Co-funded by the

European Commission

HORIZON 2020

Technical Expertise network SITEX-II Radioactive Waste Disposal

SITEX-II

(Contract Number: 662152)

Deliverable n°D2.2

Technical Guide on the Review of a Safety Case

Authored by: FANC, IRSN, CNSC, NRG, Bel V, CVREZ, LEI, MUTADIS, DECOM, ASN, REC, EA

Edited by: JP. Wouters (FANC) Date: [and signature] 22/05/2018

Checked by: F. Bernier (FANC) Work Package 2 Leader Date: [and signature] 22/05/2018

Approved by: D. Pellegrini, Coordinator Date: [and signature] 22/05/2018

Date of issue of this report: **31.01.2018**
Report number of pages: **74**

Start date of project: 01/06/2015 Duration: 30 Months

Project co-funded by the European Commission under the Euratom Research and Training Programme on Nuclear Energy within the Horizon 2020 Framework Programme		
Dissemination Level		
PU	Public	**X**
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the partners of the SITEX-II project	
CO	Confidential, only for partners of the SITEX-II project	

SITEX-II OUTLINES

Sustainable network for Independent Technical EXpertise of Radioactive Waste Disposal – Interactions and Implementation (SITEX-II)

The SITEX-II Project (Coordination and Support Action) was initiated in 2015 within the EC's Horizon 2020 programme to further develop the Sustainable Independent Expertise Function Network in the field of deep geological disposal safety. This Network is expected to ensure a sustainable capability for developing and coordinating, at the international level, joint and harmonized activities, related to the Expertise Function. SITEX-II brings together representatives from 18 organisations including regulatory authorities, technical support organisations, research organisations and specialists in risk governance and interaction with general public, including NGOs and an education institute. It is aimed at practical implementation of the activities defined by the former EURATOM FP7 SITEX project (2012–2013), using the interaction modes identified by that project. SITEX-II, coordinated by IRSN, is implemented through six Work Packages (WP).

WP1 - Programming R&D (lead by Bel V). The general objective of WP1 is to further define the Expertise Function's R&D programme necessary to ensure independent scientific and technical capabilities for reviewing a safety case for geological disposal. In this perspective, WP1 will develop a Strategic Research Agenda (SRA) and define the Terms of Reference (ToR) for its implementation accounting for the preparatory work to be carried out in the framework of the JOPRAD project for construction of a Joint Programming of research for geological disposal.

WP2 - Developing a joint review framework (lead by FANC). The key objective of WP2 is to further develop and document in position papers and technical guides a common understanding of the interpretation and proper implementation of safety requirements in the safety case for the six phases of facility development (conceptualization, siting, reference design, construction, operational, post-closure).

WP3 - Training and tutoring for reviewing the safety case (lead by LEI). WP3 aims to provide a practical demonstration of training services that may be provided by the foreseen SITEX network. A pilot training module will focus on the development of training modules at a generalist level, with emphasis on the technical review of the safety case, based on national experiences, practices and prospective views. The training modules will integrate the outcomes from WP1, WP2 and WP4 and support harmonisation of the technical review processes across Europe.

WP4 - Interactions with Civil Society (lead by Mutadis). WP4 is devoted to the elaboration of the conditions and means for developing interactions with Civil Society (CS) in the framework of the foreseen SITEX network, in view of transparency of the decision-making process. The future SITEX network is expected to support development of these interactions at different levels of governance and at different steps of the decision-making process. Three thematic tasks, namely R&D, safety culture/review and governance will be addressed by institutional experts and representatives of CS within SITEX-II as well as externally through workshops with other CS organisations.

WP5 - Integration and dissemination of project results (lead by CV REZ). The overall objective of WP5 is to produce a synthesis of the results achieved within all the WPs of SITEX-II together with an Action Plan that will set out the content and practical modalities of the future Expertise Function network. WP5 will also foster the interactions of SITEX-II with external entities and projects, as well as the dissemination of SITEX-II results so as to allow possible considerations from outside the project in the process of developing the future SITEX network.

WP6 - Management and coordination (lead by IRSN).

Contact: D. Pellegrini (IRSN), SITEX-II Coordinator
delphine.pellegrini@irsn.fr

Further details on the SITEX-II project and its outcomes are available at **www.sitexproject.eu**

ABSTRACT

As for all other nuclear facilities and activities, the overall goal of the regulatory review of a safety case for a geological disposal facility for radioactive waste is to confirm, with adequate confidence, that the geological disposal will not cause unacceptable adverse impact on safety, human health and on the environment, both now and in the future.

The objective and the content of the regulatory review must be adapted to take into account the development phase of the geological disposal facility (i.e. conceptualization, siting, reference, design, construction, operational, and post-closure) and the related licence applications.

The decision-making process must be based on graded, planned, coordinated, broad and cautious approaches in order to enhance the reliability of the whole decision-making process.

This guide describes the role of the regulatory body in the pre-licensing and in the licensing processes, identifies the needs for an efficient management system and for developing competences. It proposes also a tool for the regulatory body to analyze the safety cases through the different phases of the development of a geological disposal. The guide gives an example of table of content for the review report to be performed by the regulatory body.

CONTENT

1 Abbreviations

Table 1: List of abbreviations

AB	Assessment Basis
CS	Civil Society
DID	Defence in Depth
EBS	Engineered Barrier System
EC	European Commission
EPG	European Pilot Group
GD	Geological Disposal
GSR	General Safety Requirement
IAEA	International Atomic Energy Agency
ICRP	International Committee of Radiological Protection
IGD-TP	Implementing Geological Disposal of Radioactive Waste Technology Platform
ISAE	Integration of Safety Arguments & Evidence
MS	Management System
NEA	Nuclear Energy Agency
OLC	Operational Limits and Conditions
OPP	Operational Processes & Procedures
PSR	Periodic Safety Review
R&D	Research and Development
RRDM	Regulatory Review & Decision Making
SA	Safety Assessment
SC	Safety Case
SITEX	Sustainable Network of Independent Technical EXpertise of Radioactive Waste Disposal
SRL	Safety Reference Level
SS	Safety Strategy
SSC	Structures, systems and components
SSG	Specific Safety Guide
SSR	Specific Safety Requirement
THMC	Thermal – Hydraulic – Mechanical - Chemical (process)
TSO	Technical Safety Organisation
WAC	Waste acceptance criteria
WENRA	Western European Nuclear Regulators Association
WMO	Waste Management Organisation
WP	Work Package

2 Foreword

The aim of the SITEX-I project, launched in 2012, was to set the necessary conditions and to identify opportunities to build a sustainable network which program of work would contribute to the harmonization of technical review process among the participating countries besides other aims [ref.19, 21].

The establishment of synthesis grids for guiding the review of the safety case at key phases (see description in **appendix 1**) was found as a future work for the SITEX-II project. As a feasibility study, SITEX-I participants to WP4.1 developed an example of grid for the site investigation and selection phase.

The task 2.2 (Developing guidance on reviewing the safety case) of the SITEX-II project is performed in the continuity of the WP4.1 [ref.21] of the SITEX-I project and is aimed at completing the exchange of feedback on the regulatory review process throughout the six key phases of the development of the safety case with specific emphasis on practices to verify that safety requirements are effectively and properly implemented. The task also includes the establishment of analysis grids for guiding the review of the safety case through the key phases. Opportunities were also given to the group to involve the Civil Society (interaction with WP4.2 SITEX-II) in the discussions, in order to collect their specific needs or comments at the different steps of the review process.

3 Contributors

- **Partners**: FANC, IRSN, CNSC, NRG, Bel V, CVREZ, LEI, MUTADIS, DECOM, ASN, REC
- **Associated member**: EA

4 Introduction

As for all other nuclear facilities and activities, the overall goal of the regulatory review of a safety case for a geological disposal facility for radioactive waste is to confirm, with adequate confidence, that the geological disposal will not cause unacceptable adverse impact on safety, human health and on the environment, both now and in the future (including far and very far future).

A geological disposal project for radioactive waste will extend over decades and will go through many development phases. Therefore, the objective and the content of the regulatory review must be adapted to take into account the development phase of the geological disposal facility (i.e. conceptualization, siting, reference, design, construction, operational, and post-closure) and the related licence applications. The regulatory decision-making process may involve more than one regulatory body and involve several stakeholders (public, interested parties …).

This implies that the decision-making process must be based on graded (adapted to the depth and extent of the review process), planned, coordinated, broad and cautious approaches in order to enhance the reliability of the whole decision-making process.

The review of a safety case aims to determine 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. With this objective in mind, the regulatory body has to verify that the safety case complies with the "regulatory framework". The regulatory body has to evaluate whether the safety case provides an adequate and appropriate basis to demonstrate that the proposed facility will be operated safely and provides reasonable assurance of an adequate level of safety in the period after closure. The regulatory body has also to verify that relevant measures for mitigating uncertainties have been identified and addressed, and that adequate follow-up plans for their implementation have been developed. More specifically, the review of a safety case aims at assessing the following aspects:

- the capability of the implementer
  - to properly justify the methods used to obtain data and the confidence in the data;
  - to explain the processes that govern the performance of the Structures, Systems and Components and their ability to fulfil their safety functions;
  - to assess the long-term evolution of the disposal system, taking into account uncertainties;

- the due consideration of hazards that could impair safe operation of the repository, considering the influence of potential accidents during the operational phase on the long term safety.

- the identification of any unresolved issues and plans for resolving these issues.

The management of such a review should be treated as a project in itself and should rest on an efficient management system [ref.12]. The pre-review phase is crucial for the success of the project. During this phase the regulatory body will develop and update the regulation in accordance of the national legal framework and taking into account the last international standards, it will develop its own competences, it will exchange with the prospective licensee to making clear the regulatory body expectations and to discuss the methodologies used to develop the safety case.

This technical guide on the review of a safety case describes the role of the regulatory body in the pre-licensing and licensing processes. It identifies the needs for an efficient management system, develops the competences and expertises the regulatory body has to acquire for independent review, describes how the safety strategy has to be managed and proposes a tool to analyze a safety case through the different key phases (see appendix 1) of the development of a geological disposal. The guide gives also an example of table of content for the review report to be performed by the regulatory body.

5 Regulatory body involvement within the pre-licensing process

Early interactions with the regulatory body, prior to a formal licence being submitted, can provide valuable input in process to the prospective licence applicant, and other stakeholders such as government and the public. This is important as the prospective licensee is gathering information that may be used in the safety case as part of the future licence application and information may be used in future licensing stages.

During this pre-licensing phase (see Figure 1 on page 13), interactions with the regulatory body may be organised to ensure that regulatory expectations are understood. 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 allow to reach the safety objective and that activities, covering all subsequent steps, may be carried out such that the safety is not compromised.

Defining Role and Responsibilities

With regard more specifically to the role of the regulatory body during this phase, it 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 even 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 …) [ref.17].

Other stakeholders

The regulatory body may also have a more formal role in, for example, providing input to legislation [ref.16]. The regulatory body may also be called upon to advise government and interact with other stakeholders.

It is acknowledged that a stepwise process with discrete and evaluated steps facilitates the traceability of decisions, accommodates stakeholder needs and promotes public and political

confidence in the safety of long-term waste management arrangements [ref.23]. As such, the pre-licensing process should be understood by the parties concerned [ref.24] and milestones should be defined where they can judge the results achieved. In this respect, each step has to be clearly defined as well as the objectives and targets to be reached enabling to go forward the next step. The roles and responsibilities of each stakeholder have to be clear. The framework adopted should foster an open, transparent, fair and broadly participatory process [ref.23] 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.

Maintaining Independency

However, during this pre-licensing process, 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 [ref.17]. With this regard, the regulator should define and implement from the beginning of the project an appropriate organization to ensure allocation of sufficient resources for the review of the first stages of licensing, including the safety case, at all the stages of the development and implementation of the repository. In particular, 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. R&D work is essential for regulators as it allows maintaining and improving their scientific and technical skills, contributes to their independence and helps to build public confidence in the regulatory system [ref.16].

Define Role of Future licensee

The steps should follow a logical order. We should for example avoid going too far in the detailed design before making a decision on the choice of the host rock and of a site. Any decision “to go-back”, i.e. reconsidering previous decisions/choices, should be the result of optimisation in the sense that the benefits to go back should be balanced with harm (efforts to go-back, dose detriment…).

Roadmap for Prospective Licensee

From the earliest stages, the prospective licensee should therefore develop roadmaps with clear milestones, considering for each key decision step, the remaining uncertainties to be reduced and to what extent the performance, the robustness and the feasibility of the geological disposal have to be confirmed. The roadmaps have to be a plan that matches the objectives to be reached for each key decision step. The identified actions have to provide good prospects of achieving a disposal system meeting the safety objective. Quality assurance programmes and a properly

structured organization are needed to ensure appropriateness of these actions and of their deployment.

At each step, the regulatory body has to review the results achieved by the prospective licensee and to stipulate the conditions under which the next step may be allowed. It needs to ensure that important decisions are not made prematurely by verifying that submitted documents (e.g. safety case) provide an adequate basis for the decision they are supporting. The regulatory body review aims to determine whether the supporting documents have been developed to an acceptable level in terms of quality and confidence in safety to move to the next step of the project. It includes the verification that the developments comply with the "regulatory framework". More specifically, the regulatory body evaluates whether the supporting documents provide an adequate and appropriate basis to substantiate that the proposed safety concept and facility design provide reasonable assurance of an adequate level of safety in the period after closure. It has to verify that relevant measures for mitigating uncertainties have been identified and addressed, and that adequate follow-up plans for their implementation have been developed. It has also to verify that the prospective licensee argumentation and assessment basis rest on the findings of a sound R&D programme. For example, regulators may review prospective licensees R&D program on a frequent basis prior to submission of a licence (e.g. in Finland and Sweden, there is a requirement for waste implementers to submit their R&D program to the regulator every 3 years).

6 Regulatory body involvement within the licensing process

It is well recognised that a radioactive waste disposal programme comes down to a stepwise decision-making process. In this context, regulatory bodies are responsible for the establishment of safety requirements and conditions for the development, operation and closure of disposal facilities.

The safety cases are supporting the decisions. The safety cases are expected to provide assurance that the **safety objective** can be reached. This means [ref.1]:

a) For the operational period, that workers, members of the public and the environment will be adequately protected against radiological and non-radiological hazards, under normal and accident situations.

b) For the period after closure, that members of the public and the environment will be adequately protected against radiological and non-radiological hazards, under conditions of expected and less likely modes of evolution of the disposal system.

c) Compliance with the safety requirements specified in the national legal and regulatory framework needs to be substantiated as well.

Figure 1 shows the typical phases of a disposal programme as considered within the SITEX project: conceptualization, siting, reference design, construction, operational, and post-closure. These phases provide a broad description of the progressive development of a repository and of its safety case. The exact definition of the phases and decision-making points that cover the development and implementation of a geological disposal facility can differ among national programmes [ref.27].

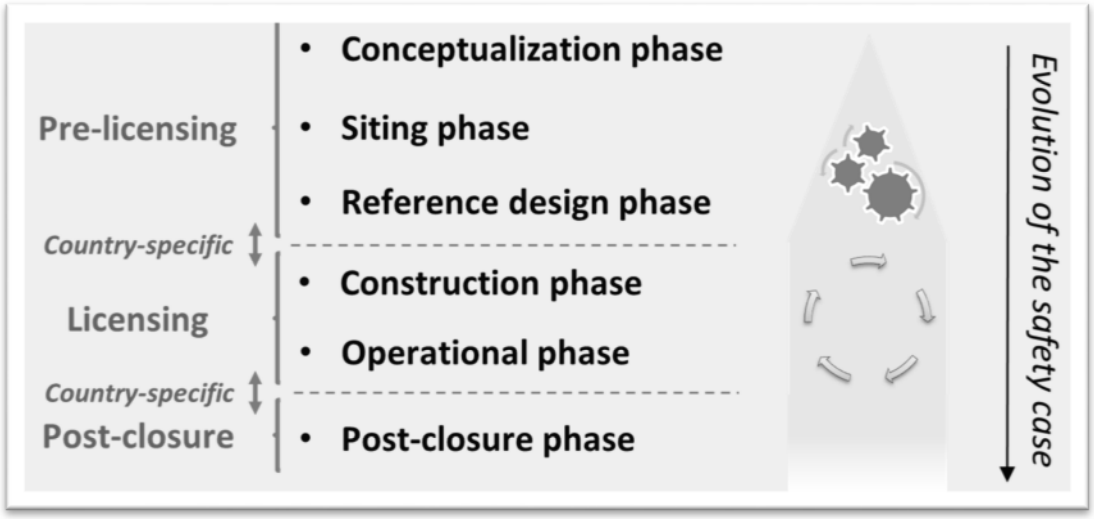


Figure 1: Repository development phases and evolution of the safety case (modified from [ref.27])

The regulatory body has a continuing role to review the safety case, which has to be regularly updated to remain an adequate basis for making decisions throughout the repository life cycle. At every successive licence, 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 implementer 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 [ref.1].

Depending on the regulatory framework in a country, regulatory approvals may be needed in phases before the first licence. Fig. 1 shows that the different components of the safety case are progressively developed during this period (i.e. conceptualization, siting and reference design phases). Therefore, it is essential that a dialogue between the prospective licensee of the disposal facility and the regulatory body (and its technical safety organization) takes place, during pre-licensing (see previous section 5, page 10) [ref.27].

7 Regulatory body integrated management system

In order to fulfil its statutory obligations (functions, activities) and to achieve and maintain, at all time, a high level of quality performance in regulating the safety of nuclear facilities and activities, regulatory body organizations[1] have to develop, establish, implement, continuously evaluate and improve an effective and efficient integrated management system, in accordance with international and national standards.

To achieve and maintain a high level of safety, the integrated management system requires a sound governmental, legal and regulatory framework. An appropriately organized and staffed independent regulatory body with well-defined responsibilities and functions and access to adequate resources is a key element of such a framework.

The management system should meet the principles and requirements set out in national and international regulatory provisions into force and should be developed in line with international recommendations / publications, codes and standards and, when applicable, commitments agreed with stakeholders.

Most of the time, those publications are related to facilities and activities and provide requirements and guidance for operators and implementers. Regulatory bodies organizations may need to adapt the requirements set out in those publications in accordance with their own organizations' accountabilities.

7.1 IAEA PUBLICATIONS RELATED TO MANAGEMENT SYSTEM

Requirements and guides for such a framework are set out mainly in IAEA publications (see categories on Figure 2). As it is not the goal here to repeat all requirements and principles, one refers simply to the related publications with mention of its scope:

[1] By regulatory body organizations one must understand *Ministries, Safety authorities, regulatory bodies, technical support organizations…*

Figure 2 : Safety Standards Categories

IAEA Safety Fundamental

The **SF-1** publication [ref.1] states the fundamental safety objective, presents the ten principles to be applied in order to achieve this objective and describes the intent and application of each principle. In particular its principle 3 about "Leadership and management for safety" requires that "*effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to radiation risks*", this is of course also true for regulatory bodies.

IAEA Safety Requirements Publications

The **GSR Part 1** publication [ref.2] (Governmental, Legal and Regulatory Framework for Safety) establishes requirements:

- for governmental responsibilities and functions for safety,
- for liaison within the global safety regime, and
- for the regulatory body.

The **GSR part 2** publication [ref.3] (Leadership and Management for Safety) sets out requirements for management systems that can be used as the basis for the management system of the regulatory body.

The **SSR-5** publication [ref.4] establishes requirements, for operators / implementers, to provide assurance of the radiation safety of the disposal of radioactive waste, in the operation of a disposal facility and especially after its closure. The requirements related to the management system of this publication can also be applied for the regulatory body's activities.

IAEA Safety Guides

Four interrelated IAEA **Safety Guides** provide also **recommendations** on satisfying the requirements concerning particular responsibilities and functions of the regulatory body in the regulation of nuclear facilities. The Safety Guides address respectively the organization and staffing of the regulatory body **GS-G-1.1** [ref.5], the regulatory review and assessment **GS-G-1.2** [ref.6], the regulatory inspection and enforcement **GS-G-1.3** [ref.7] and the documentation relating to the regulatory process **GS-G-1.4** [ref.8].

Two complementary safety guides provide the necessary guidance for implementing the requirements of the GSR-Part2 [ref.3]. The **GS-G-3.1** [ref.9] safety guide provides generic guidance to aid in establishing, implementing, assessing and continually improving a management system that complies with the requirements and the **GS-G-3.4** [ref.10] safety guide provides specific recommendations for meeting the requirements on establishing management systems suitable for waste disposal facilities and related activities.

The development of the management system for an organization will also be influenced by:

a) Internationally recognized standards such as:
   - **ISO 9001:2015** [ref.25] that describes the fundamental concepts and principles of quality management system;
   - **ISO 14001:2015** [ref.26] that specifies the requirements for an environmental management system that an organization can use to enhance its environmental performance.

b) Guidance associated with the defined regulatory and statutory requirements of States;

c) Standard practices of the nuclear industry;

d) The organization's own standard practices.

The **SSG-23** publication [ref.12] states that the management of the regulatory review of a safety case should be treated as a project in itself, to which the principles of good project management apply. It should be led and conducted by a dedicated team of well-qualified and well-experienced experts of the regulatory body and if necessary assisted or supported by its technical support organization (TSO) or any other organizations with a specific speciality. Typically, assessment specialists will be required to understand and integrate the information coming from the various specialists/experts to assess the overall adequacy of the safety case.

