EUROPEAN COMMISSION

Community research

SITEX

Contract Number: 295889

DELIVERABLE D-N°: 4.1

Available technical review guidance and further needs

Author(s): **Bel V, CNSC, DECOM, ELI, ENSI, ENSTTI, FANC, GRS, IRSN, LEI, NRG, SSM, UJV**

Reporting period: 01/01/2012 – 31/12/2013

Date of issue of this report: **30/05/2014**

Start date of project: **01/01/2012** Duration : 24 Months

Project co-funded by the European Commission under the Seventh Euratom Framework Programme for Nuclear Research &Training Activities (2007-2011)		
Dissemination Level		
PU	Public	X
RE	Restricted to a group specified by the partners of the SITEX project	
CO	Confidential, only for partners of the SITEX project	

EURATOM

Contents

1 Foreword

The objective of the FP7 program SITEX project is to set up a network capable of harmonizing European approaches to technical expertise of geological repositories for radioactive waste. Lasting 24 months, SITEX brings together 15 organisations representing technical safety organisations (TSOs) and safety authorities, as well as civil society outreach specialists. SITEX plans to help establishing the conditions required for developing a sustainable network of technical safety experts who have their own skills and analytical tools, independently of the implementers, and who are capable of conducting their own research programs.

The objective of the SITEX Work Package 4 (WP4: "Technical review method and competence building"), as written in the Coordinating Action SITEX Report in the section "Overall work plan strategy" (B1.6.1), is to *"establish the conditions for developing common technical review methodologies so as to seek for harmonisation of expertise function and contribute as well to guide the development of the Safety Case by WMOs (Waste management Organisation) in Europe*". In a first step corresponding to 2012, the WP4.1 has to elaborate a plan for the development of harmonised methods for reviewing the safety cases of geological disposals (deliverable D4.1: "Available technical review guidance and further needs"). In a second stage, in 2013, the WP4.2 concerns the elaboration of a plan for organising training activities related to technical review methodology (deliverable D4.2: "A plan for competence build up in expertise of radwaste safety"). The present report focuses on the first task. The results of this first task of the WP4 will be used as input for the second task.

As a first step, this working group 4 tried to define the profession of technical expert. This is the purpose of the Chapter 4 of the present report. The team agreed on the three following required key conditions to exert it: independence in its expertise, transparency in the approach, in particular with regards to the civil society, and last but not least, competence in all the subjects experts has to deal with. The definitions by the existing international guidance of independence, transparency and competence are given in the first parts of the sections 4.2, 4.3, 4.4, respectively.

As a second step, the team tried to describe all the processes and activities in their organisations that contribute to these three key conditions. In fact, even if it is difficult -and probably impossible- to prove that an organisation fulfilling expert function will stay definitively independent from the implementer, this independence is saved and improved by several actions done day by day. Such actions are described in the second parts of the sections 4.2, 4.3 and 4.4 of the present report. Indeed, the accomplishment of such actions by the organisations of the future SITEX network may contribute to the harmonization of their practices.

The final and most major step was to explore the work of technical expert himself. This is the purpose of the present Chapter 5. The participating organisations agreed on several steps in the analysis of the safety case of geological disposal, and described different ways to organise their team to sort out the technical review (section 5.1). After having noticed the lack of guidance on how to do the technical review, the SITEX participants elaborated a first common grid of analysis on the safety case at the end of the site investigation phase (section 5.2), constituting that way a pillar of the harmonisation of practices in technical review.

2 Summary

As far as safety cases mature and geological disposal projects evolve to the application for creation, organisations in charge of reviewing the safety cases have to prepare the review activities. The objective of this task (WP4) is to establish the conditions for developing common technical review methodologies so as to seek for harmonisation of the review methods and make as far as possible the expertise function consistent through the member states. In a first step a framework for the development of harmonised methods for reviewing the safety cases has been established and is developed in this report (WP4.1). In a second stage, a plan for organising training and tutoring activities related to review methodology will be elaborated (WP4.2).

In the present first step, a first task was related to the development of the expertise function and to the best conditions to exert it. The second task was dedicated to the overview of national practices when reviewing the safety cases. The approaches to perform the technical safety review amongst SITEX participating organisations revealed similarities, which allowed going further in the definition of a standardized review methodology. According to the draft European Pilot Group (EPG) report, the SITEX participants have developed a preliminary grid of analysis based on the specific phases of development of the disposal program defined in the EPG. The main principle driving the development of the review for each phase is to adapt the level of analysis to the level of development of the project. The general framework is presented according to a general "grid of analysis" common to all phases but with various focus and assessment depending of the progress of the project.

These common issues to be addressed relate to the description of the context of the safety case, to the focus of the technical review, then to the assessment of the implementation of the safety strategy, the assessment of the set of data used, of the processes considered, of the models and computer codes used (assessment basis), to the effectiveness of the safety functions and of the performances of barriers, then to the definition of scenarios for radiological and non-radiological impact calculations, to the management of uncertainties and finally to the integration of safety arguments and evidence.

The selected phase to test the methodology refers to the end of "site investigation and selection phase", leading to decision to select a site and start investigation for a reference design. It corresponds to the status of the SR-Can SKB report (implementer in Sweden) or to partly the Andra's Dossier 2009 (implementer in France).

The "site investigation and selection phase" grid of analysis will be further discussed and consolidated within the partners with the view to pave the way for developing similar frame for the other stages of the safety case (as mentioned in the EPG report, conceptualization, reference design, construction, operational and post-closure phases). The use of the IAEA

questionnaire developed by GEOSAF as well as the questions raised recently by GEOSAF2 on the operational safety should be considered in order to specify more precisely the issues to be reviewed by the experts. In parallel, the elaboration of a training plan will be started with the view to propose a harmonized training and tutoring activity among the partners that would allow to developing reviewing skills in concordance with the methodology developed above.

3 Introduction

3.1 OVERVIEW OF ACTIVITIES

The following organisations contributed to this report:

- Bel V (Belgium),
- Canadian Nuclear Safety Commission, CNSC (Canada),
- DECOM (Slovakia),
- Federal Agency for Nuclear Control, FANC (Belgium),
- Gesellschaft für Anlagen-und-Reaktorsicherheit, GRS (Germany),
- Institut de Radioprotection et de Sûreté Nucléaire, IRSN (France),
- Lietuvos Energetikos Institutas, LEI (Lithuania),
- Ministerie Van economischeZaken, Landbouw en Innovatie, ELI (Netherlands),
- Ustav Jaderneho Vyzkumu Rez A.S (Nuclear Research Institute), UJV (Czech Republic),
- EidgenossischesNuklearsicherheinspektorat, ENSI (Switzerland),
- SträlSâkerhetsMyndigheten, SSM (Sweden),
- Nuclear Research and Consultancy Group, NRG (Netherlands),
- European Nuclear Safety Training and Tutoring Institute, ENSTTI (Europe).

In order to collect information about the current practices (and their context) applied by participating organisations, two questionnaires were successively sent in March and May 2012. The complete questionnaires are presented in Annex IV.

Experience on the review of a safety case depends directly on the national context. It can be drawn from the review of surface disposal as in Belgium (Bel V) or in Slovakia (DECOM), Lithuania (LEI) and Czech Republic (UJV). A generic safety case was already analyzed in The Netherlands (NRG). The Canada (CNSC) is conducting a pre-project design review of the conceptual design and post-closure safety assessment for the two hypothetical sites. Germany (GRS) adopted in July 2013 a Site Selection Act (Standortauswahlgesetz – StandAG) for the selection of a repository site in particular for high-level radioactive waste. Switzerland (ENSI) is in the second stage (out of three) of the site selection process. France (IRSN) is approximately in the final stage of site selection and at an intermediate stage for the updating of reference design (several reviews of a partial safety case). Finally, in Sweden (SSM), the SR-Site study of 2011 is a preparatory Preliminary Safety Analysis Report.

The first questionnaire, sent on 6th March 2012, consists of thirteen main questions (named Q1.1 to Q3.4, see Annex IV) on the general framework of each participating organisation for reviewing the safety case (National organisation, reviewing principles, ethics), on the way to prepare the review process (Development of competences, of feedback, R&D…) and reviewing the technical review methods (Review step by step, table of contents of technical review reports, main steps of a geological disposal project). The answers to the first questionnaire were gathered and partially discussed during the WP meeting in May 2012 in Vienna. This meeting was dedicated to the internal working groups (WP 2, WP3, WP4 and WP 5) and to the interactions between these groups, nearly 6 months after the SITEX kick-off meeting.

The second questionnaire, sent on 16th May 2012, provided eight additional questions (Q4.1 to Q4.8, see Annex IV). Few questions focus on the required qualities of the expertise body and of experts. Other questions deal with a number of additional specific aspects addressed during the review process, including the expected content of a Safety Case (SC) and of a technical review report and associated existing guidance, the safety assessment (hazards which need to be assessed for the operational and post-closure phases, use of a deterministic vs. a probabilistic approach, use of safety and performance indicators) and the modelling strategy.

During the WP4 meeting in February 2013 in Amsterdam, the draft version of the report has been discussed. A tentative grid has been built, summarizing the main aspects to be addressed by the technical review of the safety case of a geological disposal at the end of the siting phase.

3.2 CLASSIFICATION OF EXISTING GUIDANCE AND RELEVANCE FOR WP4

A first collaborative mission dedicated to this WP4.1 and to the task 1 of WP 2 (WP2.1, "Regulatory expectations and needs") on "needs for technical guidance" was to identify and classify the different existing international and national guides of interest when performing the review process. The classification of the available guidance was built on the basis of answers to the question Q3.2 (see Annex IV), and after discussion with the WP 2.1 during the meeting in May 2012.

There are a number of documents issued by international and national organisations in the form of requirements, guides to prepare the safety case, to review and evaluate safety assessment from regulatory point of view. Based on the evaluation of the answers to the questionnaire the documents of International Atomic Energy Agency (IAEA) are referred mostly within the countries participating in SITEX project (Safety requirements, guides, project reports). With respect to the review of repository safety case there are some documents of OECD Nuclear Energy Agency, International Commission on Radiological Protection (ICRP documents), reports of research project funded by of European Commission (such as EC project PAMINA reports, etc.), reports of various groups of organisations (e.g. European Pilot Group (EPG) report, Western European Nuclear Regulators Association (WENRA) report, etc.) and documents developed within the national context.

The available guides that could be used by the regulatory body in order to perform the review of safety cases were divided into three groups:

- The first group corresponds to guides related to the interpretation and implementation of safety requirements to be met by the implementers and that serve as basis when performing the review of the SC.
- The second group corresponds to guidance on managing a safety review in terms of (i) identification of needs, (ii) development of competences, (iii) resource allocation.
- The third group concerns guides on how to conduct and perform the technical review of a safety case, with (i) the reviewing approach, (ii) the general expected content of a safety case and (iii) the detailed procedure for reviewing it.

The guides or reference documentation identified for each of these 3 groups are listed in the following **Table 1**. For each group, the reference number of corresponding questions of WP4.1 questionnaires (see Annex IV) is identified; guidance in the Reference list (Chapter 7) is underlined with a dotted line in the text.

The SITEX deliverable D 2.1 (Overview of Existing Technical Guides and Further Development) of the WP2 (Regulatory expectations and needs) further develops the needs of NSAs and TSOs in terms of guidance, on the basis of safety requirements identified by this working group.

Table 1: Guides or reference documentation on the safety case and its expertise; references to the WP4 questionnaires (see Annex IV**)**

(next page)

1. Guidance on the interpretation and implementation of safety requirements (WP 2.1)

IAEA's guides: Safety Fundamentals (SF 1), Safety requirements (Waste Safety requirements WS-R-4, WS-R-5; General Safety requirements GSR Part 1, GSR Part 3, GSR Part 4, GS-R-3; IAEA Specific Safety Requirements SSR-5), Specific Safety guides (SSG-14)…

ICRP 103 - The 2007 Recommendations of the International Commission on Radiological Protection

Performance Assessment Methodologies in Application to Guide the Development of the safety case, report 1.1.4 (EC project "PAMINA", PAMINA report 1.1.4)

The International Intercomparison and Harmonisation Project on Demonstrating the Safety of Geological Disposal (IAEA project "GEOSAF", GEOSAF final report)

2. Guidance on how to manage a safety review, in terms of identification of needs, review process, resource allocation, reporting… (WP4.1)

2a. identification of needs (WP4.1), assignment of resources

Q2.4 (R&D) – no guidance?
Q2.5 (efficient process) – no guidance?
Q4.4 (modelling); EC project PAMINA report 1.1.4 (chapter 11); IAEA guide SSG-23 (§ 5)

2b. development of competences (WP4.1)

Q1.2 (competences); IAEA GS-G1.1 (§ 3- Organisation of the regulatory body, § 4- staffing); IAEA GSR Part 1 (§ 4- Requirement 19), IAEA SSG-23 § 8, Systematic Assessment of the Regulatory Competence (IAEA project "SARCoN" report),
Q4.2 (qualities of experts); Safety Assessment Guide from AVN, IRSN and GRS, 2004 ("SAG")
Q2.1 (formation); IAEA GSR Part 1 (§ 4 - Requirement 1); IAEA GS-G1.1 (§ 5-Training of staff), IAEA project SARCoN report
Q2.2 (feedback) IAEA GSR Part 1 (§ 3, Requirement 15)

2c. review process (WP4.1)

GS-G-1.4 on documentation relating to the regulatory process for all nuclear facilities
EPG report 2011-Draft
Q1.4 (ethics, independence); IAEA GSR Part 1 (§ 4- Requirements 16, 17, 20); IAEA GS-G1.1 (§ 2-Regulatory independence and funding); IAEA's Guide GSG-4; SAG document
Q4.1 (records, exchanges experts-Authority/quality); IAEA GSR Part 1 (§ 4- Requirement 35), SAG
Q2.3 (exchange with implementer); IAEA GSR Part 1 (§ 4- Requirement 21)
Q2.5 (practices, stakeholders; Regulator involvement); NEA report n°6405; IAEA GS-G1.1 (Public information); IAEA GSR Part 1 (§ 4, Requirement 36)

3. Guidance on how to conduct the technical review of a SC specifying:

3a. reviewing approach (WP4.1+WP 2)

Q4.3, Q4.4 (deterministic vs. probabilistic); IAEA SSG-23 § 5; EC project PAMINA report D1.1.4 (§ 11.4)
Q4.5 (safety indicators); IAEA SSG-23 (§ 4); NEA report n°6405 (§ 3); EC project PAMINA report D1.1.4 (§ 6); IAEA project GEOSAF report
Q1.3 (reviewing principles); IAEA SSG-23 (§ 8); NEA report n°6405 (degree of prescriptive regulation)

3b. general expected content and completeness of a SC+ main steps (WP4.1; partly WP2)

Q3.4 (expected levels); EPG report 2011-Draft
Q4.7 (table of content); NEA n°6405; EPG report 2011-Draft, WENRA Report 2012-Draft; SSG-23 (§ 6); NEA report n°3679; EC project PAMINA report 1.1.4

3c. detailed procedure for review of a SC or a specific aspect/section of a safety case (WP4.1)

Q2.5 (habits… management tool); IAEA GSR Part 1; NEA n°6405 (§ 5); IAEA SSG-23 (§ 8)
Q3.1 (review steps, guide); IAEA SSG-23 (§ 8);
Q4.6 (guide); IAEA SSG-23 (§ 8) IAEA project GEOSAF final report (questionnaire), SAG,
Q4.3 (hazard assessment); NEA report n°6405
Q3.3, (table of contents of a technical review report); IAEA SSG-23 (§ 8)
Q4.8 (technical review report); SAG, NRC's Standard Review Plans (e.g., Nureg 1200)

3.3 DEFINITION OF REGULATORY AND EXPERTISE FUNCTIONS, PREFERRED USE OF TERMS AND NATIONAL CONTEXTS

The use of the words "review", "assessment", "verification" or the respective "review report", "assessment report", "verification report", if not complemented "by the regulator" or "by the applicant" might lead to confusion. The preferred terms are presented below and some of them appear in the Figure 1 illustrating the decision making process. It is therefore encouraged to clearly formulate the agent complement and preferably use the word exclusively in the following context.

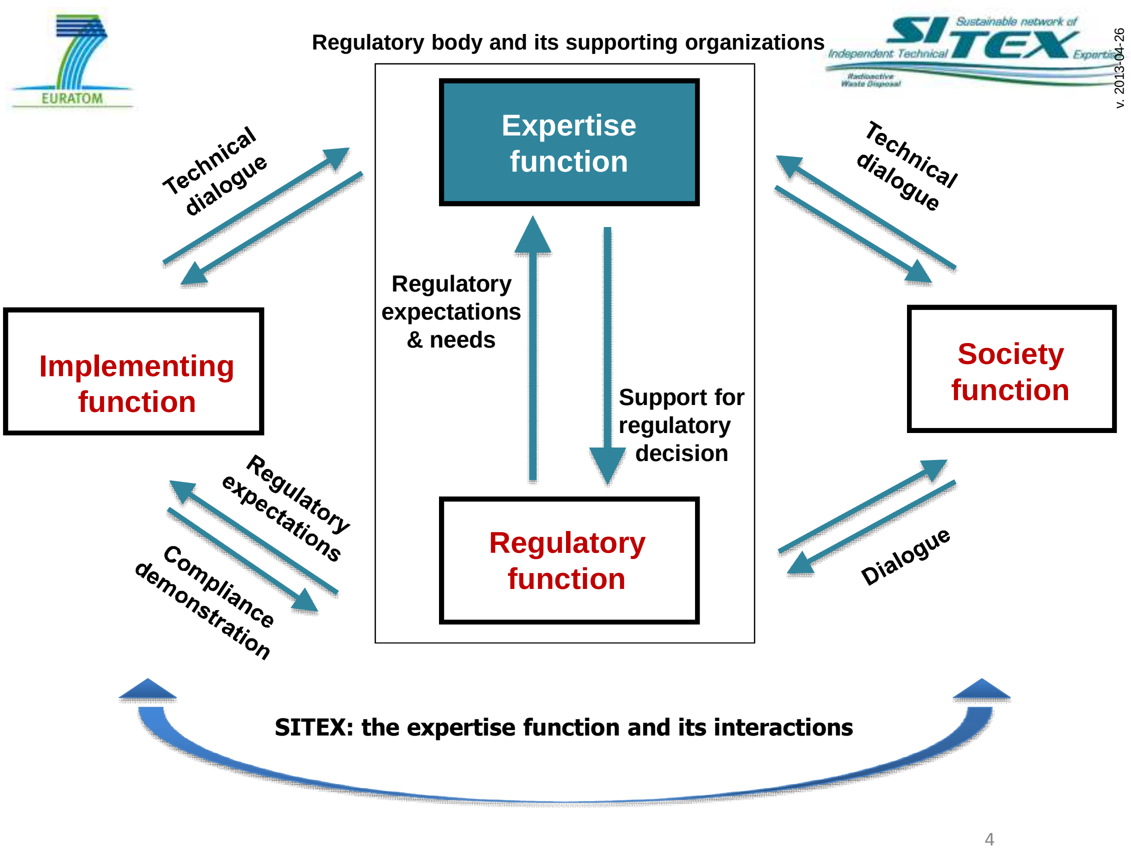

Figure 1: Decision Making Process

Regulatory body: an authority or a system of authorities designated by the government of a State as having legal authority for regulating, i.e. for conducting the regulatory process also named "**regulatory function**" in this report, including issuing authorizations, and thereby regulating nuclear, radiation, radioactive waste and transport safety. The national competent authority for the regulation of radioactive material transport safety is included in this description (IAEA safety glossary).

Expertise function or **technical expertise function:** all activities assigned to "**independent experts**" and exerted by experts employed in a regulatory body (safety authority), a TSO or another group of scientists. Activities can be summarized as giving technical support to the regulatory body for taking decisions and to the civil society for its awareness during the decision process. The necessary independence of the expertise function, the level of transparency to the public as well as competences are defined in the following Chapter 4 of this report. The expression "**technical experts**" is frequently used so as to differentiate experts giving technical support to the regulatory body from the "implementer's experts".

The national organisation, for the ones participating to SITEX, of the regulatory and expertise functions is detailed in Annex I. The implementation of expertise function varies from one country to another. Depending on the cases, the technical experts in SITEX:

- directly belong to one single regulatory body as it is the case for the national safety authority, as in CNSC (Canada), SSM (Sweden), ENSI (Switzerland);
- are spread between two distinguishable bodies forming together the regulatory body as it is the case for the national safety authority FANC (Belgium) and its technical subsidiary Bel V;
- are members of an independent organisation (Technical Safety Organisation) officially responsible for supporting the authority as IRSN for ASN (France) and GRS for Federal State Authority (Germany);
- correspond to an external group of experts from Universities or research institutes or to several external groups of expert consultants. The nuclear safety authority then select appropriate expert group based on the technical characteristics of the subject to be reviewed, as UJV for SÚJB (Czech Republic), LEI for VATESI (Lithuania).

Independent expert: expert performing its activities independently from the implementers. The IAEA guide GSG-4, in § 2.7, lists the possible sources of advice, being within or outside the State, which may give external expert support to a regulatory body.

TSO: technical safety organisation, performing "**expertise function**".

Implementer: any organisation or person applying for authorisation or authorised and/or responsible for nuclear, radiation, radioactive waste or transport safety when undertaking activities or in relation to any nuclear facilities or sources of ionising radiation (IAEA safety glossary). The terms "**applicant**" or "**licencee**" are avoided because they more specifically refer to implementers before and after the licence agreement, respectively. In the same way, the term "**operator**", rather designs the implementer during the operating phase. The implementer has an "**implementing function**".

Vigilance function: activity performed – spontaneously or in an organised manner- by civil society to follow the development of the deep geological repository (DGR).

Stakeholder or **civil society**: any individual, group or organisation that may affect, be affected by, or perceive itself to be affected by the risk (SAG), including the regulated industry or professionals; scientific bodies; governmental agencies; the media; the public and other States (Handbook on Nuclear Law).

Regulatory review process: decision making process carried out by the regulatory body, which can call on expertise function for its technical review (see IAEA SSG23).

Safety review: review of the safety case by the regulatory body.

Assessment or "**Safety assessment**": safety assessment performed by the implementer, and documented in the safety case;

Technical review: review made by the experts (within or outside the regulatory body) for the regulatory body;

Technical review report: report of the technical review performed by the responsible(s) of the expertise function according to the terms specified with the Regulatory body.

Several abbreviations or sets of initials are used in this report. Those corresponding to references are presented in the Chapter 7. Others are defined as follows:

SC: safety case (see e.g., 2008 IAEA SSG-23, PRISM draft report, EPG report 2011-Draft; WENRA report 2012-Draft, NEA n°3679, EC project PAMINA report D1.1.4).

DGR: Deep Geological Repository.

EPG: European Pilot Group

R&D: research and development.

4 Founding principles for the expertise function and ways of improvement

The technical expertise function consists in conducting and carrying out activities in the scientific and safety areas that will provide support to the regulator for taking decisions and to the civil society for developing its own technical skill and vigilance of the decision making process. Its definition, illustrated by the Figure 1 on the decision making process, consists in all activities assigned to experts in order to provide the technical and scientific basis of safety for:

- decisions by the regulatory body;
- ensuring that regulatory expectations are clearly communicated to and interpreted by the implementer;
- improving the quality of the interactions with Civil Society in the decision making process in order to contribute to build a robust safety case.

Three key conditions are required in order to implement expertise and ensure the required level of quality of the technical expertise function (see e.g., IAEA guide GSG-4):

- independence (see section 4.2);
- transparency and proximity to the public (see section 4.3);
- competence, experience and knowledge (see section 4.4).

In addition, the expertise function is exerted by individual experts associated in a team with certain characteristics in its organisation (see section 4.1).

These issues are interdependent. As an example, the competence of experts is a key point to ensure independence from the implementer and highly contribute to the trust from the civil society. However, they will be dealt with separately in the present Chapter 4.

For each of the identified conditions, the existing **international standards or guidance** are first presented below and then, if exist, the **national guides**. In complement, the opinion and practices of SITEX participating organisations are presented. Finally, when necessary**, the needs or opportunities for harmonisation** of practices and for building guidance are addressed.

4.1 MANAGERIAL ASPECTS

4.1.1 Organisation of the technical review team

The chapter 8 of IAEA SSG-23 concerns the management both in terms of time schedule and distribution of the tasks in the review process. In particular,

8.10. "Management of the review process should include the following aspects:

- *Definition of the objectives and scope of the review as well as identification of all national and international requirements, guidance and recommendations that apply to the development of the safety case;*
- *Development of a review plan that identifies the review tasks and addresses other relevant topics;*
- *Assembling a review team of competent personnel possessing the necessary expertise and experience to undertake the review;*
- *Definition of a project schedule and allocation of resources for the conduct of project tasks, including consideration of the conduct of the review if resources become limited at a later stage;*
- *Identification of the responsibilities of review team members and ensuring that they receive adequate training and guidance in the review methods;*
- *Coordination of the conduct of the review tasks, and ensuring sufficient communication between review team members;*
- *Identification, at an early stage, of the review of any areas of regulatory guidance that are important to regulatory decision making but that may be unclear or could be interpreted in different ways;*
- *Establishment of a formal process to identify issues for which resolution is necessary by the operator and a mechanism to track the further consideration and resolution of the issues;*
- *Coordination of communication with the operator of the disposal facility, and with other interested parties during the review process;*
- *Review and integration of documents generated in the review process;*
- *Synthesis, documentation and communication of the findings from the review".*

National practices

The safety case for geological disposal facilities has notably the following characteristics:

- it is developed over long time periods (several years to several decades) involving different generations of teams assigned with the expert function and evolving knowledge;
- the system description generally takes into account the R&D that is still in progress, and the outcomes are integrated progressively within the safety case (see section 4.4.4 on research and development);
- the safety case gathers knowledge in very various fields (see section 4.4.2 on staffing and competences of experts), and these fields of knowledge evolve progressively as the disposal project is developed;
- the safety assessment investigates specific fields unexplored by other nuclear facilities both in time (very long period) and space (deep underground);
- they may correspond to very thick files (several thousands to ten thousands of pages), which could be impossible to read in short periods without having a prior idea of its content. As for example, the "Dossier 2005 Argile" from Andra (the French WMO), which aimed at demonstrating the feasibility of a geological disposal facility in the Callovo-Oxfordian formation in eastern France, contains more than 12 000 pages.

Safety cases for DGR are therefore quite complex reports. Their review requires important resources (time, human resources, technical resources…) from the regulators and experts, as well as careful management of these resources. The characteristics of these safety cases justify the need for the review team to present specific organisational aspects to be well prepared for each technical review, specifically:

- by developing its own research (see section 4.4.4) on specific aspects of DGR projects (long term evolution, underground processes…), to make use of its results as augments for expertise and to develop its experience and appraise confidence in the methods to obtain these results; this topic is developed by WP 3 on “Development of TSO’s scientific skills » (in particular, D 3.1, “R&D orientations for Technical Safety Organisations”);
- by collecting experience feedback on hazards from existing nuclear facilities and from other types of facilities (see section 4.4.5, experience feedback);
- by staying aware of evolutions in the disposal concepts done by the implementer; this implies having frequent exchanges with the implementer outside of the technical review times (section 4.2.2, technical exchanges with implementers);
- by identifying and anticipating the key safety issues that require development of knowledge (section 4.4.4);
- in addition, as given in the final report of IAEA project GEOSAF, “*some guidance should be provided on the preparatory activities to be undertaken by the assessors to be ready for the technical and regulatory review*“.

Last but not least, several SITEX participants also estimate that it is important that researchers and experts work either in a same team or in a close collaboration. The efficiency of the research carried out by the regulator or the TSO does not rely only on technical skills but also on its ability to promote synergy between experts in charge of assessment and researchers. A multi-disciplinary approach integrating experimentalists, modellers and experts on safety who work together on each of the topics of interest for safety should be promoted. This synergy between research engineers and experts in safety assessment is a valuable tool to ensure consistency and quality of technical assessment. In addition, the possibility for some scientists to perform alternatively R&D and expertise may drastically increase the efficiency of the review process and anticipation of the R&D needs.

The ability for experts to identify early enough (before a technical review) the key safety issues requiring the development of R&D is made easier if:

- the implementer interacts with regulatory body and experts from the earliest stages in the development of a disposal facility, and regularly inform them on the evolutions of the disposal concepts (section 4.2.2);
- reviews are conducted at periodical steps (section 5.1.1) and systematically associated with a final feedback by experts (identification of knowledge gaps).

In addition, the way the team is organised is important for the efficiency of the technical review process. Depending on the SITEX participating organisations (see Q2.1, Annex IV), the review is managed either by a generalist expert or senior specialist or project leader, who acquired enough competence within the organisation to be comfortable within all fields of expertise required to review the safety case as well as to decide in which areas he needs a support of internal or external specialists, or competences are divided between specialists who manage the review as a team. However, at IRSN, a leader is designed among the specialist experts to gather the expert's opinions. In any case, experts participating in review of safety assessment must have very good technical and scientific expertise capabilities.

Finally, several teams have developed a management tool to streamline the technical review process by facilitating the treatment of expert's comments, such as an excel or word file to complete or a step by step reviewing procedure with a dead-line for each step (see Q2.5, Annex IV). It contributes to make the review process (often with limited time) more efficient. As an example, for both types of reviews described above, its progress is traced by IRSN in a file named "BSA" ("Bordereau de suivi d'affaires"), in which the preliminary analysis is recorded (prepared during the initial review phase: see section 5.1.2 on the successive steps of a technical review), as well as the references of the main documents, the contributors, the conclusions of the technical review and final feedback. This kind of management tool serves to identify if the technical review progresses well (to be finished at the fixed dead line, if the implementer's document is acceptable, if reviewers will correctly answers to the regulatory request or referral…) and to give various indicators in the quality process fixed by the expert team.

4.1.2 Quality related aspects

The general quality of expertise is handled by the management system and verified through traceability.

The management system of a regulatory body is a topic present in the section named "*management system within the regulatory body*" of the IAEA GS-G1.1, in the Council Directive 2011/70/EURATOM (Article 5), as well as in chapter 4 of IAEA GSR Part 1 (Requirement 19):

> *"the regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement".*

In the IAEA SSG-23, the management system calls on the need for transparency through *"public involvement"*, *"internal and external audits"* and in the *"criteria according to which the safety case is evaluated"*, the need to *"develop and maintain the competence and knowledge of the operator and the regulatory body over the whole project time frame"* as well as *"of those conducting and reviewing the safety case"* and the need *"to ensure consideration of international recommendations"*.

The management system is therefore based on the 3 pillars developed in the next sections of the present Chapter 4: independence, transparency and competence. For that reason, the present section only deals with the traceability.

For regulatory function, the traceability is developed in the chapter 4 of the IAEA GSR Part 1, dedicated to the responsibilities of the regulatory body (Requirement 35: Safety related records). The IAEA SSG-23 indicates in § 8.6*: "the regulatory review process should be structured and traceable with clearly defined roles and responsibilities and decision making processes"* (see also ASAM Regulatory Review Draft Report, §3.6).

For the expertise function, the IAEA guide GSG-4 indicates that the management system:

- *"through the traceability of processes and documentation, […] can help to demonstrate the technical competence of the organization* [and] *may provide confidence that technical competence will be maintained in the long term"*,
- *"should be such as to help the provider of external expert support to defend its advice on technical matters* [, i.e.] *supported by technical arguments, justified according to applicable requirements and supported by documentation".*

National guidance and practices

About traceability for expertise function, the section dedicated to the "Transparency and traceability of the process" in the SAG details the elements that *"shall be recorded and maintained for an appropriate period in compliance with legal and regulatory obligations"*, i.e., *"all elements having an influence on the result of the assessment"*.

As in the SAG, for DGR, participating organisations systematically record all elements having an influence on the result of the assessment (see Q4.1, Annex IV). It can be emphasised that the traceability is important for geological disposal safety because several successive review steps will be performed during probably more than 100 years (project, operation, reversibility, surveillance monitoring, closure…). At any step of a review, the experts and regulators must be able to go back to a conclusion given several years ago and to identify the rationales of this conclusion.

For several SITEX participants, communication between regulatory function, expert function and implementer before, during and after providing a technical review report should be an on-going task that contributes to the quality of this report.

4.2 INDEPENDENCE OF THE EXPERTISE FUNCTION

4.2.1 Absence of conflict of interest and resource support for expertise function

About the regulatory review, the § 8.6 in the IAEA SSG-23 indicates that*:*

- *"The regulatory review process should be free of conflicting interests, and the team of reviewers should not allow themselves to become unduly influenced during the review process by internal and external considerations that are outside the scope and terms of reference of the review".*
- *"The regulatory review should be conducted using a level of resource that is commensurate with the level of complexity of safety case and the potential risks associated with the facility under consideration".*

The effective independence in the performance of regulatory functions with regards to the implementer, i.e., the absence of conflict of interest and the sufficiency of resource support, is a well-developed theme in international guidance. It is established in particular in the chapter 2 of the IAEA GS-G1.1 and in the chapter 4 of the IAEA GSR Part 1. Therefore, it will not be further discussed in this report.

The independence of the technical expertise function is also well developed as for example in the § *2.9. (Competence aspects*) of IAEA GS-G1.1:

"The regulatory body should have independent technical expertise in the areas relevant to its responsibilities for safety. The management of the regulatory body should therefore have the responsibility and authority to recruit staff with the skills and technical expertise it considers necessary to carry out the regulatory body's functions. In addition, the regulatory body should maintain an awareness of developments in safety related technology. In order to have access to external technical expertise and advice that is independent of any funding or support from operators or from the nuclear industry to assist it in its decision making on regulatory matters, the regulatory body shall […] *have the authority to set up and fund independent advisory bodies to provide expert opinion and advice and to award contracts for research and development projects. In particular, the regulatory body shall be able "to obtain such documents and opinions from private or public organisations or persons as may be necessary and appropriate"".*

In the § 8.13 of IAEA SSG-23 it is indicated that *"the review team should be independent of the operator, and its members should not have had involvement in the development of the safety assessment work to be reviewed or in any supporting work, or be directly involved in the management, financing or operation of the facility*".

There are also some advices in the IAEA guide GSG-4 on "External Expert Support for the regulatory body":

"3.4. An important element in ensuring effective independence is to develop and implement adequate arrangements that avoid actual, potential or perceived conflicts of interest. All situations should be analysed for actual, potential or perceived conflicts of interest. Actual conflicts of interests should be eliminated. This should be done as soon as possible. Way of avoiding or detecting actual conflicts of interest includes:

- *Verifying whether the provider of external expert support has mechanisms in place such as a code of ethics and an organisational structure that promotes a strong safety culture and that these demonstrate that conflicts of interest will be avoided;*
- *Verifying whether the organisational structure of the provider of external expert support and its internal procedures provides functional and personal separation to ensure effective independence between units carrying out work for the regulatory body and units carrying out similar work for a licensee or other organisation. The links between such units should be carefully monitored.*

If neither of these can be verified, an alternative opinion from other providers should be sought. […]

3.6. It may be impossible for the regulatory body to find an external expert who is free from all potential conflicts of interest. This may be the case, for example, when:

- *The task to be accomplished requires very specific knowledge in a field where the few existing competent experts already have links with licensees or other organisations in the nuclear industry; or*
- *The complexity of the task to be accomplished is such that only a few large providers of external expert support are capable of coping with it and they may already have established connections with licensees or other organisations in the nuclear industry".*

However, from a practical point of view, existence of two separate administrative bodies is not a guarantee of independence. This must be accompanied by a clear separation of the construction of the safety case by implementer and of its technical expertise.

The same IAEA GSG-4 guide also indicates that:

3.7. "If a provider of external expert support is not entirely free from potential conflicts of interest, the task assigned to him should be closely monitored. The advice given should then be carefully assessed by the regulatory body for bias generated by conflicts of interest".

However, the collection of scientific data may be realised together in a multi-party context, such as in a Framework Programme for Research (FP). This allows avoiding a face to face and at the same time guarantees a plurality of judgements. These scientific results are then used separately by each part, for the implementer to construct its safety case and for the experts to perform their technical review.

The ASAM Regulatory Review Draft Report develops a section (§ 3.9) dedicated to the risks of conducting a review with limited resources and proposes solutions for the countries having limited number of regulatory staff, such as taking a risk-informed approach, requesting the implementer to produce a simplified assessment, or by organising national and/or international reviews, even if a partial in-house review is necessary for the regulatory body to make its own decisions.

National guidance and practices

The SAG, in the section untitled "*Expertise body independence, competence and ability to cover its full area of competence*", develops about what means the independence of the expertise function:

"To ensure its independence the expertise body shall not undertake work likely to compromise its neutrality or likely to lead it to assess its own work. Particularly, persons conducting independent assessment should not have participated directly in the work being assessed. The expertise body shall have rules enabling it to steer clear of and/or suspend any assessment or expertise subject to internal or external commercial, financial or other pressures or influences, liable to call the quality of its work into question.

