EUROPEAN COMMISSION

Community research

SITEX

(Contract Number: 295889)

DELIVERABLE D-N°2.1
Overview of Existing Technical Guides and Further Development

Author(s): **FANC, ASN, Bel V, CNSC, ENSI, GRS, IRSN, NRJ, ÚJV**

Reporting period: e.g. 01/01/2012 – 31/03/2014

Date of issue of this report : **09/04/2014**

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	
RE	Restricted to a group specified by the partners of the SITEX project	
CO	Confidential, only for partners of the SITEX project	

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Content

Abbreviations used

BSS	: Basis Safety Standards
CS	: civil society
DGR	: deep geologic repository
DiD	: defence in depth
EC	: European Commission
EPG	: European Pilot Group
FEP's	: features, events and processes
G	: guide
GSR	: general safety requirement
IAEA	: International Atomic Energy Agency
ICRP	: International Committee of Radiological Protection
IGD-TP	: Implementing Geological Disposal of Radioactive Waste Technology Platform
IGSC	: Integrated Group on the Safety Case
LT	: long term
NEA	: Nuclear Energy Agency
NSA	: national safety authority
OLC	: Operational Limits and Conditions
PSR	: periodic safety review
QA	: quality assurance
R	: requirement
RB	: regulatory body
RP	: Radioprotection
R&R	: reversibility and retrievability
RWM	: radioactive waste management
SA	: safety assessment
SC	: safety case
SITEX	: Sustainable network of Independent Technical Expertise for Radioactive Waste Disposal
SRL	: safety reference level
SSC	: structures, systems and components
SSG	: specific safety guide
SSR	: specific safety requirement
ST	: safety topic
TSO	: technical safety organisation
WAC	: waste acceptance criteria
WENRA	: Western European Nuclear Regulators Association
WMO	: waste management organisation
WP	: work package

1 Introduction

1.1 THE SITEX PROJECT

"The final objective of the FP7 program SITEX project : "Sustainable network of Independent Technical EXpertise for radioactive waste disposal" coordinated by IRSN is to establish the conditions to build a network of technical expertise independently from the operators to support the regulatory bodies in its activities of regulating, authorizing and verifying the compliance of geological repositories for radioactive waste.

Lasting 24 months, SITEX brought together 15 organisations directly or indirectly involved in these activities typically conducted by the regulatory bodies (RB), within National Safety Authorities (NSA), or/and within technical safety organisations (TSOs). The project was organised in several work packages focusing on the different roles and objectives attributed to the technical expertise or the so-called "expert function considered as the central point of the project. In the SITEX project the term "expertise function" is defined to designate all activities assigned to experts inside or outside the regulatory body in order to provide the technical and scientific support to the regulatory body for taking decisions, ensuring that regulatory expectations are clearly communicated to and interpreted by the applicant and ensuring that the Civil Society (CS) is transparently and adequately informed and aware during the decision process. The "Expertise function" and its interactions with the decisional regulatory function, the implementer function and Civil Society is illustrated in Figure 1.