Well-detailed, documented and approved processes and procedures must be available to guide the regulatory body during the all review process project of the safety case. Project specific procedures should include structured methods to document the review, allowing the verification that the review has been performed by competent people (e.g. knowledge, expertise, national or

international review experience, credibility, independence …), and has been recorded in a traceable and auditable manner. The regulatory body should specify and assign responsibilities and tasks in its organization to review and assess the safety case. Further procedures may be necessary if the review includes tasks, such as audits or independent calculations performed by the regulatory body itself.

The objectives and scope must be defined and all national and international requirements, guidance and recommendations have to be clearly identified.

A review plan associated with its project schedule and graded allocations of financial and human resources (depending on the complexity, safety significance and maturity of the project), a communication plan and a synthesis of all procedural and technical deliverables from the review process must be available as good practice for a project.

Relevant experience from similar geological disposal facilities (national and international) and the technical or safety concerns of other competent authorities must also be taken into account.

7.2 INTEGRATED MANAGEMENT SYSTEM CONTENT

The regulatory body integrated management system should have three main purposes [ref.12]:

- To foster and support a safety culture in the regulatory body through the development and reinforcement of leadership as well as good attitudes and behaviour in relation to safety on the part of individuals and teams.
- To provide the necessary guarantees for the integrated management of the organization, responsibilities, resources, processes and quality.
- To maintain and continuously improve the performance of the regulatory body by means of the planning, control and supervision of its safety related activities ;

An effective management system must be established, implemented, continuously evaluated and improved, in accordance with international standards. It shall be aligned with the safety goals of the organization.

The integrated management system of the regulatory body should describe all activities required to afford, with adequate confidence, that all legal obligations of the regulatory body will be soundly achieved, thereby contributing to build confidence among all interested stakeholders that

regulatory processes and decision makings are conducted in a systematic, efficient, consistent and stable way.

The integrated management system of the regulatory body has to integrate consistently together all the requirements for managing the regulatory body: this means not only safety, health and quality, but also all lawful aspects, security, environment, human and financial resources, processes and the societal and economic factors.

SAFETY CULTURE

An efficient integrated management system needs a strong management commitment to safety and a strong safety culture. Indeed, the well-known quality assurance system of the past is no more sufficient and developments are needed to implement an integrated management system. The application of the management system requirements to the functions and activities of the regulatory body should follow a graded approach, determining the extent of their application. The Regulatory Body should demonstrate at all levels its commitment to establish, maintain, and improve a management system by establishing appropriate management controls, feedback loops, and strong values that demonstrate the regulatory body's commitment.

The management system shall be applied to achieve goals safely and to enhance safety. It must establish a policy and an integrated management strategy that brings, with confidence, a positive answer as to the guarantee of compliance with all the requirements and the achievement of the principles and objectives for all functions and activities of the regulatory body. The main goal is to foster a strong safety culture by describing the planned and systematic actions necessary to provide confidence that all requirements are met.

The management system of the regulatory body must contribute to the strengthening of the level of safety of the installations and activities through the integration of requirements relating to safety, performance, health, quality, environment, human-and-organizational-factors and the societal and economic elements in those activities related with the regulation of facilities and activities and with their responsibilities for arrangements in relation to leadership and management. In the management system, the requirements for safety must always paramount any other requirement, ensuring that safety is taken into account in decision making and is not compromised by any decisions taken.

ORGANIZATION

The regulatory body management system shall describe the necessary organization to the implementation process and essential functions and activities to guarantee, with confidence, that the intended level of safety will be achieved. The organization shall allow to check that the quality of the regulatory functions and activities related to facilities and activities are adequate, shall

allow to establish procedures and arrangements to ensure (safety) safe and stable decision process (in all conditions) and to ensure the continuity of regulatory activities and functions (responsibility) for several generations.

RESPONSIBILITIES

The responsibilities assigned to the regulatory body have to be properly discharged.

The responsibility of the regulatory body is to develop regulations and regulatory guidance that determine the basis and scope of the safety case.

The requirement 2 of the IAEA SSR-5 publication [ref.4] requires that the regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for the development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met.

The development of an effective and efficient regulatory body management system requires a clear understanding of the different functions and responsibilities of the regulatory body. In developing the regulatory management system, the regulatory body should identify its main functions and should take into account support functions and control functions derived from the main functions.

The regulatory body should assign specific responsibilities within its organization to review and assess the safety case. A single individual or a small group should integrate all of the information from the review and assessment effort to decide whether the safety case is adequate. The individual or group must be capable of developing an overall understanding of the various safety assessments to enable evaluation of the significance of each assessment in the context of the overall safety case. Ultimately the individual or group judges whether the overall safety argument is sufficient to demonstrate that the facility is safe.

RESOURCES

The regulatory body management system must determine the specific requirements regarding human, material and financial resources necessary for the execution of its activities and functions. To avoid human and organizational failures, the interactions between people, technology and organizations must be taken into account and good performance and best practices must be encouraged.

With this in mind, the regulatory body management system must ensure the promotion, the development and the maintenance of a strong safety culture with all organizations and all persons concerned. It requires individual and collective commitment at all levels, as well as the regular evaluation of the performance. Processes should be set up to collect and analyze information on regulatory activities and functions experience to share and to decide or act accordingly.

Given the time scales for disposal of radioactive waste, the regulator must implement a programme and measures to maintain, on the long term, the skills and culture of safety by training, education and knowledge transfer. The records related to the qualification, empowerment, and training of personnel must be kept.

PROCESS & PROCEDURES

The regulatory body integrated management system must be based on a set of well-qualified and approved processes that will guide the regulatory body throughout its activities and functions.

The regulatory body integrated management system must allow the implementation of a set of planned and controlled systematic actions, based on procedures written and archived, allowing for qualification of all processes in place.

The regulatory body integrated management system must also include a check and a certification of the means implemented to ensure that the requirements are understood and properly taken into account, that the process is efficient and effective and that the process benefits from sufficient and appropriate human, material and financial resources.

QUALITY ASSURANCE PROGRAM

The regulatory body management system must involve the implementation of an extended comprehensive quality assurance program, applied to all stages and all elements of the activities and functions of the regulatory body. This principle is of course also applicable to all activities and functions related to the decision process for final disposal projects of radioactive waste. Particularly, the requirements should cover all lifetime phases of a waste disposal project and long-term records retention.

The quality assurance program must be defined and applied to functions, activities, structures, processes of the regulatory body related to the safety, with a level of attention and confidence that is proportional to its importance to safety (graduated approach).

The quality assurance program must be documented and supported in a written way by a policy, plans, procedures and instructions.

Quality assurance requirements are intended to give a sufficient and reasonable assurance to all stakeholders, that the regulatory body develop and maintain its responsibilities, functions and activities at an appropriate level of safety.

The application of the appropriate provisions of quality assurance during all these stages is a key element in getting the required trust level in all the authorization process (decision process).

Continuously and on a regular basis, the regulatory body integrated management system must be certified by an external, independent and accredited organization that audits the regulatory body management system set up and check its compliance with the requirements set in the at that time applicable standards (i.e.: ISO9001: 2015 certificate).

All used software (calculation codes and models) must be verified, validated, documented, dated and qualified.

The integrated quality assurance program must ensure, at all stages, the collection and preservation of all records related to decision making process of the regulatory body (traceability of the decision making process).

The regulatory body must ensure that the records will be produced, made available, archived and protected, for the benefit of future generations, in a durable and reliable physical form and an electronic form. In particular, the records describing the precise location and nature of the radioactive waste must be protected appropriately.

The regulatory body management system must provide for a procedure for managing nonconformities related to facilities or activities of the operator or implementer during the waste disposal project. The procedure should allow anticipating, managing, controlling, and documenting all potential deviations likely to take out the conditions of the authorization. Non conformities must be identified, recorded, documented, evaluated, processed, reported enabling the regulatory body to rule and to take adequate administrative or regulatory measures, like corrective and preventive actions commensurate with the magnitude of non-compliance.

8 Building expertise for independent review

The importance of the technical capabilities of the regulatory body is underpinned in Article 8 of the EC Directive 2011/70/Euratom [ref.22], stating that Member States shall ensure that the national framework require all parties to make arrangements for education and training for their staff, as well as research and development activities to cover the needs of the national programme for spent fuel and radioactive waste management in order to obtain, maintain and to further develop necessary expertise and skills. This requirement, when applied to the regulatory body, is indeed a prerequisite for ensuring effective independence of the regulatory body, as required by Article 6-2 of the same EC Directive. This should start early in the pre-licensing phase.

To fulfil the review of safety case, the regulatory body needs technical expertise and support in order to:

- Check adequacy, completeness and justification of technical requirements and guidance;
- Take informed decisions with full knowledge of the facts;
- Justify advices and decisions;
- Develop the capacities to understand and assess the safety case;
- Judge the adequacy of the approaches followed to reach the safety objective and of their implementation;

The overall goal of regulatory review is to verify that the disposal facility will not cause an unacceptable adverse impact on human health or safety, or on the environment, both now and in the future.

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. The team of experts in charge of a review typically includes a project manager responsible for overall coordination and for the verification that the safety case and its review process are consistent with regulations as well as senior specialists responsible for peer reviewing, integrating and synthesizing comments from other specialists.

The regulatory review should be also conducted using a level of resources that is commensurate with the level of complexity of the safety case and the potential risks associated with the disposal facility under consideration.

Assessing compliance with safety requirements requires strong technical support from the expertise function. This includes several activities such as the regulatory body's independent R&D programme and reviewing of safety demonstration. In order to provide the regulatory function with an adequate decision support, the regulatory needs associated with the evaluation of conformity have to be clearly formulated and communicated to the expertise function.

The deliverable D2.2 of SITEX-I project [ref.20] identifies the expertise and technical support needed by the regulatory function in order to perform an independent assessment of compliance with safety requirements. The report provides an identification of:

- The main key technical issues that must be assessed by the regulators at the different stages of repository development;
- The types of expertise and technical support needed at each phase of repository development.

It should be kept in mind that a multidisciplinary approach is very often needed to deal with interactions between the different fields of expertise and the coupling between various processes. Such a multidisciplinary approach can be implemented in different ways and typically calls for the collaboration of both generalists and specialists.

Regulatory body's independent R&D programme

An independent R&D programme is essential for the regulator's scientific and technical ability, because it maintains or improves the regulator's competence, it contributes to the regulator's independence and it helps to achieve public confidence in the regulatory system. The development of an independent R&D programme helps to ensure the development of independent capabilities for reviewing the safety case and assessing the scientific arguments provided by the implementer (WMOs).

More specifically, regulatory R&D activities carried out in support of reviews may contribute to one or several of the following objectives:

- To develop expertise;
- To identify key safety issues;
- To develop specific safety requirements;
- To determine the current level of scientific and technical knowledge, and to make this knowledge available for supervisory tasks;

The regulatory body's R&D programme may use results from external research conducted by academic or other research institutes. R&D activities such as independent modelling and experiments may also have to be conducted directly by or for the regulatory body in order to

investigate some specific issues where alternative methods/analyses are required to support regulatory decision. In addition, the regulatory body may decide to collaborate on R&D internationally with other regulatory bodies and/or technical support organizations. In addition, there may be international R&D projects/working groups that regulators may participate in.

The knowledge of the initial state of the disposal system and the understanding of its possible evolutions are essential to perform and gain confidence in the safety assessment of disposal systems and the management of the uncertainties. More specifically, the identification and the characterisation of the processes upon which the safety functions rest and of the processes that may affect the performance of the disposal system are keys to develop scenarios describing possible evolutions of the disposal system and its environment.

Example of processes to be investigated

THMC processes result from the coupling and mutual interactions among temperature gradients with heat flow (T), hydraulic pressure gradients with fluid flow (H), mechanical stresses with deformations (M), and chemical transport and reactions (C). Other processes such as gas generation and bacterial activity may also interact or be associated with these processes. The dynamic nature of THMC processes needs be acknowledged and properly understood, as these processes are governed by changing conditions inside the disposal system, which evolve from the open-drift period to saturation period, and eventually through the whole heating-cooling cycle of decaying waste. Varying external conditions such as loading and unloading processes to which the disposal system might be subjected (e.g., due to glaciation and erosion) will also contribute to the evolution of THMC processes within the system. THMC processes may influence radionuclide transport in the disposal system and in its surrounding environment. It is therefore necessary to study coupled THMC processes, to understand their role in the behaviour of the disposal system. THMC processes could also be influenced by microbial activity. Indeed, if bacteria have sufficient space, water and nutrients, they can become active and alter the performances of the disposal system.

Use of independent experts

It is important that the regulatory body maintains expertise in this field. Indeed, the independence of the regulatory body calls for the support from independent experts who develop and maintain the necessary know-how and skills in nuclear safety as well as in other safety-relevant scientific and technical fields. For complex issues such as those associated with the long-term safety of waste disposal facilities, this requires performing and/or coordinating R&D in support of safety analyses and inspections. R&D activities performed by the regulatory body are also necessary to build the credibility of its technical competence (i.e. vis-a-vis the civil society), integrity and judgement.

R&D programmes: Regulatory body vs implementer

It is important to highlight that the objectives of regulatory body's R&D differ from those set up by waste management organisations. For instance, the regulatory body's R&D is mostly intended to investigate safety issues with the objective to assess if the safety concept developed by the waste management organisation fulfils the defined safety requirements. In that way, a special attention will be given to the identification of possible inadequate choices, assumptions, knowledge gaps, incompleteness, inconsistencies, mistakes (of reasoning or of implementation), … in the safety assessment of the waste management organisation. The regulatory body may decide to initiate R&D work where it considers that there is a need for additional studies beyond those undertaken by the implementer. There may also be situations in which the regulatory body requires independent R&D work so that it can apply suitable critical considerations in its review and assessment. These activities are therefore more a "complement to" and "a verification of" than a "duplication of" the R&D activities performed by the implementer [ref.20]. At the European level, organizations providing a technical and scientific support to regulatory decisions have developed a Strategic Research Agenda (see WP1 – SITEX-II).

It is important to note that R&D needs and tools evolve with the development phases or stages of the repository. They depend on the objectives of the development phases or stages, associated authorisations and on available resources (human and financial).

9 Regulatory review of the Safety Strategy

The regulatory body should start the review of the safety strategy early in the pre-licensing phase. Safety Strategy is indeed a key component of the safety case for the whole development and implementation of a geological disposal for radioactive waste.

Geological disposals 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 geological disposal 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 review the safety strategy from the very beginning of the project and that a dialog and that an ongoing dialogue on this issue is maintained. It will also be important to keep other stakeholders (e.g. civil society) aware about the safety strategy and listen to their views. A sound safety strategy is crucial to maintaining a broad consensus among stakeholders [ref.16].

Fundamental aspects of the strategy are not expected to change over the course of the project; however, principles and approaches may evolve to take into account prevailing circumstances like experience, technical developments, societal issue, and new national and international standards and guidance. The prospective licensee would be expected to identify those fundamental aspects (e.g. isolation and containment strategy) that are not expected to change throughout the development of the project as distinct from specific choices that might evolve as the project progresses (e.g.: vertical or horizontal configuration) [ref.16]. An appropriate safety strategy should help the prospective licensee to managing priorities, to dialoguing with the different stakeholders and to having complete clarity when making critical decisions.

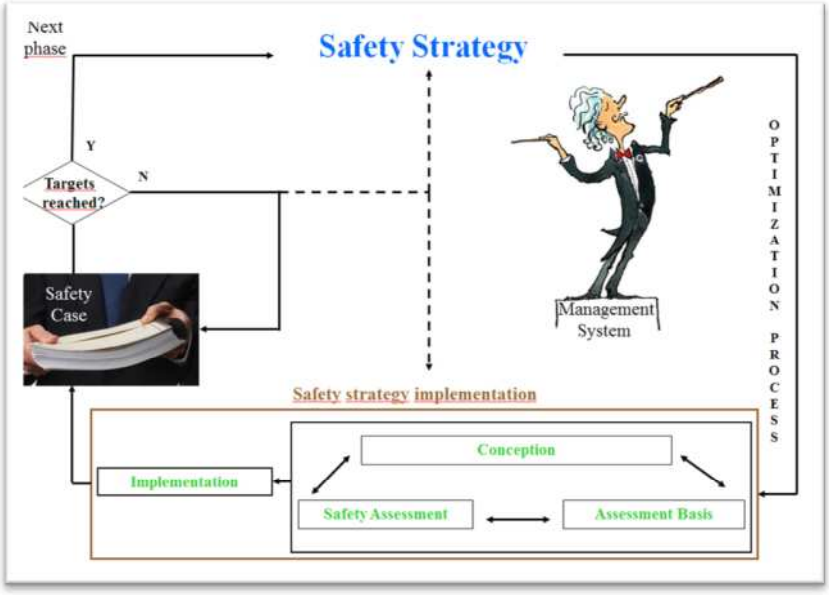


Figure 3 : Safety Strategy, a framework for the safety cases & the disposal's implementation

The safety strategy provides the framework for the safety cases under the overall project development and the implementation of the disposal (see Figure 3). As the project develops, the safety strategy should be continually validated and any changes to it should be justified in the safety case [ref.12]. At each step, constraints may be imposed by the prevailing circumstances (scientific and technical state of the art, socio-economic situation, national legislation). These constraints and their safety implications should be clearly identified. Any evolution of the safety strategy should be carefully recorded and the records should be preserved for use in the future when staff may have changed. The safety strategy should remain consistent during the different phases of disposal facility development preserving the awareness of the safety objective.

The safety strategy describes the processes and methods that will ensure that the disposal facility meets the safety objective. The safety strategy addresses a number of key elements like the implementation of the radiation safety principles and safety design principles such as demonstrability, defence in depth (use of multiple safety functions) and the use of passive means. It should also define the approach that will be followed to assess safety and manage uncertainties. The strategy for safety should explain how these issues will be achieved.

Main components of the safety strategy should be:

- The management strategy related to disposal facility development and implementation ensuring that the work focuses on the safety objectives, that adequate resources are available and that activities are correctly carried out and coordinated [ref.23].
- The conceptualization and implementation strategies including approaches and choices for selecting a site, developing a concept, implementing practical engineering solutions and monitoring [ref.23].
- The safety assessment strategy describing the approach to assessing safety and to building confidence in the assessment results [ref.23].
- The stakeholder strategy describing the approaches to involving stakeholders in key decisions, to meeting stakeholders' expectations, to communicate with stakeholders.

The safety strategy should lead to a safety concept assigning the safety functions of the disposal system components and the time frames over which they will be available; defining the performance targets; and explaining how an adequate degree of defense in depth will be ensured by the various safety functions (e.g. how degraded performance of one barrier will be compensated by another mechanism or by components of the disposal system).

10 Review Grid to review geological disposal safety cases

10.1 DESCRIPTION OF THE REVIEW GRID

The main principle motivating the development of the review for each phase is to adapt the level of review to the level of progress of the disposal project [ref.16]http://www.fanc.fgov.be/GED/00000000/4300/4322.pdf. After having noticed, in the frame of SITEX-I project, the lack of guidance on how to do the review of a safety case in practice, it has been decided to develop "analysis grids", as a support tool for the regulator during the process of safety case review, for all phases. The common issues to be addressed relate to the description of the context of the safety case, the implementation of the safety strategy, the assessment basis, the safety assessment including effectiveness of the safety functions, performances and robustness of barriers, definition of scenarios and radiological impact calculations, to the management of uncertainties and finally to the integration of safety arguments and evidence.

An example of analysis grid has been developed in SITEX-I project [ref.21] to support the review of a safety case related to site selection. One objective of WP2.2 in SITEX-II project is to pursue the exercise to the other phases of the lifecycle of a disposal.

The support tool has been developed in Excel. Since a lot of issues are common to several phases, it has been decided to establish a generic database including all issues (that have to be verified) in a database making the link with WENRA SRL's [ref.17] and the corresponding phases during which they have to be reviewed. This way, the tool will allow building adapted or specific review grids in function of desired focus, aspects or contents of the safety case and specific phases of development of the disposal program as defined in the EPG report [ref.16].

It is important to note that the developed database has to be considered as a tool to help the review of safety case. The SITEX partners do not claim to construct a complete checklist because "it has to stay relevant for any safety case and let the experts follow its own feeling. Its aim is to stay a matrix to assist the reviewer, to the contrary of the developed NRC review plans" [ref.21]. Moreover the database would have to be adapted for each countries taking into account specificities of the national regulatory context.

The review grid must be seen as an evolving tool not only to help and guide regulatory bodies during safety case reviews but also to exchange their past, present and future experiences and feedbacks with safety case reviews.