If the expertise body forms part of an organisational structure which performs activities other than expertise activities, the organisational provisions should be such that any divergent interests between the different activities of the body do not affect the opinion of any expert. The responsibilities of the personnel involved in the assessment or who may influence the latter shall be precisely defined in order to prevent any conflicts of interest.

The expertise body should be able to prove its independence with regard to any commercial, financial or other pressures or influences likely to affect its technical opinion. On account of its independence, the expertise body is duty bound to separate its activity from that of consultancy and consequently shall not provide any specific solutions to the query raised".

Independence is considered by participants of SITEX as mandatory for the nuclear regulatory body and the expertise function and it is generally "guaranteed" by the country's law (Czech, Belgium, France, Switzerland…).

Nevertheless, such independence, in the sense of absence of conflict of interest, is never definitively established and should be constantly checked. In many research or technical fields, the needed experts for the technical review are so specialized that they may have been recently solicited by the implementer (or vice-versa) on the same subject.

As an example of difficulty to maintain independence in the facts with regards to the implementer, UJV is now one of the major subcontractors both to Czech regulatory body

(SUJB) and to the implementer, Radioactive waste repository authority (RAWRA) in fields of radiological protection and nuclear safety. The role of UJV as an independent technical safety organisation must be therefore limited only to the issues, in which it will not be directly involved as a contracting organisation for RAWRA. In these areas the role of technical support organisations will have to be played by other independent research organisations. This question of independence of UJV is currently discussed in the Czech Republic not only for the evaluation of safety of radioactive waste repositories, but also for the evaluation of safety of nuclear power plants. There is under discussion that the role of independent TSO for some of issues where UJV cannot be considered to be independent could be played by the recently established “Centre of Research Rez”, a daughter company of UJV. The Czech Republic is one of the smallest countries in Europe and therefore it is not probable that only one TSO could cover all safety case issues.

Several actions contribute in the fact avoiding any situation of conflict of interest:

- A generally shared practice is that the expertise function is not directly funded by the implementers but, as an example, via the government;
- Systematically check that the solicited experts for technical expertise do not (or did not) contribute to the construction of the safety case;
- Ensure having available experts for any key safety issue, constructing a long last address book of experts as far as possible;
- However, in particular for small countries, the international cooperation is crucial to maintain their independence from the implementers.

The connected topic related with **resource support for expertise function** is developed as follows in the section “*Provision of resources*” of the SAG:

> *“The expertise body shall possess the financial and human resources required to accomplish its expertise work in an independent manner, namely it shall determine the necessary competence for personnel performing work affecting the quality of the assessment and possess a sufficient number of experts in order to cover its entire area of competence with redundancy to the extent possible in the expert organisation.*
>
> *The expertise body shall possess competence criteria and rules for selection, recruitment, role adaptation, empowerment and monitoring of the competence of its personnel: experts and persons with responsibilities in conducting the assessment. It shall determine and provide the resources needed to maintain and improve its professional competence and efficiency in its expertise work and to enhance customer satisfaction”.*

The systematic redundancy of competence in the expert organisation is however not required because the technical expertise does not need to cover all the safety aspects, and whatever impossible because of restricted resources in staff and funds.

Because of time constraints, it is of crucial importance to be able to anticipate the development of knowledge and resources required to assess risks posed by nuclear facilities in the future, and in particular waste management safety. Identifying very early the scientific issues that have to be addressed in priority enables optimisation of the resources allocated to research. These resources should be periodically assessed with respect of the progress made in studies, the new issues to be taken into account and duly planned, as well as the regulatory review agenda that requires to swap research and assessment activities (see SITEX deliverable D3.1, "R&D orientations for Technical Safety Organisations", § 11.4).

Thus, the need for financial and human resources in harmony with the level of required expertise is a topic already developed in several guides. Even if it is not detailed what could mean the "required financial and human resources" for expertise function, it can be supposed that this level of resource must allow performing both research in safety and expertise at the same time so as to maintain the scientific competences. This is for example the case in France with the resources allocated to the TSO IRSN for building research programmes, developing scientific internal skills and safety assessment capabilities performed by dedicated teams. These questions related to R&D for expertise function are further discussed in the section 4.4.4 of the present report, devoted to experts' competences.

The resource support for R&D should allow covering the following topics, as so as to further discussed in the section 4.4.4 of the present report, devoted to experts' competences: the quality of data, the understanding of the complex processes which may potentially influence the long term safety of DGR and the assessment of the future evolution of these potential processes.

Lastly, various other actions may in the fact contribute to enhance independence of expertise function, such as taking the right to emit an opinion to the public regarding nuclear safety even if outside the initial agreed scope of the review process, the possibility to make public the technical reviews (without risk of external pressure), the publication of experts' results of R&D in peer-reviewed scientific journals or their presentation in international congresses…

To conclude, "independence" for the expertise function, as defined within the frame of SITEX project (see section 3.3), must therefore be understood as a context for conducting the technical review:

- in absence of conflict of interest, provided by independent capabilities from implementer and its subcontractants; this means both independent funds and the fact that technical experts have not had involved in the development of the safety case with the implementer.
- with sufficient resource support, i.e. enough human and financial means to perform the review process; this includes carrying out its own R&D used for the purpose of assessing the safety demonstration (but not for building the safety case, which is the duty of the implementer).

Thus, no difference has been identified between countries participating in SITEX project in the definition and the way to maintain independence of expertise function. However, insuring absence of conflict of interest with implementers remains a continuous challenge for all participating organisations, especially in small countries, due to the fact that the best experts in very specialized fields of research are sought after at the same time by the

implementer and for the technical review. Several actions have been identified as contributing to increase the independence of the expertise function.

The construction of a sustainable expertise function network at European (or larger) level could be a useful tool, in particular for countries presenting limited resources, who may rely on this network to reinforce temporarily their resources both in terms of human resources and tools for R&D, to conduct a technical review, and that way reduce the risk of any conflict of interest with the studies conducted by the implementers.

4.2.2 Technical exchanges with implementers

The requirement 21 in IAEA GSR Part 1- chapter 4 (Responsibilities of the regulatory body) is dedicated to the link between the regulatory body and implementer(s):

> *"The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues, conducting a professional and constructive liaison.*
>
> *4.23. As its primary purpose, the regulatory body shall carry out oversight of facilities and activities. The regulatory body, while maintaining its independence, shall liaise with authorized parties to achieve their common objectives in ensuring safety. Meetings shall be held as necessary to fully understand and discuss the arguments of each party on safety related issues.*
>
> *4.24. The regulatory body shall foster mutual understanding and respect on the part of authorized parties through frank, open and yet formal relationships, providing constructive liaison on safety related issues.*
>
> *4.25. The decisions of the regulatory body shall be justified as appropriate, and the basis for the decisions shall be explained".*

The EPG report 2011-Draft also specifies that

> *"in addition to develop the regulation and guidance related to geological disposal the regulator will have a continuing role to review the safety case and provide feedback to the implementer throughout the whole process of developing and implementing a geological disposal facility* […]*. Aspects of the work supporting the safety case will be subject to audit and inspection by the regulator. Such audits and inspections will be conducted according to a formal programme and established procedures. In the event of serious concerns or non-compliance, the regulator will take formal action. Other, less significant issues or concerns may be discussed with the implementer, or may be formally identified in writing, in order to move to the next phase in the development, on the understanding that they are addressed to the satisfaction of the regulator in a timely manner".*

However, such requirements remain general and no specific guidance is provided on exchanges between expertise function and implementers, corresponding to the "technical dialog" as illustrated on the Figure 1 of this report.

Only the IAEA project GEOSAF final report comments the exchanges between implementers and reviewers:

> "*the reviewers should be careful of not being involved into the choices that are of the responsibility of the implementer and to avoid co-development of the safety case*".

National practices

The SITEX participating organisations having regulatory functions work in conformity with these requirements. More particularly, they favour frequent exchanges with the implementers (Q2.3) in the following cases:

- to present the regulation & guides to avoid ambiguities in the interpretation, to allow the implementer to discuss aspects on their practical implementation and to elaborate some guidance in collaboration with the implementer;
- to discuss the methodological instruments (i.e. the approach of the implementer's safety strategy, safety assessment and management system…) before their implementation;
- to organise and define the successive steps of the license application.

For participating organisations having expertise functions, frequent exchanges ("technical dialog") are also considered as necessary, for the following reasons:

- outside of the technical review times, to keep informed about the implementer's R&D program outcomes. Objectives are to know the conditions in which results were obtained (to avoid any misunderstanding of the results…), to be aware of the encountered difficulties…. To be efficient, such kind of exchange requires to be periodic and can correspond to meetings, to the communication by the implementer of its periodic technical report, to visits in the implementer's surface laboratories or URL…;
- also outside of the technical review times, to undertake technical exchanges on research topics which are still in development and not completely validated by the scientific community;
- during the review process, exchanges focus on specific topics between TSOs and implementers, in particular to examine controversial topics or which require additional information: questions may be asked to the implementer & answers can be used for the technical review in addition to the safety case; the different types of exchanges with the implementer during the technical review are detailed in the following Chapter 5.

Bel V, as subsidiary to FANC, is working in close collaboration with authority. Bel V performs its own inspections, which contribute to constructive exchanges with the implementers.

The level of involvement of technical experts to the inspections can be different from a country to another. In France, the technical experts participate to the choice of the topic and to the preparation of the inspection and are informed of the conclusions given by the authority, but do not systematically participate to the inspection itself.

To conclude, exchanges between experts and implementers on scientific and technical results that will be used in the safety case may favour the efficiency of the review.

4.3 TRANSPARENCY OF THE EXPERTISE FUNCTION AND RELATION WITH CIVIL SOCIETY

As indicated in the *Figure 1* illustrating the decision making process, civil society is an actor of the decision making process. As one of the end user, it must be able to play its role in terms of vigilance all along the process.

As specified by the Forum on Stakeholder Confidence (FSC) in the 2013 NEA Annotated Glossary on the Stakeholder Confidence in Radioactive Waste Management,

> "*transparency incudes not only allowing access to information (passive transparency) but also effort to provide information to interested parties and to unveil the logic behind decisions and processes (active transparency)*".

The FSC also suggests that *"the transparency is embedded in three elements that are paramount to decision making* […]*:*

- *process → Procedures and plans for making decision should be designed to be visible, iterative, and flexible.*
- *structure → Clear roles and responsibilities must be assigned to involved actors and their interdependencies made visible.*
- *behaviour → be open, transparent and willing to involve others".*

In other words, several levels of transparency can be considered with regards to the stakeholders:

- to **inform the public** by publishing the results of an expertise that supported a decision by the regulatory body,
- to have previously defined and made public the "**rule of the game**" (requirements and way to verify that they are applied, through technical review and inspections),
- to have exchanges being maintained over time, including **consultation** with interested parties in the decision process.

About **information of the public**, in the Article 10 of the Council Directive 2011/70/EURATOM, it is written about transparency that

> *"Member States shall ensure that necessary information on the management of spent fuel and radioactive waste be made available to workers and the general public. This obligation includes ensuring that the competent regulatory authority informs the public in the fields of its competence. Information shall be made available to the public in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, security, recognised in national legislation or international obligations".*

About the definition of the "**rule of the game**", IAEA SSG-23 develops it in § 8.6*:*

> *"The requirements and expectations of the regulatory body, as well as the criteria against which safety will be judged, should be clearly defined early in the process. The completeness and quality of the safety cases and safety assessment often depend on the clarity of the regulatory requirements, expectations and approach".*

Following the NEA report n°6405, "*the communication with the public* [is a key function of regulators] *to gain public trust and provide decision makers with all information on relevant* *matters*". The NEA report n°5418 develops the main results of the FSC meeting. Also, "*in accordance with the outcomes of the Córdoba workshop, FSC stated that "the rules of the game for the regulatory process should be known as soon as possible and in any case in advance of the licensing application". Going further, it is desirable that the general public could perceive the general system of organisation, including the formulation of relevant policy by government, as being impartial and equitable. At a minimum, regulators should communicate clearly the bases for their final deliberations and decisions*".

In the same way, the IAEA project GEOSAF final report indicates that "*early definition of requirements provides security in that the stakeholders know the "rules of the game" from the beginning*".

About the **dialog** with the interested parties, following the EPG report 2011-Draft states that:

> "*it should be borne in mind that both the implementer and the regulator will need to maintain a dialogue with stakeholders. The regulator will have to engage with a range of interested parties through, for example, formal or informal stakeholder dialogue processes and statutory consultation processes, as determined by national legislation or custom, or as circumstances require. However, the primary responsibility for the dialogue with stakeholders belongs to the implementer.*
>
> *Key stakeholders will need to be kept up-to-date with the safety case as it progressively develops. Compliance of the safety case with the safety strategy is likely to be the main means of convincing stakeholders of the continuing safety of the disposal system. A convincing safety strategy is hence crucial to maintaining a broad consensus among stakeholders throughout operation that disposal of the relevant waste streams in the particular facility concerned continues to be an appropriate waste management approach for the long term. For eventual closure and sealing of the disposal facility to proceed, key stakeholders must be convinced by the safety case that closure is appropriate".*

The participants of SITEX project agree with the fact that the implementer has a primary responsibility of convincing the public that the safety case is appropriate. However, the experts have also an important role in dialoguing with the public. The main expectation from the civil society is not only information, but also to ask questions to the institutional actors and receive answers in an adapted way. In that way, civil society must be informed on the way their concerns are considered in the decision making process, being in a positive or a negative manner.

Several international guides develop this topic on interaction with the civil society, as the requirement 36 on "*Communication and consultation with interested parties*" in IAEA GSR Part 1: *"the regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body"*.

In addition, it is mentioned in the IAEA GS G 1.1 (§ 3.39) that "*public information should be managed by individuals with expertise in the field so as to ensure that the information provided is clear and comprehensible"*.

The IAEA SSG-23 indicates in § 8.6*: "The regulatory review process should include a framework for consultation with interested parties with well-defined consultation steps, rules of procedure and* *decision making processes. The credibility of this process can be enhanced by including means for discussion of progress and the outcome of the review process within this framework".*

However, no guidance specifically develops how to conduct exchange between experts and stakeholders. This point is the purpose of WP 5 of SITEX project, on "Conditions for associating stakeholders in the process of expertise".

National guidance and practices

The transparency to the stakeholders appears necessary for all participating organisations. Transparency may even be more important for safety review of DGR than for other nuclear facilities because it is more submitted to acceptance by the public (debates, exhibitions, open house…) all along the development of the project (and is expected to be during the operational phase). However, its implementation depends on the country. Generally, it means communicating with the stakeholders and disseminating neutral and objective information (for example by publishing approved documents).

In Belgium, this mission is entrusted to FANC. Transparency is integrated in the management system. There is some interaction with the stakeholders through the publicity of the information by FANC on its website and in some cases by public consultation on preliminary versions of legal acts as it was the case of the proposal of the Royal Decree on license application for waste disposal. The information to public is foreseen in specified steps of the license application of the waste disposal facilities as prescribed in the legislation (Royal Decree of 20/07/2001 or Royal Decree on Waste disposal to be published). Transparency in the information, by the regulator is not specifically underlined in this process but it is one of the missions of FANC, stated in the law of 15 April 1994 (art. 26) to provide neutral and objective information in the nuclear domain. It is also covered by the legislation on publicity of the administration of 11 April 1994 (that considers active and passive publicity) and by to the law of 5 August 2006 on the public access to environmental information. On the other side all information might not be published as imposed by the law on classification of nuclear materials and documents of 11 December 1998 and 11 March 2011.

In France, the transparency is written in the "TSN law". The n°2006-686 Act from 13 June 2006 on Transparency and Safety in Matters Nuclear renovates the legislative framework applicable to nuclear activities and control in depth. It creates the necessity to provide information of the public by the French safety authority (ASN). To help the society to get involved in the decision-making process of geological disposal, IRSN launched in 2012 with the ANCCLI (national group representing the local committees) and the CLIS of Bure (local Committee information and monitoring of the Meuse/Haute-Marne laboratory) a technical dialogue, which fits in the long term. This action aims at clarifying the issues of the Cigeo from the point of view of the different actors and to provide technical lightening elements, through reports and opinion of IRSN, which are accessible to the public.

Finally, information of the public and participation of stakeholders in the decision process also back, in several countries participating to SITEX, on the presentation by experts of their R&D results, through scientific publications and presentation in congresses, open days of the institute or of its URL, educational expositions and interventions in schools…

In addition, many countries have experienced a process of interaction with the civil society on a specific topic through a series of workshop or public debates; the SITEX report D5.1 gives several examples of recent approaches to the stakeholder involvement in geological disposal development. However few countries have systematically integrated such exchange with the public and relevant parties in the decision process. Such integration necessitates improving the level of understanding by the public of information about proposed or licensed nuclear facilities and activities. The meaning of transparency is thus different for these countries.

There is a couple of examples presented below where a discussion with the public and relevant parties on the results of technical expertise is an integrated part of the regulatory decision process, generally for the most important licensing decisions.

Switzerland

In Switzerland, stakeholders participate through the Technical Forum on Safety. The Forum is made up of technical experts from the authorities (ENSI, Swisstopo), commissions and expert groups (NSC, CRW) and the waste producers, cantonal experts and representatives from the siting regions and neighbouring countries. Thus the Technical Forum is more an information and exchange platform. The safety case is not reviewed by the Technical Forum on Safety but by ENSI and the Technical Forum is not part of the review. Its main function is to discuss and answer technical and scientific questions on safety and geology received from the public, the communes, siting regions, organisations, cantons and public entities in neighbouring countries. The Technical forum collects and structures incoming questions and defines the procedure for processing and answering questions. The answers to questions are documented traceably and published. The Technical Forum can itself raise and answer technical and scientific questions. In general it is a one day meeting four times a year to answer the questions. If it is needed there are additional specific topical sessions. In addition the groups of the siting regions invite ENSI to specific topics but it is also more about information and no review process.

These meetings allow ENSI to be aware of the stakeholders' questions early in the process, be able to allocate resources to answer the questions and increase the general acceptance for ENSI's review documents. These discussions can be inputs for future work or requirements/technical guides. This finally contributes to make the review process more efficient (see Q2.5, Annex IV).

Finally, each of the three stages of a site selection process[1] ends with a three-month formal hearing or consultation phase, prior to the decision of the Federal Council on the drafts of the results reports and the object sheets. The proposals of the waste producers, the results of the reviews by the authorities, the opinions and reports of the cantonal commission and the siting regions and the drafts of the results reports and the object sheets to be approved by the Federal Council are opened to the public. Cantons, neighbouring countries,

[1] The siting process is composed of three stages in Switzerland:
Stage 1) Identification of sites in the selected siting regions,
Stage 2) Selection of at least two sites,
Stage 3) Site selection and general licence procedure

neighbouring federal states and regions, organisations and political parties can submit their opinion. The cantonal offices responsible for spatial planning hold hearings with the cantonal, regional and local offices and ensure that the population is involved in an appropriate manner.

Canada

In Canada, implementers are required to develop and implement a public information program: Commission Tribunal holds formal public hearings. CNSC established the Participant Funding, which gives the public the opportunity to request funding from the CNSC to participate in its regulatory processes.

CNSC has his own public outreach program, which includes the hearing process. The length of the hearing depends on the project and on the public interest (one day to several weeks). An outreach activity is an activity that conveys information to or receives information from stakeholders (communication), or actively solicits input from stakeholders (consultation). For the purposes of the CNSC, outreach activities do not include mandated licensing and compliance activities but do include meetings with municipal officials and community groups, interactions with the public, public hearings of the CNSC Commission Tribunal (particularly when they are held in a local community), meetings with licensees on non-licence specific issues (e.g., quarterly meetings with the Canadian Nuclear Association), presentations by the president and executives at various seminars and stakeholder meetings, benchmarking and other exercises with other regulators, participation in international and national conferences and events, proactive media relations events and consultations on environmental assessments.

Regarding the Commission Tribunal Public Hearing process, most major licensing decisions are made following a two day public hearing process, which may be separated by several months to allow stakeholders enough time to review the licence applicant and recommendations. However, for licence applications in regards to deep geological repositories these are likely to extend over several weeks. In advance of a Commission Hearing, CNSC staff conducts outreach activities (Open House, meetings) in the affected community and depending on the project - surrounding communities. CNSC staff conducting the technical review (led by a senior project manager in charge of coordinating the licence review and who will lead compliance inspections) may be asked to be part of the outreach team. The CNSC communicates information that is relevant to the topic, which includes information that has been submitted by the proponent to the CNSC for technical review. CNSC also welcomes written interventions and when requested by interveners, interveners are allowed to give an oral presentation at the public hearings.

An important part of the CNSC’s mandate is to disseminate objective scientific and regulatory information to the public. The CNSC will meet with communities who have expressed interest in learning more about its role, in general. Communities can also request that CNSC staff visit them to answer technical and scientific questions. In addition, to assist the public, information about the proponent is included on the CNSC's external Web site and also in "fact sheets". For example, the CNSC has developed a fact sheet, *Regulating Canada’s*

Geological Repositories, which provides an overview of the regulatory approach to repositories in Canada. The web site will be updated as the project proceeds.

To summarize, several very different actions were identified to increase transparency of expertise function:

- disseminate neutral and objective information;
- presentation by experts of their R&D results (scientific publications, open days, educational expositions…);
- make explicit the scientific uncertainties, the criteria for assessing and selecting the solution, the background documentation of expertise (see D5.2, meeting in Senec);
- organise workshops or public debates with the public (see D5.1);
- set up a long-lasting technical dialog with local committees, proximity (interactions with citizens);
- integrate, in the regulatory decision process, discussions with the public on results of technical expertise, in various forms:
  - exchange platform with stakeholders (open to the public);
  - integrate a "representative panel" of stakeholders in the review for most major licensing decisions.

To conclude, the exchanges between the technical experts and the civil society practices are currently not the same in the countries of SITEX participants. Even if the exchanges with the public can be considered as quite similar (generally restricted to information), the level of integration of stakeholders in the decision making process is highly variable. The construction of a common expertise function network requires conducting additional reflections on the level of implication of stakeholders, on the way to set up their involvement. The organisation of such reflection begins by collecting the experiences as it is intended to do in the frame of the SITEX WP5 on "Conditions for associating stakeholders in the process of expertise".

4.4 COMPETENCE OF EXPERTS

A competence corresponds to the proven ability to use fitted knowledge and skills in work or study situations and in professional and personal development. It is generally considered as a group of related knowledge, skills and attitudes (KSAs) needed to perform a particular job (e.g., IAEA project SARCoN report, see References). Knowledge is the body of facts, principles, theories and practices that is related to a field of work or study. Skills are the ability to apply knowledge and use know-how to complete tasks and solve problems. As developed below the experts' competence in this report also requires experience.

4.4.1 Required attitudes and general skills of experts

According to the SAG and the evaluation of the questionnaire, the required qualities of experts involved in assessment are presented below (Q4.2, Annex IV). They gather several attitudes and skills.

Attitudes:

- Independent, neutral, impartial, respectful of the stakeholders;
- Trustworthy, fair, sincere, honest, discrete, open-minded;
- Diplomatic, team worker and with cooperative attitude;
- In addition, the safety culture (see e.g., IAEA SF-1 guide, § 3.13) may be considered as both an attitude and behaviour with regards to safety and is of concern for all organisations and individuals (see e.g., IAEA GSG-4, § 3.22).

Finally, one can observe that there is no fair way to ensure and demonstrate that these attitudes are fulfilled by each expert (except during the effective work with them).

Skills:

- drawing-up an assessment report: be able of drawing conclusions based on reasoning and logical analysis, and of describing situations and complex phenomena in comprehensible verbal or written forms;
- Aware of the relevance and importance of their activities and of how they contribute to the achievement of the assessment;
- Capable of understanding, observing, analysing, discerning, persevering and taking different points of view into consideration.
- In option, managing a team of experts (necessary for few experts in the team);

Another specific skill for experts, corresponding to the ability to use their technical knowledge (both making the technical competence of experts) is further detailed in the next section 4.4.2.

In addition, the organisations participating to SITEX consider that the experts should also be experienced in developing or reviewing safety case. Finally, it is important in many countries that experts master several foreign languages.

4.4.2 Staffing and competences of experts

The IAEA GSR Part 1 develops a requirement related to "*Staffing and competence of the regulatory body*" (chapter 4, Requirement 18). The IAEA GS G1.1 develops the necessary qualification of staff for performing regulatory functions in the chapter 4, such as in § 4.11 about experience and knowledge of the personnel.

The IAEA SSG-23 indicates that (8.13) "*to the extent practicable, the regulatory review team should possess the following characteristics:*

- *The review team should possess a range of expertise appropriate to the review, including practical experience in areas that are most important to the particular safety case under review.*
- *The review team should have experience in conducting reviews of relevant safety cases.*

- *The review team should understand the context of the review to be conducted (e.g. they should have knowledge of the facility and of the regulations governing its authorization).*
- *The review team should have a broad knowledge of waste management practices and programmes both nationally and in other States".*

Thus the "competence" of experts in this report not only derives from scientific and technical knowledge but also includes their experience (see also IAEA GSG-4, § 3.10).

In addition, the international guidance requires being educational, as indicates by the IAEA SSG-23 in § 8.6*: "in the review process, it should be ensured that the rationale and judgements are documented as to whether or not the arguments presented in the safety case are adequately supported by the underlying science and technology, and whether these arguments are in accordance with regulatory requirements and expectations".*

The IAEA project SARCoN report is dedicated to the assessment of regulatory competence needs for regulatory bodies. These competences are divided into 4 groups:

1. Legal basis and regulatory processes competences;
2. Technical disciplines competences;
3. Regulatory practices competences;
4. Personal and interpersonal effectiveness competences.

The 1st, 3rd and 4th competences are rather required for the generalist experts (see above) and the technical disciplines (2nd) are dedicated to the specialist experts.

The technical disciplines competences are divided, in SARCoN report, in 3 groups of basic, applied and specialized technology:

- Basic technology: Engineering Mathematics, Physics, Chemistry, Earth Sciences…
- Applied technology: Nuclear Reactor and Power Plant Technologies Health Physics , Radiation Protection, naturally occurring radiation and environmental Sciences, Nuclear Safety Technology including safety and risk analysis, Nuclear Fuel Cycle Technologies
- Specialized technology: Site Evaluation, Mechanical Analysis, modelling, Fracture Mechanics, Seismic Analysis, Confinement systems, radioactive releases, Fire Analysis and Protection Systems, safety, Management of Spent Fuel and Radioactive Waste, Criticality Safety, Ageing Management, Corrosion, Decommissioning, Industrial Safety…

National practices

The SITEX participating organisations have identified that expertise of the safety case of DGR requires competences in the following domains:

- Operational safety;
- Long-term safety;
- Environmental impact assessment.

Such expertise requires various competences and associated jobs. The four main required profiles for the expertise of the SC of a DGR are the following:

- environmental scientists and risk experts in long-term safety;

- numerical modellers, mathematicians and experts in code development;
- risk experts in operational and construction phases, including material & civil engineers as well as conventional underground experts;
- experts having a federative role in the team, i.e., generalists and experts in safety assessment (scenario development & uncertainties).

As for other fields of technical expertise, the **generalist experts** (or nuclear facility experts) examining a safety case for DGR are those who know the installation and manage the whole technical review by recognising the main issues and identifying the topics that need further in-depth review using specific competences. They can be differentiated from the **specialist experts**, who have one or several of the technical competencies developed below, and on which the generalist experts can rely to build the global review of the safety case. The review of a safety case is made with a different view by specialist experts and generalist experts, and have thus important complementary role. Depending on countries, the review may be managed by one generalist expert who collects the reviews by specialist experts or by one of these specialist experts. The management of the team during the technical review process is developed in the previous section 4.1.1.

The generalist experts should have the following areas of competences:

- Organisational issues: management system;
- In-depth knowledge in national & international regulations, guidance & criteria for waste management and radiation protection; quality assurance;
- Know by heart the installation and its history;
- Are comfortable within all fields of expertise required to review the SC and is able to decide in which areas he needs a support of internal or external specialists.

The participating organisations to SITEX agree with the following list of required technical competences for specialist experts (even if it cannot be exhaustive) to review the safety case (see Q1.2, Annex IV), which must cover all aspects related to the safety of geological disposals of radioactive waste:

- Site aspect: environmental sciences (biosphere, radioecology, meteorology, climatology, geochemistry, geology, hydrology, hydrogeology, seismology, geo-technics, geo-mechanics;
- Radioactive waste origin, characteristics and behaviour, waste form, conditioning, waste degradation
- Engineering and disposal facility design, characteristics of engineering barriers and their degradation (geo-mechanics, civil & materials' engineering, materials' chemistry, radiochemistry, microbiology).
- Radionuclide migration: Numerical modelling, mathematics and computational methods,
- Operational safety in nuclear facilities: nuclear physics, physical protection, radioprotection; assessment of internal and external hazards, as human actions and earthquakes, flooding, environmental risks, fire & explosion, criticality, dynamic &

static containment failure, radiolysis and thermal effects, ventilation, handling, power supply failures…;

- Underground/mine-type hazard due to co-activity, as well as singularities with regards to others nuclear facilities: confined space, 100-year-long operational phase, reversibility;
- Long-term safety aspects: safety strategy (see Figure 2 on the SC), safety assessment (methodologies and approaches, hazard assessment, scenario development, methods for the treatment of uncertainty);
- Organisational issues and management system.

However, even if all the competences listed above are required, they should not be covered with the same profoundness. All participating organisations to SITEX have to find priorities in the R&D and development of competences, due to limited resources in staff, time and funds (see Annex IV, Q2.4). The choices are mainly made considering all safety important issues identified by the reviewers, on identified "key knowledge gaps" for the safety analysis, or on the most vulnerable issues for realizing the project.

In addition, both generalist and specialist experts should be competent in their core business: the safety evaluation. It gathers the analysis of hazards and their assessment approach, as well as the global safety approach. In the facts, all these competences may be shared in between experts and even with those having regulatory function, depending on the country's organisation.

Knowledge has to be up-to-date and their competence strengthened by training, as developed in the next section 4.4.3.

The competences needed should evolve progressively with the evolution of the disposal project, from conceptualization phase to reference design phase, then construction, operation and closure. Such change of necessary competences implies a robust personnel management system.

In addition, as developed in the section 4.1.1, several SITEX participants also estimate that it is important that researchers and experts work either in a same team or in a close collaboration.

4.4.3 Training and tutoring

For regulatory body, the need in training and tutoring is addressed by the Requirement 18 (4.13) in the chapter 4 of the IAEA GSR Part 1:

> *"a process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills.*
>
> *The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements".*

The need and the organisation of training and tutoring for the personnel of the regulatory body is developed in the Chapter 5 of the IAEA GS-G1.1. The IAEA project SARCoN report develops a systematic approach for Regulatory Bodies, the Training Needs Assessment, to identify current and desired competences, determine the gaps, and design and implement training programme to address the desired competences. Networks of training courses already exist or plan to be developed (Scholarships under Lucoex project, ENSTTI, European Credit System for Vocational Education and Training-ECVET…) but are either dedicated to the common set of fundamental competences for experts in nuclear safety, or to the waste management, but not specifically dedicated to the safety of geological disposal.

National practices

Again, a continuous training and tutoring of experts is very important because the competences needed completely change with the progress of the project (see section 4.4.2).

Various ways have been mentioned by participating organisations to develop the experts' competences (Q2.1, Annex IV):

- **on-the-job training**, and reviewing the documentation on safety and environmental impact of other nuclear facilities;
- **companionship**: the newcomers do their first technical review by working in pairs with a more experimented expert;
- **internal training sessions**, particularly for the newcomers, with the help of experienced experts, training and tutoring support by Government, participation to the national research projects, cooperation with universities;
- **external courses**: participation to the training courses and workshops organised by IAEA, attendance at international conferences;
- **participation in the research projects** of IAEA and NEA, or in various R&D European and international programmes; development and follow-up of in-situ experiments.

The experts participating to SITEX identify themselves the key uncertainties and thus specific needs in competences or R&D orientations as well as needs in training.

The technical knowledge required for specialist experts is acquired through their initial formation even if it may be reinforced through the on-going training during their work. The competence in safety approach, required for both generalist and specialist experts, is actually manly acquired by on-going work but can be initiated by a module of training courses constructed on the aspects developed in the following chapter 5 of the present report, as well as by companionship. Performing common training and tutoring at a European (or larger) level will contribute to the harmonization of practises and the construction of an expert's network. Such plan for constructing a module of training course for expertise of geological disposal a European (or larger) level corresponds to the second task of WP4 (WP4.2) on planning for organising training activities related to technical review methodology.

4.4.4 Research and development

As indicated in the IAEA GS-G1.1 guide (§ 3.33), *"there may be situations in which the operator's research and development are insufficient or in which the regulatory body requires independent research and development to confirm specific important findings*".

National guidance and practices

In the framework of the Work Package 3 (WP3) of the SITEX project, dedicated to the development of TSO's scientific skills, each participating organisation has determined the key safety issues which characterize their national DGR. These key safety issues are classified based on three main axes, divided in several topics:

- the quality of the data on which rest the safety demonstration (data accuracy and representativeness);
- the understanding of the complex processes which may potentially influence the long term safety of the DGR (processes on which rest the performance of individual components, and resulting from the perturbation of the geological disposal system);
- the assessment of the future evolution (in spatial extent and intensity) of these potential processes, as well as the assessment of their impact on the DGR safety (assessment methodologies; model reliability).

These "key" scientific and technical topics should also be of prime concern for the implementer since they relate to "key" safety issues for demonstrating the overall safety of the repository. The level of funding that the implementer should afford to research activities of concern for safety should be naturally much higher than those of the regulator and technical experts. However, it is of assessor's duty to be able to cover all the safety case issues and identify the topics that must be addressed by R&D programme and those that do not require specific R&D development. In this last case, the regulator or TSO should be able to explain why it is not necessary to develop its own research capabilities.

As it was indicated in the previous section 4.4.2 of the present report, all participating organisations have to find priorities in the R&D, due to limited resources in staff, time and funds. The choices in the development of research activities are made:

- on all safety important issues identified by the reviewers,
- on identified "key knowledge gaps" or for safety analysis of repositories for nuclear wastes, or the most vulnerable issues for realizing the project,
- following national programs, taking into account the milestones of the waste management programme and their associated objectives and decisions, the safety requirements established in decrees and guidance applying to waste disposal, the safety issues associated to the safety concept developed by the implementer,
- taking into account the research identified by EC, as IGD-TP.

In addition, the good work of a technical review necessitates for the key safety issues requiring the development of knowledge to be anticipated early enough. This aspect was developed in the section 4.1.1, dedicated to the organisation of the team and preparation of the technical review.

For the relevant fields that are outside of capabilities of TSOs experts, a close cooperation is established with other research organisations or with regulators.

As an example (see SITEX report D 3.2: "Availability and needs for technical and scientific tools for TSO's "), considering the elements that justify the IRSN R&D programme, 4 categories of major questions are addressed by IRSN: the adequacy between experimental methods and data foreseen, the knowledge of complex coupled phenomena, the identification and confidence in components performances and the ability of the components to practically meet in-situ the level of performances required.

Finally, in some specific cases of very expensive projects, some experiments can be made in collaboration with the implementer. In this case, the interpretation of the results must be carried out separately in order to preserve the independence of each partner.

The tools used by the experts of the organisations participating in SITEX project are numerical modelling, surface laboratories and studies in analogue sites or URL. The experimental installations and modelling capacities are well described for each country in the SITEX D 3.2 report cited above. In the frame of the WP4, a comparison between the used tools allowed identifying the following main differences and similarities.

Almost all SITEX participating organisations use numerical codes & modelling/simulation tools (see Q2.4, Annex IV) to assess the calculation results provided by the implementers. The modelling capacities of SITEX participating organisations are developed in the SITEX report D3.2. These codes generally correspond to commercial ones, due to quality assurance or to the limited timeframe for the review of analysis. Some codes are internally developed to better control the calculations. Their choice is based on the dataset and modelling capability. Depending on the choice of participation organisations, they are chosen as specifically different as the implementer when possible, or at the opposite exactly the same to verify the modelling/simulation tools. Generally, only few specific technical aspects of the design are checked or verified.

