aspects of the safety case (including the overall strategy of the safety case). What is the implementer required to do with respect to the safety case, post-licensing?
    - Post-licensing means that the license has been granted – not after licensing has concluded. Refers to the operational period.
- Timing of updates to the safety case could vary, not only based on legislated requirements (at least every 10 years). An update could also be prompted for other reasons, if new activities are proposed, or if something detrimental was discovered. For example, considering the speed of repository excavation, you would be acquiring new data very quickly during that time period. This accumulation of new data might prompt an update.
- In general, having regulatory requirements laid out for the safety case is helpful when interacting with the public. It is useful to point to places in the report describing how requirements are met, as a way to help communicating safety related issues. This also helps the regulator to explain on what review findings are based.

8.9 Considerations for updating a safety case in France

Sylvie Voinis (Andra, France)

Focus on HLW and ILW reference inventory: Spent fuel reprocessing waste includes vitrified waste and minor actinides. Forecasted volume of waste consists of ~75,000 m^3 ILW-LL (60% already produced) and 10,000 m^3 for HLW (40% of which is already produced).

The host geology chosen for the disposal facility is a well-studied clay formation within the Paris Basin. The clay formation possesses favourable properties for waste containment that fit with regulatory criteria.

The Cigéo project has been underway since 1991, and there have been several safety cases developed and subject to review; the most recent safety case from 2016-2017 was subject to a national (regulatory) review and international review by IAEA. The next safety case planned for 2020 will support the licence application.

Milestones and supporting safety cases:

- 2001 conceptualisation and site investigations; 2005 feasibility assessment; 2009 Intermediate safety report and site selection; 2016 Formal safety options towards licensing – subject to national and international (IAEA) review; 2020 safety case to support the construction licence application
- The first formal safety case completed in 2006 was also subject to international review to see whether it was in line with international standards.
- 2015 Cigéo "Safety Options File": Under French regulations, submission of "safety options" is possible to help operators plan for the construction licence application and related regulatory reviews. Key findings from the national review relate to operational safety.

Discussion

Differences between NEA and IAEA international peer reviews

- 2005 – NEA peer review requested by Andra as a way to confirm their practices in comparison with other organisations (benchmarking, experts came from other national waste management organisations)
- 2016 – formal request by ASN (French regulator) to IAEA, all experts from regulatory bodies, to ensure alignment with international practices and standards
- Both useful, for different goals.

The timing of the review of the 2016 dossier was based on:

- Meeting a regulatory recommendation – regulation states that [the safety dossier] should be sent in advance for feedback.
- The safety options dossier is almost a full safety case report; a way to get regulatory comments early, so that they are not all received at once.

Use of design requirements / design basis in safety case updates

- Formal requirements associated to safety for choice of design (the safety function); the design must fit with this requirement; sometimes changes to the technical solution are suggested
- Changes and modification to the design are evaluated [by committee] to ensure that changes still meet requirements

8.10 Swiss operator's considerations for updating the safety case in view of the upcoming general licence application

Thomas Kämpfer (Nagra, Switzerland)

Currently, Nagra is updating the safety case in view of the upcoming general licence application. The Swiss disposal programme has a legal framework that includes a sectoral plan and guidelines. The sectoral plan is used as a tool to advance projects of a national interest (i.e. are under federal control).

The site selection process using the sectoral plan has 3 stages; currently in stage 3, there are 3 remaining sites under consideration for locating HLW and ILW sites.

Frequency of safety case updates are set by regulations. There will be construction, operation, and closure licensing stages, each one requiring a safety case. The next one is planned for 2024.

Main challenges and key factors identified for success: knowledge and information management, and consistency across all arguments, and coherence over time – particularly with updates to the safety case, which is sensitive to its multidisciplinary nature and multiple team members over large time spans.