10.2 REFERENCE DOCUMENTS FOR THE REVIEW GRID

The database considers all phases of development of a disposal facility and has been built considering the requirements, guides, recommendations or expectations mentioned in the following agreed reference documents list:

- **SITEX-I**
    - Deliverable **D2.2** - Main key issues, expertise and support needed – 2013 [ref.20]
    - Deliverable **D4.1** - Available technical review guidance and further needs – 2014 [ref.21]
- **WENRA** - Report - Radioactive Waste Disposal Facilities Safety Reference Levels – 2014 [ref.17]
- **EPG** Report on the European Pilot Study on the Regulatory Review of as safety case for Geological Disposal of Radioactive Waste – 2015 [ref.16]
- **IAEA** Safety Standards Series
    - Specific Safety Requirements
        - **SSR-5** Disposal of Radioactive Waste – 2011 [ref.4]
    - Specific Safety Guide
        - **SSG-23** The Safety Case and Safety Assessment for the Disposal of Radioactive Waste – 2012 [ref.12]
        - **SSG-14** Geological Disposal Facilities for Radioactive Waste – 2011 [ref.11]
- **IAEA** - Application of the Safety Assessment Methodologies for Near Surface Disposal Facilities (**ASAM**) - Regulatory Review Working Group Report – 2002 [ref.14]
- **IAEA** - **GEOSAF** - The International Intercomparison and Harmonization Project on Demonstrating the Safety of Geological Disposal – draft final report [ref.13]
- **ETSON** – Safety Assessment guide – 2013 [ref.18]

10.3 CONTENT DESCRIPTION OF THE REVIEW GRID

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 [ref.12] "Specific Safety Guide over the Safety Case and Safety Assessment for the Disposal of Radioactive Waste" (see Figure 4).

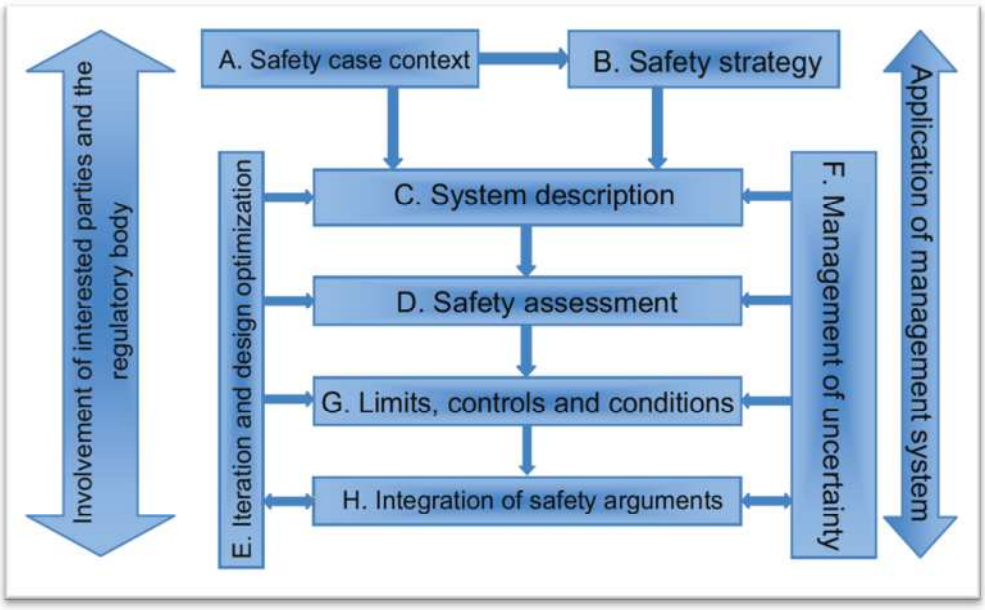


Figure 4 : Application of the management system & the process for interaction with the regulatory body and interested parties from SSG-23 [ref.12].

At this stage, the following boxes on figure 3 are considered in the review grid:

- **A**: Safety Case context = **SC**
- **B** : Safety Strategy = **SS**
- **C**: System Description (Assessment Basis) = **AB**
- **D** : Safety Assessment = **SA**
- **E** & **F** : Assessment of the safety case as a whole = **ASCAW**
- **H** : Integration of Safety Arguments and Evidence = **ISAE**
- Box on the right side: Management System = **MS**

The review grid also includes specific sections related to:

- Monitoring = **MO**, and
- Periodic Safety Review = **PSR**.

Within each section columns are describing (see appendix 2):

- the expected safety case content
- the related safety areas and issues
- the related verification(s) to be done by the regulator as a support of its review.

All lines of the review grid are numbered to provide quick reference during discussions and exchanges (e.g. SS-21 = Safety Strategy item 21).

For each line or verification the review grid specifies also the status of the content of the safety case at different steps / phases (see appendix 1) of the disposal. The phases that are considered are the following:

- Conceptualization phase;
- Site Investigation and selection phase;
- Reference design phase and licence application for construction;
- Construction phase and licence application for operation;
- Operational phase and licence application for closure;
- Closure phase and entering post-closure phase until licence release.

Status codes used to fill those columns are the following:

- *<blank>* not asked for the related phase, no status is given;
- **P** = **P**reliminary status asked for the related phase;
- **F** = 1st **F**ormal status asked for the related phase;
- **U** = possible **U**pdates (after *F status*) asked for all the related phase(s).

When items become valid for all phases (a status can be given for all phases), the column "Generic" is also marked with a cross (X), allowing a quick search of all relevant generic items.

Listed items (bulleted or not) in one Excel *column* or *cell* are not following a specific order. There is no link to establish between the order of apparition of an item relative to a subject and its potential priority, gradation or importance level.

10.4 EXCEL - CONTENT STRUCTURE

Excel file name: **Safety_Case_GD_Review_Grid.xlsx**

Worksheet: **Review_Grid**

Fields (columns Titles):

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	Site Investigation & selection	Reference Design & Lic. App. > Construction	Construction & Lic. App. > Operation	Operational phase & Lic. App. > Closure	Entering Post-Closure Until licence release

Figure 5: Review grid - Excel column Titles

A full description of the columns of the review grid is provided in **appendix 2**.

A full hardcopy of the review grid is provided in **appendix 3**.

10.5 WORKING WITH THE TOOLS (FILTER, FORMS, PIVOT TABLE…)

10.5.1Working with filters

In Excel, each column is foreseen with a filter menu. With the filter one can search on whole cell content or partial content. Attention has to be given that the results of those 2 kinds of filters will be different.

One can set a filter in a column to search:

a) **On exact cell content**, i.e. filter "DI-049" on the column WENRA DI# will result in a list of all lines which exact match the filter (= "DI-049").

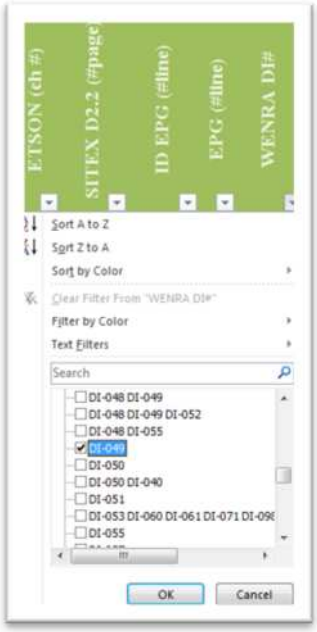


Figure 6 :example of filtering on exact cell content

The result of such kind of filter gives only the lines relative that exact match the filter, in other words, the cell contents that exact and fully match the filter. In this case only 1 line was found.

Result of the filter:

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	Site Investigation & selection	Reference Design & Lic. App. > Construction	Construction & Lic. App. > Operation	Operational phase & Lic. App. > Closure	Entering Post-Closure Until licence release
Monitoring	MO-12	**DI-049**	**2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.	Results of monitoring both within the disposal facility and in its environment	Verification that : • the regulatory requirements and licence conditions are fulfilled ; • the disposal facility and system behaves and evolves as expected in the safety case ; • deviations from the expected behavior of the disposal are identified ; • key assumptions and models are confirmed.	.	.	.	.	Ⓕ	U	U

Figure 7: example of result of filter on exact cell content

b) **On partial cell content**, i.e. filter "049" on the column WENRA DI# will result in a list of all the lines that content the string "049"

In this case, the review grid filtering will results in 4 records.

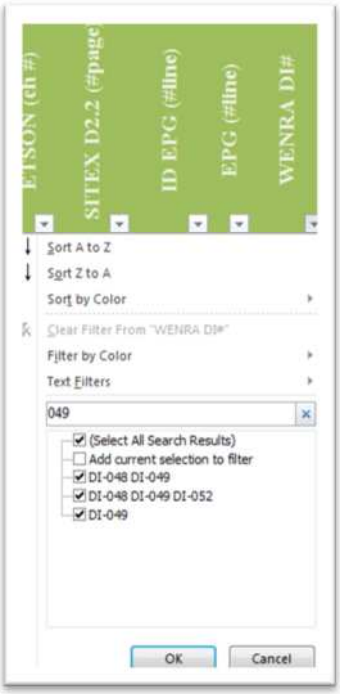


Figure 8 : example of filtering on partial cell content

Result of the filter

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	Site Investigation & selection	Reference Design & Lic. App. > Construction	Construction & Lic.App. > Operation	Operational phase & Lic. App. > Closure	Entering Post-Closure Until licence release
Monitoring	MO-4	**DI-048** **DI-049** **DI-052**	**2.2.4** **2.2.4** **2.2.5**	Disposal Facility Development • Information Gathering & Monitoring • Construction	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making & • Providing background information for any post-closure surveillance program. **DI-52**: In order to refine the assumptions of the safety case, the licensee shall gather information during construction to improve the knowledge of • The intrinsic properties of the host environment • The response of the host environment to the presence of the disposal facility.	Monitoring Program	Verification that an appropriate and systematic monitoring program is established i.e. that allows to : • Contribute to demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions ; • Confirm that the disposal facility and system behaves and evolves as expected in the safety case ; • Identify any deviations from the expected behavior of the disposal ; • Contribute to confirming and refining the key assumptions and models made in the safety case ; • Enhance understanding of the environmental conditions and of the functioning of the disposal ; • Acquire data for supporting decision-making ; • Provide background information for any post-closure surveillance program ; • identify how the results will be taken into account, as well as the way it will be treated, analyzed, organized and recorded ; • ensure the consistency of the monitoring programs updates through the different phases. Verification that the impact of the monitoring and surveillance program has been adequately	X	P	P	Ⓕ	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	Site Investigation & selection	Reference Design & Lic. App. > Construction	Construction & Lic. App. > Operation	Operational phase & Lic. App. > Closure	Entering Post-Closure Until licence release
							assessed and is acceptable							
Monitoring	MO-5	**DI-048** **DI-049**	**2.2.4** **2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.	Specific Monitoring Program - Environment	Verification that a monitoring program of the environment is established before starting construction.	–	–	P	Ⓕ	U	U	U
Monitoring	MO-6	**DI-048** **DI-049**	**2.2.4** **2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.	Specific Monitoring Program - Site	Verification that a monitoring program of the site is established before starting construction.	–	–	P	Ⓕ	U	U	U
Monitoring	MO-7	**DI-048** **DI-049**	**2.2.4** **2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.	Specific Monitoring Program - EBS	Verification that a monitoring program of the EBS is established before emplacement of the EBS.	–	–	–	P	Ⓕ	U	U
Monitoring	MO-8	**DI-048** **DI-049**	**2.2.4** **2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.	Specific Monitoring Program - Waste	Verification that before emplacement of the waste, a monitoring program of the Waste is established.	–	–	–	P	Ⓕ	U	U
Monitoring	MO-12	**DI-049**	**2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in	Results of monitoring both within the disposal facility and in its environment	Verification that : • the regulatory requirements and licence conditions are fulfilled ; • the disposal facility and system behaves and evolves as expected in the safety case ; • deviations from the expected behavior of the disposal are identified ;	.	.	.	.	Ⓕ	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	Site Investigation & selection	Reference Design & Lic. App. > Construction	Construction & Lic. App. > Operation	Operational phase & Lic. App. > Closure	Entering Post-Closure Until licence release
					the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.		• key assumptions and models are confirmed.							

Figure 9 : example of results by filtering on partial cell content

c) **On custom-made filter**, using wildcards on combined filters:

Using wildcards in Excel allows filtering on a more efficient way. Wildcards are used as follows:

Wildcard	Name	Description
?	Question mark	It takes the place of a single character. For example, "Tr?c" matches with "Truc", "Troc", and "TrRc", but not "Truckload"
*	Asterisk	Can take the place of any number of characters. For example, "Tr*c" matches with "Troc", "Truc", and also with "Truepac".
~	Tilda	Tells Excel that the following character should be treated as a normal character and not a wildcard. For example, "Tr~?c" matches only with "Tr?c", not "Trac" or "Troc".

Table 2 : wildcards description

The filter “0?9” applied on the column WENRA DI# will result in a list of lines that content a 3 characters string beginning with 0 and ending with 9 in the cells of the column WENRA DI#. The character “?” in-between represents one and only one free character (possible filter results are: rev.0-9, 0 9, 10192017, 029, 039 … 0T9, 0U9, 0!9, …, but not 0AA9, rev.09…).

If one uses the wildcard “*”, this means that any number of characters may separate the 0 and the 9 (possible results are: 0009, 098769, 0ABC9, 0A1B29)

Tips

1. Use the question mark (?) when you want to accept only a single character, and the asterisk (*) when you want to accept multiple characters.

2. The possibility exist to filter on more than one criteria, combining the filters with the OR / AND conditions.

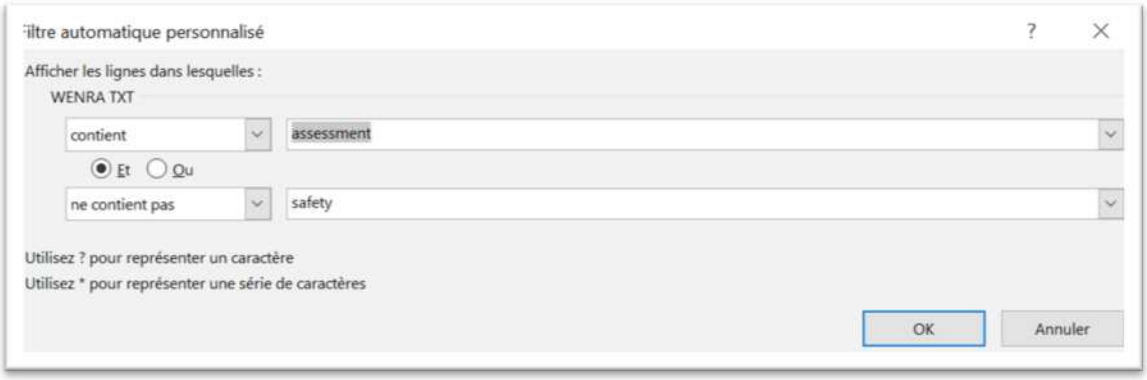


Figure 10 : example of combined personalized filters

10.5.2Working with Forms

Working with an Excel table allows also the option to get one record at the time on the screen using standard Excel form, as shown in the next figure. The standard form includes all columns (see appendix 2) for the line one have chosen in the review grid. Search or filter is also possible from this standard form, but not directly recommended.

In Excel, personalize the quick reference toolbox on the upper left top of the screen by adding the "Form" command from the menu.

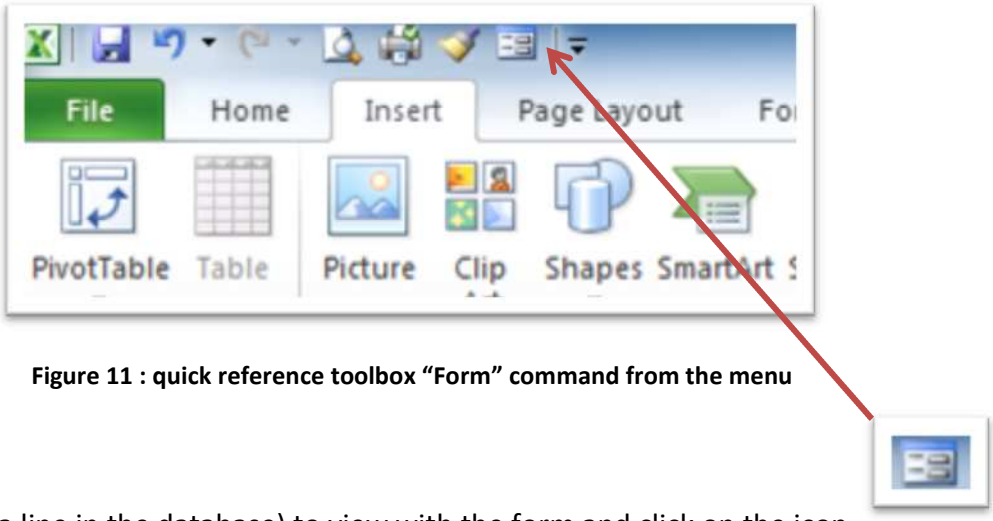


Figure 11 : quick reference toolbox "Form" command from the menu

Choose a record (a line in the database) to view with the form and click on the icon . The related record will be shown in a standard Excel form that contents all the columns from the database.

By clicking on **Find_Next** or **Find_Prev**, Excel will show the next or the previous record and able the user to browse the database.

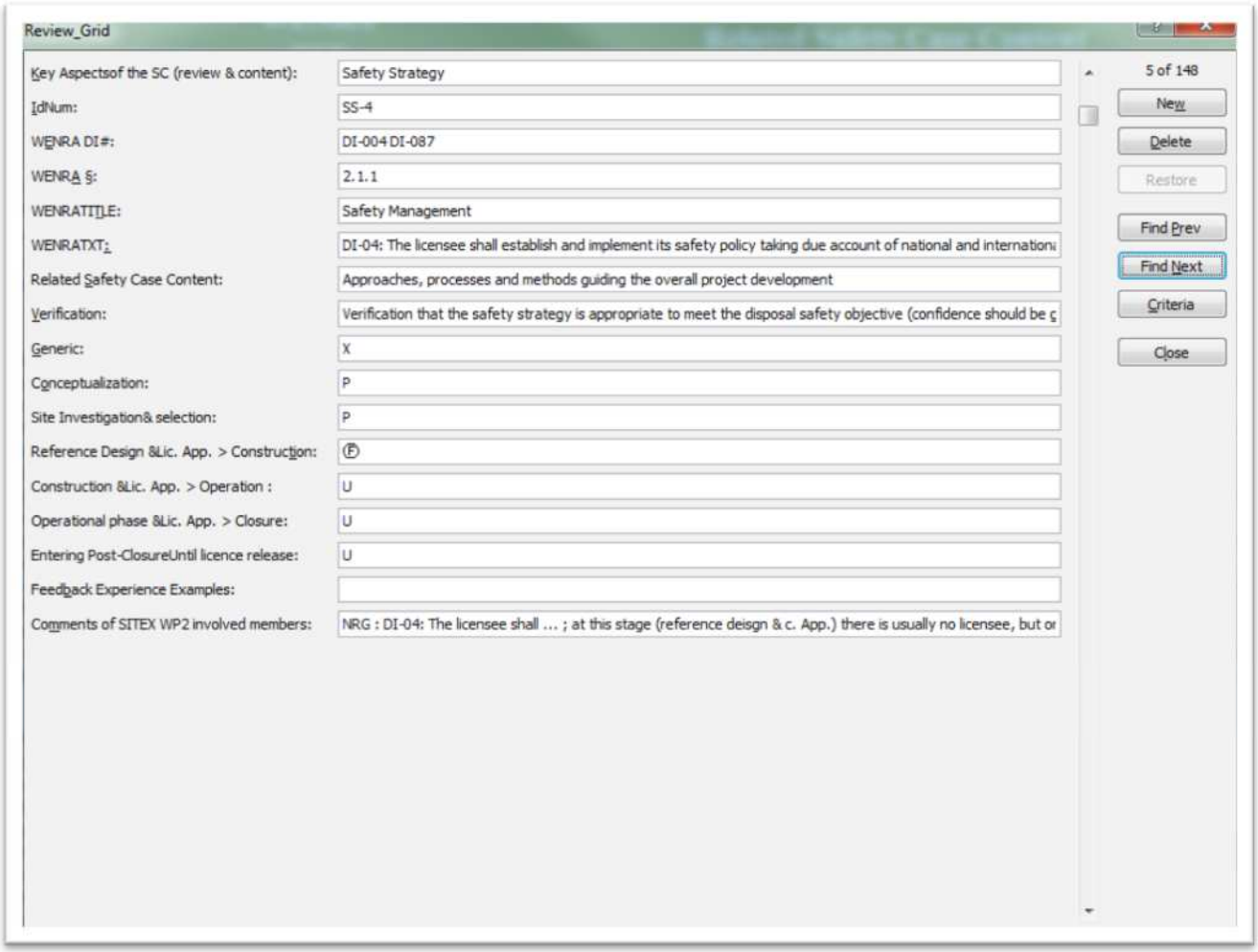
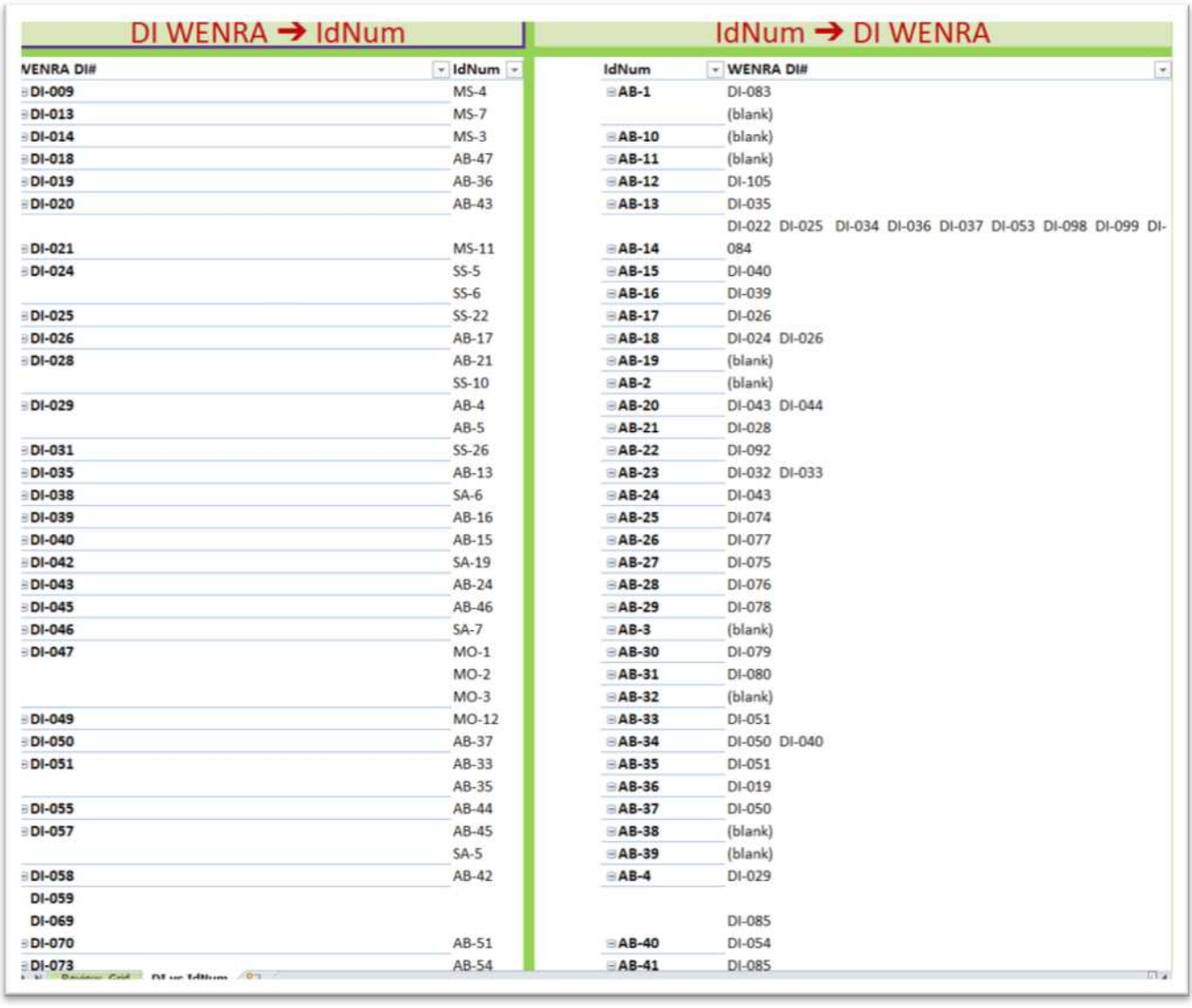


Figure 12 : example of form for the current record

10.5.3Working with Pivot table

The review grid file is also provided with already build-in pivot tables.