The numerical modelling is performed for several purposes:

- to be able to reproduce the calculations of the implementer;
- to understand the safety relevant aspects of the system/scenario and assess the appropriateness of input parameters;
- to be able to make an independent assessment;
- to maintain an expertise in the field

The SITEX participating organisations develop several kinds of models (see Q2.4, Annex IV) that are well described in the NEA report on the Outcomes of the MESA Initiative (MESA report, see References):

- "process models", "mathematical model" or "phenomenological models" (in the framework of phenomenological research): in geomechanics and geochemistry, biosphere process models, processes in the waste matrix and the engineered barrier system, flow and transport…

- “detailed models” (or “computer code”, to predict the evolution of the repository system or corresponding to modelling of sub-systems, named “component models”): hydrogeological models, biosphere, source term, packages, engineered system…

- “integrated models” or “total-system models” (using data from detailed ones), in which we can distinguish the “safety calculation models” or “safety models”, which are used to evaluate safety indicators such as dose and risk (for safety assessment - radiological consequences), and “performance models” or “conceptual model”, which are used to quantify indicators that illustrate the performance of specific system components or safety functions and their contributions to overall system performance (performance assessment of specific scenarios).

Several organisations carry out studies in analogue sites or URLs, in their own analogue sites, in collaboration with other TSOs or regulatory teams and/or with university institutes or subcontractors, or in collaboration with another team in its URL, in international R&D projects. These organisations and all the other ones take into account the experience feedback from investigations in analogue sites or in URL carried out by other teams. However, no analogue site is studied for the countries being at the stage of conceptual design or when the choice of location of the disposal in the country or elsewhere in EU is not made. The experimental installations of SITEX participating organisations are presented in details in the SITEX report D3.2.

A key criterion to select the analogue sites is the level of transferability of knowledge in terms of phenomenology to the considered potential sites for DGR.

These differences in the means to achieve R&D on analogue sites illustrate the need to construct a network of experts sharing their laboratories and exchanging their experiments as well as the results.

4.4.5 Experience feedback

As indicated in the IAEA GSR Part 1 on “*Sharing of operating experience and regulatory experience* » (Requirement 15),

> “*the regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities*”.
>
> *3.3. The reporting of operating experience and regulatory experience has led to significant corrective actions in relation to equipment, human performance and the management system for safety, as well as changes to regulatory requirements and modifications to regulatory practices.*
>
> *3.4. The regulatory body shall establish and maintain a means for receiving information from other States and from authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience. The regulatory body shall require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events.*

This process involves acquisition of the necessary information and its analysis to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience.

3.5. To enhance the safety of facilities and activities globally, feedback shall be provided on measures that have been taken in response to information received via national and international knowledge and reporting networks. Such measures could comprise promulgating new regulatory requirements or making safety enhancing modifications to operating practices or to equipment in authorized facilities and activities. Such feedback provided in response to information received via international networks also covers descriptions of good practices that have been adopted to reduce radiation risks".

Feedback of experience should be collected on hazards during operation of nuclear facilities, but also of non-nuclear underground facilities.

National guidance and practices

One example of experience feedback has been explored by SITEX participating organisations: the hazard assessment for operational phase.

In this stage, SITEX participating organisations intent to develop feedback on hazards and on the possible incidental and accidental situations for the operational phase of existing nuclear installations, from national experiences and international experiences, from the regulation of uranium mining and from accidents that may occur in any underground facility & mining activity. A complementary way is to participate in international activities, as the IAEA projects GEOSAF and GEOSAF2. However, the level of development of the analysis of hazards during the operational phase (see Q2.2, Annex IV) is extremely variable from a country to another, because probably depending on the development of the disposal program.

In France, the experience feedback is systematically collected by a dedicated team from the identified hazards in all nuclear installations, the incidents and accidents that occurred, the identification of associated of recurrent causes…

Because of lack of existing data, the requisite to collect experience feedback from larger situations than inside countries underline the need to construct a network of experts, as planned by SITEX, exchanging and sharing their national experience on hazard assessment.

4.4.6 Technical cooperation with pairs

SITEX participating organisations generally make use of the experimental installations and of modelling capacities in cooperation with other organisations. These works in cooperation are presented in the SITEX report D3.2 on "Availability and needs for technical and scientific tools for TSOs".

In addition, SITEX participating organisations contribute to international projects, such as:

- EU: PCRD for R&D
- IAEA: GEOSAF and GEOSAF2 for operational safety of DGR, PRISM for management of near-surface disposal…

Several experts of the SITEX participating organisations also already participated to a peer review, being organised by IAEA or organised by the Nuclear Energy Agency (NEA) of the Organisation for the Economic Cooperation and Development (OECD).

Occasionally, some SITEX participating organisations called upon the participation of one expert from another organisation for the technical review of a specific point. As an example, GRS contributed to the technical review by IRSN of the Dossier 2005 Argile, on the part concerning the operational safety.

Such cooperation is however scarce whereas considered as necessary for the SITEX participants and justifies the construction of a sustainable expert network. In addition, the increase of participation of foreign experts to a national technical review would constitute the best way to harmonize the review practices.

5 Implementation of the technical review process for deep geological repositories

The safety case is a concept of nearly 10 years-age; it has already been described and its content already discussed in the frame of many international projects (in particular, EPG report 2011-Draft; WENRA Report 2012-Draft, IAEA project PRISM report…) and in various international guides (e.g., IAEA SSG-23). The Figure 2 is an illustration of a way to structure the content of a "complete" safety case, divided in several units, as presented in the IAEA SSG-23. This figure has been completed with the generally expected content of each of these units, as developed in the PRISM report.

SITEX falls within the continuity of this concept and the safety case constitutes a basic building block of its developments. The content and structure of the safety case have therefore been discussed by the SITEX members (see Q4.7, Annex IV), and even if the way to organise the different units of the safety case may change from a SITEX participant to another (as it is the case depending on the international guidance consulted), they agree on the global content and the objectives of the safety case.

The international guidance associates the safety case to the concept of "stepwise approach". Indeed, the disposal facilities consists in particular nuclear facilities, and moreover DGR, very complex with a long-last operational phase and much longer post-closure phase associated with passive safety (see section 4.1.1). Also, the expectations regarding the safety case are not the same at each stage of development of the project of geological disposal. This is the object of the PRISM project. Such stepwise approach is further developed in the section 5.1.1 of the present study.

This chapter 5 deals with the technical review of the safety case, and thus, amongst other things, talks about the content of the safety case that is expected by technical experts. IAEA guide GSR Part 1 reminds of what is expected to the regulatory body (§4.42-4.45*).* However, the reviews by the regulator and by the experts do not exactly focus on the same aspects of the safety case. In fact, the technical review does not cover all the aspects of the safety case. As for example, the administrative and regulatory aspects are examined by the safety authorities, as well as the "involvement of interested parties and the regulatory body".

To the opposite, the most scrutinized units of the safety case by technical experts are the "System description" and the "Safety assessment", but the content given by the implementer and the depth of technical expertise also change with project development (see following section 5.1.1).

Following the IAEA SSG-23,

> *"8.3.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. To achieve this goal, the regulatory review process will typically have the following objectives:*

- *To determine whether the safety case has been developed to an acceptable level (in terms of its quality and the detail and depth of understanding displayed) and whether it is fit for purpose;* […]
- *To determine 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 SITEX participants understand that the technical review should check that the safety case:

- Well describes the barriers of the DGR (system description), with an identification and quantification of the mechanisms as well as of the internal and external solicitations, their safety functions and target performance level, accounting for industrial feasibility ;
- Verifies that the total system is robust with complementarities (no common mode of failure or lack of compensation of dysfunction), and covers sufficiently the possible evolution and events with defined margins (verification including performance assessment).

This chapter first examines the best way experts can organise this review in terms of time schedule, secondly investigates the method to conduct the technical analysis of a safety case and finally explore the expected content of a technical review report.

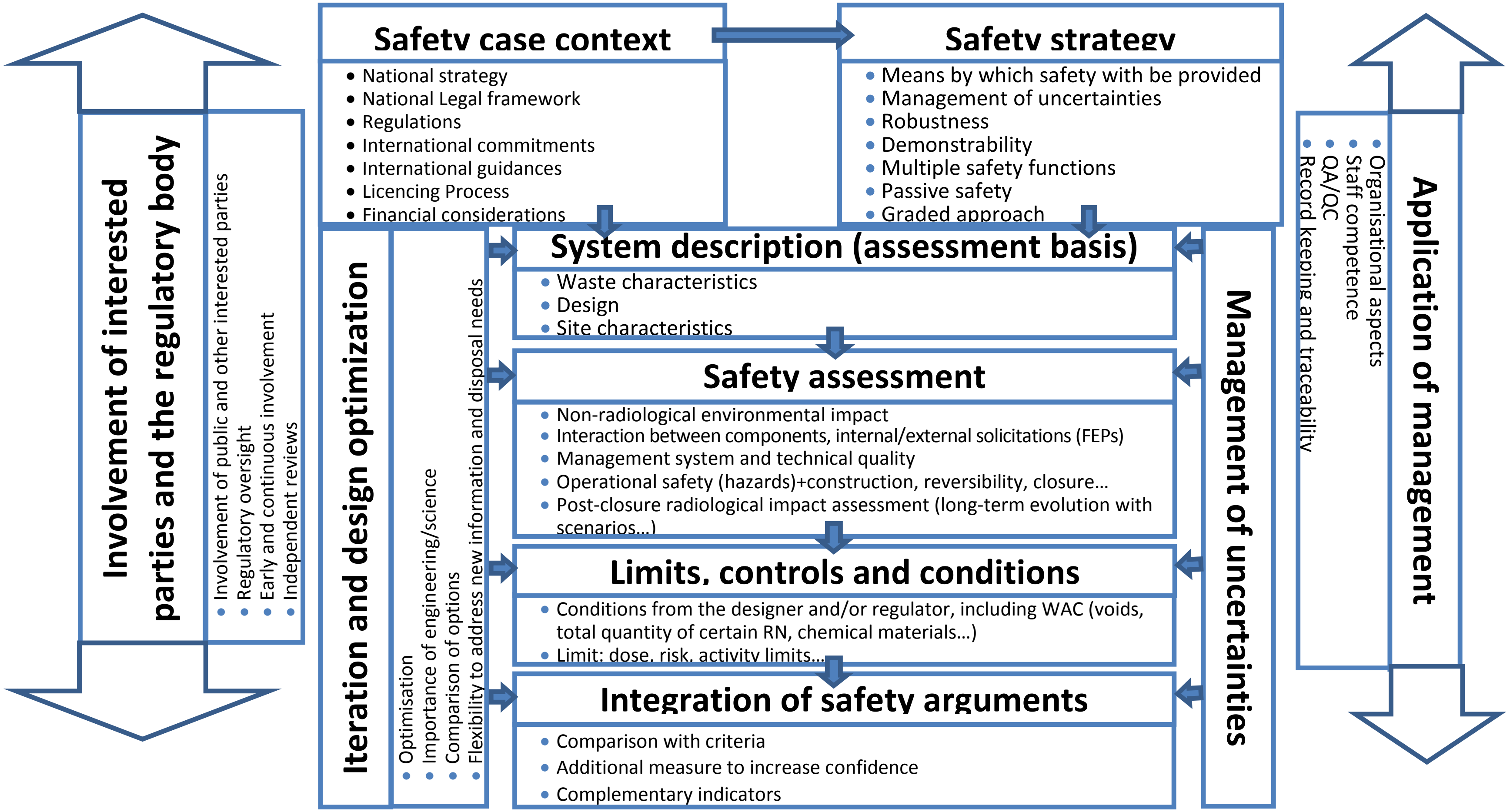

Figure 2: Content of the safety case (from IAEA SSG-23 and PRISM report, modified)

5.1 MANAGEMENT OF THE TECHNICAL REVIEW OF GEOLOGICAL DISPOSAL

5.1.1 Stepwise approach of the safety case

As developed above, the safety case is a report (or compilation of reports) evolving with the project of DGR and over its lifecycle.

The IAEA guide SSG-23 (§ 6.2) considers that *"The safety case will evolve in several stages: Concept development; Site investigation and site selection; Development of the design and construction; Operation and closure; The period after closure. Especially early in the development of a disposal facility, these stages may overlap and some iteration may be necessary".*

Following of the Franco-Belgian collaboration in 2000-2005 (Groupe Franco-Belge), the European Pilot Study on the regulatory review of the safety case for geological disposal was carried out by a group of regulators and technical support organisations from Belgium, France, Finland, Germany, Spain, Sweden, Switzerland, as well as representatives of international organisations, and named "European Pilot Group" (EPG report 2011-Draft). The EPG report 2011-Draft identifies the same phases but splits the stage "*Development of the design and construction"* in "*Development of the design and application for construction*" and "*Construction and application for operation*". Thus, the considered main phases of the safety case are the following:

- conceptualization phase;
- site investigation and selection phase;
- reference design and application for construction phase;
- construction phase and application for operational phase;
- operational phase;
- post-closure phase.

In this report, the participation organisations to SITEX tried to describe the expected state of knowledge in the implementer's safety case at each of these step. IAEA project PRISM draft report, even if dedicated to surface disposal, describes the key decision steps corresponding to the same phases.

The EPG report 2011-Draft also indicates that "*demonstrating the safety of geological disposal is a process that needs to be undertaken systematically and through all phases of the development of a disposal facility. Safety arguments must be continuously refined and supporting safety assessments must be undertaken iteratively as the disposal facility is developed. The structure of the assessments is expected to be consistent throughout for more efficient regulatory review*".

Consequently, conducting reviews of the safety case at periodical steps contributes to their efficiency and to the good progress of the safety case. The need for interactions between the regulator and the implementer from the earliest stages in the development of a disposal facility is also a conclusion of the pilot study group given in the EPG report 2011-Draft.

National practices

It may be noticed that this segmentation stays artificial, because in fact many activities may occur in parallel: as an example, design selection and siting, as well as construction, operation and partial closure (for France). This does not implicate that a licence, permit or approval is required at the end of each stage, but just at least a review by the regulator. Another option could be to take terminology that refers more specifically to decision points rather than phases. Even if such a terminology may be specific of each country, several decision points may be shared such as feasibility demonstration, site selection, licencing…

The represented countries in SITEX project are generally in a strict concept phase as Lithuania, Belgium) and/or site selection (Czech Rep., Netherlands, Switzerland, France), and/or design phase (France). In France, the site is about to be selected but such choice should be definitively approved by decree of authorization of creation of the DGR. The site is planned to be selected before 2016 in Switzerland. In the Netherland and in Canada, the implementer is developing conceptual designs for hypothetical sites (generic safety case) as the host rock type has not already been selected. In Sweden, the site has been selected and application for construction is under review. In Germany, the procedure for site selection of a DGR for high level waste has been adopted by the Site Selection Act in July 2013; the site selection procedure, developed in several successive steps, is expected to be completed by 2031[2]. In Belgium, the implementer is developing conceptual designs for two alternative geological formations, whereas a decision in principle by the Federal Government for the geological disposal of radioactive waste is still pending (January 2013). The objective of the first safety case, which is planned to be submitted in 2014 to the Safety Authority, will depend on this decision-in-principle. ONDRAF/NIRAS has submitted its Waste Plan in 2010 to the Federal Government for a decision of “go-for-siting”.

As example of stepwise review, the Swedish regulatory framework requires nuclear power plant owners to submit an updated program every three years for regulatory review (see Q2.5, Annex IV). IRSN also conducts frequent reviews of the project of DGR since 1997. Even if not performed with a regular spacing in time, nearly ten main technical reviews were performed by IRSN in 15 years.

As it is presented in the final report of IAEA project GEOSAF, among other organisational aspects for the regulatory body or TSO, an important one is “*being involved in the project at the earliest:*

- *Assessors should be involved in review activity early before a Safety Case is actually submitted to any licensing process.*

---

[2] In particular, the following steps are provided.

1. Identification of eligible site regions and selection for surface exploration
2. Decision on surface exploration
3. Definition of site-specific assessment criteria
4. Surface exploration and proposal for underground exploration
5. Selection for underground exploration: the sites for underground exploration are expected to be determined by the end of 2023 and decided by federal law.
6. Underground exploration process
7. Final site comparison and site proposal
8. Determination of the site for a licensing procedure: the Federal Government will propose a site to the German Bundestag in the form of a draft law; the site will be determined by the Bundestag and the Bundesrat in the form of a federal law.

- *Periodic meetings with proponents to give feedback, either in the form of formal review reports and/or informal discussion*
- *However the reviewers should be careful of not being involved into the choices that are of the responsibility of the implementer and to avoid co-development of the safety case".*

The organisations participating in SITEX project also estimate that it is important for the regulator and experts to be early involved in the review process and in any case prior to a licence application.

The SITEX project participants have finally decided to focus further on the identification of harmonized review needs and methods (the objective of WP4) for the safety case constructed for decision points corresponding to the end of each key phase identified in the EPG report 2011-Draft:

- **end of the conceptualization phase that leads to decision to start investigations,**
- **end of site investigation and selection phase, that leads to decision to select site and begin investigation for reference design,**
- **end of reference design and application for construction phase that leads to decision to fix design and start construction,**
- **end of construction phase and application for operational phase that leads to authorization for final closure and sealing of the facility,**
- **post-closure phase, with institutional controls and continuing monitoring and surveillance for a fixed duration.**

5.1.2 The successive steps of a technical review

The IAEA SSG-23 specifies that

"8.15. A regulatory review will normally have four phases:

(a) A pre-review phase, prior to the receipt of any documents from the operator, in which initial planning for the review should be carried out: This should normally involve meetings with the operator with a view to developing an understanding of the extent of the information that will be provided.

(b) An initial review phase, during which the regulatory body should make an initial evaluation of the documents submitted to assess the completeness of the safety case and the availability of supporting documents, and to make a preliminary identification of those issues that are most important to safety: Evaluation of the completeness of the safety case should include checking that the information submitted addresses all of the expectations of the regulatory body for the safety case. This checking should be documented and a series of detailed review comments should be prepared, which may require additional information. The regulatory body should review and assess any additional information provided by the operator in response to the review comments.

(c) A main technical review phase in which the bulk of the effort will be expended: This should include the development of detailed review comments, and may include evaluation of additional information provided by the operator in response to comments.

(d) A completion phase, in which the main conclusions of the review should be identified and used to inform the decision making process".

In practice, the processes of technical review as well as of exchange between experts and regulatory body may vary, depending on the importance of the technical review in the disposal project. The end date of the review may depend on the regulation. It also may be modified after the inception phase because it depends on the complexity of the problem and the quality of the received document, as developed in the next section 5.1.3.

Taking into account the above description in four phases as well as the development presented in § 3 of the ASAM Regulatory Review Draft Report, this stepwise approach has been slightly modified and completed (see Q3.1, Annex IV). Nevertheless, the SITEX participants agree to consider this approach as an "ideal" way to manage the review, because this is not systematically the case in practice for several reasons that are developed below.

1. The "inception" or **"pre-review" phase** generally occurs prior to receipt of any documents from the implementer. An idea of the content of these documents may however be given by the implementer by at least the title of the main documents or by organising meetings. During this phase, the portrait of the technical review is roughly painted: the required content of the implementer's report has to be described by the regulatory body, the subject and initial planning or cut-off date of the review have to be defined in agreement between the implementer, the regulator and the experts.

   This pre-review phase is more developed in the following section 5.1.3.

2. During the **initial review phase**, the review team, to whom documentation and support is provided, is set up.

   The experts make an initial evaluation of the implementer's documents to assess the completeness of the file and the availability of supporting documents (administrative admissibility)

   If the document is considered admissible, a formal request by the safety authority may be sent to the experts.

   A preliminary analysis is provided by experts to identify the first main trends of the review, the most important possible disagreements with the implementer, the needed expertise and the ability of the review (to detect blocking issues…). This normally involves an "engagement" meeting with the implementer to find agreement on the extent of the information that is provided.

   This initial review phase is further developed in the following section 5.1.4.

3. The **main technical review phase** begins with this checking to identify the needed additional information. The reviews and questions to the implementer, meetings ("technical dialog": see section 4.2.2) and hearings allow seeking more information by implementer to complete the technical review.

   This phase may last several months or years and includes the development of detailed review comments, and includes evaluation of additional information provided by the implementer in response to comments. Numerical modelling may be carried out to assess the calculation results provided by the implementers; the same way, the experts may rely on laboratory measurements, observations on analogs, compilation of existing publications... The results of R&D obtained by experts during the preparation of the technical review (during inception phase or before) are used to set out arguments on the review but may need to be completed with additional experiments or calculation during this phase, depending on the data effectively given in the implementer's reports.

The detailed technical review of the safety case for each phase of development of the safety case is developed through technical review grids in the following section 5.2.1.

The expert assessments are collected (if necessary, meetings are organised within expert team). Finally, a draft high-level technical review of the documentation is provided and is presented to the implementer (as for example during a "preparatory meeting") and open the way to a last technical dialog between the technical experts and the implementer.

The final review report is written after this meeting, taking into account these eventual agreements of the implementer and reporting the remaining recommendations from experts.

4. During the **completion phase**, the main conclusions of the review are identified and used by the Safety authority, together with conclusions drawn from inspections, from international peer reviews if exist, from the conduct of its own activities where relevant, to inform the decision making process (concluding statements).

   The regulatory body and expert team proceed to the filing of the element used to define the final assessment. The internal experience feedback from the technical review is used to identify the expected future "knowledge gaps" and define the R&D needed by experts addressed to the review team (skills …) for a next review process.

For reviews that are not much important in terms of quantity of documents to analyse or in terms of safety issue, this stepwise technical review can be simplified compared to the description above (no technical meeting with implementer…).

5.1.3 Orientation and depth of the analysis (pre-review phase)

During the inception phase, the technical review is preliminary defined in terms of planning and issue.

The need for a review may correspond to a requisite because fixed by the law, to a request from the implementer (to operate a change in the repository), to a demand initiated by the safety authority (see below), or finally to a self-request by the experts themselves (for TSO organisations), made in agreement with the safety authority. The organisation of this phase thus depends on the claimant for the review.

Whatever the context, the required content of the implementer report has to be described by the regulatory body, prior to receipt of any documents from the implementer, and the main objective of the request and an initial planning of the review have to be defined in agreement between the implementer, the regulator and the experts. As an example, the experts may give their opinion whether the request for technical review is justified or not.

The following sections of the IAEA SSG-23 are of particular interest to frame the "future" technical review:

> *"8.5.When defining the objectives and scope of the review, relevant points that should be considered include the following:*
>
> - *The important safety issues for the site;*
> - *The extent of the safety information provided by the operator, and the resources available to the regulatory body to evaluate the information;*
> - *Whether the review will consider only radiological impacts on humans or will consider other impacts as well, for example impacts relating to hazardous waste materials;*
> - *Whether the review will consider impacts on the public, on workers and on non-human species in addition to the overall impact of the facility on the environment;*
> - *Which parts of the safety case documentation should be the focus of the review;*
> - *The use to be made of the results of regulatory review; for example, whether they will be used as part of communication on licensing between the operator and other interested parties, for facility licensing or to establish conditions at an existing facility.*
>
> *8.14. The level of scrutiny and the scope of the regulatory review of a safety case should follow a graded approach. Decisions about the depth and extent of the review process should take into account the* [...] *stage of development and operation of the disposal facility or component of the disposal system; the magnitude of the hazards and risks (consequences and probabilities) in the period after closure*".

Of course, a dialog between the regulatory body and the implementer is needed to discuss and agree on the objectives, scope and planning of the review, including assessment context (see ASAM Regulatory Review Draft Report).

No difference has been identified in practice with the above description on the way to orientate and preliminary define the depth of the analysis. However, it is clear that the exact definition of the technical review could not be settled at this stage and need to back on the content of the implementer's report after its receipt.

5.1.4 Administrative admissibility and preliminary analysis (initial review phase)

When the implementer's documents are received by the regulatory body, the expert team is set up. The experts are selected by the regulatory body or informed by official referral for TSOs as detailed below, and documentation and support is provided.

The first step of this initial review phase is a verification of the administrative admissibility of the implementer's report, done by the safety authority or the experts (or both when the report is technically complex): the completeness of the file and the availability of supporting documents are assessed, and a preliminary identification of those issues that are most important to safety is made (e.g. in order to 'risk-inform' the review). Evaluating the completeness of the assessment also includes checking that the submitted information addresses all of the regulator's expectations for safety assessment. This initial evaluation is not limited to "contractual" aspects but also regards quality and relevance of the documents to perform the review. The admissibility of report may be conditioned by the transmission of additional documents by the implementer. The completeness of the report can be checked using the following key points:

- level of description of the site, design and waste inventory matching with the stage of development of the safety case;
- description of safety functions and role of each component of the disposal system to fulfil these safety functions;
- possible interaction between components (Structures, Systems and Components), description and assessment of consequences on safety function consistent with the stage of development of the safety case;
- list of possible internal and external hazards (operational phase and post-closure), and eventually, quantification of these solicitations (depending on the stage of development of the safety case);
- description of the long-term evolution of the disposal system, development of scenarios and justification at the expected level of the safety case.

This may conduct to a "kick-off" meeting with the implementer, in which the implementer summarises the structure of its report and the methods applied within its assessment, "*so that the review team can more easily conduct its review*", and summarises the results of its assessment, "*so that the review team can gain a ready appreciation of the key issues and uncertainties associated with the performance on the disposal facility*" (ASAM Regulatory Review Draft Report).

In countries where the experts are not in the same team or organisation as the Safety Authority, the demand for technical support issued by the safety authority may be formalised by an official document. This "referral" is written after the verification of the administrative admissibility of the implementer's report, and by the safety authority in collaboration with the experts. It specifies in particular the nature and the scope of the request depending on the context, the expected action (points on which the authority wishes to experts pronounce specifically), the form, the degree of urgency and the dead line. The referral states the technical and regulatory contexts in which the demand for expertise fits. To avoid any confusion, the references and their date or grade of revision of each document to analyse are given in the referral. In any case (referral or not), the review team is assembled, the responsibility of each member is identified and a review plan is developed, with identification of the review tasks.

The next step of this initial review phase is a preliminary analysis provided by the experts. This review is generally nearly ten times quicker than the main technical review and thus cannot go in profoundness. It aims at identify the topics that need to be further analysed and the potential need for specialised experts, the topics that may conduct to disagreements or tricky discussions with the implementer.

The IAEA SSG-23 (§ *8.4)* lists the general aspects to check in the safety case: *"In order to facilitate the evaluation of the safety case against the primary objectives of the regulatory review, it is common for a number of secondary objectives to be specified. These should include evaluation of whether the safety case:*

—Has been developed within an appropriate context;

—Is sufficiently complete, given the stage of development of the disposal facility;

—Is sufficiently transparent in its presentation of data and information […]*;*

—Is based on appropriate assumptions and makes use of adequate assessment techniques and models, and contains satisfactory supporting arguments […]*;*

—provides an adequate assessment and supporting justification that any radiation exposure has been optimized and demonstrates that safety has been optimized […]*;*

—demonstrates that good engineering practices with adequate defence in depth have been used in developing the design of the facility;

—defines a programme for future development of the safety case, understanding the disposal system and institutional control of the site".

Other aspects listed rather correspond to the following phase of review (main review phase) and depend on the depth of evaluation, varying with the stage of development of the safety case (see EPG report 2011-Draft), whether the safety case:

—"Demonstrates an adequate understanding of the disposal system that includes identification and screening of hazards and related scenarios, such that all relevant safety functions and all potential safety concerns are addressed;

—Clearly describes how the identification, establishment, justification and optimization of limits, controls and conditions were performed;

—Clearly identifies the uncertainties associated with the understanding of the disposal system (as well as input data and models used) and the performance of the disposal facility […]*;*

—includes adequate consideration of the justification and optimization of remedial measures for existing facilities, if applicable".

The other aspects may be considered as less important for the experts in their initial review phase but may stay important data for the regulator, whether the safety case:

—"Has been prepared by competent personnel applying an approved management system;

—Has been subjected to independent peer review […]

—Addresses all relevant factors of the management system to be applied for the siting, construction, commissioning, operation and closure of the disposal facility (e.g. internal and external audits, verification and validation, use of suitably qualified and experienced personnel, training, control of processes outsourced to subcontractors, action on conclusions and recommendations)".

The results of this preliminary analysis are generally presented to the implementer during an "engagement" meeting, to find agreement on the extent of the information that is provided.

5.1.5 Dealing with constraints in the safety assessment for operational and post-closure phase

Depending on countries, the national guidance may contain requirements that have to be followed and conduct to carry out the technical review with respect to these rules. This question has been already discussed in the frame of the EC project PAMINA and NEA project MESA projects (MESA report; PAMINA report D1.1.4, see References).

Several of these constraints are presented in the Annex II: the use of deterministic or probabilistic methods to analyse the events & processes, the way to construct the scenarios, radioprotection indicators with slight variations from a country to another, the type of regulation being rather non-prescriptive or prescriptive.

These imposed national requirements could be seen as an obstacle to the harmonization of the review practices. However, these are consistent with the existing recommendations in international safety guides. For instance, the existence of defined scenarios does not prevent the technical reviewer to recommend the implementer to consider an additional scenario. As another example, the use of a deterministic method as fixed by the law does not prevent to add probabilistic analyses on uncertainties. Specific guidance on how to deal with such constraints in the safety assessment should be developed.

5.2 PROPOSED METHODOLOGY FOR HARMONIZED TECHNICAL REVIEW (MAIN REVIEW PHASE)

5.2.1 Proposal of a technical analysis chart for each phase of development of the safety case

As described in the ASAM Regulatory Review Draft Report, the main technical review "*includes the development of detailed review comments, and may include evaluation of additional information provided by the implementer in response to comments*". Therefore, it can be divided into several sub-tasks:

- the technical dialogs with implementer, including the two following ones:
    - in a first series of exchanges, the implementer has "*to clarify where and how issues are dealt with in its documentation, and to identify possible approaches to addressing issues identified during the review*", as well as "*to provide additional technical information*" when assessed as needed by the experts (ASAM Regulatory Review Draft Report). It may thus correspond to questions by the reviewers and answers by the implementer, to a request of additional documents or explanations;
    - the final series of exchanges may correspond to a "preparatory meeting" during which the draft final technical review is presented to the implementer and after a technical dialog, subsequent actions are accepted from implementer on a series of recommendations;
- the individual expert's technical review, for which the SITEX participants produced a first example of review grid detailed below; the hazard assessment is detailed in the following section 5.2.2 of the present report;
- the management of the individual (or sub-groups') technical review comments inside the review team as well as the writing of the technical review report. A way to manage the collection of the review comments, management in case of internal disagreements, conflicting opinion on issues, of inconsistencies and duplication is well

developed in the ASAM Regulatory Review Draft Report. The Figure 3 presents a way to manage these discussions. Therefore, this topic will not be further detailed herein.

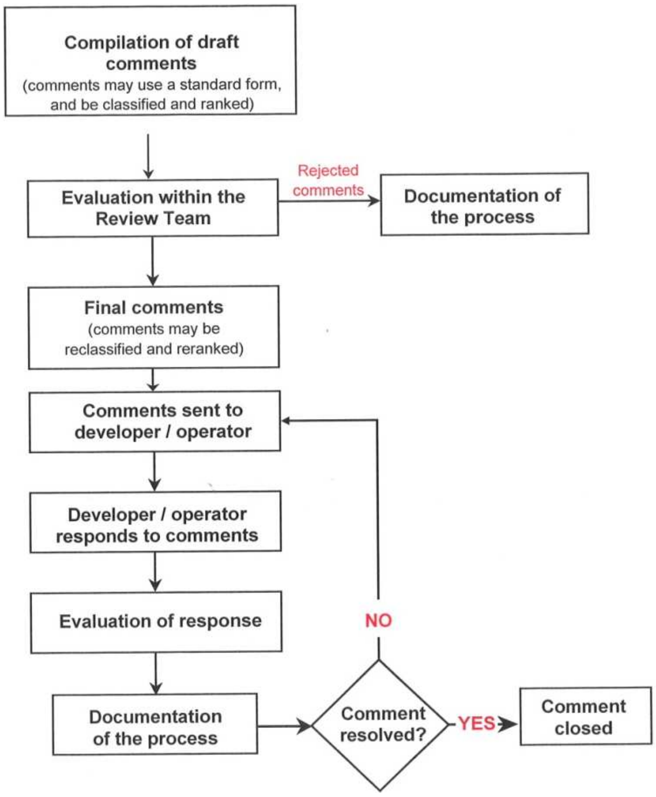

Figure 3: Illustration of a typical comment resolution procedure (from ASAM Regulatory Review Draft Report)

About the way to carry out an individual technical review, the IAEA SSG-23 expresses the need to develop a review plan in its chapter 8: "*For each regulatory review, a review plan will be necessary to guide the procedural and technical aspects of the review. Procedural guidance should include the means of documenting the review findings. Technical guidance should include the criteria against which to judge specific aspects of the safety case. The review plan can, therefore, serve as a template from which a project specific review plan can be developed. Examples of project specific review plans include those developed for the low level waste disposal site in the United Kingdom [46] and for the Yucca Mountain project in the USA*".

As a tool to verify the consistency of the safety case with the IAEA SSR-5 requirements questionnaire was constructed in the frame of the IAEA GEOSAF international project. The ASAM Regulatory Review Draft Report is also helpful for the review of the implementer's safety assessment.

As developed in the section 5.1.1, the "European Pilot Group" developed a study on the regulatory expectations for the safety case for each phase of its development (see Besnus et al., 2006, 2007). The result is presented as 2 tables for two stages of the safety case development, Concept phase and Siting phase, showing expected key milestones of the safety case at these stages.

Finally, in its final EPG report 2011-Draft, the EPG details the expected content of the Safety case at each stage as presented above in this report (see section 5.1.1).

National practices

About the existing national guides or questionnaires to lead the analysis of the safety case (Q3.1, see Annex IV), only Czech Republic, Belgium, France, Germany and Switzerland have national guides that apply to DGR. However, no specific guide has been found for the technical review of the safety case of geological disposal.

The identified national specific guides dedicated to the safety case are the following (Q4.6, see Annex IV):

- in Belgium, a guide exists for post-closure safety assessment of radioactive waste repositories primarily addressed to the implementer; the review principles of the first safety case on DGR is being written by FANC and is aimed at the regulator as well. Bel V (formerly AVN) has developed a guide summarizing the “A minima requirements on argillaceous sedimentary formations for the geological disposal of radioactive waste”
- in Czech Republic, former guidance (SUJB 1999, 2003, 2004, only in Czech language) exists for preparation of safety assessments by the implementer, and has to be renewed;
- in Germany, the Safety Requirements (BMU 2010) shall apply to the site at which the Federal Government, being responsible for the establishment of facilities for the final disposal of radioactive waste, has opted to conduct a plan approval procedure, to the final repository to be built, operated and decommissioned at that site, as well as to the organisations involved in the construction, operation, licensing and supervision of this final repository. As such these Safety Requirements shall apply to the planning, further exploration, construction, emplacement operations and decommissioning of such a final repository, and shall also address the required monitoring and evidence preservation measures following its decommissioning.
- specific guideline is developed in Switzerland (ENSI-G03) on design principles for geological disposal and requirements for the safety case for the implementer.

Other countries of organisations participating in SITEX do not have a national guide.

The participants of WP4 of SITEX project made an overview of the existing guidance for technical review and evaluated the national practices within different countries based on the questionnaire. It has been concluded that the technical review process needs some improvement in terms of guidance development, sharing a good practices in order to have an effective and successful review process. As it was mentioned before, the participants of WP4 decided to focus on the safety case evaluations at different points of repository development program (end of site investigation phase…).

Following the EPG report 2011-Draft, the SITEX participants have developed a first grid (**Table 2**) to support the experts’ analysis of a safety case constructed by the implementer at the end of one main phases of development of the safety case as fixed in this report (see section 5.1.1): the end of site investigation and selection phase, leading to decision to select site and begin investigation for reference design. It corresponds to the analysis of the SR-Can SKB report (implementer in Sweden) or to a part of the Andra's Dossier 2009 (implementer in France). Other reports, even if not corresponding to the end of siting process but to feasibility study, such as the Andra's Dossier 2005 Argile or the Report analysed by ENSI in 2005, or to one stage in the site selection as the safety review of Stage 1 by ENSI in 2010 in Switzerland, may be reviewed using this grid.

Short description of proposed review grid

Below the title of the corresponding key phase in the safety case development, this grid is divided in 8 main rows. The first one presents the main expected outcomes of the safety case are presented. The focus of the technical review is given in the next row.

The following rows correspond to the expected content of the main units of a safety case: safety strategy, assessment basis, safety assessment, optimization and management of uncertainties, as well as integration of the safety arguments. The unit of the safety case related to the "Limits, controls and conditions" (see Figure 2) is not present because it is only relevant when the operation starts. For the appropriate phases of the safety case (end of reference design and application for the construction phase, end of construction phase), the review grids should present an additional row. For each of these rows, the **Table 2** identifies what to check in the implementer's safety case. The rows dedicated to the assessment basis and to the safety assessment present an additional column of key questions to be answered. These questions do not require additional information from the safety case than the column "what to check" but correspond to a complementary approach. Finally, the Safety assessment is split with aspects corresponding to site and engineering assessment and to radiological and non-radiological impact assessment.