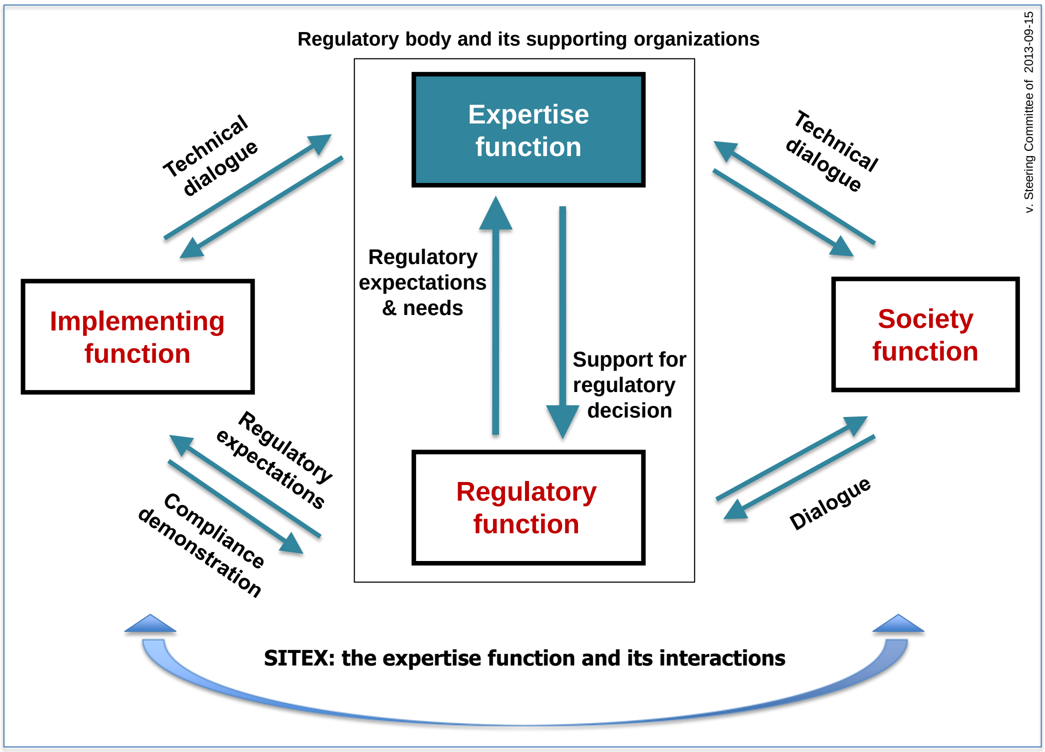

Figure 1. The expertise function and its interactions

1.2 WORK PACKAGE 2.1 (WP2.1)

According to the IAEA SSR-5 guide [2], the regulatory body has to provide guidance on the interpretation of the national legislation and regulatory requirements, *as necessary,* as well as on what is expected of the operator in respect of each individual disposal facility.

As illustrated in Figure 1, the fulfilment of safety requirements by the implementing function requires a clear formulation of regulatory expectations which may necessitate the development of technical guidance and procedures explaining how these requirements can be met in practice and how compliance should be substantiated by the implementing function.

Technical guidance may also be needed to ensure that regulatory expectations are clearly interpreted and communicated by the experts fulfilling an expertise function within or for the regulatory body.

These aspects were covered within the work package WP2.1 of SITEX: “Overview of Existing Technical Guides and Further Development” and presented in this deliverable D2-1.

WP2.1 is to be situated in a larger context of WP2, which consists in the setting up of the conditions for allowing mutual understanding between the Regulatory Body (RB) and the Waste Management Organisations (WMOs).

The main objective of WP2.1 was to identify areas where development and harmonization of technical guidance is needed in priority and topics for which it is felt that dialogue is needed. The priorities were established by taking into consideration the importance for safety and the IGD-TP vision statement that “by 2025, the first geological disposal facilities for spent fuel, high-level waste, and other long-lived radioactive waste will be operating safely in Europe” [102]. The scope WP2.1 encompasses all the aspects associated with the safety of geological disposal under development. The security of repositories and the safety of existing facilities are not addressed in this work.

An overview of existing and available technical guides addressing the main “safety topics” to consider in the development of a geological disposal and submission of safety case and which are used within the SITEX consortium is given from chapter 4 to 14. Common points and differences between the guides are presented and the needs for further development are identified according to the main “safety topics”.

1.3 INTERACTION BETWEEN WP2.1 AND OTHER WORK PACKAGES OF SITEX

Providing guidance on the interpretation of the national legislation and regulatory requirements involves an adequate support from the expertise function comprising a.o. consideration of axes of R&D, addressed in WP3 [98]. Technical guidance provides support for the verification of conformity with the safety requirements, for performing independent safety analyses and inspections and thus as well on the safety case reviewing process as covered by WP4 [97].

Additionally, technical guidance may also be useful to facilitate interactions with the public or with other stakeholders and help their participation in the process of technical expertise as developed in WP5 [99]. Finally, in identifying the technical guidance and the needs for further development, harmonization or dialogue, WP2.1 provides support to WP6 in defining potential actions of the future SITEX network for allowing better understanding of various stakeholders expectations [100] and [101].

2 Working methodology

The input and working methodology used in WP2.1 are presented in Figure 2.