The worksheet **DI vs IdNum** provides 2 pivot tables giving an overview of the links existing between the columns WENRA DI# and IdNum and vice versa (see Figure 13).



DI WENRA → IdNum

VENRA DI#	IdNum
DI-009	MS-4
DI-013	MS-7
DI-014	MS-3
DI-018	AB-47
DI-019	AB-36
DI-020	AB-43
DI-021	MS-11
DI-024	SS-5
	SS-6
DI-025	SS-22
DI-026	AB-17
DI-028	AB-21
	SS-10
DI-029	AB-4
	AB-5
DI-031	SS-26
DI-035	AB-13
DI-038	SA-6
DI-039	AB-16
DI-040	AB-15
DI-042	SA-19
DI-043	AB-24
DI-045	AB-46
DI-046	SA-7
DI-047	MO-1
	MO-2
	MO-3
DI-049	MO-12
DI-050	AB-37
DI-051	AB-33
	AB-35
DI-055	AB-44
DI-057	AB-45
	SA-5
DI-058	AB-42
DI-059	
DI-069	
DI-070	AB-51
DI-073	AB-54

IdNum → DI WENRA

IdNum	WENRA DI#
AB-1	DI-083
	(blank)
AB-10	(blank)
AB-11	(blank)
AB-12	DI-105
AB-13	DI-035
	DI-022 DI-025 DI-034 DI-036 DI-037 DI-053 DI-098 DI-099 DI-
AB-14	084
AB-15	DI-040
AB-16	DI-039
AB-17	DI-026
AB-18	DI-024 DI-026
AB-19	(blank)
AB-2	(blank)
AB-20	DI-043 DI-044
AB-21	DI-028
AB-22	DI-092
AB-23	DI-032 DI-033
AB-24	DI-043
AB-25	DI-074
AB-26	DI-077
AB-27	DI-075
AB-28	DI-076
AB-29	DI-078
AB-3	(blank)
AB-30	DI-079
AB-31	DI-080
AB-32	(blank)
AB-33	DI-051
AB-34	DI-050 DI-040
AB-35	DI-051
AB-36	DI-019
AB-37	DI-050
AB-38	(blank)
AB-39	(blank)
AB-4	DI-029
	DI-085
AB-40	DI-054
AB-41	DI-085

Figure 13 : build-in pivot tables

10.5.4Example of filtering

Figure 14 : example of filter for key aspect safety case = Monitoring and Phase = Construction & licence application for operation)

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	Site Investigation & selection	Reference Design & Lic. App. Construction	Construction & Lic. App. > Operation	Operational phase & Lic. App. > Closure	Entering Post-Closure Until licence release
Monitoring	MO-1	**DI-047**	**2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-47**: Before starting construction, the licensee shall establish a baseline state of the environment both for supporting the monitoring program and for evaluating the impact of the facility on the environment.	Approach for monitoring	Verification that the monitoring approach is line with the needs for safety assessment.	X	P	P	Ⓕ	U	U	U
Monitoring	MO-3	**DI-047**	**2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-47**: Before starting construction, the licensee shall establish a baseline state of the environment both for supporting the monitoring program and for evaluating the impact of the facility on the environment.	Baseline state of the engineered components of the facility after emplacement	Verification that a baseline state of the engineered components is established after their emplacements for • Supporting the monitoring program, and • Evaluating the ageing of the components.	–	–	–	–	Ⓕ	U	U
Monitoring	MO-4	**DI-048** **DI-049** **DI-052**	**2.2.4** **2.2.4** **2.2.5**	Disposal Facility Development • Information Gathering & Monitoring • Construction	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making & • Providing background information for any post-closure surveillance program. **DI-52**: In order to refine the assumptions of the safety case, the licensee shall gather information during construction to improve the knowledge of • The intrinsic properties of the host environment • The response of the host environment to the presence of the disposal facility.	Monitoring Program	Verification that an appropriate and systematic monitoring program is established i.e. that allows to : • Contribute to demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions ; • Confirm that the disposal facility and system behaves and evolves as expected in the safety case ; • Identify any deviations from the expected behavior of the disposal ; • Contribute to confirming and refining the key assumptions and models made in the safety case ; • Enhance understanding of the environmental conditions and of the functioning of the disposal ; • Acquire data for supporting decision-making ; • Provide background information for any post-closure surveillance program ; • identify how the results will be taken into account, as well as the way it will be treated, analyzed, organized and recorded ; • ensure the consistency of the monitoring programs updates through the different phases. Verification that the impact of the monitoring and surveillance program has been adequately assessed and is acceptable	X	P	P	Ⓕ	U	U	U
Monitoring	MO-5	**DI-048** **DI-049**	**2.2.4** **2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.	Specific Monitoring Program - Environment	Verification that a monitoring program of the environment is established before starting construction.	–	–	P	Ⓕ	U	U	U
Monitoring	MO-6	**DI-048** **DI-049**	**2.2.4** **2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in	Specific Monitoring Program - Site	Verification that a monitoring program of the site is established before starting construction.	–	–	P	Ⓕ	U	U	U

					the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.									
Monitoring	MO-7	**DI-048** **DI-049**	**2.2.4** **2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.	Specific Monitoring Program - EBS	Verification that a monitoring program of the EBS is established before emplacement of the EBS.	–	–	–	P	Ⓕ	U	U
Monitoring	MO-8	**DI-048** **DI-049**	**2.2.4** **2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.	Specific Monitoring Program - Waste	Verification that before emplacement of the waste, a monitoring program of the Waste is established.	–	–	–	P	Ⓕ	U	U
Monitoring	MO-9	**DI-048** **DI-055**	**2.2.4** **2.2.6**	Disposal Facility Development • Information Gathering & Monitoring Disposal Facility Development • Operation	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-55**: The licensee shall make and implement arrangements to detect and respond to anticipated operational occurrences and possible accidents. Provisions for doing so shall not unacceptably affect operational or post-closure safety.	Specific Monitoring Program - Occupational Safety	Verification that : • A monitoring program of the occupational safety is established before emplacement of the waste ; • Provisions are made for detecting anticipated operational occurrences and possible accidents.	–	–	–	P	Ⓕ	U	U
Monitoring	MO-10	–	–	–	–	Monitoring: implementation procedures	Verification of the adequacy of the implementation procedures with respect to the monitoring objectives.	–	–	–	Ⓕ	U	U	U
Monitoring	MO-11	–	–	–	–	Monitoring implementation	Verification of the effective and appropriate implementation of monitoring procedures: • Verification of field investigation and monitoring records ; • Verification of safety-relevant data measurement activities and devices performed by or for the (future) implementer (piezo metric measurements, …) ; • Independent tests / measurements as appropriate.	–	–	–	–	Ⓕ	U	U
Monitoring	MO-12	**DI-049**	**2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.	Results of monitoring both within the disposal facility and in its environment	Verification that : • the regulatory requirements and licence conditions are fulfilled ; • the disposal facility and system behaves and evolves as expected in the safety case ; • deviations from the expected behavior of the disposal are identified ; • key assumptions and models are confirmed.	–	–	–	–	Ⓕ	U	U

11 Example of a safety case review table of content

1. **Purpose of the review (licence application scope)**
2. **Review process**
    - Objective of the review
    - Review Approach
    - Review format
3. **Initial check on the licence application file**
    - Regulatory Framework
    - Process for licence application completeness
    - Completeness of the licence application
    - Environmental impact assessment
    - European Commission (Art.37 Euratom Treaty)
4. **Review of Management system**
    - Safety culture
    - Organization
    - Responsibilities
    - Resources
    - Processes
    - quality Assurance
5. **Review of the assessment basis**
    - Objectives
    - Phases timeframe
    - Site
    - Facilities
    - Radioactive waste to be disposed of
    - Disposal packages
6. **Review of the monitoring program**
7. **Review of Safety strategy**
    - Radiation Protection Principles
        - Justification of the practice
        - Optimization of protection
        - Dose limit and dose limitation
    - Principle of demonstrability
    - Principle of defence in depth
    - Protection of future generations
    - Burdens for future generations

- Operational Radiation Protection Concepts
- Safety concept
  - Operational safety functions
  - Long term safety functions

8. Review of Safety assessments

- Operational safety assessments
- Long Term performance assessments
- Long term radiological impact assessment
- Exclusion of criticality
- Multiple lines of reasoning

9. Review of WAC (waste acceptance criteria**)**

- Radiological
- Non-radiological
- Conformity files

10. Conclusions

- Positions of the regulatory body
- Licence conditions
- Next steps

12 Possible further improvements of the review grid

The "**Review Grid**" has been developed as a support tool for the regulators during the process of safety case review presented to the regulatory body at the different development phases of a geological disposal. A full hardcopy of the review grid is provided in appendix 3.

As already said, the tool is an evolving one and there is of course potential for further improvements and developments. The following main suggestions were provided by the SITEX WP2-contributors and associated partners:

- further populate and refine the spreadsheet ;
- improve the organization of the information in the spreadsheet and its relation to each other;
- clearly indicate the parts of the issues derived directly from internationally agreed documents and the parts where there was interpretation and judgement by the SITEX-II project;
- improve the review grid based on regulators experiences and feedbacks: issues to be verified are based on international recommendations (mainly WENRA SRL's, [ref.17]) and developed taking into account the experience of own experiences of each SITEX member. The objective should be to improve the tool gathering the experience and feedback of all members / users.

13 Conclusions

The purpose of this WP2.2 was to develop a guide on reviewing the safety case. This task was aimed at completing the exchange of feedback on the regulatory review process throughout the six key phases (see appendix 1) of the development of the safety case, with specific emphasis on practices implemented to verify that safety requirements are effectively and properly implemented.

The review of a safety case aims to determine 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. With this objective in mind, the regulatory body has to verify that the safety case complies with the "regulatory framework". The regulatory body has to evaluate whether the safety case provides an adequate and appropriate basis to demonstrate that the proposed facility will be operated safely and provides reasonable assurance of an adequate level of safety in the period after closure. The regulatory body has also to verify that relevant measures for mitigating uncertainties have been identified and addressed, and that adequate follow-up plans for their implementation have been developed.

More specifically, the review of a safety case aims at assessing the following aspects:

- the capability of the implementer to properly justify the methods used to obtain data and the confidence in the data;
- the capability of the implementer to explain the processes that govern the performance of the Structures, Systems and Components and their ability to fulfil their safety functions;
- the capability of the implementer to assess the long-term evolution of the disposal system, taking into account uncertainties;
- the due consideration of hazards that could impair safe operation of the repository, considering the influence of potential accidents during the operational phase on the long term safety.
- the identification of any unresolved issues and to verify that plans for resolving these issues have been developed.

The management of such a review should be treated as a project in itself and should rest on an efficient management system. The pre-review phase is crucial for the success of the project. During this phase the regulatory body will develop and update the regulation in accordance of the national legal framework and taking into account the last international standards, it will develop its own competences, it will exchange with the prospective licensee to making clear the regulatory body expectations and to discuss the methodologies used to develop the safety case.

This guide describes the role of the regulatory body in pre-licensing process and licensing process, identified the needs for an efficient management system, develop the competences the regulatory body has to acquired and propose a tool to analyze the safety cases through the different phases of the development of geological disposal. The guide gives an example of table of content for the review report to be performed by the regulatory body.

Review grids to support the review have been developed as well. Since a lot of issues are common to several phases, it has been decided to establish a generic database including all issues (that have to be verified) in a database making the link with WENRA SRL's [ref.17] and the corresponding phases during which they have to be reviewed. This way, the tool allows building specific review grids in function of desired focus, aspects or contents of the safety case and specific phases of development of the disposal program.

It is important to note that the developed database has to be considered as a tool to help the review of safety case. The database would have to be adapted for each countries taking into account specificities of the national regulatory context. The review grid must be seen as an evolving tool not only to help and guide regulatory bodies during safety case reviews but also to exchange their past, present and future experiences and feedbacks with safety case reviews. Having all this in mind, there is of course potential for further improvements and developments of the review grid and some suggestions were provided by the SITEX WP2-contributors and associated partners.

14 Acknowledgment

The research leading to these results has received funding from the European Atomic Energy Community's Seventh Framework Programme (FP7/2014-2018) under grant agreement No. 662152, the project SITEX-II (Sustainable network of Independent Technical EXpertise for Radioactive Waste Disposal).

15 References

1. IAEA (2006) Fundamental Safety Principles, Safety Fundamentals No. SF-1.
2. IAEA (2016) Governmental, Legal and Regulatory Framework for Safety, Safety Standards Series No. GSR Part 1 rev 1
3. IAEA (2016) Leadership and Management for Safety, Safety Standards Series No. GSR Part 2
4. IAEA (2011) Disposal of radioactive waste. Specific safety requirements SSR-5.
5. IAEA (2002) Organization and staffing of the regulatory body for nuclear facilities. Safety Guide GS-G-1.1.
6. IAEA (2002) Review and assessment of nuclear facilities by the regulatory body. Safety Guide GS-G-1.2.
7. IAEA (2002) Regulatory inspection of nuclear facilities and enforcement by the regulatory body. Safety Guide GS-G-1.3.
8. IAEA (2002) Documentation for Use in Regulating Nuclear Facilities. Safety Guide GS-G-1.4.
9. IAEA (2006) Application of the management system for facilities and activities Safety Guide GS-G-3.1
10. IAEA (2008) The Management System for the Disposal of Radioactive Waste, Safety Guide GS-G-3.4
11. IAEA (2011) Geological Disposal Facilities for Radioactive Waste - Safety Standards Series SSG-14.
12. IAEA (2012) The safety case and safety assessment for the disposal of radioactive waste - Safety Standards Series SSG-23.
13. IAEA – GEOSAF project - The International Intercomparison and Harmonization Project on DEMONSTRATING THE SAFETY OF GEOLOGICAL DISPOSAL (Draft version – working material)
14. IAEA (2002) Application of the Safety Assessment Methodologies for Near Surface Disposal Facilities (ASAM) - Regulatory Review Working Group Report - 1st Research Coordinating Meeting, 11 to 15 November 2002, Vienna, Austria.
15. ICRP (2013) Publication 122. Radiological protection in geological disposal for long-lived solid radioactive waste.
16. EPG (2015) Report of the European pilot study on the regulatory review of a safety case for geological disposal of radioactive waste - European Pilot Group (version 10/11/2015).
17. WENRA (2014) WGWD - Working group on waste and decommissioning – Report Radioactive Waste Disposal Facilities Safety Reference Levels.
18. ETSON (2013) Safety Assessment guide - European Technical Safety Organisations Network (ETSON/2013-001 January 2013)
19. SITEX (2013) Deliverable D2.1 – Overview of existing technical guides and further development.

20. SITEX-I (2013) Deliverable D2.2 – Main key technical issues, expertise and support needed development.
21. SITEX-I (2014) Deliverable D4.1 – Available technical review guidance and further needs – (Harmonized methods for reviewing the safety case).
22. CEC (2011) Council of the European Union (2011). Council Directive 2011/70/EURATOM of 19 July 2011 establishing a community framework for the responsible and safe management of spent fuel and radioactive waste.
23. NEA (2011) Regulatory research for waste disposal – Objectives and international approaches. RWMC Regulators' Forum (RWMC-RF), NEA/RWM/RF(2010)4.
24. IAEA (2010) Licensing Process for Nuclear Installations Safety Guide No. SSG-12
25. INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Quality Management Systems - Requirements: ISO 9001:2015, ISO (2015).
26. INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Environmental Management Systems - Requirements with Guidance for Use: ISO 14001:2015, ISO (2015).
27. Lemy, F., & Bernier, F. (2013). Regulatory expectations regarding the safety case: moving from conceptualisation to implementation. In Proceedings of EURADWASTE 2013, 8th EC Conference on the Management of Radioactive Waste Community Policy and Research on Disposal (pp. 167-170).

16 List of figures

17 List of tables

Appendixes

APPENDIX 1 - THE SIX KEY PHASES [REF. 16, 4] OF DEVELOPMENT OF A DEEP GEOLOGICAL DISPOSAL

1. The **conceptualization phase**, during which an implementer considers potential suitable sites and design options, establishes the safety strategy (approach to developing a disposal concept, approach to safety assessment and basis for the management system) and carries out preliminary assessments. Regulatory review of the work at this stage should guide the implementer on the likelihood of achieving the necessary demonstration of safety and should help the implementer decide whether to commit resources to move to the next phase of the project.

2. The **siting phase**, during which the implementer confirm the suitability of potentially sites accordingly the safety strategy and characterizes these sites. A safety case is developed to the extent that a decision can be made on the preferred site.

3. The **reference design (and application for construction) phase**, during which the implementer adapts the conceptual design to the site properties, substantiates and finalises the design of the disposal facility, and develops the safety case, to support the implementer's application to construct, operate and close the facility. Based on the review of the safety case, the regulator would decide whether to grant a licence for the implementer to construct the facility. This is a crucial milestone in the development of a repository.

4. The **construction (and application for operation) phase**, during which the implementer demonstrates that it has built the facility as planned in the safety case and in accordance with the conditions of the construction licence. Towards the end of this phase, the implementer will present its final approach for operation and a concept for closing the facility. In preparing for operation, the implementer will need to demonstrate safety during operation and radiation protection of workers and members of the public.

5. The **operational phase**, during which the implementer emplaces waste packages in the disposal facility. During this phase, the implementer may build new disposal units, and backfill and possibly seal, either temporarily or permanently. During this phase, the implementer also develops an application to close and seal the facility, and prepares a plan for post-closure institutional controls, monitoring and surveillance. Towards the end of this phase the regulator will decide whether to grant a licence for the implementer to close and seal the facility. When the licence is granted the implementer proceeds to the closure of the facility.

6. The **post-closure phase**, at the start of which the implementer provides evidence to demonstrate that it has closed the disposal facility in accordance with safety requirements and presents a firm plan for institutional controls and continuing monitoring and surveillance.