Discussion

- For updates to the safety case, key aspects of the structure are envisioned to be broadly the same; the system design will still use geology as the main barrier and other aspects (safety assessment modelling) will require adjustment.
- Under regulations, updates to the safety case are required every 10 years, similar to what is expected from NPPs; an updated safety case is also required at closure.
- With respect to the argumentation structure including operational and engineering requirements, the incorporation of management system requirements is a challenge. There is a need to show the impact of operational activities on long-term safety.

8.11 Digital safety case management – moving towards a 'live' safety case

Alexander Carter (RWM, UK)

What does digital mean: authored electronically, content is structured with its content marked semantically, and safety case is managed electronically. For a fully digital safety case, there is no need for paper records.

Metadata can be customised, should be added at the time of creation, and is an important component for managing information for building confidence in a safety case. In the future, metadata may remove the need for a safety case update.

Digital safety cases can provide a tool to aid decision making during updates, increasing efficiency and help to move toward the ultimate goal of a live safety case.

Discussion

- How will the process work, and how time consuming is it?
  - Commercial software is available, and people can be trained to use it and to tag (metadata) at the same time

    - An advantage of nuclear disposal projects – we do have time to build the system
- The technology has been established, and this is really a question of transferring it to a new industry
- Can be a timesaver for simple changes (e.g. changes to template and branding by organisations when they change)
- Lends itself well to dealing with multiple concepts (rock type, etc), helps with data traceability and linkages
- Challenges with entering metadata
    - Some tools can be customised
    - Some software can scan and look for words in unstructured data
- Can changes be tracked e.g. porosity value changes?
    - the idea is to be able to trace inputs – will help to understand, but won't do everything

8.12 Considerations for updating the safety case of LLWR Site (UK)

Andrew Baker (LLW Repository Ltd., UK)

This presentation is about the 'environmental safety case' (not about operational safety).

The LLW repository is located in northern England near the coast, vulnerable to coastal erosion.

There are formal requirements for when the safety case must be updated. The safety case is used for decision making – for example, revisions to waste acceptance criteria.

There is a required document structure (for the safety case) consisting of three tiers: arguments, evidence, detailed basis.

Safety case updates are continuous, and managed by a formal system – they may be comprehensive or partial. Comprehensive updates review all aspects, and included revised calculations for all pathways where some data and conceptual models are retained as appropriate. Comprehensive updates are required every ten years. Partial updates involve either new documentation of a particular pathway, new calculations assessing new data, or changes to waste acceptance (new waste stream).

Discussion

- Reviews of the safety case can be internal team reviews or external peer reviews
- Mechanisms for review depend on the type of review – from the Environment Agency reviewing the submission to reviews triggered by public interest. Liaising with public stakeholders indicates that the interest tends to be more focused on transportation, noise, intrusion issues (outwith the safety case)

8.13 The 2019 Safety Case for WIPP

George Basabilvazo (DOE, USA)

There is a defined regulatory process for updating the safety case, which is also compliance based. Planned changes are based on operator; prescribed changes are based on the regulator.

Containment requirements for WIPP are release limits set by the EPA.

Safety case updates (recertification) involve: updates to planned repository changes; parameter updates – drilling intrusion probability, etc.; refinements to performance assessment implementations – e.g. hardware and computational tools updates.

Discussion

- Changes in the safety case include (recent) closing of panels and also consider the increased drilling rate, have resulted in a less favourable safety case. Yet, the facility is still orders of magnitude below release limits (compliant with regulations).
- Local community is accepting of the facility, but there are challenges from other outside groups.

8.14 Considerations for updating the safety case in Germany

Jurgen Wollrath (BGE Germany) and Ulrich Noseck (GRS Germany)

Presentation on two facilities.

ERAM repository for LLW:

- Started disposal in 1971, 1990 transformation of license into (West) German law.
- First real safety case in 2006 due to regulatory requirements for the closure of the facility. Updated in 2009 to address comments from the licensing authority. Another update necessary to address recent changes in licensing boundary conditions. Additionally, the 2009 update shows there will need to be an adjustment of the closure concept and proof of the integrity of the salt as a barrier.