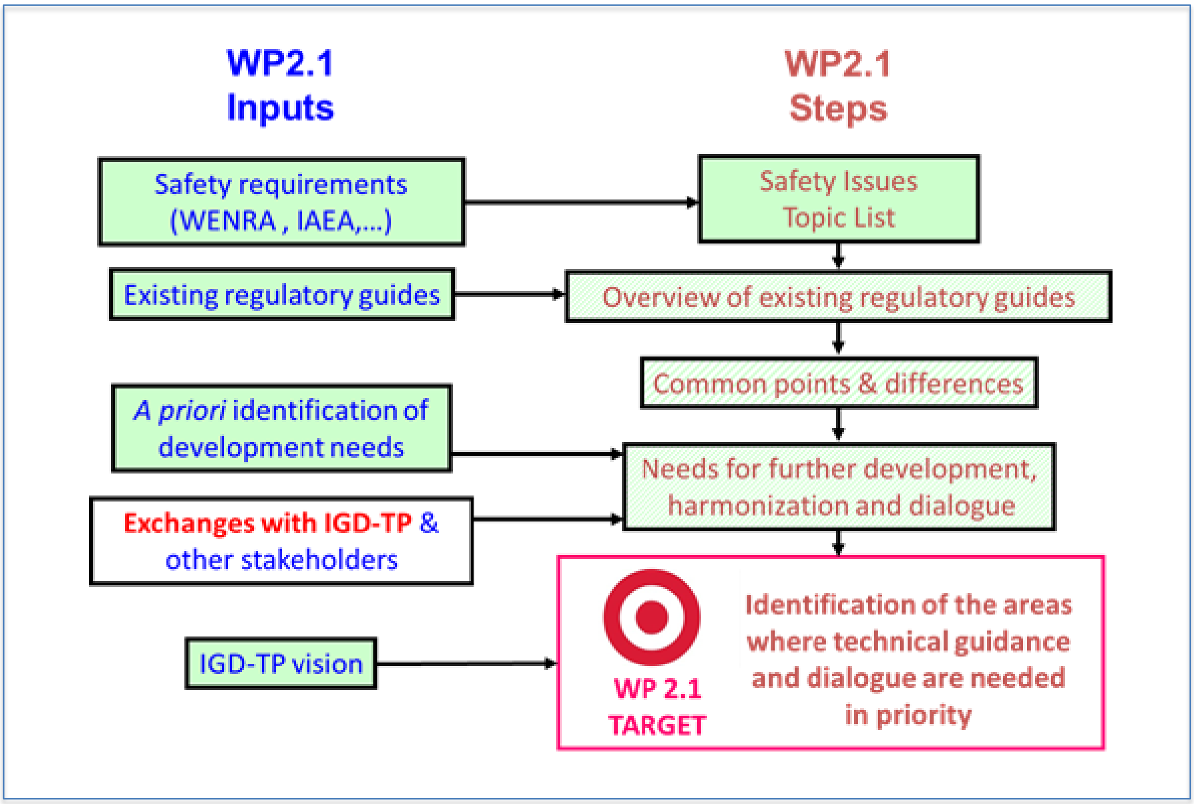

Figure 2. WP2.1 working methodology.

The identification of areas where further technical guidance, harmonization and dialogue are needed in priority is the conclusion of several steps of analysis and discussions within WP2.1 which are described in subsequent sections.

2.1 IDENTIFICATION OF "HIGH-LEVEL" SAFETY REQUIREMENTS

A set of *safety requirements* (see Table A1.1 to A1.5 of Appendix A.1) covering the different aspects of the development of a geological disposal and submission of safety case was drawn up based on following international standards:

- Draft WENRA reports on SRL's for radioactive waste disposal facilities [47]. A SRL is defined as a requirement against which the situation of WENRA member states is assessed. It is expected that each country who is part of WENRA will transpose SRLs into its national regulatory framework;
- IAEA safety fundamentals and requirements [55,2,48];

- EC Directive 2011/70/Euratom on Radioactive Waste & SF Management [3];
- ICRP recommendations [54,76,77,62].

2.2 DEFINITION OF SAFETY TOPICS

The identified safety requirements were used as a basis for the definition of areas or "safety topics", for which guidance is *a priori* expected, for the development of a geological disposal and the submission of a safety case . Some 35 "safety topics" and 17 "subtopics" were defined. These "safety topics" are also structured in "groups of safety topics" as presented in chapter 3.