APPENDIX 2 - REVIEW GRID - FIELDS (COLUMNS) DESCRIPTION

Column Title	Description or value	Remarks
Key Aspects of the SC (review & content)	Section of the review grid defined by the key aspects and components of the safety case	
IdNum	Unique numbering of items based on section and item number	
WENRA DI#	WENRA SRL "DI-" reference(s)	SRL number from WENRA disposal report [ref.17]
WENRA §	WENRA SRL § reference(s)	SRL § number(s) from WENRA disposal report [ref.17]
WENRA TITLE	WENRA SRL § Title(s) and subtitle(s)	SRL § title(s) from WENRA disposal report [ref.17]
WENRA TXT	WENRA SRL text(s) reference(s)	SRL content description from WENRA disposal report [ref.17]
Keyword 1	*Quick search with keyword level 1*	*Hidden for now (need to be further developed)*
Keyword 2	*Quick search with keyword level 2*	*Hidden for now (need to be further developed)*
Related Safety Case Content	Description of the related content and the review task	
Verification	Description of the recommended verifications to be done for the considered issue	
Generic	Checked if applicable and valid for all phases	Value = <*blank*> or X (see section 10.3)
Conceptualization	safety case Status considered for the current phase	Values = P or U (see section 10.3)
Site Investigation & selection	safety case Status considered for the current phase	Values = P, F or U (see section 10.3)
Reference Design & Lic. App. > Construction	safety case Status considered for the current phase	Values = P, F or U (see section 10.3)
Construction & Lic. App. > Operation	safety case Status considered for the current phase	Values = P, F or U (see section 10.3)
Operational phase & Lic. App.	safety case Status considered for the current phase	Values = P, F or U (see section 10.3)

> Closure		
Entering Post-Closure Until licence release	safety case Status considered for the current phase	Values = P, F or U(see section 10.3)
Feedback Experience Examples	SITEX Members feedback, experience and examples	Area dedicated for exchanges
Comments of SITEX WP2 involved members	SITEX members comments	Area dedicated for comments

APPENDIX 3 - FULL HARDCOPY OF THE REVIEW GRID

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App Construction	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
Safety Strategy	**SS-1**	**App**	**APP.3**	Typical Contents of a Safety Case	see Appendix 3	Identification of the constraints imposed by the prevailing circumstances (scientific and technical state of the art, socio-economical situation including site acceptance conditions…)	Verification that : • prevailing circumstances related to site are clearly identified ; • consequences on the safety strategy are assessed ; • safety is not unacceptably affected by prevailing circumstances.	X	P	Ⓕ	U	U	U	U
Safety Strategy	**SS-2**	**App**	**APP.3**	Typical Contents of a Safety Case	see Appendix 3	Identification of the constraints imposed by the prevailing circumstances (scientific and technical state of the art, socio-economical situation…)	Verification that : • prevailing circumstances, other than those related to site, are clearly identified ; • consequences on the safety strategy are assessed ; • safety is not unacceptably affected by prevailing circumstances.	X	P	P	Ⓕ	U	U	U
Safety Strategy	**SS-3**	**App**	**APP.3**	Typical Contents of a Safety Case	see Appendix 3	Safety strategy updates from previous phases	Verification that : • the modifications of the safety strategy from previous phases are clearly identified; • impact on safety of these modifications is assessed; • the Safety Strategy is consistent through the different phases of disposal facility development (based on a kind of "service agreement" during pre-licensing).	X	P	Ⓕ	U	U	U	U
Safety Strategy	**SS-4**	**DI-004** **DI-087**	**2.1.1** **2.4.1**	Safety Management • Responsibility Safety Verification • Scope & Content of Safety Case	**DI-04**: The licensee shall establish and implement its safety policy taking due account of national and international standards and ensure that matters related to safety are given the highest priority. **DI-87**: The licensee shall describe in the safety case all safety important aspects of the disposal facility and system including the waste to be disposed of, the design, the construction, operation, closure, decommissioning and post-closure activities. The typical content of a safety case is given in App.3	**Approaches, processes and methods guiding the overall project development**	Verification that the safety strategy is appropriate to meet the disposal safety objective (confidence should be graded taking into account the current phase).	X	P	P	Ⓕ	U	U	U
Safety Strategy	**SS-5**	**DI-024**	**2.2.1**	Disposal Facility Development • General Requirements	**DI-24**: The licensee shall ensure that safety will be achieved entirely by passive means, after closure of the facility and after any subsequent period of active institutional control.	**Description of the Safety Radiation Principles and deployment approach** **Description of other Safety Principles (such as demonstrability, DID, use of passive means) and deployment approach**	Verification that Safety Principles are correctly considered and are guiding the development of implementation of geological disposal.	X	P	P	Ⓕ	U	U	U
Safety Strategy	**SS-6**	**DI-024**	**2.2.1**	Disposal Facility Development • General Requirements	**DI-24**: The licensee shall ensure that safety will be achieved entirely by passive means, after closure of the facility and after any subsequent period of active institutional control.	**Approach for selecting a site, developing a concept, implementing practical engineering solutions, monitoring - surveillance and achieving post-closure safety by passive means**	Verification that the conceptualization and implementation approaches meet the Safety Objective and are in line with the Safety Principles and the regulatory requirements.	X	P	P	Ⓕ	U	U	U
Safety Strategy	**SS-7**	–	–	–	–	• Site selection process and selection criteria	Verification that site selection process and criteria allow to compare the safety level of the potential host rock.	X	P	Ⓕ	U	U	U	U
Safety Strategy	**SS-8**	–	–	–	–	• Basic design, construction, operational and monitoring - surveillance choices	Verification that the choices provide an optimized level of safety in the operational stage and after closure.	X	P	P	Ⓕ	U	U	U
Safety Strategy	**SS-9**	**DI-023** **DI-026**	**2.2.1** **2.2.1**	Disposal Facility Development • General Requirements	**DI-23**: The licensee shall ensure that safety is provided by means of multiple safety functions, including use of multiple barriers and controls. The performance of these barriers shall be achieved by diverse physical and chemical means. The overall performance of the disposal system shall not be unduly dependent on any single safety function according to the DID principle. **DI-26**: The licensee shall design, construct, operate, decommission and close the disposal facility in order to establish a disposal system which provides containment and isolation of the waste for a period of time suited to its radiological hazards.	• safety concept - multiple safety functions of the disposal system (e.g. containment and isolation) and their evolution with time, both during operation and post-closure	Verification of the independency and complementarity of the safety functions allocated to the components (in application of the DID principle).	X	P	Ⓕ	U	U	U	U
Safety Strategy	**SS-10**	**DI-028**	**2.2.1**	Disposal Facility Development • General Requirements	**DI-28**: The licensee shall ensure that any provisions to facilitate reversal of disposal operations, or retrieval of waste packages disposed of, have no unacceptable effects on post-closure safety.	• Arrangements to ensure reversibility and retrievability (when required)	Verification that measures taken to ensure reversibility and retrievability doesn't impair Safety.	X	P	P	Ⓕ	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
Safety Strategy	SS-11	DI-088	2.4.1	Safety Verification • Scope & content of the safety case	**DI-88**: The licensee shall in the safety case take due consideration to future human actions including inadvertent human intrusion. Such consideration should focus on reducing the likelihood and potential consequences of inadvertent human intrusion. Any measures taken to prevent inadvertent human intrusion must not compromise the operational safety of the disposal facility and the post-closure safety of the disposal system.	• Measures to reduce the likelihood and consequences of human intrusion	Verification that measures taken to reduce the likelihood and consequences of human intrusion doesn't impair Safety.	X	P	P	Ⓕ	U	U	U
Safety Strategy	SS-12	_	_	_	_	**Approach for safety assessment**	Verification that the safety assessment approach allows to verify that the Safety Objective can be met and is in line with the Safety Principles and the regulatory requirements.	X	P	Ⓕ	U	U	U	U
Safety Strategy	SS-13	_	_	_	_	• Approach to build assessment basis	Verification that the approach to build assessment basis allows to reach an adequate understanding of the system.	X	P	Ⓕ	U	U	U	U
Safety Strategy	SS-14	_	_	_	_	• Approach to assess the performance, the robustness and the radiological impact	Verification that the approach to assess the performance, the robustness and the radiological impact allows to verify that the Safety Objective can be met and is in line with the Safety Principles and the regulatory requirements.	X	P	Ⓕ	U	U	U	U
Safety Strategy	SS-15	_	_	_	_	• Approach to develop scenario and model development	Verification that the approach allows to develop a set of scenario which is envelop of the possible evolutions of the system.	X	P	Ⓕ	U	U	U	U
Safety Strategy	SS-16	_	_	_	_	• Approach for qualifying the mathematical models and codes used and building confidence in them	Verification that approach allows to qualify, validate and verify models and codes.	X	P	Ⓕ	U	U	U	U
Safety Strategy	SS-17	_	_	_	_	• Approach to treat uncertainties (Register of uncertainties and associated handling process)	Verification that the approach allows to treat the uncertainties in transparent and systematic way.	X	P	Ⓕ	U	U	U	U
Safety Strategy	SS-18	_	_	_	_	• The role of sensitivity analysis	Verification that sensitivity analysis is used to identify the importance for safety of the uncertainties.	X	P	Ⓕ	U	U	U	U
Safety Strategy	SS-19	_	_	_	_	• Approach to assess the technical feasibility based on a qualification program	Verification that the approach allows to prove the technical feasibility.	X	P	P	Ⓕ	U	U	U
Safety Strategy	SS-20	_	_	_	_	**Management approach**	Verification that the management approach allows verifying that the Safety Objective can be met and is in line with the Safety Principles and the regulatory requirements.	X	P	Ⓕ	U	U	U	U
Safety Strategy	SS-21	_	_	_	_	• Approach for managing the various activities related to the disposal facility development and implementation to ensure that :	Verification that : • work focuses on safety objectives; • adequate resources are available; • activities are correctly carried out and coordinated (e.g. QA, audit plans and managing concurrent activities).	X	P	Ⓕ	U	U	U	U
Safety Strategy	SS-22	DI-025	2.2.1	Disposal Facility Development • General Requirements	**DI-25**: Throughout the process of development (e.g. design, construction commissioning), operation, decommissioning and closure of a disposal facility, the licensee shall aim for an optimized level of safety considering both operational and the post-closure phases.	• Approach to optimization is set out and developed (sound engineering and technical solutions, sound principles of quality management applied during all phases) leading to achievement of the best level of protection under the prevailing circumstances;	Verification that optimization approach is set out, developed, recorded and lead to achieve the best level of protection under the prevailing circumstances: • if alternative options are adequately evaluated ; • if the disposal development and implementation is a result of an optimization process.	X	P	Ⓕ	U	U	U	U
Safety Strategy	SS-23	_	_	_	_	• Approach to manage uncertainties - Approach to reduce or avoid them (through R&D, design and location) - Approach to mitigate their effects (through design and location)	Verification that the approach to manage uncertainties is adequate to demonstrate the safety of the disposal system.	X	P	Ⓕ	U	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App Construction	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
Safety Strategy	**SS-24**	**DI-020** **DI-021**	**2.1.5** **2.1.5**	Safety Management • Records Knowledge Keeping	**DI-20**: The licensee shall ensure that, during design, construction, commissioning, operation, closure and post-closure until termination of the licence, knowledge and records important to safety are available and updated as appropriate for current activities, safety assessment and long term record keeping on • Characterization of the site • Design basis • Design • As built construction of the disposal facility • Operation including any operational occurrences and accidents • Inventory and emplacement of the waste • State of the disposal system after closure • All documents relating to the safety case. **DI-21**: The licensee shall ensure that, at termination of the licence, records on the site and on the as-closed state of the disposal facility are available for continuing preservation, in accordance with the national legal and regulatory framework.	Approach for long-term information management and record-keeping	Verification that the approach to preserve knowledge and records is adequate to the considered timeframe.	X	P	Ⓕ	U	U	U	U
Safety Strategy	**SS-25**	_	_	_	_	• Definition of timeframes for construction, operation and closure of the individual disposal modules and the facility	Verification that timeframes are adequately defined and in line with regulatory requirements.	X	P	P	Ⓕ	U	U	U
Safety Strategy	**SS-26**	**DI-031**	**2.2.1**	Disposal Facility Development • General Requirements	**DI-31**: The licensee shall ensure that any measures necessary for the purpose of accounting for and control of nuclear material shall not unacceptably affect operational and post-closure safety.	**Approach for accounting for and control of nuclear material**	Verification that : • appropriate measures are taken to guarantee safeguards issues ; • the measures taken in the design for the purpose of accounting for the control of nuclear material do not affect the operational and post-closure safety.	X	P	P	Ⓕ	U	U	U
Assessment Basis	**AB-1**	_	_	_	_	Establishment of the radiological criteria	Verification that radiological criteria are in line with the regulation and the safety strategy.	X	P	Ⓕ	U	U	U	U
Assessment Basis	**AB-2**	_	_	_	_	Establishment of the performance indicators	Verification that the performance indicators are in line with the safety strategy, allowing to assess the performance of the system and allowing comparing options.	X	P	Ⓕ	U	U	U	U
Assessment Basis	**AB-3**	_	_	_	_	Overall description and substantiation of the disposal system: -state of knowledge of initial state and evolution within different timeframes	Verification that the description: • is consistent with the safety strategy ; • identifies any modifications from the previous phases ; • considers processes that might disturb the normal evolution of the system and associated uncertainties ; • considers different timeframes related to the radiotoxicity evolution of the waste ; • gives a sufficient level of detail (considering the targets of the considered safety case) so that the basis of the safety case can be understood and if needed the safety case can be reproduced by a qualified independent party.	X	P	Ⓕ	U	U	U	U
Assessment Basis	**AB-4**	**DI-029**	**2.2.1**	Disposal Facility Development • General Requirements	**DI-29**: The licensee shall define and implement an appropriate program (e.g. through R&D, investigations, modelling, testing and monitoring activities) with the purpose of providing an understanding of the evolution of the disposal system adequate for the safety case.	Overall description and substantiation of the disposal system: • data related to waste, system components and environment characteristics (from characterization program and monitoring records)	Verification that : • data are collected by various techniques at various scales in different disciplines and are interpreted together to develop a coherent and consistent description of the system ; • data result from an appropriate program to understand the evolution of the disposal (e.g. through R&D, investigations, modelling, testing and monitoring activities).	X	P	Ⓕ	U	U	U	U
Assessment Basis	**AB-5**	**DI-029**	**2.2.1**	Disposal Facility Development • General Requirements	**DI-29**: The licensee shall define and implement an appropriate program (e.g. through R&D, investigations, modelling, testing and monitoring activities) with the purpose of providing an understanding of the evolution of the disposal system adequate for the safety case.	Overall description and substantiation of the disposal system: • synthesis of process understanding and of interactions between processes (both for normal evolution and disturbing events and processes), identification of safety-relevant phenomena	Verification that : • chemical (C), thermal (T), hydraulic (H), mechanical (M), gas formation (G), radiation (R), and biological (B) processes, effects and influences of waste and disposal induced phenomena, and their interactions (at present and in the future) are identified and studied in a systematic way ; • the synthesis results from an appropriate program to understand the evolution of the disposal (e.g. through R&D, investigations, modelling, testing and monitoring activities).	X	P	Ⓕ	U	U	U	U
Assessment Basis	**AB-6**	_	_	_	_	Characteristics and processes on which rest the performance of the disposal system and the transport of	Verification that these characteristics and processes allow to fulfil the safety functions defined in the safety concept.	X	P	Ⓕ	U	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site investigation & selection	Reference Design & Lic App	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
						radionuclides								
Assessment Basis	**AB-7**	**DI-030** **DI-035** **DI-036** **DI-038** **DI-091**	**2.2.1** **2.2.3** **2.2.3** **2.2.3** **2.4.1**	Disposal Facility Development • General requirements • Design Safety Verification • Scope & content of the Safety Case	**DI-30**: If construction, operation, decommissioning or closure activities take place concurrently, the licensee shall perform the works so that they will not have an unacceptable effect on operational or post-closure safety. **DI-35**: The licensee shall establish a design basis for the facility taking into account normal operational conditions, anticipated operational occurrences and possible accidents derived from a relevant set of postulated initiating events (PIEs). **DI-36**: The licensee shall design the disposal facility giving due consideration to both normal evolution of the disposal system after closure and scenarios involving events and processes that might disturb the normal evolution of the disposal system. **DI-38**: The licensee shall design the disposal facility to fulfil the following safety functions during the operational and post-closure phases • Control of the exposure of people and the environment • Containment and isolation of radioactive material • Control of sub-criticality, if applicable; If burnup credit is adopted for criticality management, the licensee shall confirm compliance with the limiting minimum burnup level with respect to initial enrichment by administrative and operational controls • Heat or gas removal, if applicable. **DI-91**: The licensee shall ensure that the safety case adequately reflects the factors (e.g. FEPs features, events and processes) that influence safety and their significance.	Identification of PIEs (postulated initiating events) and FEPs (features, events and processes) that are potentially important for safety (e.g. , internal perturbations (thermal, chemical, mechanical, radiological, nuclear,...) and external perturbations (intrusion, climate change, seismicity) that may adversely affect the safety functions of the different components, transport processes, ...) as well as addressing the questions about how, where and when this might happen.	Verification that • waste related PIEs and FEPs are considered in the design of the disposal (e.g.: heat and gas generation) and in the safety assessment ; • the operation related postulated initiating events (PIEs) and issues relevant to operational safety (documentation / data/ models) are identified, e.g.: concurrent activities, natural hazard during operation (earthquakes, floods, ...), operational accidents (fire safety, ...), ventilation, waste emplacement strategy, criticality	X	P	Ⓕ	U	U	U	U
Assessment Basis	**AB-8**	–	–	–	–	Potential impact of FEPS and PIEs	Verification that the potential impact of FEPs and PIEs are correctly identified.	X	P	Ⓕ	U	U	U	U
Assessment Basis	**AB-9**	–	–	–	–	Normal evolution	Verification that the normal evolution is correctly identified.	X	P	Ⓕ	U	U	U	U
Assessment Basis	**AB-10**	–	–	–	–	Potential radionuclides pathways (in the system and in the environment) and location of aquifer outlets	Verification that the potential radionuclides pathways are correctly identified and location of aquifer outlets	X	P	Ⓕ	U	U	U	U
Assessment Basis	**AB-11**	–	–	–	–	Identification and characterization of uncertainties relevant for safety	Verification that the uncertainties relevant for safety are correctly identified and characterized.	X	P	Ⓕ	U	U	U	U
Assessment Basis	**AB-12**	**DI-105**	**2.4.2**	Safety Verification • Operational & post-closure safety assessment	**DI-105**: In the safety assessment, the licensee shall only use models and computer codes that have undergone verification and, to the extent possible, validation.	Analysis tools (assessment methods, models, computer codes and databases) supporting the safety assessment	Verification that models and computer codes have undergone verification and, to the extent possible, validation.	X	P	Ⓕ	U	U	U	U
Assessment Basis	**AB-13**	**DI-035**	**2.2.3**	Disposal Facility Development • Design	**DI-35**: The licensee shall establish a design basis for the facility taking into account normal operational conditions, anticipated operational occurrences and possible accidents derived from a relevant set of postulated initiating events (PIEs).	Design basis	Verification that the design basis takes into account normal operational conditions, anticipated operational occurrences and possible accidents derived from a relevant set of postulated initiating events (PIEs).	X	P	P	Ⓕ	U	U	U
Assessment Basis	**AB-14**	**DI-022** **DI-025** **DI-034** **DI-036** **DI-037** **DI-053** **DI-098** **DI-099** **DI-084**	**2.2.1** **2.2.1** **2.2.3** **2.2.3** **2.2.3** **2.2.5** **2.4.1** **2.4.1** **2.4.1**	Disposal Facility Development • General Requirements • Design • Construction Safety Verification • Scope & content of the safety case	**DI-22**: The licensee shall design, construct, operate and decommission a disposal facility, ensure closure and, as appropriate, carry out post-closure surveillance so as to fulfil the objective of protecting people and the environment according to applicable radiological protection criteria, including the ALARA principle. A graded approach shall be adopted proportionate to the hazard presented by the waste. **DI-25**: Throughout the process of development (e.g. design, construction commissioning), operation, decommissioning and closure of a disposal facility, the licensee shall aim for an optimized level of safety considering both operational and the post-closure phases. **DI-34**: The licensee shall design the disposal facility to establish a disposal system which provides operational and post-closure safety. The licensee shall take into account the characteristics of the wastes to be disposed of (e.g.: radioactivity, heat and gas generation), the feasibility of the technical options and the characteristics of the selected site. **DI-36**: The licensee shall design the disposal facility giving due consideration to both normal evolution of the disposal system after closure and scenarios involving events and processes that might disturb the normal evolution of the disposal system. **DI-37**: The licensee shall design the disposal facility giving due consideration to disturbances of	Design (reference option and alternatives)	Verification that the disposal system is designed so as (following a graded approach proportionate to the hazard presented by the waste) : • to accommodate the existing and expected future waste streams ; • to fulfil the objective of protecting people and the environment according to applicable radiological protection criteria, including the ALARA principle ; • to optimize the level of safety considering both operational and post-closure phases ; • the design basis is properly accounted ; • to consider disturbances of the disposal system during operation that might affect post-closure safety ; • to consider both normal evolution and scenarios involving events and processes that might disturb the normal evolution of the disposal system. Verification that any modifications from the previous phases are identified and that their descriptions provide adequate basis to assess the safety implications of these modifications.	X	P	P	Ⓕ	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
					the disposal system during operation whose consequences may affect post-closure safety. **DI-53**: The licensee shall plan, assess, document and implement any modifications of design, construction procedures and methods using arrangements consistent with the importance to safety of the modification. These arrangements shall ensure that the modifications will not have an unacceptable effect on operational and post-closure safety. **DI-98**: The licensee shall update the safety case to reflect as a minimum • Changes to regulatory requirements and standards • Results from surveillance programs • Changes to the radioactive waste inventory to be disposed of •Results from analysis of operational occurrences and accidents • Results of the PSR; as soon as reasonably practicable and in accordance with the safety importance of the improved knowledge. **DI-99**: The licensee shall use the safety case as the basis for assessing the safety implications of changes to the disposal facility and system. **DI-84**: The licensee shall provide assurance through the safety case that workers, members of the public and the environment are and will remain adequately protected against the hazards associated with the waste being disposed of.									
Assessment Basis	**AB-15**	**DI-040**	**2.2.3**	Disposal Facility Development • Design	**DI-40**: The licensee shall base the design of the facility on applicable standards, appropriately proven techniques and the use of appropriate materials to ensure that the safety requirements will be met, throughout operation and post-closure.	Used materials and techniques	Verification that the design of the facility is based on applicable standards, appropriately proven techniques and the use of appropriate materials to ensure that the safety requirements will be met.	X	P	P	Ⓕ	U	U	U
Assessment Basis	**AB-16**	**DI-039**	**2.2.3**	Disposal Facility Development • Design	**DI-39**: The licensee shall identify and classify engineered structures, systems and components (SSCs) in accordance with their importance for operational and post-closure safety.	Identification of the structures, systems and components (SSCs)	Verification that the engineered structures, systems and components (SSCs) have been identified and classified in accordance with their importance for operational and post-closure safety.	X	P	P	Ⓕ	U	U	U
Assessment Basis	**AB-17**	**DI-026**	**2.2.1**	Disposal Facility Development • General Requirements	**DI-26**: The licensee shall design, construct, operate, decommission and close the disposal facility in order to establish a disposal system which provides containment and isolation of the waste for a period of time suited to its radiological hazards.	Description of the functions assigned to each component of the disposal system (both during operation and post-closure) and their evolution with time	Verification that the component's assigned functions allow to fulfil the safety functions of the system as defined in the safety concept.	X	P	P	Ⓕ	U	U	U
Assessment Basis	**AB-18**	**DI-024** **DI-026**	**2.2.1** **2.2.1**	Disposal Facility Development • General Requirements	**DI-24**: The licensee shall ensure that safety will be achieved entirely by passive means, after closure of the facility and after any subsequent period of active institutional control. **DI-26**: The licensee shall design, construct, operate, decommission and close the disposal facility in order to establish a disposal system which provides containment and isolation of the waste for a period of time suited to its radiological hazards.	How individually and together the components of the disposal system will ensure the passive isolation and containment functions and will function together in a complementary manner to ensure that there is adequate DID / SSCs description	Verification of independency and complementarity of disposal system components / safety functions (DID within the different considered timeframes) as to ensure the passive isolation and containment functions.	X	P	P	Ⓕ	U	U	U
Assessment Basis	**AB-19**	_	_	_	_	Performance targets (for the engineered components and the associated specifications): Safety envelop and design targets • The Safety Envelope represents the boundaries within which, at the start of the post-closure phase, the state of the disposal system (i.e. the parameters expressing the safety functions important for post-closure safety) must fall in order to deliver the post-closure safety functions. • The Design Target represents the boundaries within which, at the start of the post-closure phase, the state of the disposal system is designed to fall.) (Geosaf).	Verification that performance targets allow to fulfil the safety functions.	X	P	P	Ⓕ	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App Construction	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
Assessment Basis	AB-20	DI-043 DI-044	2.2.3 2.2.3	Disposal Facility Development • Design	**DI-43**: The licensee shall make design provisions for maintenance, testing, inspection and monitoring of SSCs, addressing also their ageing. **DI-44**: The licensee shall establish design provisions for monitoring the host environment.	Provisions for maintenance, testing, inspection and monitoring	Verification that there is adequate provisions for maintenance, testing, inspection and monitoring of : • SSCs, addressing also their ageing ; • host environment.	X	P	P	Ⓕ	U	U	U
Assessment Basis	AB-21	DI-028	2.2.1	Disposal Facility Development • General Requirements	**DI-28**: The licensee shall ensure that any provisions to facilitate reversal of disposal operations, or retrieval of waste packages disposed of, have no unacceptable effects on post-closure safety.	Provisions for retrievability and reversibility	Verification that any provisions taken to facilitate reversal of disposal operations, or retrieval of waste packages disposed of, have no unacceptable adverse effects on post-closure safety.	X	P	P	Ⓕ	U	U	U
Assessment Basis	AB-22	DI-092	2.4.1	Safety Verification • Scope & Content of Safety Case	**DI-92**: The licensee shall identify all uncertainties significant to safety and shall demonstrate that these uncertainties are adequately taken into account in the safety case. As part of the safety case, the licensee shall describe a program for uncertainty management.	Properties and characteristics of the disposal system components and their evolution with time, including uncertainties :	Verification that these properties and characteristics allow to fulfil the performance targets (Safety envelop and design targets).	X	P	P	Ⓕ	U	U	U
Assessment Basis	AB-23	DI-032 DI-033	2.2.2 2.2.2	Disposal Facility Development • Site Characterization	**DI-32**: The licensee shall prepare and implement a program for site characterization of the selected site. The program shall provide the information necessary to support the safety case. **DI-33**: The licensee shall conduct site characterization of the selected site • To establish baseline conditions for the site and the environment • To support the understanding of the normal evolution • To identify any events and processes associated with the site that might disturb the normal evolution of the disposal system • To support the understanding of the effect on safety of any FEPs associated with the disposal system.	Characterization program of the site (host rock and surrounding environment) and of the engineered components	Verification that the characterization program of the selected site(s) provides the data necessary to support the safety case : • to identify / characterize safety-relevant host rock properties and uncertainties ; • to establish baseline conditions for the site and the environment ; • to support the understanding of the normal evolution ; • to support the identification of possible disturbing (FEPs) associated with the site and the disposal facility ; • to support the understanding of the effect on safety of any FEPs features, events and processes, With respect to selection of parameter values and uncertainty ranges to be used in process models: • has "best use of available data" been used in assigning parameter values and in the estimation of uncertainties • Are any temporal or spatial "scaling" issues affecting extrapolation of parameters and associated uncertainties examined	X	P	P	Ⓕ	U	U	U
Assessment Basis	AB-24	DI-043	2.2.3	Disposal Facility Development • Design	**DI-43**: The licensee shall make design provisions for maintenance, testing, inspection and monitoring of (SSCs), addressing also their ageing.	Description of how to address ageing of facility components	Verification that the ageing of facility components is taken into account, both for the operational and the post-closure periods.	X	P	P	Ⓕ	U	U	U
Assessment Basis	AB-25	DI-074	2.3.1	Waste Acceptance • Derivation of WAC	**DI-74**: The licensee shall contribute to the safe management of the waste by establishing preliminary WAC at the earliest opportunity. The licensee shall update such preliminary to reflect the development of the disposal project.	Preliminary WACs	Verification that : • preliminary WACs are developed and established at the earliest opportunity to specify the radiological, mechanical, physical, chemical and biological characteristics of the waste packages and unpackaged waste ; • preliminary WACs refer to identified steps in the waste management program ; • preliminary Waste acceptance/conformity criteria are established for each waste types taking into account all the steps mentioned in the reference waste management program/option.	–	P	P	–	–	–	–
Assessment Basis	AB-26	DI-077	2.3.1	Waste Acceptance • Derivation of WAC	**DI-77**: The licensee shall specify criteria to ensure that waste accepted for disposal is physically and chemically stable over a timescale consistent with the safety case and compatible with other components of the disposal facility.	Final WACs	Verification that : • Appropriate WAC for disposal are established including the verification that : - They ensure the compatibility of the waste with the disposal conditions (corrosion, mechanical loads, …) and over timescales compatible with the safety case ; - Waste accepted for disposal is physically and chemically stable and compatible with the EBS and host rock.	–	P	P	P	Ⓕ	U	–
Assessment Basis	AB-27	DI-075	2.3.1	Waste Acceptance • Derivation of WAC	**DI-75**: Prior the start of waste emplacement, the licensee shall specify WAC so as to ensure the conformity of individual waste consignments to the safety case and other aspects of the disposal arrangements. The WAC shall be consistent with the operational and post-closure safety case and shall be reported to the regulatory body, for approval if appropriate.	Final WACs	Verification that : • Waste acceptance/conformity criteria are established prior the start of the waste emplacement, in accordance with the applicable regulations and license conditions ; • WAC are consistent with both the operational and LT safety ; • The contributions of the WAC to the operational safety and long term safety are identified.	–	P	P	P	Ⓕ	U	–