Konrad disposal facility / ÜSIKO

- Last safety assessment for Konrad published in 1986
- Konrad was licensed as a disposal facility for non-heat generating waste in 2002
- Currently, the Konrad facility is under construction
- R&D with respect to science and technology has developed and changes in German regulations have occurred since licensing. Therefore, the previous operator BfS decided to voluntarily perform a critical review. From 2017-2018 the ÜSIKO project phase 1 was performed, reviewing the safety requirements for the Konrad repository according to the state of the art (in science and technology). As a responsible organization the new operator BGE continues this process.

8.15 and 8.16 Discussion

Mihaela Ion (Nuclear Waste Management Organization, Canada) on why and how NWMO uses the generic safety case

- Generic safety case is appropriate for the pre-licensing phase, which is a learning period that includes how to assemble the safety case for a licence application

- In 2002 NWMO developed their first safety case in collaboration with Atomic Energy of Canada Limited (AECL), using the "skeleton" of the previous safety case but using updated codes and an updated conceptual design
    - There is no chosen site, so assumptions about the site were made
    - All post-closure safety assessments to date have been called case studies
- The final safety case will also include the pre-closure period, use real site data, and incorporate the detailed design elements
- A simplified version [of the generic safety case] evolves as the design evolves to include major elements e.g. vertical to horizontal canister emplacement, huge canisters ([e.g. Swedish design]) to the much smaller Canadian design, an adapted layout depending on the rock type (crystalline or sedimentary)
- With respect to the computer codes used, NWMO is using one that was developed for modelling the overall system of the case studies. NWMO is looking to replace this with a suite of modern and commercially available software codes that will be incorporated in the next version of the safety case.

Observations for Discussion: Tom Peake, Doug Ilett, Co-Chairs

- Safety cases and case studies, pre-licensing safety cases are driven by the programme and by regulation/legislation
- In some cases, regulations and legislation have changed requirements after safety cases have been developed requiring updates
- Periodic updates are required for some programmes; ranging from 5-10 years
- Main purpose for safety case updates
    - Demonstration of meeting requirements
    - Driven by operator
- Site characterisation data vs safety case in site selection
- Systematic and traceable methodology to safety case process – e.g., FEPs, data, analysis and documentation
    - In addition to defensibility, the appropriate documentation/tracking of information assists with long-term operational knowledge management
    - Knowledge management is an important issue for both the developer and regulator
- Need consistent picture of what is required for developing safety cases
    - Regulations can provide benchmarks and direction for developer activities
- Site data allows safety cases to move from generic to site specific analyses
    - Generic safety cases/calculations are important for preparing the real safety cases

Highlights from the Open Discussion

1. Comments on experience in using the safety case to make management decisions (Andrew Baker, UK)
    - Should updates to the safety case be ongoing or discrete (e.g. every 10 years)
        - E.g. updates can be used to evaluate new waste streams over the operational life of a facility

Needs for an update vary between the pre-licensing period and the various licensed phases (Capouet, Belgium)

- Important to make distinctions between the different phases of the programme

- We have several examples of pre-licensing safety cases
    - Once licensed – the needs for updates change. Construction and operation incorporate information such as changes to waste acceptance and protection of workers [*pre-closure safety] – must ensure operational safety and also long-term safety
    - During operation, if there are changes to the WAC, worker safety, etc the safety case would then need to be updated right away
    - The safety case constitutes a reference – should be a continuous process to ensure it remains up to date / valid
    - Concept of safety case as a contract between the operator and the regulator – changes need to be approved [by the regulator]

2. Discussing safety case with the public AND the use of site characterisation data vs safety case for site selection (Hedin, Sweden, and others)

Site characterisation data in safety case for the site selection decision:

- Site characterisation of two sites was done in two phases. Initially safety assessments were performed for both sites, and one site (Forsmark) was demonstrated to be preferable from a safety standpoint
- After site investigations were completed, a partial safety case for both sites was performed that showed the critical differences between sites; this formed part of the licence application showing the motivation in choosing Forsmark
- The final safety case was made only for Forsmark