2.3 IDENTIFICATION AND ANALYSIS OF EXISTING TECHNICAL GUIDANCE ASSOCIATED WITH THE SAFETY TOPICS

In the framework of WP2, it was assumed that technical guidance is generally associated with one or several safety requirements and serves one or several of the following purposes:

- to ensure that a requirement is properly interpreted;
- to provide an explanation of how a requirement can be met in practice and/or how compliance with a requirement should be substantiated;
- to facilitate dialogue and interactions with the public or with other stakeholders.

It was emphasized as well that technical guidance may be intended to reach one or several target audiences such as implementers, experts fulfilling an expertise or a regulatory function, the public or other stakeholders.

The technical guidance might be provided through technical guides developed by international organizations as e.g. IAEA, ICRP, NEA or EURATOM Framework Programme or at national level.

In this step, the technical guides used by the participating countries according to each "safety topic" were identified by means of a first questionnaire of WP2.1 on existing, used and needed guidance, submitted to the participating organizations.

From this list the available guides were further compared and discussed in order to identify and understand common points and differences.

The resulting list of identified technical guides is provided in Table A2.1 of Appendix A2 and the analysis of the guides is provided in the subsection related to each "safety topic" (see sections 4 to 14).

2.4 IDENTIFICATION OF NEEDS AND PRIORITIES

Needs for further development, harmonization and dialogue with stakeholders were identified based on

- An *a priori* identification of development needs and of technical guidance of TSOs and NSAs by means of the first questionnaire of WP2.1. These needs are reported in the subsection related to each “safety topic” (see sections 4 to 14);
- Interactions as with WMOs through the IGD-TP platform (see section 15.2);
- Exchanges with the civil society during the SITEX workshop organised in the frame of work package 5 (see section 15.3);

Priorities have been established (see chapter 15) by means of a second questionnaire of WP2.1 submitted to the participating organization. Taking into account the importance for safety and the IGD-TP vision statement that “by 2025, the first geological disposal facilities for spent fuel, high-level waste, and other long-lived radioactive waste will be operating safely in Europe” [102] one of the following levels of priority were assigned to each identified need:

- H = High priority (before 2016);
- M = Medium priority (before 2020);
- L = Low priority (after 2020).

3 Safety Topics

The 35 “safety topics” (ST) and their subtopics addressed in the set of safety requirements and considered in WP2.1 are listed in following Table 1. They are organised in main groups and subgroups of “safety topics”.

For each of them the following information is provided in the subsequent sections from § 4 to § 14:

1. Common points and differences between existing guides;
2. Needs for dialogue, development and harmonization;
3. Priorities, targeted audience and safety requirements associated with these needs.

The section where the ST has been treated in the document is as well indicated in Table 1.

Table 1: List of ”safety topics” analysed in the framework of WP2.1

Groups of Safety Topics	**Subgroups of Safety Topics**	**Safety Topic**		**Safety subtopic**	**ST**	**§ in D2-1**
Governing principles, safety policy and safety strategy	Governing principles	Radiation protection	a	Justification	ST1	4.2.1
			b	Optimisation of protection		4.2.2
			c	Limitation of risks to individuals +Operational period + Post-closure period		4.2.3
		Protection of present and future generations			ST2	4.3
		Protection of the environment			ST3	4.4
		Defence in depth & Robustness			ST4	4.5
		Passive means			ST5	4.6
		Good engineering practice, proven techniques & feasibility			ST6	4.7
		Isolation & Containment			ST7	4.8
		Reversibility/Retrievability vs. Safety			ST8	4.9
		Graded approach			ST9	4.10
		Stepwise approach			ST10	4.11
		Concurrent activities			ST11	4.12
	Safety Policy & Strategy	Safety policy & strategy * Safety assessment strategy * Management strategy * Design and implementation strategy	a	Safety assessment strategy	ST12	4.13
			b	Management strategy		
			c	Design and implementation strategy		
Management	Management	Management * Responsibilities * Organisational structure * Management system * Records & knowledge keeping	a	Responsibilities	ST13	5
			b	Organisational structure		
			c	Management system		
			d	Records & knowledge keeping		