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
Assessment Basis	**AB-28**	**DI-076**	**2.3.1**	Waste Acceptance • Derivation of WAC	**DI-76**: The licensee shall ensure that WACs specify limits on important parameters such as radionuclide inventories and activity concentrations in individual waste consignments. Appendix 2 presents further details of the typical content for low and intermediate level waste.	Final WACs	Verification that WAC define limits • on radiologic parameters (nuclides inventory, activities, concentrations, doserates, contamination, criticality limits and margins…); • on physical and chemical parameters.	–	P	P	P	Ⓕ	U	–
Assessment Basis	**AB-29**	**DI-078**	**2.3.2**	Waste Acceptance • Revision of WAC	**DI-78**: The licensee shall report changes to WAC to the regulatory body, for approval if appropriate. The licensee shall substantiate the consistency of any changes with the assumptions made in the safety case.	Modifications of WACs	Verification that any modifications in the WACs (final or preliminary) are well reported and are consistent with the assumptions made in the safety case.	–	P	P	P	Ⓕ	U	–
Assessment Basis	**AB-30**	**DI-079**	**2.3.3**	Waste Acceptance • Acceptance of WAC	**DI-79**: The licensee shall ensure that the waste accepted for disposal conforms to waste acceptance criteria. A conformity assessment shall be performed in accordance with written arrangements which include administrative procedures, inspections and/or tests.	Waste conformity assessment	Verification that appropriate arrangements (including audits, procedures, inspections &/or tests) are developed / implemented to ensure full compliance of the accepted waste with WAC.	–	P	P	P	Ⓕ	U	–
Assessment Basis	**AB-31**	**DI-080**	**2.3.3**	Waste Acceptance • Acceptance of WAC	**DI-80**: The licensee shall provide a system for tracing the location in the disposal facility of any waste disposed of.	Records, tracing of disposed waste	Verification that : • Waste receipt and inventory (before and during operation) are recorded and continuously updated ; • A process for tracing the location in the disposal facility of any waste disposed of is established and implemented.	–	P	P	P	Ⓕ	U	–
Assessment Basis	**AB-32**	–	–	–	–	Description of excavation and construction	Review of excavation and construction methods, procedures and implementation :	–	P	P	Ⓕ	U	U	–
Assessment Basis	**AB-33**	**DI-051**	**2.2.5**	Disposal Facility Development • Construction	**DI-51**: The licensee shall construct the disposal facility in such a way as to preserve the post-closure safety functions of the host environment.	Preservation Host rock	Verification that the facility will be excavated and constructed in such a way as to preserve the post-closure safety functions of the host environment.	–	P	P	Ⓕ	U	U	–
Assessment Basis	**AB-34**	**DI-050** **DI-040**	**2.2.5** **2.2.5**	Disposal Facility Development • Construction	**DI-50**: The licensee shall construct the disposal facility in accordance with the design as described in the safety case and by application of appropriately proven techniques. **DI-40**: The licensee shall base the design of the facility on applicable standards, appropriately proven techniques and the use of appropriate materials to ensure that the safety requirements will be met, throughout operation and post-closure.	Proven Techniques	Verification that the facility will be constructed by application of appropriately proven techniques or by qualified technics based notably on results from feasibility and demonstration tests.	–	P	P	Ⓕ	U	U	–
Assessment Basis	**AB-35**	**DI-051**	**2.2.5**	Disposal Facility Development • Construction	**DI-51**: The licensee shall construct the disposal facility in such a way as to preserve the post-closure safety functions of the host environment.	Safety functions EBS	Verification that the facility will be constructed in such a way as to fulfil the safety functions of the EBS (e.g., review of the material specifications …) based on non-destructive testing (NDT), measurement and testing activities of EBS safety-relevant properties.	–	P	P	Ⓕ	U	U	–
Assessment Basis	**AB-36**	**DI-019**	**2.1.4**	Safety Management • Record Keeping	**DI-19**: The licensee shall establish and conduct an experience feedback program to collect, screen, analyze and document in a systematic way experience important to safety in all phases of facility development until termination of the licence. This program shall cover issues of importance for both operational and post-closure safety. This information shall be used for preventing events and processes adverse to safety, and for improving the design or manner of construction and operation of the facility as necessary. Experience from other facilities shall also be considered as appropriate.	Experience and feedback	Verification that the experience feedback from the project development and from other facilities is properly taken into account.	–	P	P	Ⓕ	U	U	–
Assessment Basis	**AB-37**	**DI-050**	**2.2.5**	Disposal Facility Development • Construction	**DI-50**: The licensee shall construct the disposal facility in accordance with the design as described in the safety case and by application of appropriately proven techniques.	Conformity to the design in safety case	Verification that the disposal facility is / has been constructed in accordance with the design as described in the safety case.	–	–	–	P	Ⓕ	U	–
Assessment Basis	**AB-38**	–	–	–	–	Correct application of the procedures and material specifications	Verification that construction procedures and material specifications have been correctly applied (e.g., examination of construction records …).	–	–	–	P	Ⓕ	U	–
Assessment Basis	**AB-39**	–	–	–	–	Description of facility commissioning / trial operations to confirm that systems function as designed	Verification that : • Plans are established to commission the facility and duly implemented ; • The trial operations confirm that systems function as designed and expected.	–	–	–	–	Ⓕ	U	U
Assessment Basis	**AB-40**	**DI-085** **DI-054**	**2.4.1** **2.2.6**	Safety Verification • Scope & Content of Safety Case Disposal Facility Development • Operation	**DI-85**: The licensee shall include in the safety case, a safety assessment that demonstrates conformity with the safety requirements. The licensee shall also present an evaluation of the technical feasibility of the design and the construction, operation, decommissioning, closure and post-closure activities. **DI-54**: The licensee shall operate the facility in accordance with the conditions of the licence and the relevant regulatory requirements so as to maintain safety during the operational phase, and so as to establish and preserve the post-closure safety functions claimed in the safety case.	• Description of operational issues and how they are / will be handled for all stages	Verification that : • the necessary arrangements are taken to operate the facility in accordance with the conditions of the licence and the relevant regulatory requirements as to maintain safety during the operational phase and to establish and preserve the post-closure safety functions ; • operational issues are identified including normal operation conditions, anticipated operational	X	P	P	Ⓕ	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
							occurrences and possible accidents.							
Assessment Basis	AB-41	DI-085	2.4.1	Safety Verification • Scope & Content of Safety Case	**DI-85**: The licensee shall include in the safety case, a safety assessment that demonstrates conformity with the safety requirements. The licensee shall also present an evaluation of the technical feasibility of the design and the construction, operation, decommissioning, closure and post-closure activities.	Results from feasibility and demonstration tests	Verification of the adequacy and the technical feasibility of operation and decommissioning and closure activities.	–	–	P	P	Ⓕ	U	–
Assessment Basis	AB-42	DI-058	2.2.6	Disposal Facility Development • Operation	**DI-58**: The licensee shall make adequate arrangements for commissioning and operation of the disposal facility including arrangements for receiving, handling and emplacement of waste before these activities are commenced.	Description of waste package emplacement in the disposal	Verification that the arrangements for receiving, handling and emplacement of waste and for dealing with waste packages that do not conform to the WACs are adequate.	.	.	P	P	Ⓕ	U	.
Assessment Basis	AB-43	DI-020	2.1.5	Safety Management • Records Knowledge Keeping	**DI-20**: The licensee shall ensure that, during design, construction, commissioning, operation, closure and post-closure until termination of the licence, knowledge and records important to safety are available and updated as appropriate for current activities, safety assessment and long term record keeping on • Characterization of the site • Design basis • Design • As built construction of the disposal facility • Operation including any operational occurrences and accidents • Inventory and emplacement of the waste • State of the disposal system after closure • All documents relating to the safety case.	As-built description of the already implemented part of the disposal system.	Verification that : • The as-built state represents the real state of the disposal system at a given time (as-built vs reference option) ; • Any modifications to the reference design is indicated, documented, justified and doesn't impair the safety.	–	–	–	–	P	Ⓕ	–
Assessment Basis	AB-44	DI-055	2.2.6	Disposal Facility Development • Operation	**DI-55**: The licensee shall make and implement arrangements to detect and respond to anticipated operational occurrences and possible accidents. Provisions for doing so shall not unacceptably affect operational or post-closure safety.	Provisions and arrangements to detect and respond to anticipated operational occurrences and possible accidents	Verification that : • Arrangements are taken to detect and respond to anticipated operational occurrences and possible accidents ; • Provisions for doing so shall not unacceptably affect operational or post-closure safety.	–	–	P	P	Ⓕ	U	–
Assessment Basis	AB-45	DI-057	2.2.6	Disposal Facility Development • Operation	**DI-57**: The licensee shall establish, substantiate, document and implement OLCs to operate the disposal facility safely, to maintain the waste in a safe state during operation and to ensure compliance with the requirements for post-closure safety.	Identification and definition of the OLCs	Verification that OLCs will allow maintaining the waste in a safe state during operation and operating the facility safely.	–	–	P	P	Ⓕ	U	–
Assessment Basis	AB-46	DI-045	2.2.3	Disposal Facility Development • Design	**DI-45**: The licensee shall incorporate passive safety features for operational safety into the design of the disposal facility as far as reasonably practicable.	Passive safety features for operational safety into the design	Verification that passive safety features for operational safety into the design of the disposal facility are incorporated as far as reasonably practicable.	–	–	P	P	Ⓕ	U	–
Assessment Basis	AB-47	DI-018	2.1.4	Safety Management • Record Keeping	**DI-18**: The licensee shall ensure that, for any operational activity relating to safety, all documents required to demonstrate that it will be undertaken safely (e.g.: operational procedures, operating instructions) have been prepared before beginning that activity.	Written rules, instructions and procedures to ensure safety of the facility and protection of workers, of members of the public and of the environment covering both the operation and the maintenance of relevant equipment (instructions and procedures).	Verification that : • All documents required for an activity (e.g.: operational procedures, operating instructions) have been prepared and validated before beginning that activity ; • Any modifications to the operational processes and procedures are correctly identified, described, documented and validated as to not impair the safety.	.	.	P	P	Ⓕ	U	.
Assessment Basis	AB-48	–	–	–	–	Procedure for waste retrieval (in case of waste defect)	Verification that the feasibility to retrieve the waste is demonstrated and has no impact on both the operational and long term safety.	–	–	P	Ⓕ	U	U	U
Assessment Basis	AB-49	DI-065 DI-066 DI-067 DI-108	2.2.6 2.2.6 2.2.6 2.4.3	Disposal Facility Development • Operation Safety Verification • Periodic Safety Review	**DI-65**: The licensee shall establish and implement programs for maintenance, periodic testing and inspection, based on written procedures in order to ensure and confirm that (SSCs) are able to function in accordance with the requirements for operational and post-closure safety. **DI-66**: The licensee shall record and assess the results of maintenance, periodic testing and inspection, important to safety. Results derived from these programs shall be used to review the adequacy of the design, construction and operation of the disposal facility and to identify any implications for post-closure safety. **DI-67**: At regular intervals, the licensee shall review and as necessary revise programs for maintenance, periodic testing and inspection to incorporate the lessons learned from experience. **DI-108**: The licensee shall document the results of the PSR, and derive and implement an action plan for all reasonably practicable improvements to safety.	Maintenance, periodic testing and inspection programs	Verification that : • appropriate maintenance, periodic testing and inspection programs ensuring and confirming that SSCs are able to function in accordance with the requirements for operational safety are established, implemented and revised as necessary ; • the results of maintenance, periodic testing and inspection are recorded, assessed and taken into account i.e. in the PSR ; • these results are used to review the adequacy of the design, construction and operation of the disposal facility and to identify any implications for post-closure safety.	–	–	–	P	Ⓕ	U	–