This draft grid may be improved in the future, but these additional developments should not aim 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.

Table 2: Review grid for the SC and the end of site investigation and selection phase

<table>
<tr><td>Stage</td><td colspan="2">SITE INVESTIGATION AND SELECTION PHASE (Leads to decision to select site and start reference design phase)</td></tr>
<tr><td>safety case</td><td colspan="2">• Identifies and confirms potentially suitable sites for implementing a GD and for demonstrating the safety; characterization must be sufficient to allow taking a decision to select a site.
• Identifies the key uncertainties and shows as far as possible how they can be managed.
• Describes at least one design option which presents good prospects of feasibility in the site, in the sense that it relies on proven and/or easily demonstrable features and is able to accommodate uncertainties related to the expected performance of the various components of the disposal system.</td></tr>
<tr><td>Focus of the technical review</td><td colspan="2">• To review how implementer confirms the expected properties of the host rock (e.g. isolation and containment); Are the candidate sites characterized and investigated to a level allowing the selection of one (or more) preferred sites?
• To review the compatibility between the design(s) developed in the previous conceptualization phase and the potential site(s)
• To review how the overall concept (design + site) is adapted and refined taking into account the new data collected from investigation and characterization of the host rock and surrounding environment (iterative process)
• To gain sufficient confidence in implementer’s capability to demonstrate that at least one design option presents good prospects of feasibility, in the sense that it relies on proven and/or easily demonstrable features and is able to accommodate uncertainties related to the expected performance of the various components of the disposal system.</td></tr>
<tr><td>Safety strategy</td><td colspan="2">What to check:
• Site acceptance criteria (not necessarily quantitative, but also qualitative) established by implementer on the basis of siting requirements which are at least:
➢ Containment and isolation capabilities;
➢ Long term stability;
➢ Reduction of likelihood of human intrusion (no presence of exceptional underground resources).
• Implementer’s proposals on how the technical feasibility of the disposal facility will eventually be substantiated, using the results of the program of investigations planned during the previous conceptualization phase =
• Approach developed to implementing engineering solutions and monitoring</td></tr>
<tr><td>Assessment basis</td><td>What to check:
Relevant features, events and processes should be identified
• Verify the quality of the basic characteristics of the host rock and surrounding environment (geological, geochemical, hydro-geological and mechanical properties) as well as those of the potential construction materials of the engineered components, using the experts’ R&D and knowledge.
• The state-of-the-art knowledge on the properties of component materials important for the disposal safety should be established.
• The assessment methods, models, computer codes and databases must be shown to be reliable.
• Inventory of the waste packages, with sufficient evidence that the provided data cover with adequate margins the important features for designing a safe disposal facility (check number and volume of waste packages, radionuclide inventories, activities, thermal output, chemical composition, toxic content, gas emission, etc.).</td><td>Key questions to be answered:
• Are the basic researches on characteristics of the host rock and surrounding environment carried out?
• Are the basic characteristics of the potential construction materials of the engineered components assessed?
• Has the inventory of the waste packages been determined with adequate margins?
• Are the mechanisms identified and quantified?
• Which interactions are characterized?
• Confidence in demonstrability of</td></tr>
</table>

			physical-chemical mechanisms? • Quality of data?
Safety assessment	Preliminary site and engineering assessment	What to check: • Demonstration of the ability of each component of the disposal system to fulfill its expected function (This will primarily consist in identifying the disturbances that might affect the disposal system and its components, these being of internal (thermal, chemical, mechanical, radiological, nuclear,...) or external (intrusion, climate change, seismicity) origin (Structures, Systems and Components). • Feasibility assessment, based on the known characteristics of the host rock, which gives consideration on the suitability and effectiveness of the techniques.	Key questions to be answered: Effectiveness of safety functions, performance of barriers: • Range of possible disturbances identified and quantified? • Confidence in industrial feasibility assessment on the suitability and effectiveness of the techniques (including excavation)? Effectiveness of total system: • Is disposal system robust? Which complementarities? No common modes of failure and/or lack of compensation of (postulated) dysfunction? • Were enough possible evolutions or events considered for determining the robustness of the total system?
	Radiological and non-radiological impact assessment	What to check: • Scenarios developed (at least normal evolution and taking into account the main disturbances identified, checking the main assumptions and simplifications • Conceptual models • Confidence of the order of magnitude of the impact of the disposal system	Key questions to be answered: • Are scenarios derived systematically? • Are results of reasonable confidence (available safety margins)? • Is impact verified as not unacceptable? • Are the uncertainties sufficiently covered (comprehensive)?
Optimization, management of uncertainties	What to assess: Adaptation of the R&D program to the results of analysis by the implementer		
Integration of the safety arguments and evidence	What to assess: Updated information on compliance with the safety strategy in respect of both the evolving design and the safety assessment approach (demonstration that the safety case still provides an overall integration of the safety arguments and evidence from the assessments above, the safety case should specifically update the points addressed during the previous phase, proposals for a program of site and design qualification).		

Other grids with similar framework may be developed for the other steps of development of the SC identified in the section 5.1.1 :

- end of conceptualization phase, leading to decision to start investigations;
- end of reference design and application for construction phase, leading to decision to fix design and start construction;
- end of construction phase and application for operational phase, leading to decision to start operation.

The grid for analysis of the safety case at the end of the operational phase (before closure) may be constructed in a later stage because its technical review appears as a too far perspective for the participation organisations to SITEX. However, such construction could be an enriching exercise to better understand the whys and wherefores of the safety case for the previous phases.

As decided when building the SITEX project, the aim of the project is to set the necessary conditions and identify opportunities to build a sustainable network which program of work would contribute to the harmonisation of technical review process among the participating countries besides other aims. The establishment of synthesis grids for guiding the review of the safety case at key phases identified in EPG report 2011-Draft and SSR-5 could be an example of future work in this direction. As a feasibility study, SITEX participants decided to develop such a grid for the site investigation and selection phase.

5.2.2 Hazard assessment for deep geological repositories

The organisations participating to SITEX have established the following list of hazard that may apply for a geological disposal during operational phase and during the post-closure phase (see Q4.3, Annex IV):

- operational phase: earthquakes, flooding, environmental risks (climate), fire & explosion, criticality, dynamic and static containment failure, radiolysis and thermal effects, ventilation, handling, power supply failures, completed with failures during transport of waste packages, failure of rock wall due to structure instability, landslide on the access tunnel portal; loss of coolant, loss of heat sink, unintentional activation or faulty functioning of safety systems, and errors committed by personnel, civil or military aircraft crash, squall, lightning strike, shock wave, consequences of societal and political disturbances for the safe operation of the facility, including abandonment, ageing;
- post-closure phase: earthquakes, physical-chemical conditions of exceptional amplitude, criticality, climatic events and geodynamics including erosion, future human actions.

However, one can notice that the list for operational phase could be the same as for several other types of nuclear facilities, and that the one for post-closure phase is similar to the one for any surface disposal. Therefore, this section 5.2.2 aims at answering to the following questions:

- Is the hazard assessment for operational phase of DGR apprehended the same way as for the other types of nuclear facilities?

- For a same type of hazard (earthquakes, flooding…), which are the specificities of hazard assessment for post-closure phase, compared to operational phase?
- Is the hazard assessment for post-closure phase of DGR apprehended the same way as for the surface disposal facilities?

5.2.2.1 Operational phase

Several international guides related to specific hazards were identified but are dedicated

- to NPPs:
  - Ageing (NS-G-2.12):
  - External Human induced events (NS-G-3.1);
  - Seismic hazard (NS-G-3.3);
  - Flood hazard on coastal and river sites (NS-G-3.5);
- or to the design of NPPs:
  - Protection Against Internal Fires and Explosions in the Design (NS-G-1.7);
  - External Events Excluding Earthquakes (NS-G-1.5);
  - Internal Hazards other than Fires and Explosions (NS-G-1.11);
- or to the site evaluation:
  - Meteorological and Hydrological Hazards Site Evaluation for Nuclear Installations (SSG-18);
  - Seismic hazard (SSG-9);
  - Volcanic Hazards in Site Evaluation for Nuclear Installations (SSG-21).

Such list is not exhaustive. However, the question is how far it can be used to the hazard assessment of disposal facilities. FANC developed a guide dedicated to the radiological protection for workers and for the public during the operational period of a facility for the disposal of radioactive waste (FANC_RPC-OP, “Guide on the radiological protection during the operational period of a facility for the disposal of radioactive waste”). However this guide is not appropriate for the operational hazard assessment.

IAEA project GEOSAF had a specific Working Group for assessing the hazards for operation of DGR (Companion report GEOSAF-draft). It partially integrates the results of the French program EXREV (EXploitation et REVersibilité d’un stockage géologique) carried out by IRSN in 2008-2011, in order to build up a doctrine which accounts for safety issues related to classic nuclear facilities and to that of conventional underground installations such as mines or tunnels. It develops a safety assessment strategy for the operation (including reversibility) of a DGR (Tichauer et al., 2013).

Their main results are the following:

- The same basic principles of operational safety assessment as for other nuclear installations may apply to a DGR, with “*all structures, systems and components together with their safety functions, an identification of the activities and processes that will be* *conducted within the facility, as well as the identification of all hazards that can impact the facilities' safety* [...]. *All countries share the same basic principles of hazard* assessment" (Companion report GEOSAF-draft), which could be seen as identical as for other nuclear facilities.

- However, the specificity of hazard assessment for geological disposal is that:
  - it is performed in the frame of an underground installation, "*which has its own particular set of hazards and infers some particular boundary conditions to the way one can cope with these hazards*" (Companion report GEOSAF-draft), i.e., the important number of handling operations, the role of geological medium (as for example attenuating the seismic waves, but inducing additional hazards such as external flooding by aquifer levels crossed by the shafts…), the underground location of facilities which implies confined areas, uniqueness of accesses, important lengths and slow progression of equipment and persons, the specific components, the long-span using of equipment and engineered components (see conclusions of EXREV programme, Tichauer et al., 2013);
  - as for surface disposal facilities, it requires "*to consider also the effect of hazards and their preventive and mitigative controls on the post-closure safety of the facility*" (Companion report GEOSAF-draft). As developed by Tichauer et al. (2013), the identification of Limits, Controls and Conditions for the operational phase remains a challenge, since it has to integrate the dimension of long term safety. Given the numerous links between pre- and post-closure arguments of the safety case, it is necessary to check continuously the expected conditions of the repository at the time of closure, which forms the basis of the demonstration that the facility is sure in the long term.
- Furthermore, some specific risks or situations need to be addressed with limited experience feedback from the operation of existing nuclear facilities, as for example, concomitant activities (as excavation and emplacement of waste packages), ventilation or evacuation in the case of fire (Companion report GEOSAF-draft). "*A pilot study on fire hazard, conducted by different countries, showed that the "classical" methodology is applicable, and underlined in a certain case the difficulties associated to the assessment of hazards in the specific configurations of a geological disposal facility, revealing the need to develop new models, to search for experience feedback from underground facilities and to develop new assessment tools*" (Companion report GEOSAF-draft).

These findings lead to the unveiling of five consequences for the preparation of the regulatory review (EXREV; Tichauer et al., 2013):

- The analysis of the design, the maintenance, and the consistency between the provisions adopted and the considered hazards (especially those that are specific to a DGR) should be deepened. The demonstration of safety should rely on a simple and robust technology, a simple architecture with components intended to be replaced as far as possible. A thorough knowledge of the mechanisms associated with the aging of the components of the storage must be strengthened and developed in this regard.

- The analysis of the scenarios used by the implementer should be carried out with a good understanding of the peculiar characteristics of a DGR, in particular the justification of the choice of altered evolution scenarios and their character envelope of hazards.
- Hazards associated to long-span or concomitant activities (mining + nuclear) should be considered as essential.
- The analysis of the monitoring and surveillance program during the operational phase. Such program shall (i) identify (and re-evaluate, given the long period of operation) the thresholds associated with the actions to be taken to prevent derivatives, (ii) accumulate the REX in forecast of the safety reassessments, (iii) have data reliable and comparable over time, to take the keys decisions during the process of disposal development, (iv) for the long-term safety, check the system behaviour on the basis of the implementer's predictive models.
- A deeper knowledge of the various situations and parameters that influence the "initial state" of the closed repository (namely the characterization of the set of parameters that control the post-closure safety assessment) should be sought as well.

Concerning hazards associated to long-span operational phase for DGR, the SITEX participant suggest to consider few additional potential events, in addition to the ageing of equipment and engineered components as indicated above:

- potential societal and political disturbances may take a more important place than for other nuclear facilities and may have an important impact of the decision process at each phase of the disposal evolution;
- hazards related with climate (extreme frost or heat season, squall, lightning strike, shock wave, external flooding) and their effects to the access ways such as drifts or ramps or to ventilation system;
- a classical approach (usually used for other nuclear facilities) for estimating earthquake and flooding hazard may be considered as not enough penalizing because of the larger probability of occurrence of such events as well as of intensity because the operation phase is several times longer than other nuclear facilities.

5.2.2.2 Post-closure phase

The participants of EC project PAMINA (PAMINA report 1.1.4) have scrupulously examined the safety assessment in the post-closure phase of the DGR. In addition, dedicated guides exist in France (ASN Guide, « Guide de sûreté relative au stockage définitif des déchets radioactifs en formation géologique profonde ») and another is being written in Belgium (FANC-SAR, « Analyse de la sûreté post-fermeture des établissements de stockage définitif de déchets radioactifs »). However, the way to assess technically these hazards remains in the fact not already resolved because it requests to take into account research still in progress and not already shared by the whole scientific community. Several participating organisations do not impose an exhaustive list of hazards and processes to consider in scenarios and ask to the implementer to identify them and justify their selection ("top-down" approach, see §5.2.6). Nevertheless, this does not dampen the difficulty of the technical expertise.

SITEX participating organisations consider that all identified hazards need a specific assessment dedicated to the particular case of geological disposal due to long time frame: earthquakes, physical-chemical conditions of exceptional amplitude, criticality, climatic events and geodynamics (including denudation leading to erosion of repository overburden and shortening of preferential paths) and future human actions.

The following example of potential diversity of approaches is developed for earthquake hazard, but some considerations are the same for climatic events. IRSN organised an international technical meeting on the impact of earthquakes on the long-term safety of DGR containing high level and intermediate, long-lived radioactive waste in November 2012. The meeting on this subject was attended by some 40 experts from 22 nuclear safety organisations and academic or applied research organisations. Together, they drew up the status of knowledge in this area and identified key scientific points which warrant further study and sharing at the international level. One of these is the evaluation of seismic loads at a depth of several hundred meters and the impact of earthquakes on hydraulic flows in the host rock of the repository or in surrounding aquifers. Some of the following considerations are extracted from this meeting.

- The duration of the hazard to take into account (100s thousand years) is considerably larger than the existing duration of measurements and even the duration of human history. The way to extrapolate has to be established, both in terms of intensity and return period of earthquake events to consider. Several ways are proposed by the implementers, with deterministic (Deterministic Seismic Hazard Analysis) or probabilistic (Probabilistic Seismic Hazard Analysis) extrapolation methods using the measured events, or determination based on the maximum fault size. In addition, the way to account for the effect of potential future glaciations (buoyancy and elastic rebound) in post-glacial and peri-glacial regions remain questionable…
- Also, hazards related to such events may results in different impact because they occur underground; a different methodology as for surface could thus be applied. The vertical attenuation or amplification of waves with depth may be taken into account (attribution of a homogeneous factor, deconvolution of the wave by using a model of the successive layers, or collection of earthquake measurements from an underground structure nearby the disposal facilities…).
- The evaluation of the potential impact of such earthquake hazard on the geological medium is also a subject of scientific debates. If the recently acquired knowledge (from the analysis of earthquake triggering) is suitable to roughly evaluate the potential propagation of fractures and faults (or initiation of new ones), it is not the case for the potential effect on the hydrogeological medium, in particular in terms of transitory or permanent modifications of the aquifer properties.

Finally, the duration of the hazard to take into account may also increase the probability of combination of events and processes.

To conclude, the hazard assessment for geological disposal is a tricky issue and the diversity of approaches from the implementers in Europe reveal the distance to cover to reach a common technical review approach of technical experts. The establishment of a sustainable European (or larger) network of experts could contribute to develop a common expertise of hazard assessment both for the operational phase and for the post-closure phase.

5.2.3 Proposal of table of content for technical review reports

The IAEA SSG-23 indicates, about the content of a review report, that *"8.17- there is no single correct way in which the final review report should be organized and presented, and each such report will inevitably need to be customized to the particular review conducted. The regulatory body should consider including the following in the final review report:*

- *Introduction* [...].
- *Scope and objectives of the review* [...].
- *Applicable regulatory requirements* [...].
- *Review methodology and process* [...].
- *Main results of evaluation* [...].
- *Conclusions* [...].
- *References* [...].
- *Appropriate information to demonstrate the credentials of the individuals making up the review team.*

8.18. In the documenting of review comments and evaluations, the following should be ensured:

- *The approach taken in the development of the safety case and the results of that approach should be briefly summarized and specific references to the information should be provided;*
- *Any significant comments and the basis for the comments should be clearly stated using a standard format, and each comment should be given a unique identifier for ease of cross-reference;*
- *The relevance of the comment to safety, understanding of systems and/or control of the facility should be noted;*
- *Actions necessary to resolve the issues identified in the review comments should be clearly stated.*

National guidance and practices

The SAG describes approximately the same content as above for the technical review report of the safety case (Q4.8).

To go more deeply in the content of the technical review report, the SITEX participants tried to list the areas reviewed, which are expected to change progressively as the safety case expands. Various technical review reports from the participating organisations to SITEX were collected and sorted according to the considered phase of development of the DGR (conceptualization phase, site selection phase…). Their table of content has been dissected with regards to the analysed elements of the safety case (i.e., the development of the section entitled above "*Main results of evaluation"*), following the Figure 2. The examined technical review reports are presented in the Annex III.

Based on these examples, it appears that the tables of content of reports corresponding to the same phase of development of the SC are not the same from, and do not perfectly match with the Table 10 of the SITEX D2.2 ("Main key technical issues, expertise and support needed"), which sums up the needed review activities for six areas of expertise (i.e., safety strategy and policy, management, waste, site, engineering, operational safety).

In the perspective of harmonisation and effective reviewing process, it would be very valuable to continue this exercise by analysing additional review reports and define more precisely the expected content of the technical review reports for each phase of development of the safety case of DGR.

6 Conclusions

The participants of WP4 of SITEX project made an overview of the existing international and national guidance for the conditions of independent review of repository safety case, guidance for technical review and national practices in the participating countries. The main findings are as follows:

- **Independence of expertise function**.

Regarding the independence of expertise function, **no difference** has been identified in the definition and the way to maintain it between participating countries to SITEX. However, **insuring independence in the facts reveals difficult for several participating organisations and this issue may need the development of practical guidance**. Enough guidance has been developed on the need to possess the financial and human resources required to preserve the independence and no difference in practises has been identified between countries.

- **Transparency.**

To the contrary, **differences exist in the meaning of transparency** for the SITEX participating organisations in WP4 and **homogenisation of guidance and practices is needed**. This is due to different role of stakeholders taken in the review process and due the practices on consulting interested parties and the public. These differences may be attenuated by an increasing participation of stakeholders for countries that do not include such discussion in the safety review process. Harmonization of public or stakeholder involvement in the technical review process seems however to be difficult to propose, given it is very depending on the country laws and political systems. Nevertheless, experience from cases of involvement might be better shared (theme developed by the SITEX WP 5). On the other hand, no difference in practise has been identified on traceability of the process and on the exchanges between regulatory body and implementer or between experts and implementer (technical dialog).

- **Competence.**

About competence of expertise function, **no need for any harmonisation of practices or guidance has been identified** on staffing and competences related to expertise function. However, **a list of minimum competences needed could be described in a guide**. Even if there is no difference of view between the participating organisations on the required qualities of experts, these qualities could be better detailed in international guidance, as well as the way to ensure it. **Harmonization could be useful, as well as a European (or larger) experts network for performing training and tutoring;** this corresponds to the second task of WP4 (WP4.2). Finally, the extremely variable stages of development of the projects of geological disposal and the **existing various approaches carried out by participating organisations to WP4 to collect experience feedback underline the need of establishment of a network of experts**, as identified by SITEX, exchanging and sharing their national experience on hazard assessment.

- **Management of technical review.**

About the way to manage the technical safety review of DGR, the way the WP4 SITEX participating organisations manage the technical review process is quite the same, and **no difference has been identified in practices** with the above description on the way to orientate and define the depth of the analysis at the beginning of the initial review phase. **For the schedule of a technical review, a more detailed guide than in the IAEA SSG-23 would be useful**. Finally, some existing imposed laws or rules could be seen as an obstacle to harmonizing of technical review practices is the safety assessment. However, these rules should not restrict the identification of any problem for safety. Specific guidance on how to deal with such constraints in the safety assessment should be developed.

- **Content and evaluation method of the technical review.**

The existing guidance on how to check the completeness of a safety case can be considered as useful and sufficient by WP4 SITEX participating organisations. To the contrary, **following the report drawn up on the absence of technical guidance, the SITEX participants to WP4 have proposed several grids** for analysis of the safety case developed by implementer during the main phases of repository program development. **This type of analysis grid could be further developed by the network of technical experts once established**. **For the hazard assessment, guidance is needed both for operation phase and post-closure phase**. Lastly, **the need of detailed the content of the technical review report is identified**.

7 References

Coordinating Action SITEX Report, 20 Oct. 2011.

SAG, Safety Assessment Guide from AVN, IRSN and GRS, 2004.

EPG Report 2011-Draft, Report on the European Pilot Study (EPS) on the Regulatory Review of a Safety Case for Geological Disposal of Radioactive Waste. Version for consultation. EPG report, 26 November 2010.

WENRA Report 2012-Draft, Working Group on Waste and Decommissioning, Radioactive waste disposal safety reference levels, Draft report (V1.4.2).

Nureg 1200, Standard Review Plan for the review of a licence application for a Low-Level Radioactive Waste Disposal Facility. U. S. NRC, 1994.

Council Directive 2011/70/EURATOM of 19 July 2011.

ICRP 103, The 2007 Recommendations of the International Commission on Radiological Protection.

Besnus et al., 2006, Besnus F., Bruno G., Jensen M., Metcalf P., Nys V., Röhlig K.-J., Ruiz-Lopez C., Ruokola E., Smith R., Vigfusson J., 2006.European pilot study on the regulatory review of the safety case for geological disposal of radioactive waste. Eurosafe, 13/11/2006, Paris

Besnus et al., 2007, Besnus F. (IRSN), Bodenez P. (ASN), Bruno G. (EC), Jensen M. (SSI), Metcalf P. (IAEA), Nys V. (AVN), Röhlig K.-J. (GRS Köln), Ruiz-Lopez C. (CSN), Ruokola E. (STUK), Smith (Environment Agency) R., Vigfusson J. (HSK), 2007. European Pilot Study: Uncertainty Management. Safety Case Symposium, Paris, 23-25 January 2007

EC projects

PAMINA report 1.1.4, Performance Assessment Methodologies in Application to Guide the Development of the Safety Case, Deliverable 1.1.4, 2011.

NEA publications

NEA n°3679, Post-closure safety case for geological repositories, 2004.

NEA n°4429, Stepwise Approach to Decision Making for Long-term Radioactive Waste Management: Experience, Issues and Guiding Principles, 2004.

NEA n°4437, Features, Events and Processes Evaluation Catalogue for Argillaceous Media, 2003.

NEA n°5418, Stakeholder Involvement Techniques, 2004.

NEA n°6405, Regulation and Guidance for the Geological Disposal of Radioactive Waste, 2010.

NEA n°6923, Outcomes of the MESA, (Methods for Safety Assessment for Geological Disposal Facilities for Radioactive Waste) Initiative (NEA), 2012.

NEA n°6988, Annotated Glossary on the Stakeholder Confidence in Radioactive Waste Management, 2013.

IAEA projects

PRISM draft report, The International Project on "practical illustration and use of the safety case concept in the management of near surface disposal". Overview report. Draft working material. 5 November 2012.

GEOSAF report, The International Intercomparison and Harmonisation Project on Demonstrating the Safety of Geological Disposal: draft final report 1; draft questionnaire, 2011.

GEOSAF companion report, Report on the GEOSAF Working Group on Operational Safety, draft version, July 2011.

SARCoN, Systematic Assessment of the Regulatory Competence.

ASAM, Application of the Safety Assessment Methodologies for Near-Surface Disposal Facilities - Mining and Mineral Processing Waste Working Group Report, December 2002; Safety Reassessment Working Group, December 2002.

ASAM Regulatory Review Draft Report, "Guidance on the Regulatory Review of Safety Assessment for Radioactive Waste Disposal Facilities", RCM3.9, 10 march 2006.

ISAM, Safety Assessment Methodologies for Near Surface Disposal Facilities, volume 1, volume 2, 2004.

IAEA, Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management; Fourth Review Meeting of the Contracting Parties 14 to 23 May 2012, Vienna, Austria; Final Summary Report; JC/RM4/04/Rev.2.

IAEA guides

IAEA safety glossary, Terminology used in nuclear safety and radiation protection, 2007.

Handbook on Nuclear Law, 2003.

<u>Safety fundamentals</u>

SF1, Fundamental Safety Principles, 2006.

<u>Safety Requirements</u>

WS-R-4, Geological Disposal of Radioactive Waste, 2006.

WS-R-5, Decommissioning of Facilities Using Radioactive Material Safety Requirements.

GSR Part 1, Governmental, Legal and Regulatory Framework for Safety.

GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Std.

GSR Part 4, Safety Assessment for Facilities and Activities General Safety Requirements, 2009.

GS-R-3, The Management System for Facilities and Activities.

SSR-5, Disposal of Radioactive Waste, 2011.

<u>Safety guides</u>

GS-G1.1, Organisation and staffing of the regulatory body.

GS-G1.4, Documentation relating to the regulatory process.

GS-G2.1, Review and Assessment of Nuclear Facilities, 2002.

SSG-14, Geological Disposal Facilities for Radioactive Waste, 2011.

SSG-23, The Safety Case and Safety Assessment for the Disposal of Radioactive Waste, 2012.

GSG-4, Use of External Experts by the Regulatory body, 2013.

National guides and projects

France

ASN guide, Safety Guide on Radioactive Waste Disposal in a Deep Geological Formation, « Guide de sûreté relative au stockage définitif des déchets radioactifs en formation géologique profonde », ASN, France.

Tichauer et al., 2013, Tichauer M., Pellegrini D., Serres C. and Besnus F., 2013. “Operational Safety of a Geological Disposal: IRSN Project ‘EXREV’ for Developing a Safety Assessment Strategy for the Operation & Reversibility of a Geological Repository”, extended abstract, AEN symposium “Safety Case”, 2013.

Belgium

FANC-SAR, “Analyse de la sûreté post-fermeture des établissements de stockage définitif de déchets radioactifs” (Technical Guide “Post-closure safety analysis”).

FANC_RPC-OP, Guide on the radiological protection during the operational period of a facility for the disposal of radioactive waste, FANC-MP1-03a; Memo 008-007 EN, rev. 5 (Technical Guide “Operational Radiation Protection”).

FANC_RPC-POP, Technical guide "Radiation Protection Criteria for Post-Operational Safety Assessment for Radioactive Waste Disposal", FANC External Note 2011-06-28-CAD-5-4-3-EN of 2011/08/23.

FANC_RPC-LT, Technical Guide “Post-closure Radiation Protection” (FANC) ().

FANC Technical Guide “Geological Disposal” (FANC).

PSIN-GEN.

Regulatory guidance for the geologic disposal of radioactive waste: « A minima requirements on argillaceous sedimentary formations » (Bel V)

Canada

Regulatory Guide G-320: Assessing the Long Term Safety of Radioactive Waste Management

Switzerland

Guideline ENSI-G03: Specific design principles for deep geological repositories and requirements for the safety case

SGT, Sectoral Plan for Deep Geological Repositories (“Conceptual part” is available in English)

Germany

BMU, Safety Requirements Governing the Final Disposal of Heat-Generation Radioactive Waste, 30 September 2010

German RPO, German Radiation Protection Ordinance, 2012

GRS-240, Gesellschaft für Anlagen- und Reaktorsicherheit (GRS) mbH, Safety and Performance Indicators for Repositories in Salt and Clay Formation, GRS-240, July 2008.

Netherlands

Nuclear Energy Act

Environmental Management Act

Annexes

I. Annex I – National organisation of regulatory and expertise body

The following description of National organisation of regulatory and expertise body has been developed by using answers to the first question sent to participants (Q1.1, see annex 1).

I.1- Belgium

FANC and Bel V constitute together the Belgian Regulatory Body.

The Federal Agency for Nuclear Control (**FANC**/AFCN) is **the authority** responsible for safety assessment review. It examines the safety cases (SC) and their compliance with the regulation. FANC is indeed, according to the Law of 15 April 1994 on the Protection of the Public and the Environment against Radiation, responsible for the Belgian government, of the supervision of nuclear activities, including the radioactive waste disposals. It is supervised by the Federal Minister of Home affairs and advised by its own Scientific Council.

In the license application for waste disposal, the licenses are granted by the King and FANC is responsible for the examination ("instruction" in French) of the application file (or SC related to this license application), according to the Royal Decree of 21 of July 2001 and to the new Royal Decree on waste disposal (being submitted).

Bel V is a technical subsidiary of FANC. Bel V performs certain regulatory missions legally delegated by the FANC. It is through the association of the FANC on one side, and Bel V on the other that the function of Regulatory Body is ensured in Belgium.

Within the framework of the Belgian legislation and depending on the delegated missions, Bel V:

- Supervises the delivery and the operation of nuclear installations, verifies the compliance with the licence requirements and recommends the licensee to take corrective measures if conditions of degraded safety are detected. Bel V has no enforcement power to impose actions on the licensee but has the possibility to indicate the problems to the FANC, if necessary.

- Advises the authorities on the development of nuclear emergency planning and intervenes in the management of nuclear and/or radiological crisis situations.

- Performs and evaluates technical reviews in the nuclear and radiation protection fields.

I.2- Czech Republic

National organisation for safety assessment review in the Czech Republic is State Office for Nuclear Safety (**SÚJB**). Until now no safety assessment review of preliminary safety cases of deep geological repository has been conducted. Several safety assessment reviews of three near surface repositories in the Czech Republic (Dukovany, Richard, Bratrstvi) have been made only by SÚJB experts. They are aware of their limited capabilities to conduct safety assessment review of deep geological repository without TSOs. Nuclear Research Institute Rez (NRI: UJV in Czech) participates in SITEX project after agreement with SÚJB that indicates that, in future safety assessment review of geological disposal safety assessments, **UJV** can serve as **a technical support organisation** for SÚJB in the safety assessment review of DGR. The role of UJV as an **independent** technical safety organisation will be, however, limited only to the issues, where it will not be directly involved as a contracting organisation for RAWRA. In these issues the role of technical support organisations will have to have other research organisations, possibly from other European countries.

The Czech Republic belongs to smaller countries in Europe and therefore it is not probable that one TSO covering all DGR safety case issues could be established.

I.3- Lithuania

The main **regulatory authorities** in Radioactive Waste Management in Lithuania are:

- State Nuclear Power Safety Inspectorate (**VATESI**),
- Radiation Protection Center (**RSC**),
- The **Ministry of Environment.**

Main operators in Radioactive Waste Management in Lithuania are:

- Radioactive Waste Management Agency (RATA),
- Ignalina Nuclear Power Plant.

National TSOs are: Lithuanian Energy Institute, Institute of Center for Physical Sciences and Technology, Kaunas University of Technology, Vilnius Gediminas Technical University, State Institute of Information Technology, ITECHA JSC, the Scientific Research Center of Electromagnetic Compatibility and Institute of Chemistry.

All these organisations are involved in nuclear or nuclear related activities, as the Technical Support Organisations mainly. They provide VATESI with expertise and necessary technical-scientific support during safety reviews, verification of safety justifications, drafting of norms and regulations. Some of these TSOs are also involved in international projects implemented through international and bilateral cooperation.

Lithuanian energy institute (LEI) is a TSO which performs wide range of nuclear-related activities.

Apart from above mentioned institutes, there are some other technical support organisations. As the first step to develop better technical support, the Centre for Non-Destructive Testing at Kaunas University of Technology and the Laboratory of Welding and Material Analysis at Vilnius Technical University were established. With the support of the European Commission, these facilities were equipped with modern instrumentation.

I.4- Canada

The Canadian Nuclear Safety Commission (**CNSC**) **is the** sole **regulator** of nuclear facilities and activities in Canada. The CNSC is responsible for licensing geological repositories intended to provide for long-term management of radioactive wastes. In Canada, unlike with many other nuclear regulators, the technical and scientific support functions for the Canadian Nuclear Safety Commission (CNSC) are provided by **in-house technical staff**; there is **no separate technical support organisation** (TSO). The in-house Canadian Nuclear Safety Commission experts and technical specialists carry out the technical assessment of information submitted by implementers in support of the applications. This assessment is carried out with input from other federal, provincial and territorial government departments and agencies responsible for regulating health and safety, environmental protection, emergency preparedness and the transportation of dangerous goods.

Canadian law requires regulatory agencies to respond in a short period of time once a proposal for the nuclear waste management is filed. A fair and objective assessment is not possible, without the knowledge and background associated with the years of research and development work that contributes to the final proposal. Therefore, CNSC staff has started a Coordinated Assessment and Research Plan (CARP) in order to be ready for the assessment of upcoming proposals from OPG and the NWMO. The CARP in essence would consist of review of ongoing publications from OPG and NWMO at critical milestones, combined with an independent research program through the CNSC research and support funding.

I.5- Switzerland

ENSI, the Swiss regulator reviews safety assessment. In addition, ENSI **has an expert group** (experts from universities and research institutes) which reviews specific topics to support ENSI's safety assessment. For specific topics, ENSI has also subcontracting experts.

I.6- The Netherlands

In The Netherlands, present legal requirements that are relevant for the safety case are provided in the Nuclear Energy Act and related decrees, the Environmental Management Act and related decrees and the Mining law and related decrees. For the review, Dutch authorities can contract Dutch or foreign organisations with relevant expertise.

The main regulator is the Ministry of Economic Affairs (ministerie van Economische Zaken, Landbouw en Innovatie, EL&I).

Nuclear Research and Consultancy Group (NRG) is a Dutch institute that performs nuclear research for the government and private companies. It is the most important producer of radionuclides in Europe and maintains and operates the Petten nuclear reactor.

The Dutch utilities and the Dutch Authorities jointly coordinate and finance the Dutch R&D program OPERA ("OnderzoeksOnderzoeks Programma Eindberging Radioactief Afval" – Research Program for the Disposal of Radioactive Waste), which started in June 2011, runs for five years, and is organised in seven Work Packages comprising most if not all elements that are considered important in modern Safety Cases for geological disposal of radioactive waste. At this time it is not possible to distinguish between key technical issues identified by the WMO and key technical issues identified by the TSO.

At present, the Dutch WMO, COVRA, is preparing a generic Safety Case to be released in 2015. This Safety Case, addressed as the OPERA Safety Case or OSC, is not associated with a license application, since actual geological disposal of the waste is not planned before 2120. Therefore, a review of the OSC is not required.

On the other hand, the policy of the government with respect to nuclear new build relies on existing safety reports and the OSC. Therefore, it can be expected that an organisation like NEA will be asked to perform a scoping review of the OSC.

I.7- Sweden

The Swedish Radiation Safety Authority (SSM) is the responsible regulator for nuclear safety and radiation protection and thus responsible for regulating management and disposal of spent fuel and radioactive waste. SSM prepares statements to the government on license applications for e.g. spent fuel and radioactive waste disposal facilities.

There is no separate technical support organisation. Technical and scientific support functions are provided for by in-house technical staff as well as by contracting external resources, e.g. universities and expert consultant companies, both within and outside Sweden. SSM has a mandate to provide funding for research activities within its remit and has an annual research budget totalling approximately € 9 million. The research activities financed by SSM are mainly conducted by institutions of higher education and expert consulting companies. This research gives new knowledge, which in turn is applied as part of the Authority's regulatory supervision.

I.8- Germany

In the Federal Republic of Germany (Germany) there is no central licensing authority like in most other countries because Germany is a federal parliamentary republic that consists of 16 states (Länder). The implementation of a nuclear licensing procedure falls within the competence of the supreme authorities of the Länder but the Federal Government (with the Federal Ministry of Environment, Nature Conservation and Nuclear Safety – BMU) reserves the right of lawfulness and expediency supervision. Thus, the license of a disposal facility will be granted by the respective Land authority acting as the nuclear licensing authority. The supervisory authority is the Federation.