Groups of Safety Topics	Subgroups of Safety Topics	Safety Topic		Safety subtopic	ST	§ in D2-1
Repository development	Site selection	Site selection			ST14	6
	Design	Design			ST15	7
	Construction	Construction			ST16	8
	Operation	Operation	a	General aspect on operation	ST17	9.1
			b	Investigations and feedback of information on operating experience		9.2
			c	Operational limits and conditions		9.3
			d	Modifications		9.4
			e	Emergency preparedness and response		9.5
			f	Maintenance, periodic testing and inspection		9.6
			g	Occupational exposure		9.7
			h	Public exposure		9.8
			i	Receiving, handling and emplacement of waste		9.9
	Closure & Decommissioning	Closure & Decommissioning			ST18	10
	Period after closure and institutional controls	Period after closure and institutional controls			ST19	11
Waste acceptance & monitoring	Waste acceptance	Waste acceptance			ST20	12
	Monitoring	Monitoring * Occupational exposure * Public exposure			ST21	13
Safety Case & Safety Assessment	Objective scope, approach and content of SC & SA	Objectives and scope, Graded approach, SC/SA content vs regulatory decision steps			ST22	14.2
	Characterization, knowledge and system understanding	Characterization, knowledge and system understanding	a	General aspects	ST23	14.3.1
			b	Waste	ST23	14.3.2
			c	Engineered components	ST23	14.3.3
			d	Site	ST23	14.3.4
			e	Use of operating experience & monitoring data	ST23	14.3.5
	Safety assessment methodologies, approaches & tools	Timescales and timeframes			ST24	14.4.1
		Assessment of the possible radiation risks			ST25	14.4.2
		Uncertainties			ST26	14.4.3
		Deterministic vs. probabilistic approaches			ST27	14.4.4
		Conservative & realistic assessments			ST28	14.4.5
		Scenarios			ST29	14.4.6
		Models			ST30	14.4.7
		Indicators & criteria			ST31	14.5
	Operational Safety assessment	Operational Safety assessment			ST32	14.6
	L-T Safety assessment	L-T Safety assessment	a	Performance, defence in depth and robustness assessment	ST33	14.7

Groups of Safety Topics	Subgroups of Safety Topics	Safety Topic		Safety subtopic	ST	§ in D2-1
			b	Assessment of the radiological impact		
			c	Integration of analyses, arguments & evidences		
	Periodic safety review	Periodic safety review			ST34	14.8
	Independent verification	Independent verification			ST35	14.9

Note that following topics addressed in the set of high-level safety requirements were not considered in the framework of SITEX:

- Safeguards and nuclear security;
- Existing disposal facilities.

4 Governing Principles, Safety Policy & Strategy

4.1 INTRODUCTION

The safety policy including the safety strategy is defined as the high-level approach for achieving safe disposal [1]. It defines the objectives and principles to guide the overall project development.

The safety strategy should address the implementation of the *governing principles* identified in the framework of WP2.1. The safety strategy should also identify the safety functions of the disposal system (containment and isolation), as well as those allocated to its components. Moreover, the safety strategy should describe all the approaches, processes and methods that will ensure that the disposal facility meets the safety objective. The safety strategy is further developed in section 4.13.

4.2 RADIATION PROTECTION

4.2.1 Justification

4.2.1.1 Requirements

No SRL from the Draft WENRA reports on SRL's [47] is being proposed as these requirements are likely located in higher level requirements.

The following safety requirements from IAEA & ICRP are associated with the subtopic of Radiation Protection: "justification":

- IAEA SF-1 [55] P4: Justification of facilities and activities
- IAEA GSR Part3 [56]:
- R1: Application of the principles of radiation protection
- R10: Justification of practices
- IAEA ICRP 103 [54] (art. 205 to 210): Justification principle
- IAEA ICRP 122 [62] (art. 44): Justification principle applied to geological disposal

International safety fundamental principle IAEA SF-1 P4 states that the benefits must outweigh radiation risks. The decision may have been taken by a Government or in other cases the regulator may determine whether proposed facilities and activities are justified.