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App Construction	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
Assessment Basis	AB-50	DI-062 DI-063 DI-064	2.2.6 2.2.6 2.2.6	Disposal Facility Development • Operation	**DI-62**: The licensee shall prepare and implement an on-site emergency plan to respond to possible accidents requiring protection of the personnel and members of the public. This emergency plan shall be proportionate to the consequences of the possible accidents considered and shall provide for • Regaining control of the disposal facility in an emergency • Preventing or mitigating the consequences of any such emergency; If an off-site emergency plan is required, the licensee shall provide the technical basis for its development and implementation. **DI-63**: For the purposes of emergency planning the licensee shall, as appropriate • Establish and implement the necessary organizational structure for clear allocation of responsibilities and authorities, • Ensure that, based on the on-site emergency plan, appropriate trained and qualified personnel, facilities and equipment needed to control an emergency will be available whenever they might be required, and • Establish arrangements as necessary for coordinating emergency activities and cooperating with external response organizations throughout all phases of an emergency. **DI-64**: The licensee shall submit the on-site emergency plan to the regulatory body. At regular intervals, the licensee shall carry out emergency exercises, some of which shall be witnessed by the regulatory body. Some of these exercises shall, as appropriate, include the participation of external emergency response organizations. The plan shall be subject to review and updating in the light of the experience gained.	Emergency Plan	Verification that the emergency plan : • is prepared to respond to possible accidents, implemented and updated ; • is proportionate to the consequences of the possible accidents considered ; • provides for regaining control of the disposal facility in an emergency, preventing or mitigating the consequences of any such emergency ; • establishes arrangements for coordinating emergency activities and cooperating with external response organizations throughout all phases of an emergency ; • provides the technical basis for the development and implementation of an off-site emergency plan when required. Verification that the emergency exercises are foreseen, including the participation of external emergency response organizations.	–	–	–	P	Ⓕ	U	–
Assessment Basis	AB-51	DI-059 DI-069 DI-070	2.2.6 2.2.7 2.2.7	Disposal Facility Development • Operation • Closure of Disposal Facility	**DI-59**: Before starting the emplacement of any waste, the licensee shall review the plan for decommissioning, closure and post-closure activities. **DI-69**: Before starting decommissioning and closure, the licensee shall define the corresponding program so that it takes into account, as appropriate • The state of the facility, as constructed and operated including information on waste inventory and emplacement • Dismantling and removal of operational equipment • Remaining backfilling and sealing • Decommissioning of auxiliary structures, e.g. parts of the facility on the surface • Environmental remediation as required • Programs for monitoring and surveillance • Programs for security and safeguards • Plans for preserving knowledge and records about the waste disposed of and the disposal system. **DI-70**: The licensee shall perform decommissioning and closure activities in accordance with the national legal and regulatory framework so as to maintain safety during decommissioning and closure, and so as to establish and preserve the post-closure safety functions claimed in the safety case.	Decommissioning program	Verification that the decommissioning program : • is established in accordance with the regulation and that associated financial guarantees are given ; • ensures and maintains safety during decommissioning, preserving the post-closure safety functions ; • takes into account notably the dismantling and removal of operational equipment, decommissioning of auxiliary structures, environmental remediation as required ; • is effectively implemented.	–	–	–	P	P	Ⓕ	–
Assessment Basis	AB-52	DI-068 DI-069 DI-094	2.2.7 2.2.7 2.4.1	Disposal Facility Development • Closure of disposal facility Safety Verification • Scope & content of the Safety Case	**DI-68**: The licensee shall close the disposal facility in such a way as to provide for the safety functions required after closure. **DI-69**: Before starting decommissioning and closure, the licensee shall define the corresponding program so that it takes into account, as appropriate • The state of the facility, as constructed and operated including information on waste inventory and emplacement • Dismantling and removal of operational equipment • Remaining backfilling and sealing • Decommissioning of auxiliary structures, e.g. parts of the facility on the surface • Environmental remediation as required • Programs for monitoring and surveillance • Programs for security and safeguards • Plans for preserving knowledge and records about the waste disposed of and the disposal system. **DI-94**: The licensee shall present as part of the safety case the program, plans and provisions for closure of the disposal facility and for any post-closure activities. The program, plans and provisions shall be revised and updated as appropriate.	Closure program	Verification that : • the closure program is established in accordance with the regulation and that associated financial guarantees are given ; • the closure program is effectively implemented ; • the modifications to the closure program during the previous phases and/or its implementation are clearly identified ; • the impact of the modifications on the safety is assessed ; • the closure program ensures and maintains safety during closure activities, preserving the post-closure safety functions ; • the closure program takes into account notably the remaining backfilling and sealing activities.	.	.	.	P	P	Ⓕ	.
Assessment Basis	AB-53	DI-072 DI-094	2.2.8	Disposal Facility Development • Post Closure phase & release from Regulatory Control	**DI-72**: After closure and until termination of the licence, the licensee shall implement a post-closure surveillance program, if appropriate. In the event that surveillance demonstrates the need for remedial actions, the licensee shall implement such actions in accordance with the licence. **DI-94**: The licensee shall present as part of the safety case the program, plans and provisions for closure of the disposal facility and for any post-closure activities. The program, plans and provisions shall be revised and updated as appropriate.	Post Closure	Verification that : • a post-closure surveillance program, if appropriate, is established until termination of the licence ; • remedial actions are foreseen (in accordance with the licence) in the event that surveillance demonstrates the need for such actions ; • the post-closure surveillance program is effectively implemented ;	–	–	–	P	P	Ⓕ	–