Discussing the safety case with the public:

- Used in talking to stakeholders – by presenting the safety cases in open meetings; both municipalities have technical groups. Experts were able to ask more in-depth questions on behalf of communities. Municipalities were also able to invite opponent NGOs to meetings.
- The partial safety cases used in the decision making clearly laid out the advantages of one site over another, and helped to focus discussions

3. Changes to regulations
    - [Disposal projects span long timeframes and] elements in some requirements may change, as the state of the art evolves – what security is there for the implementer, after the licence is granted if the regulations change
        - Haven't yet reached the point after licensing – everyone is in the pre-licensing stage or at the licensing stage – assume that most will stick with the requirements at the time of licensing
        - For LLW sites in the US, there have been changes to the licensing conditions
    - In Sweden, SFR [shallow bedrock (50m) disposal for short lived LILW, isolation timeframe is 500 years] is licensed – but when the safety case is updated, it is updated using new regulations
        - When regulations are changed (SSM) there needs to be a full assessment of what this means for the implementer, it cannot be changed in an arbitrary fashion

    - The same methodology used for SFR updates can be applied to Forsmark (DGR), because both safety cases would need to meet the same regulations
- An example of how updates are made when there are new requirements can be taken from NPPs (Sweden); there is usually a 10-15 year period over which difficult to fulfill requirements are typically introduced
- Finland is similar – quite recently regulations have been updated, the regulator has asked the implementer how they plan to meet the new requirements, which is then assessed [by the regulator]

4. Live Safety Case (Finland)
    - Safety case used to demonstrate it meets requirements and handles uncertainties, but it should also be a decision making tool – and thus be a "live" document
        - As repository construction and preparations for the operational phase are ongoing, the safety case is acquiring and incorporating a wealth of data on the site and engineered barrier design and installation
        - During operation, is more of a decision making tool e.g. for design improvements. During operation, it is also a tool to verify that the disposal system is correctly understood.
    - Updates to the safety case are required at least every 15 years. An example from a LILW repository that is currently being reviewed [by the regulator] illustrates the evolution of the safety case structure and methodology over the years

5. Quality assurance management system
    - Finland has a data clearance process, which is a way of transferring the correct information between groups – aiming to prevent errors.
    - In Belgium, quality assurance measures for modelling, safety assessment, and other processes (such as construction) need very good quality assurance measures; the management system is a key chapter in the safety case
    - The safety case is complex, quality assurance should ensure that consistent data are used, in all disciplines; also very important for building confidence with stakeholders
    - In Canada in the pre-licensing period a regulatory review was undertaken of the NWMO's management system for data acquisition, including contractor procurement and quality assurance programmes that were in place; the data wasn't reviewed, just the processes – i.e. a management system review
    - Quality assurance was reviewed in Sweden – the regulator aimed to reproduce SKB's modelling results using other codes, which was mostly done by external experts; was done for radionuclide transport, hydrogeology, and some other areas. Differences in assessment results were the focus of discussions.
    - For LLWR (UK) the process of updating the safety case is controlled by procedures in the management system; ensures relevant safety case managers are consulted.

6. Monitoring / verification activities
    - Role of monitoring when transitioning from operational to post-closure safety;
        - Post-closure monitoring requirements tend to be country dependent
        - What is meant by "monitoring", vs surveillance (in IAEA guidance); there are debates in terms of how they play into each other, and how they can be used to

ensure changes in the operational phase do not affect assumptions made in the licence application phase, or post-closure safety

- Key factors / values / assumptions must be identified, and checked on a regular basis during construction/operation; to ensure actual outcomes are still within the envelope of what is being assumed in the safety case;
    - one way to assess this is by monitoring of selected parameters, there are also others e.g. inspections, non-destructive testing
- Monitoring or verification activities would be proposed to the regulator in some type of institutional control plan (Canada) – no current requirement