ICRP 122 [62] states that justification of the practice should include the justification of the geological disposal. This justification should be reviewed over the lifetime of the disposal whenever new and important information becomes available.

4.2.1.2 Common points and differences between existing guides

Regarding existing national guidance [9, 10, 11], the concept of "Justification" was not readily found. Since radiation protection requirement/ ordinances in countries are typically applicable to all nuclear facilities (unless other reasoning given), regulatory expectations related to the ICRP justification principle are generally included in the high-level regulatory requirements and therefore does not need to be re-enforced in technical guidance.

4.2.1.3 Needs for dialogue, development and harmonization

No needs were identified for this topic because high-level regulatory requirements related to justification are generally included in countries radiation protection regulations or ordinances. Furthermore, the IAEA indicates that justification may have been given by a government (for example to start a nuclear program).

4.2.2 Optimization of Protection

4.2.2.1 Requirements

The following safety requirements are associated with the subtopic of Radiation Protection: "optimization of protection":

- In the Draft WENRA report on SRL's [47]:
    - SRL 2.1.1: on the application of the ALARA principle in the development of disposal facility and the adoption of a graded approach depending on the hazard presented by the waste;
    - SRL 2.1.4: Optimized level of operational and post-closure safety

- In IAEA SF-1 [55] P5: Optimization of protection

- In IAEA GSR-Part3 [56]:
    - R11: Optimization of protection and safety
    - R19: Responsibilities of the regulatory body specific to occupational exposure
    - R29: Responsibilities of the government and the regulatory body specific to public exposure

- In IAEA SSR-5 [2]:

- alinea 2.9: Optimization of protection in the operational period
- alinea 2.18: Optimization under constraints of the radiation protection in the post-closure period
- R4: Importance of safety in the process of development and operation of a disposal facility

- In EC directive 2011/70/Euratom [3]:
  - Article 5.1e: Enforcement actions from the national framework in respect of a.o. alternative solutions that lead to improved safety;
  - Article 7.2: Continuous improvement of the safety in a systematic and verifiable manner.

- In ICRP 103 [54] art. 211 to 224: Justification principle
- In ICRP 122 [62] art. 44 & 69 to 86: Justification principle applied to geological disposal

Draft WENRA SRL 2.1.1 and 2.1.4 focus on the requirement to reach an optimized level of operational and post-closure safety throughout the process of development, design, construction, operation, decommissioning and closure of a disposal facility applying ALARA principle.

The principle of optimisation is defined by the Commission (ICRP 101 [77] and ICRP 103 [54]) as the source-related process to keep the likelihood of incurring exposures (where these are not certain to be received), the number of people exposed, and the magnitude of individual doses as low as reasonably achievable, taking economic and societal factors into account.

The ICRP principle of optimisation of radiological protection when applied to the development and implementation of a geological disposal facility has to be understood in the broadest sense of an iterative, systematic and transparent evaluation of options for enhancing the protective capabilities of the system and for reducing impacts (radiological and others).

Optimisation of protection has to deal with the main aim of disposal systems, i.e. to protect humans and the environment, now and in the future, by isolating the waste from humans, the environment and the biosphere and by containing the radioactive and other toxic substances in the waste to the largest extent possible. Optimisation of protection has to deal with the protection of workers and the public during the time of operation, as well as with the protection of future generations including possible periods with no oversight, and safety has to be ensured by a passively functioning disposal system.

The assessment of the robustness of the disposal facility can contribute to system optimisation, because it provides insight, quantitative or qualitative, in the performance of the disposal facility and its components, in the relative contributions of the various components to the overall system [62].

It is recognized that socio-economic factors (including e.g. policy decisions and societal acceptance issues) can constraint the optimisation process to various extents, e.g. by limiting the available options (e.g. siting) and/or by defining additional conditions (e.g. retrievability). It is important that these constraints are identified in a manner transparent to all involved stakeholders and that their safety implications are understood.

4.2.2.2 Common points and differences between existing guides

Regarding the national technical guides [9,11,12,13,14,15,17,18,] some guides refer to ALARA [17]; some others address the “Optimisation of protection” explicitly.

Several national guides indicated that optimization should be looked at each decision in lifecycle step. It was also indicated that there is a need to look, at each steps, at alternatives balancing both operational and long-term safety.