The following advisory bodies and one co-ordination panel (Federal Government/Länder) are available to the BMU for the purpose of federal supervision of the Länder:

- Reactor Safety Commission (RSK)
- Commission on Radiation Protection (SSK)
- Nuclear Waste Management Commission (ESK)
- Länder Committee for Nuclear Energy

RSK, SSK and ESK prepare recommendations for the BMU concerning special safety-related matters in general or on a particular nuclear facility.

The Länder Committee for Nuclear Energy debates and co-ordinates questions related to the application and interpretation of statutes and ordinances pursuant to Atomic Act and Radiation Protection Ordinance. As an advisory and co-ordination body of the Federal Government, its decisions are only recommendations, in practice, however the Committee for Nuclear Energy plays an important role.

In the licensing and supervisory procedure pursuant to the Atomic Act or Radiation Protection Ordinance the competent authorities may consult experts on all technical or scientific matters related to regulatory licensing and supervision. There are either expert organisations, e. g. GRS, or individual experts.

However, the authority is not bound by the assessments of their experts. The experts are merely "consultants to the authorities" in establishing the facts of the case. They do not have any authority to make decisions. Their opinions are subject to the free evaluation of the evidence by nuclear licensing and supervisory authorities who make the final decisions.

I.9- France

In France, the Nuclear Safety Authority (ASN) is an independent administrative authority set up by the law 2006-686 of 13 June 2006 on nuclear transparency and safety. On behalf of the State, ASN regulates nuclear safety and radiation protection in order to protect workers, patients, the public and the environment from the risks involved in nuclear activities. It also contributes to informing the citizens. It contributes to the process of drawing up regulations by giving its opinion to the French government on draft decrees and draft ministerial orders or by making regulatory decisions of a technical nature.

Generally speaking, to make its decisions, ASN usually draws strongly on external technical expertise, particularly that of IRSN, which is currently ASN’s main technical support agency (average of 700 expert opinions rendered each year). In the specific field of DGR, IRSN is the only TSO concerned with the safety assessment of repositories for ASN. However, when preparing a decision-making, ASN also seeks the opinions and recommendations of seven standing committees of experts co-opted to ASN, all with diverse scientific and technical backgrounds. These committees, each one focusing on a specific topic, are made up of experts appointed on the strength of their expertise.

In the particular field of DGR, responsibility of the design and construction of a DGR has been entrusted to Andra. The requested authorization directive to create the facility is foreseen in 2015 and its operation should start in 2025. During this process, IRSN is responsible for assessing, on behalf of the public authorities, the safety of the project that will effectively be proposed by Andra.

I.10- Slovakia

The main regulatory authorities supervising nuclear installations are Nuclear regulatory Authority (NRA) and Public Health Authority of the Slovak republic (PHA).

The mission of the **NRA** state is to perform the state supervision upon the nuclear safety of nuclear installations with the objective to use the nuclear energy in Slovakia in such a way that no threat will jeopardize the public health, property and environment. The regulatory authority ensures that the public health and safety are protected in different peaceful uses of nuclear energy and that the nuclear installations in Slovakia are safe and well regulated.

PHA deals with all issues of radiation protection in general, including radiation safety of professionals in nuclear installation and regulates nuclear waste management and disposal radioactivity limits.

Under EIA process for DGR the **Ministry of Environment** is responsible decision maker giving permission for siting process.

As in other small countries nor Slovakia has any TSO specially dedicated to NRA support. The strongest research organisation dealing with all nuclear safety issues in Slovakia is VUJE. DECOM is focused particularly on decommissioning and nuclear waste management.

Experiences from past reviewing processes have shown that more complicated reviews, which cannot be performed by NRA internal experts, are subcontracted by organisation not directly involved in the safety assessment preparation. If necessary, NRA contracts foreign European reviewer, the most often an institution from Czech Republic is hired thanks to common nuclear history and almost no language barrier.

II. Annex II: Constraints in the safety assessment for operational and post-closure phase

Deterministic or probabilistic methods to analyse the events & processes

In few countries, deterministic or probabilistic methods are recommended for the analysis of part or all the events & processes. In other countries, there is no requirement in the approach to follow (MESA report).

As developed in the IAEA SSG-23, the demonstration that the radiation dose or risk from the possible migration of radionuclides from the disposal facility will remain below a prescribed dose or risk constraint can be assessed either by a deterministic or probabilistic approach or both:

> *"It is, however, important to be aware of the benefits and limitations associated with these two approaches.*
>
> *5.12. A deterministic approach is easier to implement and might be more easily explained to a range of interested parties. This approach can also be useful for illustrating the impact of specific individual uncertainties or alternative model assumptions. Limitations of the deterministic approach include the inability to take probabilities and variability into account, and difficulty in justifying the choice of best estimate or conservative values for the parameters.*
>
> *5.13. A strength of the probabilistic approach lies in its ability to provide a more comprehensive and explicit representation of uncertainty by considering the whole range of variation of the uncertain parameters. Such approaches also provide for more thorough and systematic sensitivity analyses, and can be used to derive risk estimates. Another strength of the probabilistic approach is that it allows examination of the projected performance of the disposal system under a range of conditions and assumptions, and therefore contributes to the robustness of the safety case and the regulatory decisions.*
>
> *5.14. Challenges associated with a probabilistic approach include difficulties in obtaining or specifying appropriate probability distributions for the parameters, difficulties in assigning probabilities that can be justified to alternative model assumptions, the difficulty in communicating probabilistic assumptions and results, and the additional resources necessary*".

National practices

For the analysis of events & processes, the method is deterministic for events with probability exceeding 10^{-7}/y in Belgium, and risks have to be lower than given level in the Netherlands; this implies to apply probabilistic methods to estimate the credibility of this risk (NRG).

For the analysis of the consequences, there is no requirement in the approach to follow for Belgium, France and Lithuania but deterministic approach is generally favoured by implementers (as reported by Bel V, FANC, IRSN, LEI) and complemented with probabilistic calculations (as reported by Bel V, NRG) or sensitivity analyses (as indicated by IRSN). In Switzerland and Germany, the safety analysis is probabilistic for the operational phase and deterministic (scenarios) for post closure phase with calculations on the most realistic modelling possible and sensitivity analyses (as reported by ENSI, GRS).

For Czech Republic, the method is deterministic except for future human actions for which probabilistic methods are recommended (UJV).

As concluded for regulatory perspective in the MESA report, "*Whatever approach is chosen, probabilistic or deterministic, the proponent should show where the uncertainties come from, what their implications are and that the uncertainty space has been reasonably well explored*".

Construction of scenarios

The types of scenarios to consider may be imposed whereas not in other countries, as well as for an exhaustive list of hazards and processes to consider in these scenarios.

As developed in the IAEA SSG-23 (or in NEA reports n°6923 (MeSA), n°2549), "*5.40.Two main methods have been used for constructing scenarios. The method described, for example, in the ISAM project* [see below] *may be described as a 'bottom-up' method and is based on screening of features, events and processes* [FEPs, e.g., NEA report n°4437]. *For the relevant features, events and processes, a thorough examination of interactions between them and their combination in suitable scenarios is performed.* […] *An alternative ('top-down') method for developing scenarios is based on analyses of how the safety functions of the disposal system may be affected by possible events and processes*" […]. "*This may be followed by a process of auditing the scenarios developed against an appropriate list of features, events and processes*".

The ISAM project (Improvement of Safety Assessment Methodologies for Near Surface Disposal Facilities, 1997-2000) followed by ASAM (Application of the Safety Assessment Methodologies for Near-Surface Disposal Facilities) developed a consensus on the methodological aspects of the post-closure safety assessment of a radioactive waste disposal facilities with a bottom-up approach. As an example, NRG indicates that its approach is the same as for other nuclear facilities: events and processes are listed, then analysed considering their probability of occurrence and their type of impact on safety. The safety of geological disposal may however be verified by identifying the safety functions and verifying whether these functions are fulfilled for each component of the disposal (top-down). FANC imposes types of scenarios corresponding to the exposure situations as proposed by ICRP and according to the degree of uncertainties in the prediction and timescale (see FANC-SAR and FANC-RPC-OP&POP) but, as IRSN does not impose an exhaustive list of hazards and processes to consider in these scenarios and ask to the implementer to identify them and justify their selection. As an example, Andra (French implementer), in its Dossier 2005 Argile, identified the safety functions for operating phase and for post-closure phase, then detailed the sub-functions to define each needed component of the system. Andra then evaluated the potential effects of expected and less expected hazards. The impact of the most expected hazards allowed constructing the scenarios and improve the general disposal concept; the impact of the less expected hazards allow checking the robustness of the disposal system.

Finally, both methods may be applied by implementers and by the experts during their technical review, on condition that the chosen scenarios are well justified. The ideal way is thus probably using both methods as complementary approaches.

Radioprotection indicators

National regulations may differ on radioprotection indicators as individual dose (in mSv per year) and individual risk (per year). The ICRP recommended that "*assessed doses or risks arising from natural processes should be compared with a constraint of no more than about 0.3 mSv per year or its risk equivalent of around 10-5 per year*". The different types of indicators are described in the EC project PAMINA report 1.1.4 and NEA project MESA report as well as in IAEA Tecdoc 1372 (safety indicators, performance indicators, safety functions indicators related with concentrations, fluxes, status of barriers…).

Safety criteria in mSv/yr from national regulations (Q4.5) are given in the following Table .

These values should not be compared each other because they are not considered the same way from a country to another. However, they illustrate the existing difference in between them on this topic. As indicated in the NEA project MESA report, "*numerical criteria of different countries cannot be compared in a meaningful way without considering the underlying country-specific reasoning on what is an acceptable level of consequences today and in the future and how it should be evaluated*".

In Belgium, FANC radioprotection indicators as individual dose in (mSv/y) and individual risk (/y) are imposed to demonstrate the compliance with the radioprotection criteria for the radiological impact assessment. For increasing uncertainties and timescale, constraint values become reference values, and complementary indicators are recommended to be used as well [FANC_RPC-POP]. In the performance analyses the same indicators are at least to be used, complemented at least by concentration (Bq/m³) and flux of radionuclides (Bq/y) [FANC_SAR]. There is no constraint value imposed. It is asked to the operator to identify and justify the required indicators and safety targets according to the safety functions taking the optimisation into account.

Performance indicators such as dose (mSv/y), radionuclide fluxes (Bq/y) or individual risk (/y) are expected. Bel V foresees to use the same indicators in its numerical models.

In Czech Republic the effective dose is used as the main indicator by UJV. In Lithuania, only safety indicators are used in impact assessment in terms of effective dose. In the Netherlands (as reported by NRG), the safety and performance indicators are used as defined in the IAEA TECDOC 1372. In Germany, the safety & performance indicators are used for evaluation of calculated/estimated risks or doses.

Table AII: Radioprotection indicators as individual dose (in mSv per year) and individual risk (per year) in national regulations.

Country	Public - Workers (mSv/yr)	Adults - Children (mSv/yr)	Normal evolution or reference scenario - emergency or other scenarios (mSv/yr)	Individual risk due to release (/yr)
Belgium	1 - 20/12 rolling months		Expected: 0.1[3] Alternative: 10^{-6}/y or 0.1[1] Penalizing: <3[1]	10^{-6} /yr
Czech	1 - 50/yr and 100/5yrs; 6 for students (16–18 yr)		0.25 - 1	
Lithuania	0.2 - 100/5 yrs and 50/yr	0.2 - different dose conversion factors for children	10	
Canada	1 - 50/yr and 100/5 yrs			
Slovakia	1 - 50/yr and 100/5 yrs		No legislation requirement. In practice: 0.25 -1	
Switzerland	1 (up to 5/5yrs) - 50/yr and 100/5 yrs; 6 for students (16–18 yr)			
Nether-lands	1 - 20/yr; 50/ accident	0.015 to 15mSv/ accident - 0.04 to 40	0.001 - 0.1	10^{-6} /yr + Societal risk: limited number of fatalities/ accident
Sweden	0.1 - 50/yr and 100/5 yrs			
France	1 - 20/12 rolling months; 6 for 16–18 yr; 1 for pregnant		0.25 + ALARA	
Germany	Public < 1 Public < 0,3 - Workers Cat. A< 20; Cat. B< 6 <400mSv +ALARA		Probable 0,01 less probable 0,1	

Non-prescriptive, prescriptive or mixed regulation

[3] Dose constraint that becomes a reference level after several thousand years (depending on the uncertainties)

Finally, depending on countries, the regulation may be rather "non-prescriptive", prescriptive or mixed (Q1.3, Annex II). As developed in the NEA report n°6405, both have their advantages and disadvantages:

> "*more prescriptive regulation provides clear messages to the implementer and the general public. However, if unduly restrictive, it may hamper the development of techniques and procedures. Less prescriptive regulation provides more opportunity for a constructive dialogue between regulator and implementer and could be beneficial for the development of technical procedures, but it could leave too much to interpretation and perhaps give the impression of insufficient control by the authorities*".

When regulation is "non-prescriptive", the licence applicant must propose and justify. Methods developed by the applicant for the safety assessment are first examined as well as the conformity of the developed methods with relevant requirements and norms; however, the acceptance criteria and/or limit values defined by the regulatory body are also verified (Belgium, France and Canada). When regulation is rather prescriptive, it is based on compliance with the requirements in terms of limits in the country's legislation or using the international recommendations (Netherlands, Czech Republic, Slovakia). Finally, the review principles can be mixed, with both a verification that release limits are respected and an assessment of the methods & safety practices developed by the implementer (as in Sweden and Lithuania), but several countries have an order of preference in their analysis.

III. Annex III : Examples of technical review reports; examination of their table of content

For each main phase of a geological disposal project (i.e., conceptualization phase, siting phase, design phase and construction phase), the content of several technical review reports is presented below, in terms of analysed divisions of the safety case (see Figure 2), with the colour coding given in the Figure AIII, representing the safety case flow chart.

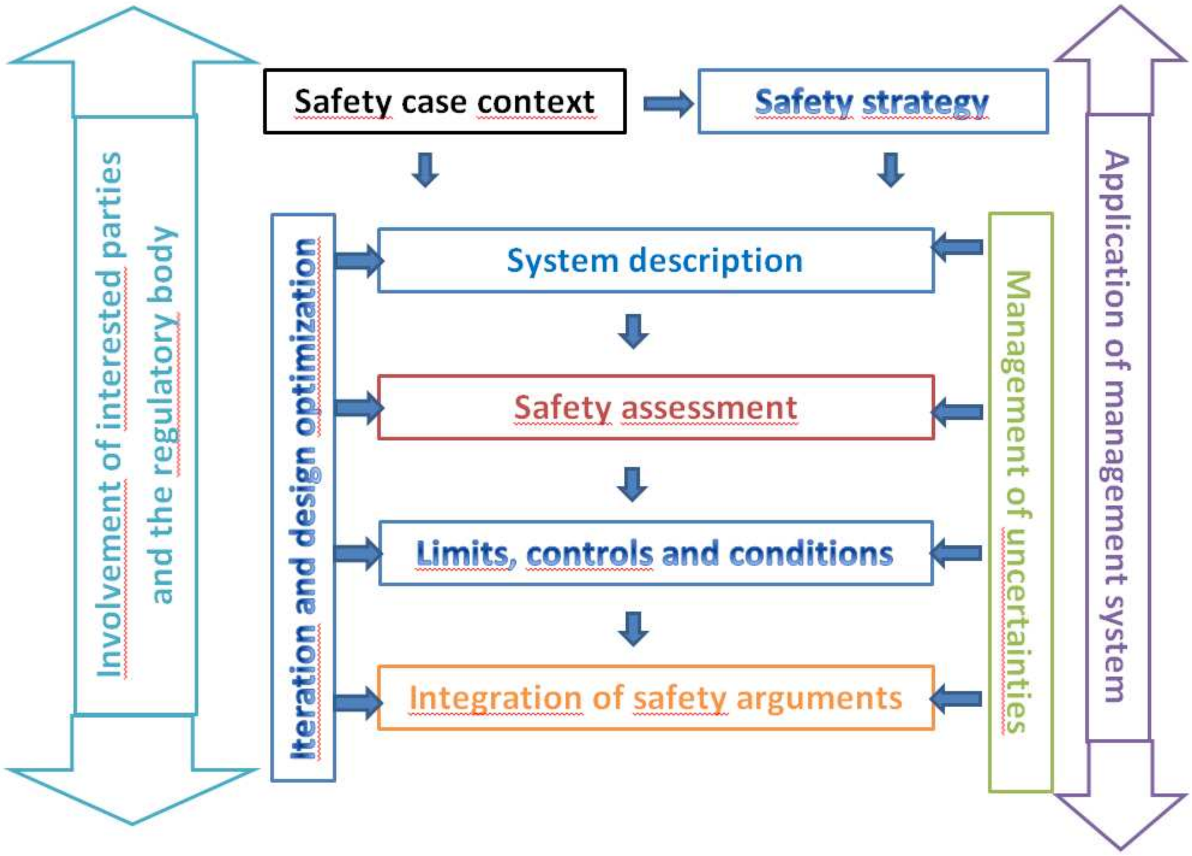

Figure AIII: Colour coding of the safety case flow chart

Conceptualization phase

Table of content of IRSN's review reports of Dossier 2001 Argile on geological disposal concepts in Meuse/Haute-Marne (DES n°566, 2003)

1- *Introduction*

2- *Presentation of the « Dossier 2001 »*

- Objectives and structure of the « Dossier 2001 »
- IRSN's evaluation

3- *Approach*

4- *Reference data*

- Waste packages **Waste**
  - Introduction
  - Preliminary waste inventory
  - Behaviour of packages in disposal context
- Geological environment **Site**
- Material reference data **Materials**

5- *Concepts*

- Facility design **Design**
- Minimization of the perturbations induced by the disposal facilities **Interactions**
  - Thermal and mechanical perturbations
  - Chemical perturbations
  - Conclusion
- Phases of construction, operation, reversibility and closure of the disposal facilities **Operation, …**
  - Phases of construction and operation
  - Phase of reversibility
  - Phase of closure : sealing
  - Conclusion

Siting phase

Example 1.Table of content of IRSN's review report of Dossier 2005 Argile on feasibility of a geological disposal in Meuse/Haute-Marne (DSU n°106)

1. The basic data

- Model inventory of waste packages — **Waste**
- Meuse/Haute-Marne geological, geodynamical and hydrogeological context
- The Callovian-Oxfordian Argillites formation: Geochemical, hydrodynamic, mechanical characteristics — **Site**

2. Safety approach — **Safety approach**

3. Description of the concepts — **Design**

- General configuration of facilities
- "B" waste packages and cells
- "C" waste packages and cells
- Spent fuels waste packages and cells

4. Evolution of the disposal components — **Interactions**

- Thermal perturbations
- Hydraulic transitory phase water and fate of gases
- Mechanical disturbances
- Chemical disturbances

5. Evaluation of safety in construction, operating, reversibility and closure phase — **Operation, …**

- Normal operation of the installation
- Analysis of internal and external hazards
- Reversibility phases

6. Safety assessment in the post-closure phase — **Post-closure**

- Evolution of performance of disposal barriers containment
- Analysis of internal and external hazards
- Role of disposal barriers on the overall safety (scenarios of disposal evolution)
- Dosimetric impact calculations

Example 2. Table of content of ENSI's review report in 2005: Review of demonstration and feasibility of a repository for high-level waste

1. Introduction
2. Assessment of siting area (geology, hydrogeology, long time evolution, erosion) — **Site**
3. Assessment of feasibility (engineering/construction, operation, retrievability, monitoring and closure) — **Operation, …**
4. Assessment of long term safety (methods of the safety case, waste inventory, engineered components, multiple barrier system, scenario analysis, biosphere modelling, radiological consequences) — **Post-closure**
5. Final conclusions of the review

Example 3. Table of content of ENSI's review report in 2010: Safety Review of stage 1 (identification of sites in the selected siting regions) of the site selection process, composed of three stages in Switzerland

1. Introduction

2. Allocating the waste to the L / ILW and HLW repositories — **Waste**
3. Defining the safety concept and quantitative and qualitative requirements — **Safety approach**
4. Identification of suitable large-scale geotectonic units — **Site**
5. Identification of potentially suitable host rocks and effective containment zones
6. Identification of suitable configurations — **Design**
7. Final conclusions of the review

Example 4. Expected content of a safety report to issue license for siting a repository in the Czech Republic (Q3.1, Annex II)

1. General Information
   - Introduction
   - Basic information on construction
2. Characteristics of selected site
   - Data on site — **Site**
   - Location and description of site
   - Geography and demography of site
   - Meteorological and climatic conditions
   - Hydrological conditions
   - geological and hydrogeological conditions
   - Natural sources and environmental impact assessment
3. Characteristics and assessment of repository concept — **Operation**
   - Emergency situations
   - Operational monitoring
   - Proposal of operational limits and conditions
   - Proposal of ways of physical protection
4. Assessment of operation on health and environment
   - Inventory of radionuclides
   - Assessment of transport pathways and release mechanisms of radionuclides in the environment
   - Scenarios of normal evolution — **Post-closure**
   - Alternative scenarios
   - Uncertainty assessment
   - Radiation protection – assessment of impact on health and compliance with regulation
5. Proposal of safe closure and decommissioning concepts
   - Stabilization of site
   - Decontamination, disposal of waste generated and decommissioning
6. Evaluation of Quality Assurance

Example 5. Table of content of IRSN's technical review note (not a report) of the Andra's (French implementer) site selection, 2009

1. Introduction: context, ASN request
2. Conclusions of the previous expertise on the « Dossier 2005 argile »
3. Results of the survey campaign of geological characterization of the "transposition zone" **Site**
   - Thickness of the clayey formation
   - Structural context
   - Homogeneity of the host formation
   - Depth of the middle of the host formation
   - Permeability
4. Conclusions

Reference design phase

Example 1. Table of content of IRSN's review report on the Andra's Dossier 2009 assessment report for definition of a possible design

1. Context, origin of the query (regulator, laws...), scope and limits of assessment

2. Waste package inventory model — **Waste**
3. Implementer's safety approach — **Safety approach**
4. General description of the site and installations — **Site** **Design**

5. Safety assessment in operating phase for each identified (internal, external) hazard — **Operation**
6. Safety evaluation in the post-closure phase for each identified hazard — **Post-closure**
7. Assessment of repository global containment: geological barrier, clay engineered barriers, waste packages, long-term global containment — **Barrier performance**

Example 2. Table of content of SKI's (Swedish Nuclear Power Inspectorate) and SSI's (Swedish Radiation Protection Authority) review of SKB's safety Report SR-Can (SKB TR-06-09) on post-closure safety for a KBS-3 spent nuclear fuel repository at Forsmark and Laxemar respectively (SKI report 2008:23, SSI report 2008:04 E)

1. Introduction
2. Regulatory criteria
3. Implementation of the review
4. Documentation and quality issues
5. Safety functions — **Safety approach**
6. System description
7. Geosphere conditions — **Site**
8. Design of the repository — **Design**
9. The biosphere and its evolution
10. Engineered barriers and spent fuel — **Waste**
11. The initial evolution of the repository — **Interactions, long-term evolution and consequences**
12. The long-term evolution of the repository
13. Consequence analysis and radionuclide transport
14. Scenarios and risk analysis — **Post-closure**
15. SKB's summary of results and report on compliance evaluation
16. SKI's and SSI's concluding remarks

Construction phase (licencing)

Example 1. Table of content of International peer review of the SKB license-application study of March 2011- The post-closure radiological safety case for a spent fuel repository in sweden (NEA/RWM/PEER(2012)2)

1. Introduction
2. Findings according to the remit of the review
   - Overall statement to the Swedish Government
   - Findings in specific areas identified in the ToR
3. Summary of findings, recommendations and conclusions in key technical areas
4. Detailed findings from the review of specific technical aspects
   - Geosphere — **Site**
   - Buffer and Backfill — **Design**
   - Copper Canister
   - Fuel and cladding — **Waste**
   - Biosphere
   - Practical Implementation
   - Performance assessment — **Post-closure**
     - Safety assessment methodology
     - Credibility of scenarios
     - Corrosion failure
     - Shear failure
     - Factors Governing the Total System Performance — **Barrier performance**
     - Evaluation of the Total System Performance Assessment Results
   - Performance confirmation — **Integration of safety arguments**
   - Societal aspects — **Involvment of interested parties and the regulatory body**
     - Public outreach, input and consent
     - Continuity of knowledge

IV. Annex IV: Questionnaires

IV.1 QUESTIONS

Global framework for reviewing the safety case

1.1- What is your national organisation for safety assessment review (authorities vs. TSOs…)?

1.2- In your opinion, what are the required competences for reviewing the safety case (develop the necessary ones in earth sciences, in expertise in operational phase and in long term related risks, numerical modelling, mathematics, civil engineering…) and how do you manage them: internal competences are all "concentrated" by each "generalist" engineer, or are dispatched between specialists; do you call subcontracting, collaborations with academic research…?

1.3- What are your reviewing principles (based on conformity to limit values vs. assessment of the methods & safety practices developed by the operator, or mixed)? If it depends of the analysed domain, please detail it.

1.4- Regarding ethic matters (independence, transparency…), what are the adopted principles in your country (degree of transparency to the public, which documents…)?Do you agree with the part of the Safety Assessment Guide entitled "Expertise body independence, competence and ability to cover its full area of competence" (p. 5)? Do you have any other suggestions on this subject?

Preparing the review process

2.1- How do the experts (see 1.2) develop their competences in your institute(training and tutoring)?

2.2- Are you attempting to you develop feedback on risks and on the possible incidental and accidental situations for operational phase? Do you develop it in your institute together with other engineers in charge of the safety of other types of installations, and/or with teams from other countries in charge of geological disposal project?

2.3- Are you favouring frequent exchanges with the operators (exchanges may take place for various subjects, especially between specialists on technical points for which you don't have the possibility to discuss in detail during a review process…)? If not, please explain the main reasons.

2.4- R&D:

- Do you use numerical codes and modelling/simulation tools in order to assess the calculation results provided by the operator? Do you develop your own ones or do you use the same ones as the operator? Could you argue these choices (or the reasons why you don't have the choice!)?
- How do you guide your choices in the development of research activities? Did you make selections between these too many possibilities: on which criteria did you skip parts of them?
- Are you carrying out studies in your own analogue sites and/or in the operators' URL (studies may correspond to data collection so as to analyse a specific phenomenon, or so as to evaluate a specific survey method)? If you investigate analog sites, on which criteria did you based on to select them?

2.5- Do you (and/or your team) have other habits that contribute to make the review process (often with limited time) more efficient?

Review method

3.1- What are you doing step by step during a review process? Do you have an internal guide from your organisation, a questionnaire to guide the analysis, a guide from the regulator or other references? Please briefly synthesise the main outlines of these guidelines. If an English version is available, please attach it to your answer…

3.2- For international/European references (as "requirement" or as "guidance" guides), I have collected the followings, but do you have others to suggest?
- IAEA Safety Standards, Disposal of Radioactive Waste, Specific Safety Requirements SSR-5. *However it is dedicated to both operators and regulatory and TSO bodies*.
- The Safety Assessment Guide written in 2004 by IRSN, GRS & AVN. *However, it has been elaborated for any type of nuclear activity and thus has to be adapted to the particular case of geological disposals*.
- NEA n°6405 2010, Regulation and Guidance for the Geological Disposal of Radioactive Waste. *It presents the general regulatory issues*.
- PAMINA, Performance Assessment Methodologies in Application to Guide the Development of the Safety Case. European Handbook of the state-of-the-art of safety assessments of geological repositories-Part 1. n°: 1.1.4

3.3- What were the tables of contents of your last main general review reports on geological disposal project? At which step did they correspond (siting or previous one, design, licensing, construction…?)

3.4- Finally, to begin the reflections (with WP 2 in May) on the expected levels in operator's report for each step of the project, a first step could be to agree on the main steps of a project.

- What about the IAEA ones (e.g., SSR-5): development (siting, design, construction), operation, closure? Do you need to refer to other intermediate steps?

- At which stage is the disposal project in your country?

- For these project steps, what state of knowledge do you expect in the operator's safety case?

4.1. In the *Safety Assessment Guide* from AVN, IRSN and GRS, one of the listed required qualities of the expertise body is "transparency and traceability of the process" (quality assurance): Do you systematically record all elements having an influence on the result of the assessment? For TSO organisations, do you communicate with the safety authority after the delivery of the safety assessment report to exchange information and to collect feedback and possible complaints?

4.2. What are the required qualities of experts involved in assessment? Do you agree with the following list (from *Safety Assessment Guide*)?
- Independent, neutral,
- Trustworthy, fair, sincere, honest, discrete, open-minded,
- Competent technically in its domain and/or in managing a team of experts
- Competent in drawing-up an assessment report: be able of drawing conclusions based on reasoning and logical analysis + describing situations and complex phenomena in comprehensible verbal or written forms
- Aware of the relevance and importance of its activities and of how he contribute to the achievement of the assessment
- Capable of understanding, observing, analysing, discerning, persevering and taking different points of view into consideration

4.3. Which hazard assessment do you expect for in a safety case of geological disposal, during operational phase? And during the post-closure phase? If you want, you can complete or modify the following list:

operational phase: earthquakes, flooding, environmental risks, fire & explosion, criticality, dynamic and static containment failure, radiolysis and thermal effects, ventilation, handling, power supply failures…

post-closure phase: earthquakes, physical-chemical conditions of exceptional amplitude, criticality, climatic events, future human actions…

- For each of the above identified hazard, do you think that it may be assessed the same way as for other (already existing) nuclear facilities? If differences exist, please detail it and indicate if research is needed.

Do you have a guide for assessing each of these identified hazards? National or international guide?

- For hazard assessment, what is the regulation about probabilistic or deterministic methods?

4.4. Modelling:

- Which kind of model do you/your organisation develop?
- Process models (in the framework of phenomenological research)or detailed models (of sub-systems or to predict the evolution of the repository system)
- Integrated models (using data from detailed ones) to perform consequence analysis for selected scenarios, to analyse radiological consequences (safety indicators), for performance assessment?
- Deterministic vs. probabilistic approaches to determine values of the parameters to input in models: what is the regulation of your country about the operator's approach? Do you favour one or the other for you own calculations and in which cases?

4.5. - Safety indicators from national regulations only: could you complete and/or modify the following table?

- Does the operator use performance indicators (or functions indicators) in impact assessment to verify the safety functions and to optimize the safety? Which ones and for which safety functions? Do you use the same indicators in your numerical models?

4.6. Do you already have a national specific guidance on how to conduct a safety review of (part of) a safety case for geological disposal? And for other facilities (such as *Safety Assessment Guide* from AVN, IRSN and GRS)?

4.7. Do you agree with the following basic list of content of the safety case at any particular step of the project development (see EPG report 2011-Draft; WENRA Report 2012-Draft, 2008-Draft IAEA DS355, NEA n°3679 2004, PAMINA report 1.1.4)?
- Description of the safety strategy (siting and design approach, management strategy, assessment strategy)
- Assessment basis (implementation of the safety strategy): detailed description of the data (site, repository, waste inventory), tools (methods, experiments and models)
- Description of the safety assessments performed: analysis of hazards (operational and long-term), scenarios, impact assessment, performance indicators, adequacy with dose limits…
- Synthesis of the results aimed at giving a statement of confidence in the safety demonstration of the disposal facility

4.8. Could you comment, modify or complete the following list that the assessment report shall at least include (from the SAG)?
- General information relating to the assessment (scope, date of issue, identification of the customer and of the expertise body, information concerning the input data, the query raised, the safety problems to be considered),
- the limits of the scope of the assessment and the depth of the analysis performed,
- reminder of the facts, the current state of knowledge at the time of the assessment and any additional information aiding understanding, and allowing the recipients to verify the relevance and the validity of the assessment,
- reminder of the positions of the parties and of any element required for verifying the relevance of the assessment and of its conclusions, particularly in the case of conflicting positions,

- the assessment and related expertise execution conditions (data sources and investigations performed), resources used, inspections and verifications carried out and the limits of validity (transparency of the approach),
- the summary of the safety demonstration by the operator, the preliminary discussions, the summary of the reasoning followed together with the appropriate references of the related documentation and of the conflicting opinions, if any, to support the conclusions to which the expertise body came and to ensure that the result itself is properly understood,
- the clear formulation of the opinion, recalling to mind, if necessary, the limits of the assessment and related expertise as well as the additional work to be carried out, in order to facilitate its use by the customer.

IV.2 ANSWERS

1.1- What is your national organisation for safety assessment review (authorities vs. TSOs…)?

FANC

FANC is the authority responsible for safety assessment review. It examines the safety cases (safety case) and their compliance with the regulation. Bel V, its subsidiary, can be involved in the safety review process. The Federal Agency for Nuclear Control (FANC/AFCN) is indeed, according to the Law of 15 April 1994 on the Protection of the Public and the Environment against Radiation responsible for the Belgian government, of the supervision of nuclear activities, including the radioactive waste disposals. It is supervised by the Federal Minister of Home affairs and advised by its own Scientific Council.

In the license application for waste disposal, the licenses are granted by the King and FANC is responsible for the examination (“instruction” in French) of the application file (or safety case supporting this license application related to this license application), according to the Royal Decree of 21 of July 2001 and to the new Royal Decree on waste disposal (being submitted).

GRS

According to the site selection law (July 2013) a new federal office called “Federal Office for Nuclear Waste Management” (BfE) has to be established which is responsible for reviewing safety relevant work regarding disposal of radioactive waste. The responsibility refers to the following tasks:

- Mining licences and supervision
- nuclear licenses
- regulatory implementation of site selection
- information/involvement of the public
- preparatory work for site selection decision

UJV

National organisation for safety assessment review in the Czech Republic is State Office for Nuclear Safety (SÚJB). Until now no safety assessment review of preliminary safety cases of deep geological repository has been conducted. Several safety assessment reviews of three near surface repositories in the Czech Republic (Dukovany, Richard, Bratrstvi) have been made only by SÚJB experts. They are aware of their limited capabilities to conduct safety assessment review of deep geological repository without TSOs. Nuclear Research Institute Rez (NRI; Ustav Jaderneho Vyzkumu Rez A.S, UJV in Czech) participates in SITEX project after agreement with SÚJB that indicates that in future safety assessment review of DGR safety assessments UJV can serve as a technical support organisation for SÚJB in the safety assessment review of DGR. The role of UJV as an independent technical safety organisation will be, however, limited only to the issues, where it will not be directly involved as a contracting organisation for RAWRA. In these issues the role of technical support organisations will have to have other research organisations, possibly from other European countries.

The Czech Republic belongs to smaller countries in Europe and therefore it is not probable that one TSO covering all DGR safety case issues could be established.

Bel V

Bel V is a technical subsidiary of the Federal Agency for Nuclear Control (FANC). Bel V performs certain regulatory missions legally delegated by the FANC. It is through the association of the FANC on one side, and Bel V on the other that the function of Regulatory Body is ensured in Belgium.

Within the framework of the Belgian legislation, Bel V:

- Supervises the delivery and the operation of nuclear installations, verifies the compliance with the licence requirements and recommends the licensee to take corrective measures if conditions of degraded safety are detected. Bel V has no enforcement power to impose actions on the licensee but has the possibility to indicate the problems to the FANC, if necessary.

- Advises the authorities on the development of nuclear emergency planning and intervenes in the management of nuclear and/or radiological crisis situations.

- Performs and evaluates safety reviews in the nuclear and radiation protection fields.

LEI

Status of the regulatory framework in the country

The main regulatory authorities in Radioactive Waste Management in Lithuania are:

- State Nuclear Power Safety Inspectorate (VATESI),
- Radiation Protection Center (RSC),
- The Ministry of Environment.

Main operators in Radioactive Waste Management in Lithuania are:

- Radioactive Waste Management Agency (RATA),
- Ignalina Nuclear Power Plant.

National TSOs

Lithuanian Energy Institute, Institute of Center for Physical Sciences and Technology, Kaunas University of Technology, Vilnius Gediminas Technical University, State Institute of Information Technology, ITECHA JSC, the Scientific Research Center of Electromagnetic Compatibility and Institute of Chemistry – all these organisations are involved in nuclear or nuclear related activities, as the Technical Support Organisations mainly. They provide VATESI with expertise and necessary technical-scientific support during safety reviews, verification of safety justifications, drafting of norms and regulations. Some of these TSOs are also involved in international projects implemented through international and bilateral cooperation.

Status of Lithuanian energy institute (LEI): TSO which performs wide range of nuclear-related activities.