7. Evolution of the safety case – series of safety case updates
    - Typical safety case evolution from generic to site specific and further; (in Swizterland, there is an expectation that with time you get safer and safer)
        - Problem could arise, for example an operational event – at WIPP for example; when all of a sudden you are closer to your regulatory limit
    - Is there a way to keep the safety case and design open? – the safety case may have overly conservative assumptions, but there are other techniques / experiences to help with safety case robustness. Or rely on saying that using all the tools employed, releases remain orders of magnitude below regulatory limits
        - Example from LLWR (UK) – when new tests are invented, the idea of being below regulatory limits does not work for new things that were surprising (e.g. historic waste, when characterised, had an unexpectedly radiological component)
    - Belgium has developed a safety statement tree, giving the big picture of RD&D and how it is managed, which helps to derive the safety case argumentation; the argumentation tree is an efficient tool but requires a huge amount of work (connecting data, different software); a digital argumentation tree is really helpful for developing the safety case, for updates, and also for managers – training is necessary at all levels.
        - This is similar to the RWM (UK) Claims-Arguments-Evidence (CAE) structure, which lies at the heart of the developing digital safety case.
    - Note - with respect to the different safety cases during the pre-licensing period, discussed throughout the meeting. Safety cases at other intermediate phases need to be complete enough to be able to support decision-making
        - Between the regulator and the waste management organisations, must have clarity on what constitutes a ‘complete’ safety case (for different phases)
        - Involvement of all stakeholders, showing that their views are taken into account could help with both the review and potentially with acceptance.

Annex 1: Question set for the Operator/Regulator duet portion of the session (talks 8.3, 8.4, 8.6, 8.7)

	Operator's Questions	Regulator's Questions
1	To what frequency & depth do you review your safety case?	To what frequency & depth do you review the operator's safety case?
2	What reasons prompt safety case updates (or updates to component parts e.g. the PA)?	optional
3	Apart from regulators and legislation, who decides or influences these updates? (e.g. developers, independent reviewers, stakeholders, others?)	What is the minimum frequency & depth that the operator must update the safety case?
4	How do you balance the use of new (and sometimes less certain) data or techniques against relying on existing (and sometimes more certain) data? - How do updates to site investigation data influence changes to the PA and/or safety case? - How do updates to, or changes of, models & computer codes influence safety case updates? - What strategy is used to deal with safety case updates arising from the continuous evolution and input from R&D activities? Do you have any good examples of safety case updates that were needed because of changes over time, new data or requirements or expert reviews?	Optional
5	What are the important points to consider when deciding the timing and scale of updates (major, minor, no update)? - What makes a change "significant" or not? - When do several small changes or gradual changes make a "significant" change? - Who decides what is significant? (operator, regulators, stakeholders, others?) - Are calculations or particular processes used to determine what is "significant"?	
6	How do you make changes consistently and comprehensively throughout the safety case? How do you ensure that all effects of a change are addressed, even the unexpected?	What approaches do you take to ensure that updated parts of the safety case remain consistent with the rest of the safety case?
7	How are (long-term) knowledge and information management issues addressed? What were the problems and which approaches worked well (or less well)? - How is the safety case development or review kept coherent over time e.g., as approaches change? - How is safety case knowledge maintained (e.g., of PA) over time? - How is it ensured that information/knowledge used previously in development or review of safety cases is appropriately accounted for)	
8	What are the main difficulties/challenges for you before, during and after updating or reviewing the safety case?	
9	Have safety case updates called into question previous key statements over strategic choice, knowledge, safety or feasibility that were previously believed to be well supported? If so, how was this communicated? Can projects be made resilient to these type of potential changes?	
10	Is anyone else apart from the regulators involved in reviewing your updated safety case? Are there any specific aspects to be considered? - role of the public in the siting area - role of the general public - role of NGOs/activists	What is the role of the regulator in reviewing an updated safety case? What kind of verification analyses/calculations does the regulator (plan to) do when the implementer updates the safety case? To what extent does/should the regulator compare the new safety case with the old one?