It is also stated that design should be optimized with regard to continuous advancement, reduce radiological impact to the extent that is possible and reasonable based on state of the art technique under prevailing circumstances.

4.2.2.3 Needs for dialogue, development and harmonization

There are various uses of the word “optimization” throughout international and national guidance. For the regulatory body, it is important to focus on the optimisation of protection as defined by ICRP (103 & 122) including ALARA principle.

There is a need for the future SITEX platform of regulators & TSOs to discuss on the practical implementation of this principle as well as on the verification that this principle and associated requirements have been adequately implemented throughout the repository development process. This could involve addressing questions such as e.g.:

- How to determine that the factors taken into consideration in the comparison of options are suitable and appropriate to the associated decision (e.g. site selection, optimisation of repository lay-out, …) ?
- Are the weights allocated to these factors appropriate (e.g. operational vs. post-closure safety, isolation vs. containment, demonstrability vs. robustness, …) ?
- Are socio-economic factors considered in the licensing process?

These discussions may lead the conclusion that further guidance needs to be developed.

4.2.3 Limitation of risks to individuals

4.2.3.1 Requirements

It does not appear to be a SRL from the Draft WENRA report [47] directly related to the subtopic of Radiation Protection “Limitation of risks to individuals” in operational period and closure although the topic is addressed in following international requirement standards (IAEA, ICRP) :

Limitation of risks to individuals

- In IAEA SF-1 [55] P6: Limitation of risks to individuals
- IAEA GSR Part3 [56] R12: Dose limits. Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm

Operational period

- In IAEA SSR-5 [2] §2.7-14: Radiation protection in the operational period
  - 2.7: Same related safety criteria for the operational period of a disposal as those for any nuclear facility
  - 2.8: Planned exposure situation and ALARA
  - 2.9: Optimization of protection
  - 2.10: Relevant considerations in the optimization measures
  - 2.11: No releases of radionuclides, or only very minor releases
  - 2.12: Confirmation of absence of significant radiological consequences
  - 2.13: Operational radiation protection programme
  - 2.14: Handling doses and risks associated with the transport of radioactive waste

Post-closure period

- In IAEA SSR-5 [2] 2.15-19: Radiation protection in the post-closure period
  - 2.15: The safety objective and criteria
  - 2.16: Radiation doses to people in the future
  - 2.17: Protection of people and environment as primary goal
  - 2.18: Optimization under constraints
  - 2.19: Different methods for Impact assessment & compliance demonstration

- In ICRP 103 [54] art. 243 to 251: Dose limits in § 5.10
- In ICRP 122 [62] art. 44 & 45 to 68: The Principle of Application of Dose Limits in § 4.2 on the fundamental radiological principles & the dose and risk concept in § 4.3 & requirements on the radiological protection in operational, post operational and particular circumstances including the inadvertent human intrusion, in §4.4 to 4.7.

ICRP 103 [54] states the principle of limitation and the dose and risk limits, which apply only for planned situation. The different applications according to the categories of exposure are presented. The ICRP 103 explains also the concept of dose constraint as source-related restriction that is also used in planned exposure and its link with the optimization. The concept of reference levels used in case of emergency or existing situation is also addressed by ICRP. The human intrusion situation is not explicitly considered.

ICRP 122 [62] recalls the same principle and application of dose or risk limits and constraints for the planned situation. ICRP 122 develops the different categories of exposure within the planned and existing situations related to a geological disposal. Human intrusion is explicitly addressed but no values of criteria are provided.

For operational criteria IAEA SSR-5 [2] §2.7 indicates, as for ICRP, that since disposal facilities will most likely be defined as a nuclear facility, BSS should be used. Therefore, for the operational phase, disposal facilities should follow the 1mSv/year, however there is expected to be no or very minimal radiological release during the operational phase. Therefore, ALARA/optimization of RP is suggested.

For post-closure IAEA SSR-5 §2.15 provides criteria and also provides criteria for human intrusion scenarios.

4.2.3.2 Common points and differences between existing guides

It appears from national guidance documents [11,12,18,20] that countries have proposed dose criteria for operational and post closure (Canada, Switzerland, Germany, Czech Republic). Post-closure criteria are the same or more conservative then the IAEA.