Apart from above mentioned institutes, there are some other technical support organisations. As the first step to develop better technical support, the Centre for Non-Destructive Testing at Kaunas University of Technology and the Laboratory of Welding and Material Analysis at Vilnius Technical University were established. With the support of the European Commission, these facilities were equipped with modern instrumentation.

SSM

Regulatory authority

CNSC

The Canadian Nuclear Safety Commission (CNSC) is the sole regulator of nuclear facilities and activities in Canada. The CNSC is responsible for licensing geological repositories intended to provide for long-term management of radioactive wastes. In Canada, unlike with many other nuclear regulators, the technical and scientific support functions for the Canadian Nuclear Safety Commission (CNSC) are provided by in-house technical staff; there is no separate technical support organisation (TSO). The in-house Canadian Nuclear Safety Commission experts and technical specialists carry out the technical assessment of information submitted by applicants in support of the applications. This assessment is carried out with input from other federal, provincial and territorial government departments and agencies responsible for regulating health and safety, environmental protection, emergency preparedness and the transportation of dangerous goods.

ENSI

ENSI, the Swiss regulator reviews safety assessment. In addition, ENSI has an expert group (experts from universities and research institutes) which reviews specific topics to support ENSI's safety assessment. For specific topics, ENSI has also subcontracting experts.

NRG

In The Netherlands, present legal requirements that are relevant for the safety case are provided inthe Nuclear Energy Act and related decrees, the Environmental Management Act and related decrees and the Mining law and related decrees. For the review, Dutch authorities can contract Dutch or foreign organisations with relevant expertise.

At present, the Dutch WMO, COVRA, is preparing a generic Safety Case to be released in 2015. This Safety Case, addressed as the OPERA Safety Case or OSC, is not associated with a license application, since actual geological disposal of the waste is not planned before 2120. Therefore, a review of the OSC is not required.

On the other hand, the policy of the government with respect to nuclear new build relies on existing safety reports and the OSC. Therefore, it can be expected that an organisation like NEA will be asked to perform a scoping review of the OSC.

1.2- In your opinion, what are the required competences for reviewing the safety case (develop the necessary ones in earth sciences, in expertise in operational phase and in long term related risks, numerical modelling, mathematics, civil engineering…) and how do you manage them: internal competences are all "concentrated" by each "generalist" engineer, or are dispatched between specialists; do you call subcontracting, collaborations with academic research…?

FANC

The required competences for reviewing a safety case must cover all aspects related to the safety of geological disposals of radioactive waste as e.g.:

- Nuclear physics, physical protection, radioprotection, engineering including a.o. design, construction, geotechnics, environmental sciences including biosphere, geochemistry, geology, seismology, hydrology, hydrogeology, meteorology and climatology; numerical modelling, risk analysis and management systems,

- Additional abilities to conduct critical analyses; process and synthesize large amounts of information from different areas are required to ensure adequate investigation of the SC.

The competences for reviewing the safety cases related to geological disposal of radioactive waste are managed within the waste disposal service of FANC (IAABA). The competences are organised in centres of competences among general topics that embraces several disciplines and or aspects of a SC and involves several experts. Examples of such general topics are:

-Safety aspects (incl. safety strategy, safety assessment methodologies and approaches)

- Site aspects (covering all environmental aspects of the facility as biosphere, meteorology, climatology, geochemistry, geology, hydrogeology, seismology and geotechnics);

- Design and feasibility aspects (covering most of the engineering and phenomenological aspects related to the design and construction of the facilities, including the waste form, waste conditioning and the engineering barrier system).

- Operational issues (incl. physical protection)

-Organisational issues (incl. management system)

Within IAABA, the "Geological disposal" project organises the tasks among the experts according to their competences, identifies the needs in R&D and the needs for additional human resources or for subcontracting tasks.

IAABA works in synergy with other services within FANC and its subsidiary Bel V for security aspects, operational issues and for some other specific technical aspects.

Subcontracts with universities, research institutes or external consultants are possible when necessary.

GRS

The responsible organisation for reviewing the Safety Case for geological disposal should have the competences to evaluate the work of the implementer regarding safety relevant aspects. This implies the assessment whether or not the provided work complies with the underlying safety requirements. Such an evaluation needs the technical expertise in almost all scientific fields.

UJV

To be able to review safety cases prepared by operators, experts participating in review of safety assessment must have very good technical and scientific expertise capabilities. This is confirmed also by specific safety requirements of IAEA (SSR 5, 2011) that consider as one of governmental responsibilities to ensure that necessary scientific and technical expertise remain available both for operator and for the support of independent regulatory reviews and other national review functions. Independent safety assessment review must be an inherent part of safety cases. In my opinion TSO experts should be available for all safety important issues. One of the most important experts of TSO is always a generalist, who understand the all issues of safety assessments and knows in which areas he can decide oneself or with other researchers from his TSO and in which areas he needs a help of specialists from other organisations.

Bel V

Competences and expertises required for assessing a SC for geological disposal

The following list of fields of competences and expertises is based on the IAEA-ASAM report "Guidance on Regulatory Review of Safety Assessments for Radioactive Waste Disposal Facilities" and on Bel V experience in safety assessment.

- National and international regulations, guidance and criteria for waste management and radiation protection
- Safety and risk assessment (e.g., scenario development and methods for the treatment of uncertainty)
- The characteristics and sources of radioactive wastes
- Waste characterisation, conditioning and packaging
- Engineering and disposal facility design
- Waste and facility degradation (e.g., chemical and physical degradation of concrete …)
- Site characterisation
- Geology and hydrology
- Seismology
- Climatology (e.g., climate change …)
- Chemistry (particularly radiochemistry, geochemistry, …)
- Biology (e.g., microbial degradation of engineered barriers …)
- Contaminant transport
- Radiation protection
- The assessment of human actions
- Mathematical modelling and computational methods
- Quality assurance
- Operational safety in nuclear and/or underground facilities (e.g. Fire protection …)

How does Bel V manage these competences?

Bel V is organised in both a vertical and a horizontal structures. The vertical structure provides Bel V with a hierarchical organisation in three main departments (Respectively responsible for inspections, project management and safety assessment), themselves divided in several branches or areas. Besides this top down organisation, Bel V has a horizontal structure in Technical Responsibility Centres (TRCs) gathering experts from various departments and branches or areas into dedicated fields of competences (e.g., "Waste management and Chemistry", "Site analysis, external hazards and meteorology", "Radiation protection, ALARA, radiation measurements", "Fire protection and ventilation" …). The creation of TRCs has the objective to provide Bel V with an organized structure that enables the short and medium term management of expertise and resources dedicated to nuclear safety and radiation protection assessments.

To perform the review of a safety case for a waste disposal facility, a project management team will be first defined within Bel V. The branch “Radiation protection and waste” belonging to the department “Nuclear safety and Radiation protection Assessment” will be naturally deeply involved in this project team. The members of the project team will be “generalist” engineers able to manage the safety assessment of a geological repository as a whole. They will dispatch the specific assessment tasks between the relevant TRCs for a comprehensive review of the safety case. Within Bel V, the competences are therefore concentrated in “generalist engineers” responsible for project management, as well as dispatched between several specialists working in the various TRCs.

Does Bel V call subcontracting or collaborate with academic research centres?

Concerning the subcontracting, in the past Bel V (and formerly AVN) has rarely called upon external support for safety evaluations. At present, Bel V has no objection in principle for subcontracting specific tasks of safety assessment. The potential subcontracting of specific tasks by Bel V is foreseen in its Quality Management System, which includes procedures for selection and evaluation of external experts. Recently, some members of FANC have been integrated in Bel V TRCs (Technical Responsibility Centres) to provide external expertise. In the future, collaborations such as ETSON might facilitate the use of external experts (although language problems when evaluating safety files in national languages are limiting the possibilities).

Concerning collaboration with academic research centres, Bel V collaborates with universities or research centres on specific key issues for which the necessary human or technical resources are not readily available within Bel V. At present, efforts are undertaken to extend Bel V collaboration on R&D with Universities.

LEI

The reviewers should have experience in the reviewing the previous Safety Cases or safety assessments of the nuclear facility or to have experience in the development of the Safety Case (safety assessment). The experts need to have background in the fundamental sciences such as physics, mathematics, also in chemistry, mechanics, earth sciences, the knowledge of numerical modelling, the principles of nuclear safety and radiation protection are obligatory as well.

LEI do have practice to call subcontractors or initiate the collaboration with academic institutions, when necessary and on the specific issues only.

The internal competences in nuclear safety, radiations protection, environmental impact assessment, radionuclide transport, chemical aspects are not concentrated all in one engineer, but are distributed among the group of specialists in the Nuclear Engineering Laboratory of LEI. The experts are specialized in one of the mentioned area, but also can be competent in several areas.

DECOM

Slovakia is not in stage of reviewing of Deep Geological repository.

SSM

Structural engineering, civil engineering, plant technology, geology, hydrology, chemistry, materials chemistry, materials engineering, social sciences, technical physics and radioecology.

In a general sense, the authority is required to acquire enough competence within the organisation to be able to function as an “intelligent customer” within all fields of expertise required to review safety cases as well as supervise on-going activities.

Usually, staff members have expert knowledge in at least one discipline, sometimes more than one. The situation changes with exchange of staff members as one-to-one replacement of resigned/retired staff members is usually not possible to achieve. Especially as the specific application of expert knowledge involving nuclear - as well as post-closure – safety is acquired by a “learning-by-doing” process. Depending on the current staff competences at a given time, the need for external expert support varies.

Exchange of information between regulatory functions and expert organisation in different countries is one important part of the work. Formal subcontracting of experts from expert organisation or academic research institutions is another.

CNSC

There is currently no licensing application for a spent fuel repository in Canada, and one is not expected for 7-10 years. At this time, it is not known where the repository will be located in Canada; therefore the applicant is developing conceptual designs for two hypothetical sites in representative rock formations. The CNSC is conducting a pre-project design review of the conceptual design and post-closure safety assessment for the two hypothetical sites. The word “pre-project” signifies that a design review takes place before a licence application is submitted to the CNSC. Information about this pre-licensing review is the main subject of this report.

The technical review will be lead by a senior specialist with significant expertise and experience in safety assessment of radioactive waste facilities, with focus on geological disposal. The senior specialist is responsible for peer reviewing, integrating and synthesizing comments from other specialists. Specialists with advanced knowledge in the following areas have been identified: geology, hydrogeology, geomechanics, geochemistry, environmental and human risk assessment, radiation protection, quality assurance, transportation, safeguards, nuclear security, material science and mathematical modelling.

The Canadian Nuclear Safety Commission maintains a research and support program to address key knowledge gaps for safety analysis of repositories for nuclear wastes. This program consists of independent scientific research conducted by CNSC staff in collaboration with national and international institutions. It also includes monitoring and review of state-of-the-art scientific advancements, and participation in international forums to exchange information and knowledge related to geological repositories.

Expertise is also supplemented, as necessary, by contracting academic and recognized experts to perform reviews, or provide input in key subject areas.

ENSI

ENSI has internal competence in geology, physics, numerical modelling and geochemistry. The competence is divided between specialists. However, for review purposes scientific questions are assessed as a team to ensure that all relevant aspects are taken into account.

NRG

The main question answered by previous safety studies and that will be addressed by the OSC is: “is it possible to deal on the long term with the nuclear waste by geological disposal in The Netherlands?” The main competencies of the reviewers must be in the field of:

- geology and mining
- nuclear waste management
- radiation protection
- policy studies

In the OSC there is a special focus on:

- stakeholder involvement
- (wireless) monitoring

requiring competence of the reviewers in these specific fields.

1.3- What are your reviewing principles (based on conformity to limit values vs. assessment of the methods & safety practices developed by the operator, or mixed)? If it depends of the analysed domain, please detail it.

FANC

A prerequisite to the safety review is the confirmation that all elements of the SC have been addressed as defined in our regulation.

In its SC review FANC verifies besides the compliance of criteria, the conformity with all requirements provided in the regulation. This includes the verification that:

- The objective of the SC is well-defined, situated in a decision process and suited for the identified development step.
- - The safety strategy (including approaches guiding design and implementation, safety assessment and management system) allow fulfilment of the safety objectives in compliance with IAEA fundamental principles, radioprotection principles and safety principles, which are integrated and/or developed in our regulation.
- The safety strategy is appropriately implemented in the design.

- The adopted technical solutions are technically feasible.

- The safety analyses and argumentation comply with the proposed safety strategy; demonstrate the fulfilment of the safety objective of the specific SC step and provide confidence in the development of the waste disposal solution by identifying the remaining uncertainties and the way to manage them in the next phases. The provided information needs to be unambiguous, traceable and to allow independent review.

These items will be assessed according to the development phase of the geological disposal.

FANC attaches as much importance on the logic decision and the justification of choices as for the analyses themselves. At any key steps in the development of a geological disposal, the SC must be sufficiently developed to convince FANC that an adequate level of confidence in safety has been reached for making the decision to proceed to the next phase.

GRS

The reviewing principles for heat-generating radioactive waste take into account the safety requirements of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU). These safety requirements provide the basis for a check list when reviewing a Safety Case.

UJV

Current reviewing principles for safety assessment review of near surface repositories in the Czech Republic are based mainly on conformity with limits, but methods used for safety assessment are reviewed as well. The structure of safety assessment should follow the structure of a guide issued by SÚJB for various stages of repository preparation (siting, construction, operation, closure). The results are compared with limits and on the basis of this comparison and uncertainties of safety assessments waste acceptance criteria for repositories are established. There is no experience with safety assessment review of DGR safety cases.

Bel V

In the review process of a safety case, Bel V first examines the methods that have been developed by the applicant for the safety assessment. These methods encompass among others the scenarios development and justification, the models formulation and development, as well as the management of uncertainties. The conformity of the developed methods with relevant requirements and norms (national guides, IAEA safety standards, WENRA SRL, …) is examined by Bel V. Finally, if the methods are appropriate to the considered safety assessment, the conformity with the acceptance criteria and/or limit values defined by the regulatory body is verified.

LEI

The reviewing principles in Radioactive Waste Management in Lithuania are of mixed nature. If there are the requirements in terms of limits in the Lithuanian legislation, the compliance with those limits are being checked firstly. If such a limit values do not exists, the recommendations of IAEA, WENRA, NRC are used.

For example, in case of radioactive waste disposal in Lithuania there are requirements for the public exposure in terms of dose constrain (0.2 mSv/yr) and dose limits for the workers (the limit for effective dose – 100 mSv in a in a consecutive 5 year period and the limit for annual effective dose – 50 mSv) respectively. Usually a limit of 20 mSv per year is applied in order to comply with the limit of 100 mSv in a consecutive 5 year period. The requirements on risk in terms of limit values are not established in national legislation on radwaste disposal.

DECOM

/

SSM

Mixed. The outcome of a safety assessment should constitute credible verification that release limits are respected. But in order to gain credibility, assessments of the methods & safety practices developed by the operator constitute a very important component.

CNSC

• CNSC regulates under the Nuclear Safety and Control Act and its associated regulations. The CNSC is more on the "non-prescriptive" side of regulating. The licence applicant must propose and justify.

• The CNSC does not have regulations specific to repositories for radioactive waste; generic requirements are applied to all major facilities. For example, radiation protection, quality assurance.

• The CNSC also produces regulatory documents. Regulatory documents specific to the long term management of radioactive waste and decommissioning are: CNSC Policy P-290 "Managing Radioactive Waste" and CNSC Regulatory Guide G-320 "Assessing the Long term Safety of Radioactive Waste Management.

• G-320 is based on the IAEA's draft DS-355 and addresses the assessment of long term safety to support licence applications, and includes discussion of assessment methodologies, structures, and approaches. This guide does not address other issues that are also taken into consideration in the licensing process, such as waste characterization, the assessment of facility operations, transportation of waste, or the social acceptability or economic feasibility of long term waste management methods. The pre-project conceptual design review evaluates the applicant's conceptual design and post-closure safety assessment against the long-term safety requirements in G-320.

• For decommissioning, CNSC has P-219 "Decommissioning of Nuclear Facilities". Further guidance can be found in Canadian Standards Association (CSA) 294.09.

ENSI

Show conformity to the nuclear energy law and ENSI's guidelines. Perform independent reviews of all safety relevant topics. Since the realisation of a geologic repository, the assessment depth becomes greater with time.

NRG

??

1.4- Regarding ethic matters (independence, transparency…), what are the adopted principles in your country (degree of transparency to the public, which documents…)? Do you agree with the part of the Safety Assessment Guide entitled "Expertise body independence, competence and ability to cover its full area of competence" (p. 5)? Do you have any other suggestions on this subject?

FANC

Independency and transparency are principles that are recommended at international level as e.g. by IAEA recommendations (cf. IAEA GSR Part 1, 2010) and laid down in IAEA Joint Convention of 1997 (mainly independency) and in the 2011/70/Euratom Directive establishing a framework for the responsible and self-management of spent fuel and radioactive waste (see Article 6, 10, 12-j). It is also adopted at the country level.

FANC is a public body with legal personality as established by law of 15 April 1994. This law grants FANC broad independency. The role of FANC is also to disseminate neutral and objective information. It has to organise the circulation of the technical information on radioprotection. An annual report on its activities is transmitted to its supervising minister and to the legislative chambers. Annual reports, press releases, newsletter, leaflets or files on specific issues, formal advices and answers to questions from the legislative chambers are made available to the public on its website.

GRS

The adopted principles are in line with international recommendations and requirements. For example the EU DIRECTIVE 2011/70/EURATOM of 19 July 2011 requires that every member state shall establish a national programme that includes comprehensive measures for the sustainable management of radioactive waste and irradiated fuel assemblies already existing and expected to arise in future. This programme aims at establishing and increasing transparency and traceability for the public regarding decisions necessary for the management, including the disposal of radioactive waste and irradiated fuel assemblies. Each national programme will be reviewed by an international group of experts and further developed at regular intervals. This ensures transparency and traceability for further proceedings and full participation of the citizens on the basis of sound knowledge.

The mentioned Safety Assessment Guide was developed in collaboration of the Belgian, French and German Technical Safety Organisations (AVN, IRSN and GRS). Therefore, GRS still fully agrees with the section "Expertise body independence, competence and ability to cover its full area of competence".

UJV

The issue of transparency is discussed intensively currently mainly in connection with the effort of RAWRA to find sites for deep geological repository acceptable to local communities, but not independency of experts involved in safety assessment review. Independency of regulatory (SUJB) is guaranteed by Czech Atomic Law 18/1997 Coll. We agree with the part of the Safety Assessment Guide concerning independence, competence and competence and ability to cover its full area of competence, but this issue has not be discussed properly in the Czech Republic so far.

Bel V

The general principles of Independence of the nuclear regulatory body and Transparency are adopted in Belgium. Concerning the Transparency, FANC has a primary role in communicating with the public.

Bel V (previously AVN) has participated with IRSN and GRS in the development of the "Safety Assessment Guide" mentioned in question 1.4. Bel V fully agrees with the section of this guide entitled "Expertise body independence, competence and ability to cover its full area of competence".

LEI

According to Lithuanian legislation for any proposed economic activity related to radioactive waste management the Environmental Impact Assessment (EIA) has to be performed considering the design, erection, installation, setting-to-work, commissioning, operation and decommissioning on new facility. The EIA assessment content and structure follows the requirements of the Republic of Lithuania Law on the Assessment of the Impact on the Environment of the Planned Economic Activities and the Regulations on Preparation of Environment Impact Assessment Program and Report. As defined in Lithuanian legislation the EIA results need to be presented to and discussed with the public and relevant parties.

Moreover, Member States are required to provide the Commission with a general data on any plan to construct, to modify or dismantle an installation that may give rise to discharges of radioactive effluents. Currently, General Data Set on the Buffer Storage of the Landfill Repository and General Data Set on the Disposal Modules of the Landfill Repository were prepared and are approved by the European Commission. These documents are reviewed and submitted to the EC by the regulatory bodies and EC opinion on review documents are not public available.

Safety analysis reports (SAR) which are being developed by operator for the licensing are provided to and reviewed by the regulatory bodies and associated authorities only.

The Aarhus convention on access to information, public participation in decision-making and access to justice in environmental matters was ratified by Lithuanian Parliament in 2001.

In case of independence we agree with the statements indicated in the Safety Assessment Guide (IRSN, GRS & AVN), section "Expertise body independence, competence and ability to cover its full area of competence". However if such a the description of expertise body independence is going to be included in the report of WP4 on harmonization of review, the description of several aspects mentioned in Safety Assessment Guide (IRSN, GRS & AVN) need to be included too. These are the rules of expertise bodies enabling to steer clear of and or suspend any assessment or expertise subject to internal or external commercial, etc and the definitions of the responsibilities of the personnel involved in the assessment. The commonly accepted rules and definitions would contribute to the process harmonization as well.

Excerpt from document Safety Assessment Guide (IRSN, GRS & AVN):"**Expertise body independence, competence and ability to cover its full area of competence.**

To ensure its independence the expertise body shall not undertake work likely to compromise its neutrality or likely to lead it to assess its own work. Particularly, persons conducting independent assessment should not have participated directly in the work being assessed. The expertise body shall have rules enabling it to steer clear of and/or suspend any assessment or expertise subject to internal or external commercial, financial or other pressures or influences, liable to call the quality of its work into question. If the expertise body forms part of an organisational structure which performs activities other than expertise activities, the organisational provisions should be such that any divergent interests between the different activities of the body do not affect the opinion of any expert. The responsibilities of the personnel involved in the assessment or who may influence the latter shall be precisely defined in order to prevent any conflicts of interest. The expertise body should be able to prove its independence with regard to any commercial, financial or other pressures or influences likely to affect its technical opinion. On account of its independence, the expertise body is duty bound to separate its activity from that of consultancy and consequently shall not provide any specific solutions to the query raised."

DECOM

National regulation adopts international standards in the independence and transparency. Degree of transparency to the public in practice has to be summarised up by public. In general, the transparency in east European countries is weak and there is lots of room for increasing as first understanding of transparency among professionals as well as transparency itself.

Transparency and independence are not measurable by any standards therefore it is very subjective to measure these parameters. To compare their application in the various countries, very special questionnaire have to be developed.

SSM

Transparency is a very important feature un the Swedish national administrative system. In a general sense all documents that are referred to in a regulatory review becomes public after being approved.

We agree (at least in principle) to the referred part of the AVN/IRSN/GRS document.

CNSC

The CNSC is committed to operating with a high level of transparency. The Commission has a mandate to disseminate objective scientific, technical and regulatory information to the public concerning nuclear activities. This obligation is defined in the Nuclear Safety and Control Act.

To improve the level of understanding by the public of information about proposed or licensed nuclear facilities and activities, licensees and licence applicants are required to develop and implement a public information program that includes a disclosure protocol. Licence applicants are encouraged to adopt the most appropriate and effective means of communication. The requirements for public information to strengthen public disclosure are outlined in a CNSC regulatory document (RD/GD-99.3 “Public Information and Disclosure”).

The CNSC engages affected communities to provide factual and unbiased information about how it regulates the nuclear sector to protect the health, safety and security of Canadians and the environment, and how it respects Canada’s international commitments on the peaceful use of nuclear energy. A number of communities have participated in a day-long presentation at CNSC headquarters in Ottawa to learn about CNSC’s early role in the approach to manage Canada’s used nuclear fuel in a deep geological repository.

The Commission Tribunal holds formal public hearings. Members of the public are welcome to observe the Tribunal’s public hearings, or to actively participate as interveners. Recently, the Canadian Nuclear Safety Commission (CNSC) established the Participant Funding Program (PFP). This program gives the public, Aboriginal groups and other stakeholders the opportunity to request funding from the CNSC to participate in its regulatory processes.

The CNSC maintains an up-to-date website and offers online videos, or Webcasts, of its Commission Tribunal’s public hearings and meetings.

ENSI

Switzerland is currently carrying out its site selection programme, based on the government approved sectoral plan (SGT). Within the plan the transparency of decisions is paramount. Parliament passed an act to set up ENSI as an independent agency with the necessary staff and funds to fill its role as a competent, independent expert body.

NRG

No general principles, but it is important that the review is independent.

2.1- How do the experts (see 1.2) develop their competences in your institute (training and tutoring)?

FANC

According to the 2011/70/Euratom Directive, arrangement for education and training and R&D to cover the needs of national programme for spent fuel and radioactive waste are mandatory for all parties.

By its Law of 15 April 1994, FANC must, ensure the on-going training of staff members at the international level, according to the missions entrusted to them.

As explained in the answer to question 1.2, the centres of knowledge allow the experts to share their knowledge and experience, to exchange information and to assist the project management in identifying specific needs in competences or R&D orientations as well as needs in training.

Training are organised at FANC and Bel V on specific topics as e.g. radioprotection and safety analyses. Experts follow also external training (e.g. ITC "School of underground waste management") or specific training as numerical modelling.

FANC also maintains and develops the competences and experiences of experts through their participation in various R&D programmes ranging from international working groups (e.g. IGSC, Clay-Club,…) and projects (e.g. FORGE) to the development and follow-up of in-situ experiments in collaboration with the Belgian Nuclear Research Centre (SCK•CEN) at the Mont Terri rock laboratory (CH).

GRS

The aim of the international co-operation of GRS is to contribute to the highest possible safety of nuclear installations worldwide. This is achieved on the one hand by participating in working groups (e.g. of the IAEA or the OECD/NEA) and on the other hand by networking. This is to ensure a constant exchange of information about the development of new methods and the advancement of the state of the art in science and technology. The most important networks and initiatives of GRS are ETSON (European Technical Safety Organisation Network) and EUROSAFE.

The aim of ETSON is on the one hand to establish a forum for voluntary exchanges about the assessment, research and development in the field of reactor safety. On the other hand, ETSON would like to make a contribution to the promotion of a harmonisation of nuclear safety practices and initiate and carry out joint nuclear safety research programmes.

The EUROSAFE Initiative is an international network for the discussion of safety -relevant issues from the nuclear field. It consists of representatives of several national licensing and supervisory authorities and their TSOs.

The partners of EUROSAFE and ETSON have launched two further education and training programmes: ENSTTI – the European Nuclear Safety Training and Tutoring Institute – and the ETSON Summer School. The aim of ENSTTI is to impart knowledge and competences from research and development, offering participants the possibility of on-the-job training (tutoring). The focus of the ETSON Summer School lies mainly on giving young experts the opportunity to make the acquaintance of other junior scientists on a scientific as well as social level.

Besides the network and working group activities the training on the job is one of the most valuable resources to keep the staff state of the art. There are lots of projects in the different fields of nuclear waste management where GRS employees enhance their knowledge and background on a daily basis.

UJV

Waste Disposal Department of Nuclear Research Institute Rez (NRI: UJV in Czech) is focused on all aspects of safety assessment issues of radioactive waste repositories covering all the safety important areas (degradation of waste matrices, canister materials, migration of radionuclides in engineered barriers and host rocks, modelling, and total safety assessment). UJV has a very close cooperation with Czech universities. Students from these universities often conduct their diploma or dissertation work in UJV and several of them often after finishing their work join the permanent staff of UJV. Training and tutoring of young researchers is supported in projects funded by Ministry of Trade and Industry.

Bel V

A structured training approach was adopted in Bel V, on the basis of the IAEA Systematic Approach to Training (SAT). Training programmes were developed for all staff members, and in particular for newcomers, on the basis of the function descriptions and the related needed competencies. Implementation of the training programmes is carried out by different methods depending on the availability of training materials and the adequacy of external courses: self-study, internal training sessions, external courses or on-the-job training.

The training approach is fully incorporated in the Bel V Quality Management System where the role of each key actor is defined: the upper and mid management, the human resources manager, the technical training manager and the coach. In the Bel V practices, the role of the coach is emphasized: he is in charge of the good development of the knowledge, skills and attitudes of its newcomer and of its successful integration in the organisation.

A key element of the initial training of newcomers is the programme of internal training sessions implemented by the technical training manager with the help of experienced experts (mainly from Bel V and FANC) as lecturers. The programme is structured as recommended in the new Systematic Assessment of Regulatory Competencies Needs (SARCoN) guidelines of the IAEA, i.e. with the distribution of training subjects in four quadrants (legal basis & regulatory processes, technical disciplines, regulatory practices, personal & interpersonal effectiveness).

LEI

The experts participates in the training courses, workshops organized by IAEA, participates in the research projects of IAEA and European Commission (FP7 program) and national research projects. The competence of experts is constantly increased with the experience gained during the developing/reviewing the documentation on safety and environmental impact of other nuclear facilities implemented or under implementation in Lithuania (Landfill facility for Short-lived Very Low Level Waste, Near Surface Repository for Low and Intermediate Level Short-lived Radioactive Waste, Solid Waste Management Facility (SWMSF) at Ignalina NPP, SNF dry storage facility, etc.).

LEI experts have an experience to participate in the multi-disciplinary team for the performance of hazard and operability study (HAZOP), safety assessment (and review) of the facilities for radwaste treatment, storage and disposal and SNF interim storage

DECOM

Particular trainings on modelling, practicing of competencies in modelling on various cases, intercomparison of various modelling tools.

SSM

In a general sense, export knowledge as regards nuclear - as well as post-closure – safety is acquired by a “learning-by-doing” process. Competence building is also achieved through participating in international project/workshops/conferences and sometimes by participating in special courses on within specific areas.

CNSC

In order to develop independent expertise, the CNSC has initiated a Coordinated Assessment and Research Plan (CARP). The CARP consists of the review of ongoing publications from the applicant at critical milestones, combined with an independent research program in collaboration with Canadian and European experts, and participation in international collaborative projects on geological disposal led by the International Atomic Energy Agency (IAEA) and the Nuclear Energy Agency (NEA). The CNSC independent research program examines key uncertainties that will contribute to or refute safety arguments for geological disposal in Canadian candidate host rock formations.

ENSI

There is knowledge transfer within the groups. ENSI lays emphasis on international contacts to foster knowledge exchange. Attendance at international conferences is an integral part of ENSI’s expert training.

NRG

On the job training, courses, external training.

2.2- Are you attempting to develop feedback on risks and on the possible incidental and accidental situations for operational phase? Do you develop it in your institute together with other engineers in charge of the safety of other types of installations, and/or with teams from other countries in charge of geological disposal project?

FANC

Yes, FANC intends to develop feedbacks on risks and on the possible incidental and accidental situations for the operational phase of nuclear installations both from international and national experiences, focussing on the consequences for waste disposal facilities. A systematic list of these situations will be made in synergy with the engineered involved with the safety of the other nuclear installations.

GRS

According to the safety requirements of the BMU, comprehensive safety analyses for the operational phase of a repository are needed. This includes an analysis of operational accidents. Such analyses are done so far on the basis of deterministic approaches and expert judgement. A general systemic approach like the one that is used for scenario development in the post closure phase is not available for an operational accident analysis. Therefore it is intended to develop a respective method which allows the systematic derivation of operational accident scenarios on the basis of gained experience with scenario development in the long term analysis. The specific objectives for this task are:

- Compilation and studying of existing international methods
- Compilation of relevant influencing factors (similar to FEPs)
- Evaluation of operational experience and incidents
- Evaluation of incident rates
- Distinction of different disposal concepts and host rocks
- Definition of safety functions for components of the disposal system
- Exemplarily derivation of accident scenarios on the basis of influencing factors

UJV

The radiological protection requirements for the operational period of a disposal facility and the related safety criteria are considered to be practically the same as for any licensed nuclear facility, for example Nuclear Power Plants. UJV has a number of specialised departments focused on operational safety of nuclear facilities. A recent preliminary safety case prepared in the framework of update of Czech DGR concept involved also safety assessment of DGR in operational period.

Bel V

By delegation of the FANC, Bel V is notably responsible for performing regular inspections during operation of nuclear facilities in order to verify the compliance with the licenses, as well as to ensure that a high level of nuclear safety is maintained. Within the framework of this mission, Bel V always favours constructive exchanges with the operators to examine topics that are controversial or which require additional information.

More specifically for the license application of the geological repository, exchanges between ONDRAF/NIRAS (the license applicant), FANC and Bel V are favoured. For instance, a convention between Bel V, AFCN and ONDRAF/NIRAS was set up between 2003 and 2005 in order to exchange information on the R&D programme developed by ONDRAF/NIRAS, to identify the key issues that required further investigations, as well as to determine the following steps of the license application. Moreover, Bel V participates in the exchange meetings organised by EURIDICE — an Economic Interest Group between ONDRAF/NIRAS and SCK-CEN (the Belgian research centre for nuclear energy) — for presenting the main outcomes of the R&D programme developed in the HADES underground research laboratory.

LEI

Currently no full scale demonstrating/testing of certain technology (e. g., transportation/emplacement equipment) is performed in LEI or in collaboration with teams in foreign countries.

DECOM

Usually the modelling and any analysis are performed on the short term contracts in time stress.

There is no room and time to develop such a cooperation and improve

SSM

According to Swedish legislation, the responsibility to develop a sound and safe disposal concept rests with the implementer. All the same, staff members from the authority participates in international activities, e.g. the IAEA project GEOSAF.

CNSC

The information required in licence applications would include evaluation of safety assessment and development of the safety case in several phases: Site preparation; Construction; Operation; Decommissioning (closure); Post-closure Operational phase. Accidents and mitigation measures are reviewed during the environmental assessment of the project and a follow-up program is developed. The follow-up program becomes part of the licence requirement and verifies facility performance and that mitigation measures are in-place.

Expertise gained from the regulation of uranium mining can be applied to the repository construction and operational phases (e.g. radiation protection, ventilation, rock stability). The CNSC recently participated in an IGSC Topical Session entitled, “Balancing operational and long-term safety considerations”, which discussed how mining experience can be related to operational safety for geologic repositories.

ENSI

Within ENSI’s “Systems” division analyses national and international experiences with nuclear facilities. The results are used to amend ENSI guidelines if necessary. ENSI has two external expert groups how give feedback on risk related issues.

NRG

Not in this stage.

2.3- Are you favouring frequent exchanges with the operators (exchanges may take place for various subjects, especially between specialists on technical points for which you don’t have the possibility to discuss in detail during a review process…)? If not, please explain the main reasons.

FANC

Yes, FANC is favouring frequent exchanges with the operators. A programme of “dialogue” is established with the operator in the framework of a pre-licensing work programme between ONDRAF-NIRAS and FANC.

FANC is in favour of such exchanges to:

- present the regulation and guides in order to avoid ambiguities in the interpretation;
- allow the operator to discuss aspects on practical implementation of those regulation and guides;
- discuss the methodological instruments (i.e. the approach that the operator intends to use in the safety strategy, safety assessment and management system…) before their implementation and
- discuss specific technical points.

Given we are currently in the early stage of the pre-licensing phase concerning the geological disposal of radioactive waste, the focus during this phase has been up to now mainly given on the first three points.

GRS

It is common practice to have an information exchange with the operator on a frequently basis. The information exchange takes place in the various fields of competences. There are lots of projects, field studies and experiments where several organisations including TSO and the operator collaborate together.

UJV

We are in favour of a close cooperation and discussion with operator experts, involving particularly TSOs in more complex experiments, which can be conducted together with operator. The independency should be kept mainly in evaluation and interpretation of the results of experiments.

Bel V

LEI

The exchange with the operators is favourable in principal. The communication should be when necessary only in order to keep the required level of independence.

DECOM

It used to be a practice in the research projects, but with changes in the management and ownership of facilities in time discussion became more complicated. There are few reasons, e.g. requirement of control on every exchange of information, lots of managerial levels in between instead of direct communication with experts.

SSM

The need for more or less frequent exchange with the operators/implementers depends very much on the national situation. In situations where (very) detailed requirements and guides exist, the need for meetings with the operators/implementers is less, compared to situations where requirement and guidance is less detailed. The Swedish regulatory framework represents the latter. A special pre-licensing consultation process was set up for an 8-10 year period before the implementer submitted an application to create a spent fuel repository.

CNSC

The CNSC has regular exchanges with the applicant in order to (1) keep informed about the applicant's R&D program outcomes and (2) review pre-licensing conceptual designs and identify any regulatory concerns with the concept meeting regulatory requirements. A service arrangement has been developed between the applicant and the CNSC to facilitate these functions.

For review of R&D programs, the CNSC typically reviews publications posted on the applicant's website and attends workshops and conferences hosted by the applicant.

For pre-project reviews, the applicant provides the CNSC with a presentation summary and documentation. The CNSC exchanges the review outcomes during meetings and seminars with the applicant.

ENSI

Yes, ENSI favours frequent exchanges for various subjects with the implementer who plans and designs the repository. Even during the review process we have discussions on specific topics with specialists. If we need further or more detailed information to specific aspects, we ask questions to the implementer. The questions and answers will be published in a report. This further information can be used for the safety assessment.

NRG

No, in this stage (generic safety Case) independency of the reviewers is more important.

2.4- R&D:

- Do you use numerical codes and modelling/simulation tools in order to assess the calculation results provided by the operator? Do you develop your own ones or do you use the same ones as the operator? Could you argue these choices (or the reasons why you don't have the choice!)?