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
							• the modifications to the post-closure surveillance program during the previous phases and/or its implementation are clearly identified ; • the impact of the modifications on the safety is assessed.							
Assessment Basis	**AB-54**	**DI-073**	**2.2.8**	Disposal Facility Development • Post Closure phase & release from Regulatory Control	**DI-73**: As a condition for the termination of the licence, the licensee shall • Demonstrate that the results of any surveillance program are consistent with the assumptions of the safety case, to the satisfaction of the regulatory body • Propose any restrictions on land use, suggest and substantiate the way they shall be implemented, or any other measures deemed appropriate for the post-licensing phase.	Licence termination	Verification that : • results of surveillance programs are consistent with the assumptions of the safety case ; • restrictions on land use are proposed ; • any other measures deemed appropriate for the post-licensing phase are foreseen.	–	–	–	–	–	–	Ⓕ
Monitoring	**MO-1**	**DI-047**	**2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-47**: Before starting construction, the licensee shall establish a baseline state of the environment both for supporting the monitoring program and for evaluating the impact of the facility on the environment.	Approach for monitoring	Verification that the monitoring approach is line with the needs for safety assessment.	X	P	P	Ⓕ	U	U	U
Monitoring	**MO-2**	**DI-047**	**2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-47**: Before starting construction, the licensee shall establish a baseline state of the environment both for supporting the monitoring program and for evaluating the impact of the facility on the environment.	Baseline state of the site and the host environment before starting construction	Verification that a baseline state of the site and the host environment is established before starting construction and that the baseline conditions are adequate for : • Supporting the monitoring program, and • Evaluating the impact of the facility on the environment.	–	–	–	Ⓕ	–	–	–
Monitoring	**MO-3**	**DI-047**	**2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-47**: Before starting construction, the licensee shall establish a baseline state of the environment both for supporting the monitoring program and for evaluating the impact of the facility on the environment.	Baseline state of the engineered components of the facility after emplacement	Verification that a baseline state of the engineered components is established after their emplacements for • Supporting the monitoring program, and • Evaluating the ageing of the components.	–	–	–	–	Ⓕ	U	U
Monitoring	**MO-4**	**DI-048** **DI-049** **DI-052**	**2.2.4** **2.2.4** **2.2.5**	Disposal Facility Development • Information Gathering & Monitoring • Construction	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making & • Providing background information for any post-closure surveillance program. **DI-52**: In order to refine the assumptions of the safety case, the licensee shall gather information during construction to improve the knowledge of • The intrinsic properties of the host environment • The response of the host environment to the presence of the disposal facility.	Monitoring Program	Verification that an appropriate and systematic monitoring program is established i.e. that allows to : • Contribute to demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions ; • Confirm that the disposal facility and system behaves and evolves as expected in the safety case ; • Identify any deviations from the expected behavior of the disposal ; • Contribute to confirming and refining the key assumptions and models made in the safety case ; • Enhance understanding of the environmental conditions and of the functioning of the disposal ; • Acquire data for supporting decision-making ; • Provide background information for any post-closure surveillance program ; • identify how the results will be taken into account, as well as the way it will be treated, analyzed, organized and recorded ; • ensure the consistency of the monitoring programs updates through the different phases. Verification that the impact of the monitoring and surveillance program has been adequately assessed and is acceptable	X	P	P	Ⓕ	U	U	U
Monitoring	**MO-5**	**DI-048** **DI-049**	**2.2.4** **2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for	Specific Monitoring Program - Environment	Verification that a monitoring program of the environment is established before starting construction.	–	–	P	Ⓕ	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
					supporting decision-making and • Providing background information for any post-closure surveillance program.									
Monitoring	MO-6	DI-048 DI-049	2.2.4 2.2.4	Disposal Facility Development • Information Gathering & Monitoring	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.	Specific Monitoring Program - Site	Verification that a monitoring program of the site is established before starting construction.	–	–	P	Ⓕ	U	U	U
Monitoring	MO-7	DI-048 DI-049	2.2.4 2.2.4	Disposal Facility Development • Information Gathering & Monitoring	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.	Specific Monitoring Program - EBS	Verification that a monitoring program of the EBS is established before emplacement of the EBS.	–	–	–	P	Ⓕ	U	U
Monitoring	MO-8	DI-048 DI-049	2.2.4 2.2.4	Disposal Facility Development • Information Gathering & Monitoring	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.	Specific Monitoring Program - Waste	Verification that before emplacement of the waste, a monitoring program of the Waste is established.	–	–	–	P	Ⓕ	U	U
Monitoring	MO-9	DI-048 DI-055	2.2.4 2.2.6	Disposal Facility Development • Information Gathering & Monitoring Disposal Facility Development • Operation	**DI-48**: Before starting construction, the licensee shall define and document a systematic monitoring program to be implemented during construction, commissioning, operation, decommissioning and closure, and as appropriate after closure. **DI-55**: The licensee shall make and implement arrangements to detect and respond to anticipated operational occurrences and possible accidents. Provisions for doing so shall not unacceptably affect operational or post-closure safety.	Specific Monitoring Program - Occupational Safety	Verification that : • A monitoring program of the occupational safety is established before emplacement of the waste ; • Provisions are made for detecting anticipated operational occurrences and possible accidents.	–	–	–	P	Ⓕ	U	U
Monitoring	MO-10	–	–	–	–	Monitoring: implementation procedures	Verification of the adequacy of the implementation procedures with respect to the monitoring objectives.	–	–	–	Ⓕ	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App Construction	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
Monitoring	**MO-11**	_	_	_	_	Monitoring implementation	Verification of the effective and appropriate implementation of monitoring procedures: • Verification of field investigation and monitoring records ; • Verification of safety-relevant data measurement activities and devices performed by or for the (future) implementer (piezo metric measurements, …) ; • Independent tests / measurements as appropriate.	_	_	_	_	Ⓕ	U	U
Monitoring	**MO-12**	**DI-049**	**2.2.4**	Disposal Facility Development • Information Gathering & Monitoring	**DI-49**: The licensee shall ensure that the monitoring program contributes to • Demonstrating adequate protection of people and the environment and demonstrating compliance with the regulatory requirements and licence conditions • Confirming that the disposal facility and system behaves and evolves as expected in the safety case • Building confidence in and refining the key assumptions and models made in the safety case • Enhancing understanding of the environmental conditions and of the functioning of the disposal system • Acquiring information for supporting decision-making and • Providing background information for any post-closure surveillance program.	Results of monitoring both within the disposal facility and in its environment	Verification that : • the regulatory requirements and licence conditions are fulfilled ; • the disposal facility and system behaves and evolves as expected in the safety case ; • deviations from the expected behavior of the disposal are identified ; • key assumptions and models are confirmed.	.	.	.	.	Ⓕ	U	U
Safety Assessment	**SA-1**	**DI-083**	**2.4.1**	Safety Verification • Scope & content of the safety case	**DI-83**: The licensee shall provide to the regulatory body a safety case substantiating that operational and post-closure safety requirements as specified in the national legal and regulatory framework are met. The licensee shall update the safety case in accordance with regulatory requirements.	Operational and post-closure safety requirements specified in the national legal and regulatory framework	Verification that operational and post-closure safety requirements as specified in the national legal and regulatory framework are substantiated in the safety case and can be met.	X	P	Ⓕ	U	U	U	U
Safety Assessment	**SA-2**	**DI-025** **DI-093**	**2.2.1** **2.4.1**	Disposal Facility Development • General Requirements Safety Verification • Scope & content of the Safety Case	**DI-25**: Throughout the process of development (e.g. design, construction commissioning), operation, decommissioning and closure of a disposal facility, the licensee shall aim for an optimized level of safety considering both operational and the post-closure phases. **DI-93**: The licensee shall ensure that the safety case shows that the principle of optimization has been addressed in relevant choices and decisions on the disposal system.	Process to optimize operational and post-closure safety issues, review of different options	Verification that choices and decisions related to operational and post-closure safety derive from a process involving optimization of radiological protection.	X	P	Ⓕ	U	U	U	U
Safety Assessment	**SA-3**	**DI-053** **DI-060** **DI-061** **DI-071** **DI-098** **DI-097** **DI-099**	**2.2.5** **2.2.6** **2.2.6** **2.2.7** **2.4.1** **2.4.1** **2.4.1**	Disposal Facility Development • Construction • Operation • Closure of Disposal Facility Safety Verification • Scope & content of the safety case	**DI-53**: The licensee shall plan, assess, document and implement any modifications of design, construction procedures and methods using arrangements consistent with the importance to safety of the modification. These arrangements shall ensure that the modifications will not have an unacceptable effect on operational and post-closure safety. **DI-60**: The licensee shall ensure that any modifications to the disposal facility will not have an unacceptable effect on operational and post-closure safety. **DI-61**: The licensee shall plan, assess, document and implement any modifications of design, WAC, SSCs, OLCs and operational procedures and methods using arrangements consistent with the importance to safety of the modifications. **DI-71**: The licensee shall plan, assess, document and implement any modifications in the decommissioning and closure procedures and methods using arrangements consistent with the importance to safety of the modifications. **DI-98**: The licensee shall update the safety case to reflect as a minimum • Changes to regulatory requirements and standards • Results from surveillance programs • Changes to the radioactive waste inventory to be disposed of • Results from analysis of operational occurrences and accidents • Results of the PSR s; as soon as reasonably practicable and in accordance with the safety importance of the improved knowledge. **DI-97**: The licensee shall update the safety case to reflect current knowledge and submit it to the regulatory body • in support of applications for major regulatory decisions • as a result of major changes relevant to safety (e.g. in basic assumptions) • at least at regular (periodic) intervals as defined in the national legal and regulatory framework **DI-99**: The licensee shall use the safety case as the basis for assessing the safety implications of changes to the disposal facility and system.	Assessment of operational occurrences, accidents and modifications / updates (from previous phase) related to operational and post-closure safety issues	Verification that : • operational occurrences, accidents and modifications / updates will not have an unacceptable effect on operational and post-closure safety ; • all modifications are substantiated against their importance to safety ; i.e. modification of design, waste acceptance criteria, SSCs, OLCs, operational • decommissioning • closure procedures and methods.	_	_	_	P	Ⓕ	U	U
Safety Assessment	**SA-4**	**DI-100** **DI-086**	**2.4.2** **2.4.1**	Safety Verification • Operational and post-closure safety assessment • Scope & content of the safety case	**DI-100**: The licensee shall consider in the operational safety assessment, both occupational exposure and public exposure resulting from normal operation, and anticipated operational occurrences and possible accidents. **DI-86**: The licensee shall include in the safety assessment for the operational and post-closure phases • An evaluation of the performance and robustness of the disposal facility and system and its components • An evaluation of the radiological impact.	Assessment of the radiological exposures and impacts that might arise during operation Assessment of the performance and robustness of the installation and of the radiological exposures	Verification that : • the assessment covers both occupational exposure and public exposure during normal operation, anticipated operational occurrences and possible accidents ; • the facility (as planned, designed or constructed) allows to meet the operational safety requirements, the performance and robustness of the disposal system and the	_	_	_	P	Ⓕ	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
							radiological criteria ; • the radiological impact during the operational period is as expected in the safety case.							
Safety Assessment	SA-5	DI-057	2.2.6	Disposal Facility Development • Operation	**DI-57**: The licensee shall establish, substantiate, document and implement Operational limits and conditions (OLCs) to operate the disposal facility safely, to maintain the waste in a safe state during operation and to ensure compliance with the requirements for post-closure safety.	Monitoring records of occupational exposure (radiation, radon, ...)	Verification of compliance with Operational limits and conditions (OLCs), e.g... • Verification and if necessary independent dose / contamination measurements ; • Verification that the individual and collective doses do not exceed the dose constraints ; • Verification that the doserates / contamination measurements stay below the operational limits.	–	–	–	–	–	Ⓕ	–
Safety Assessment	SA-6	DI-038	2.2.3	Disposal Facility Development • Design	**DI-38**: The licensee shall design the disposal facility to fulfil the following safety functions during the operational and post-closure phases • Control of the exposure of people and the environment • Containment and isolation of radioactive material • Control of sub-criticality, if applicable; If burnup credit is adopted for criticality management, the licensee shall confirm compliance with the limiting minimum burnup level with respect to initial enrichment by administrative and operational controls • Heat or gas removal, if applicable.	Assessment of effective fulfilment of safety functions associated with operational safety	Verification that the safety functions associated with operational safety during normal operation, anticipated operational occurrences and possible accidents are fulfilled as required in the safety case.	–	–	–	–	–	Ⓕ	U
Safety Assessment	SA-7	DI-046	2.2.3	Disposal Facility Development • Design	**DI-46**: The licensee shall design the equipment of the disposal facility to take account of radiation protection aspects, ease of maintenance and inspection, and minimization of the probability and consequences of anticipated operational occurrences and, as far as practicable, possible accidents during handling.	Assessment of the handling equipment with regards to safety issues	Verification that the equipment of the disposal facility take account of radiation protection aspects, allow ease of maintenance and inspection, and minimize the probability and consequences of anticipated operational occurrences and, as far as practicable, possible accidents during handling.	–	–	–	P	P	Ⓕ	U
Safety Assessment	SA-8	–	–	–	–	Sensitivity analysis	Verification that the sensitivity analysis contribute to : • identify the key dependencies on parameter values and assumptions ; • quantify the situations and phenomena that may affect the performance and the radiological impact ; • identify the uncertainties and evaluate their importance for safety.	–	P	Ⓕ	U	U	U	–
Safety Assessment	SA-9	DI-103	2.4.2	Safety Verification • Operational and post-closure Safety Assessment	**DI-103**: The licensee shall substantiate the timescale over which the safety assessment is carried out in the safety case.	Substantiation of the timescales over which assessments are carried out	Verification that the timescale over which assessments are carried out is substantiated. E.g. timescale considered to assess the performance and the robustness of the disposal system; timescale considered to assess the radiological impact; ...	–	P	Ⓕ	U	U	U	–
Safety Assessment	SA-10	DI-104	2.4.2	Safety Verification • Operational and post-closure Safety Assessment	**DI-104**: The licensee shall assess the possible evolution of the criticality hazard after closure in the light of long-term uncertainties.	Assessment of the criticality hazard	Verification that the criticality hazard has been assessed including its possible evolution after closure in the light of long-term uncertainties.	–	P	Ⓕ	U	U	U	–
Safety Assessment	SA-11	DI-105 DI-101	2.4.2 2.4.2	Safety Verification • Operational and post-closure Safety Assessment	**DI-105**: In the safety assessment, the licensee shall only use models and computer codes that have undergone verification and, to the extent possible, validation. **DI-101**: The licensee shall include in the post-closure safety assessment a scenario analysis that considers the possible FEPs that might affect the performance of the disposal system, including events of low probability.	Scenarios, models and codes development, simplification and substantiation	Verification that the models and computer codes have undergone verification and, to the extent possible, validation. Verification that the selected scenarios : • cover the possible FEPs that might affect the performance and the robustness of the system ; • are adequate to assess the performance and the robustness of the system ; • are adequate to assess the radiological impacts (the conservative simplifications might not lead to underestimate the radiological impacts).	.	P	Ⓕ	U	U	U	.
Safety Assessment	SA-12	DI-086	2.4.2	Safety Verification • Operational and post-closure Safety Assessment	**DI-86**: The licensee shall include in the safety assessment for the operational and post-closure phases • An evaluation of the performance and robustness of the disposal facility and system and its components • An evaluation of the radiological impact.	Assessment of radiological impact that might arise during the long term evolution of the facility, based on the predictions and/or monitoring records and interpretations	Verification that : • the radiological impact on long term safety is acceptable ; • the confidence and the conservatism level of the assessment results are adequate with the objectives of the assessment.	X	P	Ⓕ	U	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App Construction	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
Safety Assessment	**SA-13**	**DI-027** **DI-026** **DI-086**	**2.2.1** **2.2.1** **2.4.1**	Disposal Facility Development • General Requirements Safety Verification • Scope & content of the Safety Case	**DI-27**: The licensee shall ensure that the disposal system provides isolation and containment during normal evolution and shall establish to a high level of confidence that the disposal system can be relied on to provide isolation and containment over the timescales necessary. **DI-26**: The licensee shall design, construct, operate, decommission and close the disposal facility in order to establish a disposal system which provides containment and isolation of the waste for a period of time suited to its radiological hazards. **DI-86**: The licensee shall include in the safety assessment for the operational and post-closure phases • An evaluation of the performance and robustness of the disposal facility and system and its components • An evaluation of the radiological impact.	Assessment of the performance i.e. the ability of the disposal system and its component to fulfil its expected role under normal evolution	Verification that : • the performance of the system and its components, as described in the safety concept, effectively provide post-closure safety (i.e. isolation and containment for a period of time suited to the radiological hazards) ; • the confidence and the conservatism level of the assessment results are adequate with the objectives of the assessment.	X	P	P	Ⓕ	U	U	U
Safety Assessment	**SA-14**	**DI-027** **DI-086** **DI-102**	**2.2.1** **2.4.1** **2.4.2**	Disposal Facility Development • General Requirements Safety Verification • Scope & content of the Safety Case • Operational and post-closure safety assessment	**DI-27**: The licensee shall ensure that the disposal system provides isolation and containment during normal evolution and shall establish to a high level of confidence that the disposal system can be relied on to provide isolation and containment over the timescales necessary. **DI-86**: The licensee shall include in the safety assessment for the operational and post-closure phases • An evaluation of the performance and robustness of the disposal facility and system and its components • An evaluation of the radiological impact. **DI-102**: The licensee shall determine in the assessment whether adequate DID has been provided, as appropriate, through a combination of several layers of protection (e.g. safety function provided by physical barriers, systems to protect the barriers, and administrative procedures) that would have to fail or to be bypassed before there could be any consequences for people or the environment.	Assessment of the robustness i.e. safety margins and ability of each component of the disposal system to fulfil its expected role under disturbing events both reasonably anticipated and less likely	Verification that : • the robustness of the system and its components, as described in the safety concept, effectively provide post-closure safety with margins ; • the confidence and the conservatism level of the assessment results are adequate with the objectives of the assessment ; • effective and adequate DID is provided through a combination of several layers of protection.	X	P	P	Ⓕ	U	U	U
Safety Assessment	**SA-15**	_	_	_	_	Assessment of the feasibility i.e. substantiation that the waste package emplacement, EBS construction and closure operations can be performed, in order to show that the planned system is feasible (based on results of demonstration tests – see assessment basis)	Verification that the waste package emplacement, EBS construction and closure operations can be effectively performed fulfilling their assigned safety functions.	_	P	P	Ⓕ	U	U	_
Safety Assessment	**SA-16**	_	_	_	_	Substantiation that monitoring does not lead to unacceptable adverse impacts on the performance of the system and the long term safety	Verification that monitoring does not lead to unacceptable adverse impacts on the performance of the system and the long term safety.	X	P	P	Ⓕ	U	U	U
Safety Assessment	**SA-17**	_	_	_	_	Demonstration that the as-built underground disposal units, facility systems and EBS components meet the design basis and requirements presented in previous phases with respect to operational and long term safety	Verification that the as-built underground disposal units, facility systems and EBS components meet the design basis and requirements with respect to operational and long term safety.	_	_	_	_	Ⓕ	U	U
Safety Assessment	**SA-18**	**DI-027** **DI-026**	**2.2.1** **2.2.1**	Disposal Facility Development • General Requirements	**DI-27**: The licensee shall ensure that the disposal system provides isolation and containment during normal evolution and shall establish to a high level of confidence that the disposal system can be relied on to provide isolation and containment over the timescales necessary. **DI-26**: The licensee shall design, construct, operate, decommission and close the disposal facility in order to establish a disposal system which provides containment and isolation of the waste for a period of time suited to its radiological hazards.	Assessment of monitoring records against safety case expectations and hypothesis	Verification that : • The disposal facility and components behave and evolve as expected in the safety case ; • Key assumptions and models made in the safety case are confirmed ; • Any deviations from the expected behavior of the disposal are acceptable.	.	.	.	.	Ⓕ	U	U
Safety Assessment	**SA-19**	**DI-042**	**2.2.3**	Disposal Facility Development • Design	**DI-42**: The licensee shall design the disposal facility so that the engineered components (including barriers) are, to an adequate extent, physically and chemically compatible with each other, with the waste disposed of and with the host environment.	Assessment that the engineered components are physically and chemically compatible with each other, with the waste disposed of and with the host rock/environment	Verification that the engineered components are physically and chemically compatible with each other, with the waste disposed of and with the host rock/environment.	X	P	P	Ⓕ	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
Management System	**MS-1**	**DI-014** **DI-017** **DI-016** **DI-015** **DI-095**	**2.1.3** **2.1.3** **2.1.3** **2.1.3** **2.4.1**	Safety Management • Management System Safety Verification • Scope & content of the safety case	**DI-14**: The licensee shall establish, document, implement, assess and continuously improve its management system to achieve and enhance safety by bringing together in a coherent manner all the requirements for managing the organization by • Describing and implementing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied • Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety • Promoting the development of a safety culture, which includes individual and collective commitment to safety and encourages a proactive, questioning and learning attitude at all levels in the organization • Ensuring that the work performed in each process is carried out using approved procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness, and is subject to quality arrangements appropriate to a graded approach. **DI-17**: The licensee shall document in its management system at least the following • Its safety policy • A description of its management system • A description of its organizational structure • A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work • A description of the licensee's interactions with contractors, including the control of activities carried out by contractors • A description of the processes and supporting information that explain how work is to be prepared, carried out, recorded, assessed, reviewed, and improved • A description of the provisions to record and review knowledge, information and data about all aspects related to safety of the disposal facility and system and to preserve the records • A description of the provisions to ensure appropriate transfer of knowledge to its personnel throughout the different phases until termination of the licence. **DI-16**: The licensee shall ensure that its management system takes into account safety in design, construction, commissioning operation, decommissioning, closure and after closure. The licensee shall review its management system at regular intervals to ensure continuing suitability and effectiveness. **DI-15**: The licensee shall ensure that its management system covers normal operation conditions, anticipated operational occurrences and possible accidents. **DI-95**: The licensee shall describe in the safety case the management system, including the principles on which it is based, and how it will evolve during future phases of development, operation and closure of the disposal facility.	Description of the management system during all activities and all phases, including : • Licensee's commitment to safety and its safety policy • A description of how safety culture is promoted; • A description of its organizational structure; • A description of the resources for all necessary activities until termination of the licence • A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work; • A description of the licensee's interactions with contractors, including the control of activities carried out by contractors; • A description of the processes to provide adequate confidence that safety requirements will be satisfied ; • A description of the provisions to record knowledge, information and data about all aspects related to safety of the disposal facility and system and to preserve the records	Verification that the management system : • Encompasses with safety in design, construction, operation, decommissioning, closure and after closure ; • Covers normal operation conditions, anticipated operational occurrence and possible accidents ; • Ensures the transparency, the traceability and the consistency of the whole process. Verification that : • safety paramounts within the management system, overriding all other demands ; • the work performed in each process is carried out using approved procedures, instructions, drawings or other appropriate means (periodically reviewed to ensure their adequacy and effectiveness, and is subject to quality arrangements appropriate to a graded approach).	X	P	P	Ⓕ	U	U	U
Management System	**MS-2**	**DI-001** **DI-006** **DI-004**	**2.1.1** **2.1.1** **2.1.1**	Safety Management • Responsibility	**DI-01**: The licensee shall have the responsibility for ensuring and demonstrating that the facility is safe until termination of the licence, and for demonstrating that the facility will continue to be safe thereafter. **DI-06**: After closure and until termination of the licence, the licensee shall remain responsible for surveillance of the disposal system in accordance with the safety case and for any remedial action that might be required. **DI-04**: The licensee shall establish and implement its safety policy taking due account of national and international standards and ensure that matters related to safety are given the highest priority.	Licensee's commitment to safety and its safety policy	Verification that : • the implementer commitment to safety and its safety policy cover all phases of the disposal – from construction, operation to closure and the achievement of post-closure safety ; • the safety policy takes due account of national and international standards and ensures that matters related to safety are given the highest priority.	X	P	Ⓕ	U	U	U	U
Management System	**MS-3**	**DI-014**	**2.1.3**	Safety Management • Management System	**DI-14**: The licensee shall establish, document, implement, assess and continuously improve its management system to achieve and enhance safety by bringing together in a coherent manner all the requirements for managing the organization by • Describing and implementing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied • Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety • Promoting the development of a safety culture, which includes individual and collective commitment to safety and encourages a proactive, questioning and learning attitude at all levels in the organization • Ensuring that the work performed in each process is carried out using approved procedures, instructions, drawings or other appropriate means that are periodically reviewed	Description of how safety culture is promoted	Verification that : • The MS promotes safety culture ; • Safety culture supports and strengthens individual and collective commitment to safety and encourages a proactive, questioning and learning attitude at all levels in the organization.	X	P	Ⓕ	U	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site investigation & selection	Reference Design & Lic App	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
					to ensure their adequacy and effectiveness, and is subject to quality arrangements appropriate to a graded approach									
Management System	MS-4	DI-009	2.1.2	Safety Management • Organizational Structure	**DI-09**: The licensee shall establish an organizational structure to enable its safety policy to be implemented with a clear definition of responsibilities, lines of authority and communication.	Description of its organizational structure;	Verification that the organizational structure • Enables the implementation of the safety policy and strategy ; • Allows undertaking the project giving appropriately high priority to safety and enabling integration of the different aspects of work to be undertaken in a coherent manner.	X	P	Ⓕ	U	U	U	U
Management System	MS-5	DI-005 DI-010 DI-011	2.1.1 2.1.2 2.1.2	Safety Management • Responsibility • Organizational Structure	**DI-05**: The licensee shall ensure that the resources (including organizational structure, individuals, experience and skills, infrastructure, working environment, information and knowledge, suppliers, materials) for all necessary activities before termination of the licence will be available at the time they are needed. **DI-10**: The licensee shall establish the capability in terms of staffing, skills, experience and knowledge to build and maintain the competences required to undertake all relevant activities and adapt its organization progressively in accordance with future plans. **DI-11**: The licensee shall define the necessary qualification, experience and skills for all staff involved with activities that may affect safety.	Description of the resources (including individuals, experience and skills) for all necessary activities until termination of the licence	Verification that : • The resources for all necessary activities before termination of the licence will be available at the time they are needed ; • The organization has the capability in terms of staffing, skills, experience and knowledge to build and maintain the competences required to undertake all relevant activities and adapt its organization progressively in accordance with future plans ; • The necessary qualification, experience and skills are defined for all staff involved with activities that may affect safety.	X	P	Ⓕ	U	U	U	U
Management System	MS-6	DI-009 DI-008	2.1.2 2.1.1	Safety Management • Organizational Structures • Responsibility	**DI-09**: The licensee shall establish an organizational structure to enable its safety policy to be implemented with a clear definition of responsibilities, lines of authority and communication. **DI-08**: The licensee shall ensure that interfaces between its responsibilities and those of other organizations are clearly defined, agreed and documented.	Description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;	Verification that : • Responsibilities, lines of authority and communication are clearly defined ; • The interfaces between licensee's responsibilities and those of other organizations are clearly defined, agreed and documented.	X	P	Ⓕ	U	U	U	U
Management System	MS-7	DI-013	2.1.2	Safety Management • Organizational Structure	**DI-13**: Where any activity related to safety is carried out by a contractor, the licensee shall retain within its organization the capability to assess the adequacy of the contractor's resources and skills for ensuring safety and the quality of the deliverables.	Description of the licensee's interactions with contractors, including the control of activities carried out by contractors;	• Verification that : • All licensee's interactions with contractors are identified ; • For all activities related to safety, the licensee retains within its organization the capability to assess the adequacy of the contractor's resources and skills for ensuring safety and the quality of the deliverables.	X	P	Ⓕ	U	U	U	U
Management System	MS-8	DI-007 DI-003 DI-019 DI-041 DI-002 DI-012	2.1.1 2.1.1 2.1.4 2.2.3 2.1.1 2.1.2	Safety Management • Responsibility • Record Keeping Disposal Facility Development • Design	**DI-07**: The licensee shall ensure that all activities, including those carried out by contractors, are performed and controlled according to the licensee's management system. **DI-03**: The licensee shall continuously improve safety by, in particular, using experience feedback and advances in science and technology. **DI-19**: The licensee shall establish and conduct an experience feedback program to collect, screen, analyze and document in a systematic way experience important to safety in all phases of facility development until termination of the licence. This program shall cover issues of importance for both operational and post-closure safety. This information shall be used for preventing events and processes adverse to safety, and for improving the design or manner of construction and operation of the facility as necessary. Experience from other facilities shall also be considered as appropriate. **DI-41**: The licensee shall have a process for identifying any conflicting design requirements from different regulatory regimes, and seeking to resolve them. **DI-02**: The licensee shall make and implement programs and procedures necessary to maintain safety. **DI-12**: The licensee shall establish training programs to develop and maintain the professional skills of its staff, and to ensure that personnel are appropriately trained before beginning each activity.	Description of the processes to provide adequate confidence that safety requirements will be satisfied ;	Verification that the management system includes at least processes ensuring that : • all activities, including those carried out by contractors, are performed and controlled according to the licensee's management system ; • the management system is continuously improved to achieve and enhance safety ; • an experience feedback program is conducted and enforced ; • any conflicting design requirements from different regulatory regimes are identified and that the licensee seeks to resolve them ; • all programs and procedures necessary to maintain safety are established and implemented ; • training programs are established to develop and maintain the professional skills of its staff, and to ensure that personnel are appropriately trained before beginning each activity. Verification that those processes are adequate.	X	P	Ⓕ	U	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
Management System	**MS-9**	**DI-081** **DI-082**	**2.3.3** **2.3.3**	Waste Acceptance • Acceptance of WAC	**DI-81**: To provide an adequate level of assurance that waste characteristics conform to the waste acceptance criteria, the licensee shall satisfy itself that the management system of the organization submitting waste for disposal appropriately addresses waste quality issues. **DI-82**: The licensee shall establish procedures for dealing with waste that does not conform to waste acceptance criteria, and shall not accept such waste unless acceptability with regard to operational and post-closure safety has been demonstrated on a case by case basis.	Management system related to WAC	Verification that the management system includes waste acceptance processes to ensure that : • the waste characteristics will be conform with the WAC ; • the organizations producing, processing or submitting waste for disposal duly address waste quality issues in their management system ; • adequate arrangements (written, approved and well applied procedures) are taken to deal with non-conformities (reject such waste unless operational and post-closure safety have been demonstrated and accepted on case by case basis).	X	P	Ⓕ	U	U	U	U
Management System	**MS-10**	**DI-020** **DI-056**	**2.1.5** **2.2.6**	Safety Management • Records Knowledge Keeping Disposal Facility Development • Operation	**DI-20**: The licensee shall ensure that, during design, construction, commissioning, operation, closure and post-closure until termination of the licence, knowledge and records important to safety are available and updated as appropriate for current activities, safety assessment and long term record keeping on • Characterization of the site • Design basis • Design • As built construction of the disposal facility • Operation including any operational occurrences and accidents • Inventory and emplacement of the waste • State of the disposal system after closure • All documents relating to the safety case **DI-56**: In order to refine the assumptions of the safety case, the licensee shall continue to gather information during operation to improve the knowledge of • The intrinsic properties of the host environment • The response of the host environment to the presence of the disposal facility.	Description of the provisions to record knowledge, information and data about all aspects related to safety of the disposal facility and system and to preserve the records until termination of the licence;	Verification that, until termination of the licence, knowledge and records important to safety are available and updated as appropriate for activities, safety assessment and long term record keeping on : • Site Characterization of the site ; • Design basis ; • Design ; • As built construction of the disposal facility ; • Operation including any operational occurrences and accidents ; • Inventory and emplacement of the waste ; • State of the disposal system after closure ; • All documents relating to the safety case.	X	P	Ⓕ	U	U	U	U
Management System	**MS-11**	**DI-021**	**2.1.5**	Safety Management • Records Knowledge Keeping	**DI-21**: The licensee shall ensure that, at termination of the licence, records on the site and on the as-closed state of the disposal facility are available for continuing preservation, in accordance with the national legal and regulatory framework.	Description of the provisions to make records on the site and on the as-closed state of the disposal facility available for maintaining institutional memory of the disposal facility (site, radioactive inventory, …);	Verification that, at termination of the licence, records and on the as-closed state of the disposal facility are available for continuing preservation, in accordance with the national legal and regulatory framework.	X	P	Ⓕ	U	U	U	U
Management System	**MS-12**	_	_	_	_	Information showing that the provisions (legal, financial, technical) for institutional control including a description of the organization that will carry out post-closure activities (monitoring, security, potential actions to be implemented, periodic assessment of the institutional control arrangements) will be adequate for subsequent phases. This information should include: • the organization and provisions for periodic assessment of the institutional control arrangements (including confirmation that implementation is correct) • the safety and security provisions (e.g. safeguards) including those to prevent from human intrusion;	Verification that the implementer's organization has adequately defined financial guarantees for decommissioning and managing any resulting waste.	X	P	P	Ⓕ	U	U	U
Management System	**MS-13**	_	_	_	_	Organization and procedures in place to assure the quality (QA) of the work performed	Verification that QA covers adequately all issues related to the safety case.	X	P	Ⓕ	U	U	U	U
Integration of Safety Arguments & Evidence	**ISAE-16**	**DI-096**	**2.4.1**	Safety Verification • Scope & content of the safety case	**DI-96**: The licensee shall include in the safety case, subject to a graded approach, a synthesis of multiple lines of reasoning regarding post-closure safety and an evaluation of the level of confidence reached.	Synthesis of all assessments and monitoring data. Integration of the safety arguments and evidence from the assessments. The information should be	Verification that integration emphases the following items:	X	P	Ⓕ	U	U	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
						assembled in a manner that allows independent appraisal of the level of safety that the as-built facility will achieve in operation. Information and (multiple) lines of reasoning should be readily traceable through the safety case to the supporting evidence.								
Integration of Safety Arguments & Evidence	**ISAE-17**	–	–	–	–	–	• Verification of the compliance with the safety strategy in respect of both the evolving design and the safety assessment approach ;	X	P	Ⓕ	U	U	U	U
Integration of Safety Arguments & Evidence	**ISAE-18**	–	–	–	–	–	• Verification that all relevant data and information have been considered, all models have been tested adequately and a rational assessment procedure has been followed ;	X	P	Ⓕ	U	U	U	U
Integration of Safety Arguments & Evidence	**ISAE-19**	–	–	–	–	–	• Verification that the arguments of the synthesis are supporting decision-making e.g. decision on continuing to proceed to the next phase based on the global evaluation of the design concept and the overall compatibility of the system components ;	X	P	Ⓕ	U	U	U	U
Integration of Safety Arguments & Evidence	**ISAE-20**	–	–	–	–	Identification of the limitations of the currently available evidence, arguments and analyses Identification where knowledge is lacking, the uncertainties that need to be reduced and the work needed in the next step (Particularly in respect of: development of the design, RD&D and data acquisition, scenario development and modelling)	• Verification that the uncertainties that will remain after the closure of the disposal do not undermine primary safety arguments ;	X	P	Ⓕ	U	U	U	U
Integration of Safety Arguments & Evidence	**ISAE-21**	–	–	–	–	Identification of futures needs to support demonstration for next stage. Program of planned activities through the different phase (with a special focus on the targets/criteria to be reached at the end of each phase) that will ensure that each activity will in time provide necessary and sufficient information taking into account progress, unexpected developments and results from other activities	• Verification that plans (e.g. R&D program) to manage unresolved questions and uncertainties are good prospects for dealing adequately with them in future phases.	X	P	Ⓕ	U	U	U	U
Assessment safety case as whole	**ASC-1**	**DI-089** **DI-090**	**2.4.1** **2.4.1**	Safety Verification • Scope & content of the safety case	**DI-89**: The licensee shall ensure that the safety case provides a clear understanding of the safety arguments, is suitably comprehensive and documented with a content and level of detail appropriate to the step reached in the disposal facility development. **DI-90**: The licensee shall ensure that the safety case provides clarity, substantiation and traceability of the assumptions, choices and decisions made.	Adequacy and quality of the safety case as whole and supporting the current decision for the considered phase	Verification that : • overall safety case content, its quality and level of detail, is appropriate for supporting the considered decision ; • assumptions, choices and decisions made are clearly substantiated and traceable in the safety case.	X	P	Ⓕ	U	U	U	U
Periodic Safety Review	**PSR-1**	**DI-106** **DI-107** **DI-108**	**2.4.3** **2.4.3** **2.4.3**	Safety Verification • Periodic Safety Review	**DI-106**: The licensee shall carry out at regular intervals a review of the operational and post-closure safety of the facility (PSR), to confirm compliance with licensing requirements. The frequency of the review shall be established by the national legal and regulatory framework (e.g. every ten years). **DI-107**: The licensee shall define, substantiate and submit to the regulator the Scope of the PSR and shall ensure that, as a minimum, the following are taken into account in the PSR • Review and analysis of operational experience • Review of operating experience in radiation protection aspects • Review of the WAC and waste quality	Periodic safety review	Verification that : • A review of the operational and post-closure safety of the facility (PSR) is foreseen at regular intervals, to confirm compliance with licensing requirements ; • The national legal and regulatory framework establish the frequency of the review (e.g. every ten years) ; • the scope of the Periodic Safety Review is defined, substantiated to ensure that, as a minimum, the following are taken into account in the PSR: • Review and analysis of	–	–	P	P	Ⓕ	U	U

Key Aspects of the SC (review & content)	IdNum	WENRA DI#	WENRA §	WENRA TITLE	WENRA TXT	Related Safety Case Content	Verification	Generic	Conceptualization	site Investigation & selection	Reference Design & Lic App	Construction & Lic App > Operation	Operational phase & Lic App > Closure	Entering Post-Closure Until licence release
					controls • Review of knowledge and experience of aspects affecting post-closure safety • Review of the assumptions made in the safety case to confirm that they are still valid • Review of compliance with current regulatory requirements. A guide to the content of the PSR is given in Appendix 4. **DI-108**: The licensee shall document the results of the PSR, and derive and implement an action plan for all reasonably practicable improvements to safety.		operational experience • Review of operating experience in radiation protection aspects • Review of the WAC and waste Quality Controls • Review of knowledge and experience of aspects affecting post-closure safety • Review of the assumptions made in the safety case to confirm that they are still valid • Review of compliance with current regulatory requirements.							