FANC

Yes, FANC uses several numerical codes modelling/simulation tools in order to assess the calculation results provided by the operator. The used codes are currently not developed by FANC. The codes may or may not be the same as those used by the operator. They are mainly well-recognised, often international codes (e.g. HYDRUS, RESRAD…). FANC uses modelling/simulation tools for several purposes:

- to be able to reproduce the calculations of the operator;
- to understand the safety relevant aspects of the system/scenario;
- to be able to make an independent assessment and
- to maintain an expertise in the field.

GRS

Yes, for further information please cf. question 4.4.

GRS developed the computer code MARNIE for the simulation of fluid and tracer transport in the near field of a disposal facility.

UJV

We use a number of numerical codes and modelling/simulation tools (FEFLOW, GoldSim, TOUGH, PHREEQE, etc). Currently, operator (RAWRA) in the Czech Republic utilizes a number of contracting organisations for modelling issues. For example for hydrogeological description of a potential site for a repository RAWRA used numerical code developed in one of the Czech university (FLOW123). The results of this code are currently verified in UJV using FEFLOW code.

Bel V

Bel V conducts independent modelling investigations in order to assess the calculation results provided by the operators. The main objectives of these independent calculations are to improve the Bel V understanding of the modelling approach followed by the operator (e.g. the conceptual model, the main hypotheses, the calculation code), to assess the appropriateness of input parameters (e.g. by performing sensitivity analyses) and to confirm model capabilities (e.g. by using multiple models or codes). Within the framework of the review of safety cases for waste disposal facilities, Bel V notably uses the following calculation tools:

- Contaminant migration: Hydrus 1D/2D, MELODIE (developed by IRSN)

- Geochemical evolution of engineered barriers: PHREEQC

- Radiation protection: MCNPX

Bel V does not develop its own calculation tools for assessing the safety of waste disposal facilities. However, collaboration between IRSN and Bel V allows using the software MELODIE developed by IRSN for the regulatory review of safety assessment for waste disposal facilities.

LEI

The specialists on Nuclear Engineering Laboratory of LEI use various numerical codes and modeling/simulations tools in order to assess the results presented by the operator. The development of the software internally does not occur frequently considering the limited timeframe for the review of analysis, but there are some codes developed by the personnel of Laboratory for the particular analysis. More often the commercial software is used, which could not necessarily be the same as used by the operator.

DECOM

It is case by case. If the contract for reviewing is sufficient to make our own assessment, our experts do it. But more general practice is to review the methodology and data used by operator without recalculation.

SSM

We use numerical codes and modelling/simulation tools in order to assess the calculation results provided by the operator. In addition to in-house modelling we contract external experts to verify the modelling/simulation tools used by the operator as well as other codes to verify the results from the assessments.

CNSC

CNSC carries out independent modelling exercises using different commercial numerical codes and simulation tools that are widely accepted in practice. The codes are selected based on the dataset and modelling capability, and are not limited by the choice of the operator.

The CNSC does not perform extensive modelling of the facility design; only specific technical aspects of the design are checked or verified.

ENSI

Yes, we perform independent calculations to review results of a safety case. Therefore, we use numerical codes and modelling/simulation tools. In general we use tools that are commercially available or widely used. We try to use different codes and tools than the implementer. We prefer to use commercially available codes due to quality assurance.

NRG

No, the review is on a generic level

- How do you guide your choices in the development of research activities? Did you make selections between these too many possibilities: on which criteria did you skip parts of them?

FANC

Needs and priorities for R&D priorities are identified considering the following elements:

- the milestones of the Belgian waste management programme and their associated objectives and decisions;
- the safety requirements established in royal decrees and guides applying to waste disposal;
- the safety issues associated to the safety concept developed by the operator and
- the state of the art.

GRS

The maintenance of competence and independence are key requirements for any TSO and safety authority. Therefore R&D by the TSOs and regulators are obligations that might help to fulfil these requirements. In awareness of this role the GRS as a TSO, performs in a continued way respective R&D work. The R&D work comprises more or less four main areas:

- Development of tools and methods
- Elaboration of safety requirements and criteria
- Guidelines
- Maintenance of competence, education and training

UJV

We focus on all safety important issues particularly, for long-term safety of DGR, except some fields, such as geotechnical, some THMC processes, which are outside of capabilities of UJV experts. But in these are there is a close cooperation with other research organisations. Always it is necessary to make some choice. It is made usually on the identification of uncertainties of safety case issues and their importance determined usually on the basis of expert judgement.

Bel V

The R&D activities of Bel V are primarily related to the development and the maintenance of expertise in nuclear safety and to a lesser extent in radiation protection (the latter being covered extensively by FANC). Bel V's R&D activities are fully integrated in its Quality Management System. Within that framework, Bel V issues about every 5 years a R&D Strategy, a yearly R&D Program (defining Task Leaders and budgets) and a yearly R&D Report. The overall R&D effort foreseen by Bel V has been recently significantly increased to about 10% of the total available time for the technical staff. Within the framework of radioactive waste disposal safety, Bel V participates in international working groups (like IAEA PRISM and more recently IAEA GEOSAF) and previously participated in international projects like 6th FP EC MICADO, 6th FP PAMINA, …

Within the framework of safety disposal of radioactive waste, a two-fold R&D methodology is followed by the Belgian regulatory body. The Key technical issues and R&D priorities are principally identified based on the following elements:

- the milestones of the Belgian waste management programme (see section 5.1) and their associated objectives and decisions;
- the safety requirements established in royal decrees and guidance applying to waste disposal;
- the safety issues associated to the safety concept developed by the operator.

R&D actions are then identified for each key issue. The three main types of R&D actions that may be undertaken can be summarized as follows:

- Literature survey, participation to conferences or international working groups (IAEA, OECD). Such R&D actions are undertaken to cover fundamental issues that are already addressed by the international community.
- Sub-contract to other organisations (universities and research centres). These R&D actions are undertaken to cover specific key issues for which the regulatory body does not have the necessary resources.
- R&D within regulatory body or in collaboration with other organisations (Framework Programmes of EC,…).

The choice of the action type is dictated by the importance and priority of the issue and by the availability of resources and competences within the regulatory body.

LEI

The priorities in the research to be carried out by LEI experts follows the research directions identified in the National Energy Strategy, the national Program for assessing the possibilities of spent nuclear fuel and long-lived radioactive waste disposal. The priorities for the research identified by EC (IGD-TP) are taken into consideration also.

DECOM

We look to develop research in the prospective areas for future requirements of nuclear industry development in Slovakia as well as we need to keep continuity and develop skills we are already experienced in.

SSM

In a general sense, the regulator has limited resources and focus research activities on what we would call "critical issues", i.e. those issues that may prove to be most vulnerable for realizing the project.

CNSC

The Canadian Nuclear Safety Commission also maintains a Research and Support Program to address key knowledge gaps for safety analysis of repositories for nuclear wastes. The knowledge gaps were identified based on: the characteristics of the candidate host rock types and preliminary design concepts; past experience with the Canadian URL and staff expertise; and state-of-art literature and international collaboration.

For example, the current R&D program is focused on attributes of sedimentary rock formations. In the past, CNSC staff have been focused on Precambrian granitic rocks of the Canadian Shield. It is only in 2005 that the applicant has recommended consideration of sedimentary rocks for geological disposal of used fuel.

ENSI

ENSI's review of long term safety includes a review of processes, models, data, scenarios and uncertainties. This identifies the relevant processes and gives input for further research.

NRG

The review competences are based on known experience of the reviewers

Are you carrying out studies in your own analogue sites and/or in the operators' URL (studies may correspond to data collection so as to analyse a specific phenomenon, or so as to evaluate a specific survey method)? If you investigate analog sites, on which criteria did you based on to select them?

FANC

FANC participates on the development and follow-up of in-situ experiments at the Mont Terri rock laboratory (CH) through a collaboration with the Belgian Nuclear Research Centre (SCK•CEN). FANC does not have analogue sites nor carries out studies in URL or investigation sites in Belgium. The key criterion to select the analog sites is the level of transferability of knowledge in terms of phenomenology to potential sites considered in Belgium.

GRS

(cf. answer from UJV)

In former times the Asse salt mine was used as a disposal facility for low and intermediate level waste and as an underground research laboratory. Especially disposal techniques in salt were developed from 1965 to 1995. These techniques included also demonstration tests for the direct disposal of spent fuel e. g. the thermal simulation of drift emplacement, heating tests, construction of a dam and emplacement methods.

Currently the Asse mine is in a decommissioning state.

Some tests and investigations in salt are performed also in the salt mines Bernburg and Salzdetfurth.

UJV

Own analogue studies were conducted on so called Ruprechtov site in cooperation with GRS and for operator. This site is unique in the sense that a granite host rock layer (preference host rock in the Czech Republic) is covered by clay layer. The analyses were conducted to get a deeper understanding of uranium mobilization.

Bel V

Bel V does not carry out investigations in analogue sites or in underground research laboratories.

LEI

There is no any URL in Lithuania or the analogous site currently in relation to the present status of geological disposal in Lithuania.

DECOM

not Slovakian case

SSM

The authority does not conduct studies/experiments in our own facilities. But the authority participates in international research and development projects.

CNSC

There is currently no licensing application for a spent fuel repository in Canada, and one is not expected for 7-10 years. At this time, it is not known where the repository will be located in Canada; therefore the applicant is developing conceptual designs (i.e. models), for two hypothetical sites which are representative of Canadian rock formations.

CNSC staff are participating and contributing to, international research activities at other URLs.

There is currently no operating URL in Canada. A URL was operated in Canada for over 20 years and is in the final stages of decommissioning.

ENSI

ENSI performs its own research in URL in collaboration with university institutes or subcontractors.

NRG

The expectation is that the review is done by a multinational team, bringing in knowledge from various national research programmes.

2.5- Do you (and/or your team) have other habits that contribute to make the review process (often with limited time) more efficient?

FANC

We developed a management tool to streamline the review process by facilitating the treatment of expert's comments (avoiding duplicate, allowing comparisons, analyses, etc.).

GRS

GRS developed guidelines for example the treatment of human intrusion in safety cases and the assignment of scenarios in probability classes which support both the implementer and the reviewer. Another issue refers to the development of criteria for a comparison of disposal sites for heat generating radioactive waste. The relevant objectives are:

- Derivation of criteria to compare different disposal sites in salt and clay
    - o Temperature criteria for the surrounding rocks and aquifers adjacent to the repository
    - o Site specific application of fluid pressure criteria and dilatancy criteria
    - o Gas pressure compatibility of different rocks
    - o Influence of hydrocarbon occurrences
- Derivation of minimum scope of investigations
- Dealing with different scopes and qualities of siting data
- Derivation of robustness criteria

UJV

I do not understand the question properly

Bel V

As described in the response to the question 1.2, Bel V has a horizontal structure in Technical Responsibility Centres (TRCs) gathering experts from various departments and branches or areas into dedicated fields of competences (e.g., "Waste management and Chemistry", "Site analysis, external hazards and meteorology", "Radiation protection, ALARA, radiation measurements", "Fire protection and ventilation", …). The creation of TRCs makes the review process more efficient as it enables the short and medium term management of expertise and resources dedicated to specific aspects of nuclear safety and radiation protection assessments.

To ensure a high level of consistency in the review of safety assessments, Bel V has created a Safety Issue Committee (SIC) which defines common positions on the main nuclear safety issues. The SIC equally arbitrates when strong differences appear in expert opinions during a safety review.

LEI

During the process with limited time we do have practice to report the work done during the weekly meetings, constant update of the summary table of work done (weekly). The knowledge of more foreign languages (English, Russian) contributes to speed up the analysis and preparation of the documentation.

DECOM

If there is a possibility to compare results of reviewed document with various comparable cases or previous assessment, significant differences can indicate ideas where to look deeper for reviewing.

SSM

The Swedish regulatory framework requires nuclear power plant owners to jointly develop a research and development program (on a national basis) and submit an updated program every three years for regulatory review. This process has proven to be crucial in the development of a repository program in the sense of preparatory work.

CNSC

The review process will be made more efficient through early involvement of the regulator (prior to a licence application) (see also response to 2.3) and by developing guidance for the review process, including the early identification of reviewers and expertise. The development of staff review guides (SRG), where time and resources permit, can improve the efficiency and effectiveness of reviews in the subject areas.

ENSI

The sectoral plan implemented the Technical Forum Safety where all stakeholders (in the Swiss case representatives of federal, cantonal and regional authorities, as well as representatives from neighbouring countries) take part. The aim of the forum is to discuss technical questions regarding the geological repository project. These meetings allow ENSI to be aware of the stakeholders' questions early in the process, be able to allocate resources to answer the questions and increase the general acceptance for ENSI's review documents.

NRG

??

3.1- What are you doing step by step during a review process? Do you have an internal guide from your organisation, a questionnaire to guide the analysis, a guide from the regulator or other references? Please briefly synthesise the main outlines of these guidelines. If an English version is available, please attach it to your answer…

FANC

FANC does currently not have an internal guide for the reviewers.

However, FANC is developing the review principles that will be used for the SC of geological radioactive waste disposal in the framework of the B&C programme. Principles for the reviewing as they are briefly given in the answer to question 1.3 will be developed. The purpose is also to refer to the fundamental principles, radioprotection and safety principles and safety requirements developed in the regulation. FANC intends to draw the Table Of Content (TOC) of the safety case, which will be based on the TOC that was developed for the surface waste disposal programme (cAt).

GRS

The above mentioned Safety Assessment Guide was developed in collaboration of the Belgian, French and German Technical Safety Organisations (AVN, IRSN and GRS). This guide includes detailed information about the requirements for safety assessment of nuclear activities, the basis for a safety assessment and the safety assessment process.

Since GRS organised the so called preliminary safety assessment of the Gorleben site all the necessary steps for such an analysis were developed and performed.

UJV

The guides (only in Czech language) were issued by SÚJB for preparation of safety assessments, but these guides do not take into account a new knowledge acquired in last years in a number of IAEA, 6 and 7. RP EU and NEA/OECD projects.

Bel V

Bel V (previously AVN) has participated with IRSN and GRS in the development of the "Safety Assessment Guide" (SAG) that covers the overall safety assessment of nuclear installations. Currently, Bel V does not have a specific guide for reviewing safety case of radioactive waste disposal facilities.

LEI

There is no internal guide in LEI for the review process neither the questionnaire. During the review conducted by TSO some guidance is provided by the regulator usually in terms of task specification. In absence the guidance from the regulator in terms of standard review plan or questionnaire, the current method used by the reviewers is to assess the compliance to the Lithuanian legislation requirements and also the compliance with radioactive waste management principles of the International Atomic Energy Agency (IAEA) and with good practices in force in the European Union Member States.

During the review process the reviewers analyse the content of the documentation, its compliance with the relevant regulatory requirements. The document under review is provided with reviewers comments for each section and a summarized overview.

In principle most of national requirements are based on the IAEA requirements. There is no national legislation for geological disposal yet.

The guidance on the review process with the key issues based on the regulatory expectations would definitely help to perform review more effectively within the limited timeframe and with limited resources. The key issues identified from the regulators point of view should be based on the requirements developed by IAEA mainly as these international requirements and guidance are expected to be incorporated in Lithuanian legislation.

DECOM

There is no special guide for reviewing of safety documentation.

SSM

There is no specific guidance. As a general rule, regulations should not be developed for s specific facility but should be general in character. As any disposal project of an order of magnitude occurs only once, every situation becomes unique and requires a unique approach with due regard to that specific situation and facility.

CNSC

There is currently no licensing application for a spent fuel repository in Canada, and one is not expected for 7-10 years. At this time, it is not known where the repository will be located in Canada; therefore the applicant is developing conceptual designs for two hypothetical sites in representative rock formations. The CNSC is conducting a pre-project design review of the conceptual design and post-closure safety assessment for the two hypothetical sites. The pre-project conceptual design review will verify, at a high-level, that the conceptual design and illustrative post-closure safety assessments meet the requirements with respect to the CNSC regulatory guide G-320, "Assessing the Long Term Safety of Radioactive Waste Management".

The review process is divided into four phases:

Phase 1: Preparatory Activities – Prior to any submission of conceptual designs and related documents, the Canadian Nuclear Safety Commission (CNSC) holds a series of meetings with the applicant to examine the outlines for the conceptual designs and illustrative post-closure safety assessment reports for crystalline rock and for sedimentary rock.

Phase 2: Initial Review – The CNSC makes an initial evaluation of the conceptual designs and illustrative post-closure safety assessment reports for crystalline rock and for sedimentary rock. The CNSC assesses the completeness of the reports and supporting documentation. In this phase, the CNSC may seek more information, if needed, to complete the assessment.

Phase 3: Main Technical Review – In this phase, the CNSC carries out an overall, high-level technical assessment of the documentation provided and goes into further detail with a focus on the long-term safety requirements for a deep geological repository for the long-term management of used nuclear fuel.

Phase 4: Completion – Once the CNSC completes the reviews, the concluding statements will indicate whether or not the applicant has presented sufficient evidence to demonstrate that, at a high level, the conceptual design and illustrative post-closure safety assessments meet the above safety requirements in accordance with G-320, Assessing the Long Term Safety of Radioactive Waste Management.

ENSI

ENSI has a specific guideline on specific design principles for deep geological repositories and requirements for the safety case (ENSI-G03). In general, guidelines are support documents that formalise the implementation of legal requirements and facilitate uniformity of implementation practices. They further concretise the state-of-the-art in science and technology. The guideline ENSI-G03 applies to deep geological repositories. It specifies the applicable protection objective and protection criteria and the requirements applying to a deep geological repository. It also sets out the details of the procedure to be followed for demonstrating the safety of a geological repository. This guideline is also a base for the review of ENSI. (See enclosed English document)

NRG

1 Description of the expertises required for the review

2 Selection of the experts

3 Providing documentation and support to the selected experts

4 A sequence of expert meetings and hearings

5 Writing review report

3.2- For international/European references (as "requirement" or as "guidance" guides), I have collected the followings, but do you have others to suggest?

FANC

For international/European references, three types of guidance might be distinguished:

1. guidance on the interpretation and implementation of the safety requirements;
2. guidance on how to prepare and organise a safety review, in terms of identification of needs, development of competences, and assignment of resources…, and
3. guidance on how to conduct a safety review of a SC or part of a SC, for which different aspects can be enhanced or not as (a) the reviewing approach, (b) the general expected content of a SC and (c) detailed procedure for specific technical aspects of a SC.

<u>References for guidance of type 1</u>

For guidance of type 1, one refers, to the "Questionnaire on Existing, Used & Needed Guidance" elaborated in the framework of SITEX WP 2.1, which provides a compendium of the existing main requirements.

<u>References for guidance of type 2</u>

- Safety Assessment Guide (IRSN, GRS & AVN, 2004). This safety assessment guide can provide some interesting elements guidance of type 2. It is also complementary to recommendations of IAEA (2010) GSR Part one on the Governmental, legal, and regulatory framework for safety : general safety requirements.

- IAEA Specific Safety Guides on regulatory bodies functions (2002). Several specific guides of IAEA Safety Standard Series address indeed specific issues related to the organisation by the regulatory body as a.o. GS-G-1.1 on organisation and staffing of the regulatory body and GS G 1.4 on documentation relating to the regulatory process.

<u>References for guidance of type 3</u>

- EPG (2011-DRAFT) Regulatory review of a safety case for geological disposal of radioactive waste Report on the European Pilot Study, Version of 26.11.2010 for consultation. This report, which is a preliminary version of the deliverable of the European Pilot Group project, has been reviewed by stakeholders and should be finalized soon. It proposes a common view on what are the typical elements of SC. It focuses on the different steps that can be considered in the development of a final SC and sets out what the regulators expect at each of these steps (guidance of type 3b).

- NEA. (2004). Post-closure safety case for geological repositories: Nature and purpose. NEA publication 3679, Issy-les-Moulineaux, FRANCE. This document presents the elements to consider in a safety case of a geological disposal and is considered as useful reference. It has been considered as a base as well in the EPG report 2011-Draft (guidance of type 3b).

- IAEA (2008-Draft) DS355: The Safety Case and Safety Assessment for Disposal of Radioactive Waste, mainly as establishing the TOC of the SC, Draft of 2008-08-01.This reference is as well worth to mention although it is not in a final form, for its presentation of the main elements to consider in a safety case for all types of radioactive waste disposal facility and its guidance in on how to document the safety (guidance of type 3b)

WENRA (2012-Draft) : Radioactive Waste Disposal Facilities Safety Reference Levels Report currently developed by the WENRA Working Group on Waste and Decommissioning (WGWD), version 1.2 of 2012-02-29, Annex 2 on the content of a safety case. Next to the list of safety requirements to consider (see WP 2.1) this report proposes indeed a typical Table Of Content of a SC (guidance of type 3b).

- NRC "Standard Review Plans" (SRP). There are numerous SRP that are developed by the NRC, which provide very detailed guidance in the review process and specific technical aspects. Although there is no SRP specifically developed for geological radioactive disposal facilities, one can find similarities with those developed for other nuclear installations or for the waste determinations (guidance of type 3b and 3c).

- IRSN, GRS & AVN (2004) Safety Assessment Guide. This reference provides interesting input considering approach and outlines of a safety review. It is a.o. based on IAEA Safety Guide N°GS-G-1.2: "Review and Assessment of Nuclear Facilities of 2002 worth to be mentioned as well.

GRS

W. Weiss, C-M. Larsson, C. McKenney, J-P. Minon, S. Mobbs, T. Schnei-der, H. Umeki, W. Hilden, C. Pescatore, M. Vesterlind, ICRP PUBLICATION 122, Radiological Protection in Geological Disposal of Long-lived Solid Radioactive Waste, 2013

IAEA, Disposal of Radioactive Waste, Specific Safety Requirements No. SSR-5, 2011

IAEA, Geological Disposal Facilities for Radioactive Waste, Specific Safety Guide No. SSG-14, 2011

IAEA, The Safety Case and Safety Assessment for the Disposal of Radio-active Waste, Specific Safety Guide environment, No. SSG-23, 2012

UJV

A number of NEA/OECD documents, particularly the last one (under preparation) prepared in the framework of MeSA project, are very useful as a guidance (

Bel V

The above mentioned documents are used as a basis for the review of safety assessments devoted to waste disposal facilities. In addition, the following documents are considered by Bel V:

- IAEA-DS355 (The Safety Case and Safety Assessment for Radioactive Waste Disposal, in publication by IAEA)

- EPG report 2011-Draft (Regulatory review of a safety case for geological disposal of radioactive waste Report on the European Pilot Study)

- WENRA (Radioactive Waste Disposal Facilities Safety Reference Level Report: Draft 2012)

- NRC "Standard Review Plans"

LEI

The requirements for the Safety Case and its components are listed in the IAEA publication "IAEA Safety Standards, Disposal of Radioactive Waste, Specific Safety Requirements SSR-5", 2011 as mentioned. The requirements and components of the safety assessment supporting the Safety Case are defined in IAEA publication "Safety Assessment for Facilities and Activities", General Safety Requirements, Part 4, 2009.

The guidance and recommendations relating to the development and regulatory control of the facilities for the geological disposal of radioactive waste to meet requirements established in IAEA SSR-5 are presented in the IAEA Specific Safety Guide No. SSG-15 "Geological Disposal Facilities for Radioactive Waste", 2011. Some recommendations are provided for the development of Safety Case and for safety assessment there also.

In the draft of IAEA Safety Guide "Safety Case and Safety Assessment for Disposal of RadWaste, DS 335" , 2011, the guidance on how to assess, demonstrate and document the safety of all types of radioactive waste disposal facility is provided. As it is indicated, this guidance is relevant for operating organisations which bear the responsibility to prepare the safety case as well as for the regulatory body, which is responsible for developing regulations and regulatory guidance that determine the basis and scope of the safety case. To further support regulatory processes, the Safety Guide also provides guidance on the review by the regulatory body of the safety case.

The approaches for the safety assessment developed in the IAEA publications (Safety Assessment Methodologies for Near Surface Disposal Facilities (ISAM), Vol. 1. Review and enhancement of safety assessment approaches and tools, Vol. 2. Tests Cases (2004); Application of Safety Assessment Methodologies for Near Surface Waste Disposal Facilities (ASAM) (2000)) are now integrated into the broader context of the safety case.

Thus our suggestion would be to include the following IAEA publications into the consideration within the SITEX project:

1. IAEA General Safety Requirements "Safety Assessment for Facilities and Activities", Part 4, 2009.

2. IAEA Specific Safety Guide No. SSG-15 "Geological Disposal Facilities for Radioactive Waste", 2011.

3. Draft of IAEA Safety Guide "Safety Case and Safety Assessment for Disposal of RadWaste, DS 335", 2011.

WENRA Safety Reference Levels developed for disposal in 2009 (draft) and which are in the finalization stage now should be considered also as Lithuanian State Nuclear Power Safety Inspectorate is a part of this association and participates in its activities.

3.3- What were the tables of contents of your last main general review reports on geological disposal project? At which step did they correspond (siting or previous one, design, licensing, construction…?)

FANC

FANC did not yet produced safety review on geological disposal of radioactive waste.

GRS

GRS has not reviewed a comprehensive Safety Case for a disposal facility so far. But GRS is involved in periodic safety reviews e. g. the assessment of the Morsleben repository permanent operation license. This assessment is required on an every five years basis. Furthermore, GRS provides expertizes to specific approval documents of the operator.

UJV

No review of a safety assessment of DGR has been made.

Bel V

Bel V has not reviewed a safety case for geological disposal yet.

LEI

Considering the early stage of Lithuanian national program on SNF and long-lived radioactive waste disposal, the Safety Case for geological disposal has not been developed yet.

DECOM

/

SSM

Not applicable. The most recent report is from 1989 and out-dated. Periodic safety reviews has been carried out but is not representative in this context.

CNSC

Please refer to response 3.2.

ENSI

2005: Review of demonstration and feasibility of a repository for high-level waste (before siting)

- Introduction
- Assessment of siting area (geology, hydrogeology, long time evolution, erosion)
- Assessment of feasibility (engineering/construction, operation, retrievability, monitoring and closure)
- Assessment of long term safety (methods of the safety case, waste inventory, engineered components, multiple barrier system, scenario analysis, biosphere modelling, radiological consequences)
- final conclusions of the review

2010: Safety Review of stage 1 of the site selection process (The siting process is composed of three stages in Switzerland: Stage 1) Identification of sites in the selected siting regions, Stage 2) Selection of at least two sites, Stage 3) Site selection and general licence procedure)

• Introduction

• Allocating the waste to the L / ILW and HLW repositories

• Defining the safety concept and quantitative and qualitative requirements

• Identification of suitable large-scale geotectonic units

• Identification of potentially suitable host rocks and effective containment zones

• Identification of suitable configurations

• Final conclusions of the review

NRG

Nothing

3.4- Finally, to begin the reflections (with WP 2 in May) on the expected levels in operator's report for each step of the project, a first step could be to agree on the main steps of a project.

- What about the IAEA ones (e.g., SSR-5): development (siting, design, construction), operation, closure? Do you need to refer to other intermediate steps?

FANC

We recommend starting from the list of elements that were presented in the framework of the EPG project, as explained in answer to question 3.1.

GRS

The specified steps in IAEA safety requirements are appropriate.

UJV

In the Czech Republic the following reports are needed to get approval of regulatory body in various DGR development phases:

1) Initial safety report, which is part of documentation to get permission to site radioactive waste repository.

2) Preliminary safety report, which is part of documentation to get permission to construct a repository.

3) Preoperational safety report, which is part of documentation to get permission to enter various operational phases of a repository.

4) Closure report, which is part of documentation to decommission and close repository

Another safety reports are needed for approval of any changes in approved design od a facility.

Bel V

Bel V agrees with the main steps defined by IAEA for a project of geological repository

LEI

The steps identified in IAEA documentation are applicable.

SSM

We think staging/phasing should be less emphasised as regards link to specific activities, as many activities may occur in parallel. The proposed concept (KBS-3) for spent fuel disposal in Sweden involves design, construction, operation and partial closure to occur in parallel over many decades. We do not oppose staging/phasing as such but we suggest a terminology that refers more specifically to hold-points rather than phases.

ENSI

A simplified schematic representation of the processes involved in planning, construction, operation and closing of a deep geological repository is given in the Regulatory Guideline ENSI-G03:

NRG

Even in the pre-siting stage, it is important that work financed by the operators is reviewed

- At which stage is the disposal project in your country?

FANC

In 2010, ONDRAF/NIRAS developed a Waste Plan proposing that high-level and/or long-lived radioactive waste be disposed of in a unique repository located at depth in a poorly indurated clay formation, on the Belgian territory. ONDRAF/NIRAS considers that the start of the implementation of this Waste Plan should be approved by the Federal government through a decision-in-principle setting a clear policy for the long-term management of high-level and/or long-lived waste in Belgium. In March 2012, the decision of the government to accept the Waste Plan is still pending.

Exchanges are however organised between FANC and ONDRAF-NIRAS in the frame of the preparation and the review of the first pre-licensing SC to be submitted in 2015, of which the objective will depend on the government's decision.

GRS

Disposal facility for HLW (Siting phase):

With the adoption of the Site Selection Act (Standortauswahlgesetz – StandAG) in July 2013, a repository site is to be selected, in particular for high-level radioactive waste, in a transparent procedure on the basis of scientific criteria until 2031 that ensures "best possible safety" for a period of one million years. There will be no pre-selection of certain host rocks or site regions.

Dispsoal facility Konrad (Construction phase):

In May 2002 the Konrad mine, a former iron ore mine, has been licensed for disposal of alpha-bearing low and intermediate level waste with negligible heat generation. This plan approval became final in April 2007 by court decision.

At present the construction of the Konrad repository for low and intermediate level waste proceeds. First new buildings have been erected and existing constructions have been altered for continued use. Underground drivage has been continued to prepare the first emplacement drifts. Revision of the existing detailed planning to ensure compliance with rules and standards is ongoing. Start of operation is planned 2019 earliest.

Dispsoal facility Morsleben (Decommissioning phase):

The Morsleben repository (ERAM) was in operation until September 1998. An amount of approximately 37.000 cubic meter of low and intermediate waste was emplaced in the Morsleben disposal. Now the plan-approval procedure for the decommissioning of the Morsleben disposal is in the final stage. In October 2011 the public hearing relating to the objections took place. Decommissioning can only start once the plan-approval procedure for the decommissioning of the ERAM has been completed. It is expected, that the plan-approval procedure will finish in the year 2014.

Disposal facility Asse (Retrieval and decommissioning phase):

Until 1978 the Asse salt mine was used as disposal facility for low and intermediate level and as an underground research laboratory. An amount of 47.000 cubic meter waste has been emplaced. Since 1988 the mine is jeopardized by a groundwater inflow of about 12 cubic meters per day actual. The mine is under ongoing deformation, roof and pillars are weakened.

In 2010 the decision for full retrieval of all emplaced radioactive waste was taken by comparing the advantages and disadvantages of different options (retrieval, relocation, or complete backfilling). A compilation of facts for the retrieval has started. Reopening of two chambers is planned.

Multiple measures for operational safety and radiation protection needed to be in place before compilation of facts can start. For the full compilation of facts including drilling, opening the two chambers and testing the handling of the barrels with radioactive waste three years were planned originally.

The recent experiences of the Federal office for Radiation Protection show that the collection of facts takes much more time than previously expected.

UJV

Concept – siting phase

Bel V

Based on the RD&D performed until 2011, ONDRAF/NIRAS has developed a Waste Plan recommending the option of geological disposal for high-level and/or long-lived radioactive waste. This Waste Plan has been submitted to the federal government for a decision-in-principle, in order to set a clear policy for the long-term management of high-level and/or long-lived waste in Belgium. In March 2012, the decision of the government was still pending.

If the government approves the principle of a geological disposal, the next milestone of the high-level and/or long-lived waste disposal programme will be the development of a first "Safety and Feasibility Case" (SFC 1), planned in 2015. The SFC 1 will consider the construction of a reference disposal system in a definite zone of the Boom Clay formation. The Ypresian clay formation will be considered as an alternative host formation, with fewer details. The main objective of the SFC 1 is to substantiate that the proposed disposal system ensures a high level of operational and long-term safety. Based on the outcomes of the SFC 1, it will be considered whether to launch the siting phase.

A second Safety and Feasibility Case (SFC 2) is expected to be finalised around 2020. The SFC 2 will be site-specific and will provide evidence that no major safety or feasibility issues prevent the implementation of the geological disposal facility. Based on the SFC 2, it will be considered whether to prepare the licensing application.

LEI

The current SNF management concept in Lithuania foresees dry storage of SNF bundles for about 50-100 years. During this time the final SNF management concept shall be developed. The revised Strategy for Management of Radioactive Waste (approved by Lithuanian Government in 2008) indicates three potential options for management of SNF after interim storage:

- - Disposal in the national repository.

-- Disposal in the EU established regional repository

-- Transfer to other country which possesses suitable SNF management technologies and can take full responsibility for management of the waste.

If the international policy regarding to SNF transfer to other countries will not change and new SNF management technologies will not be developed, at earliest in 2030 the Lithuania will start siting process for the national repository. Also the alternative to prolong interim storage of SNF will be considered (depending on status of containers and storage facilities).

Currently Lithuania is at the early stage of geological repository development program.

In Lithuania, the national research program (2003-2007) and its updated version (2008-2012) managed by RATA (Radioactive Waste Management Agency) for assessing the possibilities of spent nuclear fuel and long-lived radioactive waste disposal were established. The research conducted with the assistance from Swedish experts (2000-2005) showed both, the Triassic clay formations, and the crystalline basement rocks to be promising. The two geological media merit further studies.

The results and conclusions of the work done in 2003-2007 were taken into consideration during the preparation of the national Program for 2008-2012. The following aspects foreseen to be carried out also:

-- Analysis of the possibilities of managing radioactive waste through joint efforts of several countries;

-- Feasibility study of borehole disposal of spent sealed sources;

-- Analysis and synthesis of information about spent nuclear fuel and other long-lived radioactive wastes, and assessment of properties important for disposal of these types of waste;

-- Updating a concept of disposal of spent nuclear fuel and long-lived radioactive waste;

-- Development of detailed geological investigation programme, development of database of geological investigation results;

-- Performance of studies of geological formations in the Ignalina NPP region (in situ, laboratory tests), analysis of geological survey, identification of prospective geological formation;

-- Safety assessment of geological repository for SNF and intermediate level waste (ILW);

-- Updating the estimation of costs related to implementation/construction of repository.

The program of necessary geological studies was elaborated in "Geological Investigations Program for Possible Underground Disposal of Long-lived Radioactive Waste" in 2011.

ENSI

Switzerland is in the site selection process at the beginning of stage 2 (see enclosed PDF sectoral plan (SGT))

NRG

Pre-siting stage

- For these project steps, what state of knowledge do you expect in the operator's SC?

FANC

Again, one recommends referring to the EPG project (see answer to question 3.1).

GRS

A sufficient state of knowledge is expected in the different states of the disposal projects according to the underlying requirements and regulations.

UJV

The state of knowledge required for siting and construction phase was summarised by SÚJB experts in 2003 and 2004. In the initial to get permission for construction, the design of a repository must be described in detail. Safety assessment requirements for both phases are described, however, only generally. In our opinion these guides do not reflect the current knowledge acquired recently and included in the documents mentioned

Bel V

The state of knowledge described in the IAEA-DS355 and in the EPG report 2011-Draft (see response to question 3.2) for the main project steps will be used as a basis to define the regulatory body expectations.

LEI

The state of knowledge corresponding to the regulators's expectations (key issues) at particular stage is expected in operators Safety Case. The regulators expectation should be in agreement with the common expectations from regulatory body for particular stage of the project.

ENSI

For the licence applications for a geological repository (general, construction and operating licences) and the application for closure of the repository, the Nuclear Energy Act requires a safety case to be provided for the operational phase (demonstration of operational safety) and the post-closure phase (assessment of long-term safety) of the repository. A further safety case has to accompany the application for the confirmation of final closure. The required degree of detail of the safety case depends on the stage of the licensing procedure. The safety case has to be updated periodically to reflect the current condition of the facility and the state-of-the-art in science and technology.

For stage 2 we specified our requirements for the safety analysis in a document. Unfortunately it is only in German. However there is a short summary written in the sectoral plan (document of the site selection process):

For the sites identified in step 1, the waste producers then carry out quantitative provisional safety analyses. Based on the planned waste inventory and the properties of the engineered barriers and the host rock, these safety analyses have to provide information on

• the retention properties of the system as a whole (engineered and geological barriers and their interaction) and the maximum dose from realistically expected releases

• the contribution of the geological barrier to long-term safety and

• the long-term behaviour of the barrier system.

Together with the results of a qualitative assessment of other safety criteria and aspects according to the conceptual part of the sectoral plan (SGT) (Table 1), the results of the provisional safety analyses lead through an overall evaluation to proposal of at least two sites each for HLW and L / ILW. When preparing the proposals, the waste producers have to consider the following:

• The site has to fulfil dose protection objective of 0.1 mSv / year.

• No site can be proposed as an interim result if, based on a provisional safety analysis, it has been assessed as being clearly less suitable than the others. The evaluation and comparison of sites has to follow a standardised procedure.

Provisional safety analysis (stage 2)

Objective: The provisional safety analysis aims to provide information on the functioning and behaviour of the individual barriers and to show that the calculated doses lie below the protection objective of ENSI-G03. Numerical calculations form part of the provisional safety analysis for the site in question. The results allow sites to be compared in terms of safety and give indications of the investigations that will be required in stage 3 to achieve the level of data certainty required for a general licence application.

Content: Based on the disposal concept and taking the defined waste inventory and available technical and scientific data into account, the provisional safety analyses required in stage 2 must provide information on:

• the retention capacity of the overall system (engineered and geological barriers and their interactions) and the maximum dose from realistically conceivable releases (reference scenario)

• the contribution of the geological barrier to long-term safety

• the long-term evolution of the barriers.

The potential release of radionuclides (migration from the repository to the biosphere) is determined quantitatively in the provisional safety analysis. The analysis is based on a defined waste inventory and founded assumptions and empirical values for the properties of the engineered and geological barriers. The dose to an individual person is calculated taking into account water flowpaths in the biosphere and possible uptake of radionuclides via drinking-water and foodstuffs. The measure for safety is the value of 0.1 mSv / a in the ENSI-G03 Guideline.

Additional aspects of system behaviour and robustness are to be taken into account in the analysis. This is understood to include the following:

• Variability and uncertainties in the parameters used in the modelling and their influence on dose calculations

• Sensitivity of the calculated dose to system behaviour that deviates from expectations.

• Reliability of spatial and temporal predictions (explorability, predictability, reliability of data).

Comparison of sites (stage 2)

As an interim result in stage 2, no site can be proposed that, based on the provisional safety analysis and other safety aspects, would be evaluated as clearly less suitable than the others. At the same time, sites may not be ruled out because of differences in dose arising only from uncertainties in the underlying data.

For the safety-based comparison of potential sites, a standardized procedure is required that takes into account the quantitative results of the provisional safety analyses as well as the qualitative aspects of the safety considerations. The comparison consists of the following elements:

1. Presentation of the quantitative results of the release calculations for the realistically expected evolution of the repository (reference scenario, personal dose curve with time).

2. Discussion of the robustness of the repository system with respect to internal and external perturbations and identification of uncertainties / variabilities in the parameters used in the modelling and the influence of these on the dose curve.

3. Evaluation of other (qualitative) criteria relating to safety and technical feasibility (e.g. reliability of geological information, possible degradation due to erosion). Other qualitative safety indicators (e.g. residence or containment times of natural tracers in the porewater of the host rock) are to be taken into consideration where available.

The comparison of the sites in terms of safety is done first using the method described in the sectoral plan (SGT), which also includes a comparison of numerical calculations. The expected evolution of the whole system (repository, near-field, geosphere) and its robustness and the uncertainties and variability in the quantitative parameters are taken into account. Sites that emerge from this comparison as being clearly less suitable than the others or do not fulfil the dose protection objective are ruled out.

The remaining sites are then evaluated using the qualitative safety criteria (under point 3). A site can be excluded if clear disadvantages compared to the other are identified at this stage.

NRG

The statement in the operators generic SC should be “to the best of our knowledge, safe disposal of radioactive waste is possible in The Netherlands”.

4.1. In the *Safety Assessment Guide* from AVN, IRSN and GRS, one of the listed required qualities of the expertise body is “transparency and traceability of the process” (quality assurance): Do you systematically record all elements having an influence on the result of the assessment? For TSO organisations, do you communicate with the safety authority after the delivery of the safety assessment report to exchange information and to collect feedback and possible complaints?

FANC

As regulatory body, in the pre-licensing phase, FANC systematically records during the examination of the SC reports all types of comments provided by the experts (general ones and specific ones) and their link to the reviewed document. These comments are as well reviewed and validated by other experts. From this list, the most relevant comments being validated are selected and used as basis for the formulation of general and specific official comments that are published in documents in the form of advice.

This advice is officially transmitted to the operator and can be the subject of meeting or dialogue.

GRS

1° Yes

Elements which might have an influence on the outcome of a safety assessment are to some extent the result of a systematic scenario development. This includes also a comprehensive collection of relevant Structures, Systems and Components. Those elements are systematically recorded.

2° Yes

The communication of regulators, TSOs and implementer should be an on-going task before, during and after providing a safety assessment report.

UJV

Safety assessments of near surface repositories prepared by RAWRA (operator) have been reviewed only by Czech regulatory body staff without any further experts from UJV or other research institutes.

No review of safety assessment of DGR prepared by operator has been made so far by regulatory body or by UJV.

Bel V

In order to ensure a high level of transparency and traceability, Bel V systematically records all elements having an influence on the result of the assessment. As specified in the Bel V QS system, these elements are recorded in internal Safety Analysis Documents (SAD).

As mentioned in question 2.3 (see first questionnaire), Bel V is notably responsible for performing regular inspections during operation of nuclear facilities in order to verify the compliance with the licenses, as well as to ensure that a high level of nuclear safety is maintained. Within the framework of this mission, Bel V always favours constructive exchanges with the operators to examine topics that are controversial or which require additional information. Such exchanges will also be favoured before, during and after the review of the safety case for the geological disposal facility.

LEI

Safety Case of geological repository has not been prepared and reviewed yet in Lithuania. Based on the experience in the previous safety assessment of near surface repositories, other nuclear facilities it could be mentioned that the quality assurance plan is usually developed at the beginning of project. Typically the documentation is systematically updated and the records (i.e. comment resolution sheets) are kept to be capable to trace all changes. As prepared documentation is submitted to the regulator LEI experts communicate/discuss/update it in order to get the approval from the regulatory body (if WMO is subcontracting LEI for development of safety assessment).

NRG

Transparency and traceability of the process

Systematically record all elements

In The Netherlands, at present the TSO services are delivered on limited project and contract conditions. The authorities keep records in a „dossier‟. Depending on the project or dossier, records are maintained for 5 to 20 years. Presently there is no long term systematic record of all elements of the process.

Communicate with the operator

Until recently the Dutch WMO (COVRA) was not involved in the Safety Assessments which were carried out in the past, i.e. up to the year 2000. At present, the WMO is facilitating the new Dutch research program OPERA („Onderzoeks Programma Eindberging Radioactief Afval‟ – Research Programme for the Disposal of Radioactive Waste), but the program is financed by the Dutch authorities and the utilities. This is in our view a normal situation for the early stages of the disposal process, in which the feasibility of the deep geological disposal has to be assessed and concepts are developed.

4.2. What are the required qualities of experts involved in assessment? Do you agree with the following list (from *Safety Assessment Guide*)?

- Independent, neutral,
- Trustworthy, fair, sincere, honest, discrete, open-minded,
- Competent technically in its domain and/or in managing a team of experts
- Competent in drawing-up an assessment report: be able of drawing conclusions based on reasoning and logical analysis + describing situations and complex phenomena in comprehensible verbal or written forms
- Aware of the relevance and importance of its activities and of how he contribute to the achievement of the assessment
- Capable of understanding, observing, analysing, discerning, persevering and taking different points of view into consideration

FANC

FANC agrees with this list.

A distinction could be made between the technical competencies and additional skills.

A good knowledge of the international and national regulation and recommendations is also strongly recommended.

A thought on the way to ensure and demonstrate that these competencies and qualities are fulfilled might be interesting.

GRS

Yes

From our point of view the list seems to be comprehensive.

We would like to add the aspects that the involved experts should have sufficient experience in such assessments and that he or she should be a national and/or international acknowledged expert.

UJV

I agree with this list. Here I would like to emphasize also a very important role of generalists that should have a very good experience with performing safety assessment studies from past.

Bel V

Bel V agrees with this list of qualities. According to Bel V, the experts panel should be composed of both generalists and specialists experts, since experts specialized in specific competences such as chemistry, geology, hydrology,… will review a safety assessment with a different view as generalists experts. These complementary perspectives are enriching and will allow performing comprehensive safety reviews.

LEI

Besides listed qualities the experts need to be diplomatic, to have experience in this area (developing safety case, reviewing safety case), keeping his knowledge up-to-date (in technology, regulatory requirements), increasing his competence, to know foreign languages.

DECOM

I do not think that there are extraordinary requirements on expert for DGR case comparing experts in any other area. What I am missing from the list is cooperative attitude and teamworker.

NRG

All of them, since these qualities are supposed to be common in general for experts and scientists Note that most of these qualities cannot be verified, and that personalities are not "black or white", e.g. with respect to competencies. Also, some qualities, such as independency, depend not only on the expert, but also on the environment in which the expert is operating.

4.3. Which hazard assessment do you expect for in a SC of geological disposal, during operational phase? And during the post-closure phase? If you want, you can complete or modify the following list:

operational phase: earthquakes, flooding, environmental risks, fire & explosion, criticality, dynamic and static containment failure, radiolysis and thermal effects, ventilation, handling, power supply failures…

post-closure phase: earthquakes, physical-chemical conditions of exceptional amplitude, criticality, climatic events, future human actions…

FANC

As regulatory body FANC does not impose an exhaustive list of hazards and processes to consider in the assessment but asks to the operator to identify all possible internal and external events and processes that might affect the safety of the disposal system and in a second step to analyse them according to their impact on the safety functions and in general on the safety assessment. It has to include hazards related to construction as deviation from the expected construction must cover human and non-human induced hazards and processes.

This is asked in general through requirements within:

- the Royal Decree on the safety of nuclear installations (PSIN/VVKI-GEN: chapter 1 & 2: generic for all types of nuclear installations published on 31-12-2011 and PSIN/VVKI-Disposal: chapter 4: for waste disposal being submitted).

- the DRAFT guide on Post-closure safety analysis of waste disposal (SAR) of 2012-02-28.

GRS

Operational phase: Yes

(According to Chapter 7.1 of (BMU))

A comprehensive safety case shall be documented for all operating states of the repository, including the surface facilities. In particular, facility-specific safety analyses shall be conducted for emplacement operation and decommissioning, with due regard for defined design basis accidents, which should verify the protection of operating personnel, the general population and the environment as required by the Radiological Protection Ordinance.

Post-closure phase: Yes

A comprehensive, site specific safety analysis and safety assessment covering a period of one million years must be carried out to provide evidence of long-term safety. This shall comprise all information, analyses and arguments verifying the long-term safety of the repository, and shall justify the reasons why this assessment is to be trusted (BMU).

In the future it should be checked if there are any topics for consideration in this project which deviated in assessment of the Fukushima accident (see e.g. Para 37, 59 and 61 of IAEA JC/RM4/04/Rev.2)

UJV

The following initiation events and hazards have been considered during operational phase:

1) Part failure of power supply
2) Full failure of power supply
3) Flooding
4) Failure of rock wall due to structure instability
5) Landslide on the access tunnel portal
6) Earthquakes

7) Fire and explosion
8) Ventilation failure
9) Failures during transport of waste packages
10) Failures during handling of waste packages

In post-closure period the following initiation event have been considered

1) Earthquake with immediate failure of different number of waste packages
2) Denudation leading to erosion of repository overburden and shortening of preferential paths
3) Human error leading to premature failure of waste packages
4) Human error leading to premature failure of buffer around waste packages
5) Human intrusion leading to exposure of workers
6) Human intrusion leading to immediate failure of one waste package

Bel V

Bel V agrees with this list of hazards. However, Bel V would like to stress that hazards identified for the operational phase may have an impact on the post closure safety. For instance, a fire that occurs during the operational phase may change the host rock properties on a certain thickness and therefore affect the radionuclide migration during the post closure phase.

LEI

For operational phase some of hazards are expected to be similar and could be evaluated using the same methodology. However for the post-closure phase due to long-term effect (difference in time frame) the same methodology could not be used (for example, for aging management, screening of events based on the probability of its occurrence, impact of earthquakes, climatic events on the geological repository).

NRG

SC for operational phase geological disposal: not applicable yet in the Netherlands. All topics are relevant to address. Since a facility is expected to be in operation for a long time, consideration should be given to the consequences of societal and political disturbances for the safe operation of the facility, including a possible unforeseen abandonment of the facility In particular, there should be fail safe operation options for the operator.

SC for post-closure phase geological disposal: In the Netherlands all topics are relevant to address. The SC must systematically explore all potentials that may affect the long term safety, e.g. through a FEP analysis, and subsequent scenario evaluation.

- For each of the above identified hazard, do you think that it may be assessed the same way as for other (already existing) nuclear facilities? If differences exist, please detail it and indicate if research is needed.

Do you have a guide for assessing each of these identified hazards? National or international guide?

FANC

There are similar aspects to consider as e.g. the different steps in the analysis.

It is indeed asked to first consider a list of events and processes that might impact the safety, which must be as exhaustive as possible. It is asked to analyse and screen these events and processes categorized according to their origin considering their probability of occurrence and their type of impact on safety (a.o. specific safety functions or other elements of the safety).

The main difference relies obviously in the screening of these events and processes for the long term in the fact that one must deal with increased probability of occurrence and of combination of events and processes as well as increased uncertainties and where, after the oversight phase, one cannot rely on human intervention.

There is no guide at the national level, used for assessing each of these identified hazards in the framework of geological waste disposal.

GRS

Operational phase: Yes

Remark:

According to BMU, the operation of the final repository shall be measured against similar requirements as the operation of other nuclear facilities.

Post-closure phase: Yes

Remark:

This applies only for nuclear facilities which take the geological disposal of radioactive waste into account due to the long post operational period.

UJV

For operational safety assessment there is a combination of mining safety analyses and nuclear facilities analyses. There difference, but it is difficult to detail them with current knowledge probably more detailed research is needed.

For post-closure period the use of common approaches for nuclear power plant is probably limited, but further research is needed.

Bel V

Considering the specific character of geological disposal facilities (GDF), the hazard assessment for the operational phase will contrast with that carried out for existing nuclear facilities. The hazard assessment for GDF is at the boundary of that conducted for deep uranium or conventional mines, for other underground repositories (for short lived nuclear LILW or for certain non-radioactive wastes) and for other nuclear facilities.

LEI

The hazards related to the earthquakes, climatic events may results in different impact on the geological repository thus different methodology could be applied.

DECOM

This is very wide question. I think that NEA list of Structures, Systems and Components is more or less complete and it is difficult to add something more.
We are not in stage of identifying of hazards for DGR.

NRG

On an abstract level the assessment may be the same; some kind of harmonisation is sensible and desirable. However, the weight of the hazards is often very different for different facilities. In addition, the time scales of geological disposal are much longer than the time scales relevant for e.g. nuclear reactors. This fact enhances the probability of occurrence of the hazards. The impact of the hazards will be very different though, since the repositories are not located on the earths‟ surface.

- For hazard assessment, what is the regulation about probabilistic or deterministic methods?

FANC

For the analyses of the events and processes that might affect the safety a deterministic method is usually proposed for all events that have a probability higher than 10^{-7}/year (PSIN-GEN and RPC-OP: Guide on the radiological protection during the operational period of a facility for the disposal of radioactive waste, published on 2008-12-11).

The method used in the analysis of the consequences might although be deterministic or probabilistic or a combination of both methods (PSIN-GEN).

GRS

Reference (BMU) requires assessments in the operational phase and post operational phase.

Operational phase: Chapter 7.1 of (BMU)

The relevance of analysed failures to operational safety must be investigated using probabilistic methods.

Post closure phase: Chapter 7.3 of (BMU)

For a numerical analysis of the final repository’s long-term behaviour with respect to integrity of the isolating rock zone, radiological consequences etc. deterministic calculations should be based on the most realistic modelling possible (e.g. median values as input parameters).

Additionally, uncertainty and sensitivity analyses must be carried out in order to highlight the potential solution space and be able to estimate the influence of uncertainties.

UJV

Probabilistic methods are in the Czech legislative for assessments of repositories recommended only for future human actions.

Bel V

There is no requirement on the approach (deterministic or probabilistic) to follow for safety assessments. The deterministic approach is generally favoured by operators, whereas complementary probabilistic calculations may be provided.

LEI

For existing nuclear facilities (nuclear power plant, storage facilities) the deterministic and probabilistic approach could be used. In case of geological disposal there is no regulatory requirement on the approach in Lithuania.

NRG

For hazard assessment, regulation requires that the risks are below a given level, implying probabilistic methods. To assess the potential radiological consequences of normal operation of the facility, methods are initially deterministic. However, uncertainties in the radiological consequences of the normal operation (e.g. because of the long time scale) are usually addressed in a probabilistic approach.

4.4. Modelling:

- Which kind of model do you/your organisation develop:

- Process models (in the framework of phenomenological research) or detailed models (of sub-systems or to predict the evolution of the repository system)

- Integrated models (using data from detailed ones) to perform consequence analysis for selected scenarios, to analyse radiological consequences (safety indicators), for performance assessment?

FANC

Both types of models can be developed.

GRS

The simulation and modelling of processes relevant to deep geological disposal systems requires a broad range of numerical tools. Several thermal, mechanical, hydraulic and chemical processes and their interactions have to be considered which calls for sophisticated software that is capable to simulate coupled processes.

Codes for the simulation of flow and transport processes

Codes for the simulation of flow and transport processes are designed to meet specific requirements. Performance assessment models which consider the evolution of the entire repository system or are suitable for probabilistic analysis have to speed up calculation time by simplifying certain aspects e.g. by using networks of 1-dimensional grid structures or by neglecting certain processes. Process models, on the other hand, allow an in-depth analysis of specific problems but are not able to cover the whole range of relevant processes, components or time frames.

<u>TOUGH2</u>

The code TOUGH2 (Transport of Unsaturated Groundwater and Heat) was developed by Lawrence Berkeley Laboratory, USA, for the simulation of 3-dimensional multi-phase, heat and radio nuclide transport in porous media. A generalized Darcy-law is used to simulate density driven flow. By means of a set of alternative equation-of-state (EOS) modules different processes can be simulated. Saline ground waters e.g. can be treated with the EOS modules EOS7 and EOS7r.

Since 1991 GRS uses codes of the TOUGH2 code family to investigate processes in geological disposal systems. GRS has introduced several code modifications for processes which are relevant to such systems and are not covered by the standard TOUGH2 code. The modifications cover non-linear, salinity-dependent sorption, time-dependent boundary conditions, and pore compaction due to convergence of salt rock cavities. Code development continues.

In order to simulate thermal-hydro-mechanical interactions and gas migration processes in clay formations the code TOUGH2 was coupled to the geo-mechanical code FLAC3D by GRS in order to simulate three-dimensional, coupled thermal-hydro-mechanical interactions. In another branch of the code the mechanism of micro-crack dilation, which may significantly affect the migration of gas in argillaceous host rock and the pressure evolution inside the repository, was introduced.

The possibility to adapt the source code of TOUGH2 according to the current needs is a strong advantage of the software. In the review of the safety case of an applicant it gives the regulator the needed flexibility to investigate alternative physical processes and models. In principle, multi-purpose codes offer a similar flexibility, but the experience shows that in-depth knowledge of a source code and self-contained code development fosters the required in-depth understanding of processes and numerical aspects.

MARNIE

The code MARNIE is an in-house development of GRS designed for the simulation of fluid and tracer transport in the near field of a repository on the basis of a network of 1-dimensional drift structures. The focus of MARNIE lies on repositories in rock salt. It simulates advective-diffusive transport processes including hydrodynamic dispersion, the effect of gases on liquid transport, convergence of cavities with corresponding compaction of the backfill, container failure, radionuclide mobilisation and decay, solubility limits, sorption, and the impact of temperature.

FLAC3D

FLAC3D (Fast Lagrangian Analysis of Continua in 3 Dimensions) is a commercial explicit Finite Difference Code developed by Itasca Consulting Group. It can be used for all kinds of computational engineering mechanics, but it is focused on geotechnical problems. Elastic and plastic deformation for many types of materials (soils, rocks etc.) can be simulated with a variety of different constitutive relations. The basic version is capable to combine hydraulics and mechanics. For more complex situations add-on modules are available.

GRS currently uses the basic version combined with the Thermal, Creep and C++ add-on modules. This enables GRS to model thermal-hydro-mechanical processes for many different repository settings, e.g. for all probable host rocks (Soft Clay, Rock Salt, Hard Rock). Additionally, it is possible to extent the code either with self-developed C++ functions or by employing an easy to use intrinsic language in FLAC3D.

GRS has developed an extensive, carefully maintained, library of functions and add-on tools written in Perl, Python and C++ for FLAC3D. The possibility to easily extent, modify and develop codes has been used to couple FLAC3D with the multi–phase transport code TOUGH2. The C++ add-on allows GRS to use new published and reviewed constitutive relations as well as to develop our own or modify existing constitutive relations. Additionally, graphical pre- and post-processing capabilities of FLAC3D are used to visualize model output from TOUGH2.

Spring

SPRING is a commercial program system for the generation and calculation of groundwater- and mass transport models. It is based on the finite-elements-method. This system is used for complex problems and also for simple estimations by questions of flow, temperature and transport. The main areas for the application of Spring are geothermal aspects, waste disposal, groundwater resources management, permanent storage and mining.

Development of modelling capabilities

The future development will presumably involve the coupling of some above described computer codes or new codes. For example the coupling of the TOUGH2 code with FLAC3D or geochemical codes with TOUGH2.

UJV

All type of models have been used, from process models for example geochemical (PHREEQE, Geochemical workbench) and hydrogeological and other transport models (FEFLOW, TOUGH),

Form integrated, robust models GoldSim, AMBER, Pagoda). For radiological consequences RESRAD or own analytical models are used.

Bel V

Our organisation principally develops integrated models to perform sensitivity analyses and the safety assessment (radiological consequences and performance assessment) of specific scenarios. If necessary, the development of detailed models for analysing specific aspects in more details may be undertaken.

LEI

In the area of waste disposal LEI experts are using/developing the integrated models.

NRG

NRG develops integrated models, and process models that are specific for waste disposal, such as models for processes in the waste matrix and the engineered barrier system (EBS).

Geological, hydro-geological and biosphere process models are developed by the relevant geological survey and environmental institutes.

- Deterministic vs. probabilistic approaches to determine values of the parameters to input in models: what is the regulation of your country about the operator's approach? Do you favour one or the other for you own calculations and in which cases?

FANC

In the Belgian regulation the method in estimating radiological consequences (probabilistic or deterministic) is not imposed. A combination of both methods is possible as well. Indeed probabilistic analyses provide useful input within the sensitivity and uncertainty analyses.

GRS

There is no specific requirement in the regulation (e.g. concerning Safety Requirements Governing the Final Disposal of Heat-Generation Radioactive Waste (BMU)) for operator's approach.

In principle it is essential

- Using scientific methods
- Using suitable models based on sufficiently conservative assumptions
- Application of the state of the art and technology

In general probabilistic methods are to use for safety analysis (see Chapter 7.1 of BMU).

There is no favourite approach.

Bel V

There is no requirement on the approach (deterministic or probabilistic) to follow for safety assessments. The deterministic approach is generally favoured by operators, whereas complementary probabilistic calculations may be provided.

LEI

The deterministic approach with uncertainty analysis is usually applied for waste disposal facilities in Lithuania.

DECOM

We use integrated models with possibility of evaluation of deterministic as well as probabilistic assessment.

NRG

See above: regulation requires that the risks are below a given level, implying probabilistic methods. To assess the potential radiological consequences of normal operation of the facility, methods are initially deterministic. However, uncertainties in the radiological consequences of the normal operation (e.g. because of the long time scale) are usually addressed in a probabilistic approach.

Note that for some scenarios, such as human intrusion, it is difficult to estimate the probability. A probabilistic treatment of such a scenario is difficult, often a deterministic treatment is chosen.

4.5. - Safety indicators <u>from national regulations only</u>: could you complete and/or modify the following table?

FANC, Bel V - Belgium

The provided table focuses on the criteria which are, in Belgium referenced in the Royal Decree of 2001 on protection of workers and public (RGPRI/ARBIS) and complemented for the Radioactive Waste Disposal by mainly two guides on radioprotection (RPC-OP: Guide on the radiological protection during the operational period of a facility for the disposal of radioactive waste, published on 2008-12-11 and RPC-LT: Draft Guide on Radiation Protection Criteria for Post-Operational Safety Assessment for Radioactive Waste Disposal of 2011-08-23).

The used indicators (in bold regular) with their corresponding limits or references (in bold italic) as applied in the Belgian regulation through these guides are completed in the Table for each type of scenario (underlined). Complementary indicators must be used as well such as the radiotoxicity or radioactivity in the accessible environment (soil, air and water), which might not be significantly increased compared to that naturally present at a regional level.

Public-workers: **Effective dose** compared to a ***Dose limit***: 1mSv/yr-20mSv/yr

Normal evolution or reference scenario-emergency or other scenarios:

Expected evolution scenario: **Individual dose** compared to a ***dose constraint***[a] of 0.1 mSv/y

Potential exposure (non-quantified occurrence): **Individual dose** compared to a ***reference level*** of 0.1 mSv/y if the probability of occurrence can't be quantified

Human intrusion: is not yet defined for geological disposal

Penalizing scenarios[b]: **Individual dose** compared to a ***reference level*** of 3 mSv/y, when no confidence anymore in the evolution of performances and with high level of conservatism in the scenario

Individual risk due to release : Potential exposure (quantified occurrence): **Individual risk** (**of radiation–related death/cancer or radio-induced heredity effects**) compared to a **risk constraint** of 10^{-6}/yr, if the probability occurrence can't be quantified

[a] Note that for the Expected Evolution Scenario after a few thousand years, uncertainties increase and the dose constraint is considered as a reference value.

[b] Note that when the performance evolution of the waste disposal system cannot be assessed with confidence the use of Penalising Scenarios is required. Those scenarios are associated with a higher reference level but should be developed assuming the lowest performance level.

GRS - Germany

Public-workers: General: operational phase, see German RPO

Public: < 1 mSv/a (§46)

Public (regard: discharge of radioactive substances): < 0,3 mSv/a (§47, German RPO)

Workers Kat. A: < 20 mSv/a (§54, German RPO)

Workers Kat. B: < 6 mSv/a (§54, German RPO)

Workers (in all calender years):

< 400 mSv (§56, German RPO)

Principle: ALARA (§6, German RPO)

Normal evolution or reference scenario-emergency or other scenarios: Disposal facility: Post closure phase, see (BMU)

Public (regard: release of radionuclides during probable development): 0,01 mSv/a (Chap. 6.2, BMU)

Public (regard: release of radionuclides during less probable development): 0,1 mSv/a (Chap. 6.3, BMU)

UJV – Czech Rep

Public-workers: 1mSv/yr - 100mSv/5 yr or 50mSv/yr

Adults-children: 1mSv- -6 mSv/yr – students (16 – 18 yr)

Normal evolution or reference scenario-emergency or other scenarios: 0.25mSv/yr-1mSv/yr

LEI - Lithuania

Public-workers: 0.2 mSv/yr - 20 mSv/yr

Adults-children: 0.2 mSv/yr, different dose conversion factors for children

Normal evolution or reference scenario-emergency or other scenarios: 10 mSv/yr

DECOM - Slovakia

Public-workers: 1mSv/yr - 100mSv/5yrs

Adults-children

Normal evolution or reference scenario-emergency or other scenarios: No legislation requirements, practice is 0.25mSv/yr-1mSv/yr

NRG – The Netherlands

For surface based nuclear facilities in the Netherlands:

Public-workers: 1 mSv/year– 50 mSv/accident

Adults-children: Ch: 0.04 to 40- Ad: 0.015 to 15 mSv/accident

Societal risk: Limited number of fatalities per accident

Normal evolution or reference scenario - emergency or other scenarios: 0.001 - 0.1 mSv/year

Individual risk due to Release: 10-6 /yr

IBC-criteria (Isoleren, Beheersen, Controleren = isolation, control, monitoring).

- Does the operator use performance indicators (or functions indicators) in impact assessment to verify the safety functions and to optimize the safety? Which ones and for which safety functions? Do you use the same indicators in your numerical models?

FANC

It is indeed asked to the operator to identify and justify the performance indicators. They have to be identified according to safety functions (See SAR2.2 in DRAFT guide on Post-closure safety analysis of waste disposal of 2012-02-28).

GRS

For the post-closure phase using of indicators and criteria's concerning evaluation of calculated or estimated risks or doses (Chap. 6, BMU).

There are safety indicators and performance indicators (see GRS-240, 2008])

UJV

No safety indicators other than effective dose are used.

Bel V

The safety case for a geological disposal has not been submitted yet. It is expected that the operator will use performance indicators such has dose (mSv/y), radionuclide fluxes (Bq/y) or individual risk (/y). Bel V foreseen to use the same indicators in its numerical models.

LEI

Currently only the safety indicators are used in the impact assessment of waste disposal facilities.

NRG

For the Safety case presently under development in the OPERA program, the WMO uses safety and performance indicators as defined in IAEA TECDOC 1372, September 2003.

4.6. Do you already have a national specific guidance on how to conduct a safety review of (part of) a SC for geological disposal? And for other facilities (such as *Safety Assessment Guide* from AVN, IRSN and GRS)?

FANC

No, FANC does not have a guide specific for the regulator.

GRS

There is no specific national guidance how to conduct a safety review.

The essential elements which a safety assessment should provide are included in the safety requirements of (BMU). These safety requirements provide the basis for a check list when reviewing a Safety Case.

For information this Safety Assessment Guide concerns all nuclear facilities not only disposal facilities.

It should be checked if the outcome of the NEA MeSA Initiative "Methods for Safety Assessment of Geological Disposal Facilities for Radioactive Waste" from 2012 (see http://www.oecd-nea.org/rwm/reports/2012/nea6923-MESA-initiative.pdf) is helpful for WP4.

UJV

No

Bel V

An overall guidance on the Post Closure Safety Assessment for radioactive waste repositories is currently in development by the Federal Agency for Nuclear Control (FANC, "Analyse de la sûreté post-fermeture des établissements de stockage definitif de déchets radioactifs"). In addition, a guidance specific to geological disposal facilities is currently in development by FANC and will notably cover the Safety Assessment of these repositories (FANC, "Guide technique dépôt géologique (déchets de type B&C)").

LEI

There is no national specific guidance on safety review for safety case of for waste and disposal facilities.

DECOM

No safety guides for DGR

NRG

No formal guideline yet in the Netherlands for geological disposal. For other (existing) facilities, the overall process is prescribed in the regulations. For the (technical) review, several governmental agencies (e.g. agentschap.NL) support the authorities in the review and decision process. The agencies use internal guides for common issues. In addition, IAEA guides are often used as a reference for nuclear related safety reviews.

The *Installations and Licensing Decree* of the Environmental Management Act (wet Milieubeheer) defines the procedures that are needed in order to obtain a particular licence. These permits are required under various Dutch laws, relating to air pollution, soil protection, nuclear energy, etc. This decree establishes the consultation and appeal procedure in relation to applications for such licenses. It co-ordinates also the application procedures for different permits relating to the same project. The Nuclear Energy Act has the highest priority. This means that the Nuclear Energy Act can overrule the Environmental Management Act.

4.7. Do you agree with the following basic list of content of the SC at any particular step of the project development (see EPG report 2011-Draft; WENRA Report 2012-Draft, 2008-Draft IAEA DS355, NEA n 3674 2004, PAMINA report 1.1.4)?

- Description of the safety strategy (siting and design approach, management strategy, assessment strategy)

- Assessment basis (implementation of the safety strategy): detailed description of the data (site, repository, waste inventory), tools (methods, experiments and models)

- Description of the safety assessments performed: analysis of hazards (operational and long-term), scenarios, impact assessment, performance indicators, adequacy with dose limits…

- Synthesis of the results aimed at giving a statement of confidence in the safety demonstration of the disposal facility

FANC

FANC agrees on these elements with following additional comments and/or issues:

- The safety strategy includes as well the implementation strategy
- One should keep in mind that as a result of the safety strategy a safety concept should be provided
- The management system should be described and a list of procedure and programmes added as well.
- In particular the monitoring programme should be described and well justified in relation with the safety assessment.
- In the safety assessment special attention is required on the uncertainty analyses. On should as well consider the feasibility assessment.
- Special attention has to be devoted through the SC on the logic of decisions and justification of choices regarding the demonstration and the optimisation of the safety.

GRS

Yes

UJV

Yes

Bel V

- Description of the safety strategy (siting and design approach, management strategy, assessment strategy)

- Assessment basis (implementation of the safety strategy): detailed description of the data (site, repository, waste inventory), tools (methods, experiments and models)

- Description of the safety assessments performed: analysis of hazards (operational and long-term), **input data,** scenarios, impact assessment, performance indicators, adequacy with dose limits…

- Synthesis of the results aimed at giving a statement of confidence in the safety demonstration of the disposal facility

LEI

Yes.

DECOM

Nothing to add.

NRG

The WMO uses in the present OPERA program the definitions from IAEA DS355 and from the IAEA PRISM project. The scheme below serves as a basis to establish the Safety Case.

4.8. Could you comment, modify or complete the following list that the assessment report shall at least include (from the *Safety Assessment Guide* from AVN, IRSN and GRS)?

- General information relating to the assessment (scope, date of issue, identification of the customer and of the expertise body, information concerning the input data, the query raised, the safety problems to be considered),
- the limits of the scope of the assessment and the depth of the analysis performed,
- reminder of the facts, the current state of knowledge at the time of the assessment and any additional information aiding understanding, and allowing the recipients to verify the relevance and the validity of the assessment,
- reminder of the positions of the parties and of any element required for verifying the relevance of the assessment and of its conclusions, particularly in the case of conflicting positions,
- the assessment and related expertises execution conditions (data sources and investigations performed), resources used, inspections and verifications carried out and the limits of validity (transparency of the approach),
- the summary of the safety demonstration by the operator, the preliminary discussions, the summary of the reasoning followed together with the appropriate references of the related documentation and of the conflicting opinions, if any, to support the conclusions to which the expertise body came and to ensure that the result itself is properly understood,
- the clear formulation of the opinion, recalling to mind, if necessary, the limits of the assessment and related expertise as well as the additional work to be carried out, in order to facilitate its use by the customer.

FANC

FANC can a priori agree with this proposal but some aspects need to be clarified as:

- the definition of the “Assessment report” that should be defined on an unambiguous way.
- the scope of the “Assessment report” as well
- the parties meant…

Special attention should be devoted to the regulatory context, which needs to be recalled and identified as an item in the list and which should be considered as referential for the reviewer.

The points of the list might be developed in further steps.

GRS

No further comments

UJV

The content of a safety report to issue license for siting repository should be in the Czech Republic as follow:

Text part

1. General Information
   a. Introduction
   b. Basic information on construction
2. Characteristics of selected site
   a. Data on site
   b. Location and description of site
   c. Geography and demography of site
   d. Meteorological and climatic conditions
   e. Hydrological conditions
   f. geological and hydrogeological conditions
      i. Geology
      ii. Geochemistry
      iii. Hydrogeology
      iv. Seismicity and tectonics
      v. Engineering geology and geotechnics
   g. Natural sources and environmental impact assessment
3. Characteristics and assessment of repository concept
   a. Emergency situations
   b. Operational monitoring
   c. Proposal of operational limits and conditions
   d. Proposal of ways of physical protection
4. Assessment of operation on health and environment
   a. Inventory of radionuclides
   b. Assessment of transport pathways and release mechanisms of radionuclides in the environment
   c. Scenarios of normal evolution
   d. Alternative scenarios
   e. Uncertainty assessment
   f. Radiation protection – assessment of impact on health and compliance with regulation
5. Proposal of safe closure and decommissioning concepts
   a. Stabilization of site
   b. Decontamination, disposal of waste generated and decommissioning
6. Evaluation of Quality Assurance

B. Appendix part

1. Maps
2. Drawings
3. Pictures, schemes, tables
4. Others

C. Documentation part

1. Protocols
2. Other

The safety reports to issue licence for construction, operation, decommissioning, etc. should be more detailed concerning both data and analyses, but in principle the structure is the same. Each safety report should include identification of uncertainties and proposal of their management. According to Czech regulations (307/1997 Coll.) the safety assessment must demonstrably and credibly assess all risks both in pre-closure and post-closure period.

Bel V

Bel V (previously AVN) has participated in the development of this document. We fully agree with this list of topics to be at least covered.

LEI

It should be indicated that this is a content of review report and is not a content of the safety assessment.

NRG

All of them.