4.2.3.3 Needs for dialogue, development and harmonization

No needs were identified for this topic at this stage although human intrusion is seen as a possible discussion topic for the SITEX platform. It is also noted that the two-years IAEA project HIDRA: “Human Intrusion in the context of Disposal of Radioactive Waste”, which has been launched end 2012, aims of providing guidance in human intrusion.

4.3 PROTECTION OF PRESENT AND FUTURE GENERATION

4.3.1 Requirements

No SRL from the Draft WENRA report [47] is being proposed for the "safety topic" "Protection of Present and Future Generation". This "safety topic" is expressed as a fundamental principle of IAEA:

- IAEA SF-1 [55] P7: Protection of present and future generations

- EC directive 2011/70/Euratom [3]: Article 1, alinea 1 on the subject-matter being "a responsible and safe management of spent fuel and radioactive waste to avoid imposing undue burdens on future generations".

The IAEA Safety Fundamentals SF-1 [55] provides very high-level guidance – "Where effects could span generations, subsequent generations have to be adequately protected without any need for them to take significant protective actions" This principle is also generally adopted in other international guidance (EC, ICRP 122 [62]) without being mentioned as a specific requirement.

4.3.2 Common points and differences betwe*en* existing guides

In general, the existing national technical guidance [21, 18, 11, 12] includes the concept of the IAEA SF-1 Principle P7. For example to prevent unreasonably risk to future generations or ensure long-term protection with imposing undue burden and obligations on future generations.

Some national guidance [11, 18] mentions the additional requirement for financial funding. However, the German technical guide mentions prompt funding and the Canadian Policy mentions funding as soon as available. None of the national guidance documents found to define "undue burden" or "future generation". However, the German technical guide provided more details on how to avoid unreasonable burden and obligations to future generations, for example to ensure; no intervention required during post-closure, construction as fast as possible and prompt financing should be in place.

4.3.3 Needs for dialogue, development and harmonization

It may be interesting to see if regulators & TSOs have a discussion on common understanding of "undue burden" and/or "future generation" as these terms are commonly used in international and national technical guidance. It is also understood that the two-year IAEA project MODARIA "Modelling and Data for Radiological Impact Assessments", which has been launched end 2012, may be looking at this topic.

4.4 PROTECTION OF THE ENVIRONMENT

4.4.1 Requirements

No WENRA SRL is being proposed for the “safety topic”: “Protection of the environment”. Following international safety requirements, associated with this topic are:

- IAEA SSR-5 [2] alinea 2.21-23: Environmental and non –radiological concerns
    - alinea 2.21: Principle of protecting the environment is assumed
    - alinea 2.22: Environmental transfer pathways as indicators of environmental protection
    - alinea 2.23: Comparison of concentration and fluxes of contaminants with those of natural origin in geosphere and biosphere

International guidance provided was limited. It is currently assumed that the protection of people against the radiological hazards associated with a disposal facility will also apply the principle of protecting the environment. It should also be noted that the “issue of the protection of the environment from harmful effects of ionizing radiation and the development of standards for this purpose are under discussion internationally”.

4.4.2 Common points and differences between existing guides

Regarding national technical guidance [11,12,18], protection of environment is mentioned at a high-level, however, further details/criteria are not mentioned or information is limited. The RP criteria found seems to only apply to public, workers or population. Countries may have environmental legislation or Environmental Code and this does not fall under the mandate of the country’s nuclear regulator; however the licence applicant still has to meet all applicable regulations.

4.4.3 Needs for dialogue, development and harmonization

Information/criteria on protecting the environment are limited. However, countries may have environmental legislation and this does not fall under the mandate of the nuclear regulator, however the licence applicant still has to meet regulations.

Needs in the definition of indicators and criteria to use were identified in section 14.5. As part of the future SITEX platform, it is suggested to first have exchanges with other regulators & TSOs on the protection of the environment (radiological and non-radiological).

It is also noted that the four-years IAEA project MODARIA: “Modelling and Data for Radiological Impact Assessments”, which has been launched end 2012, is looking at this topic.

4.5 DEFENCE IN DEPTH AND ROBUSTNESS

4.5.1 Requirements

The following safety requirements are associated with the “safety topic”: “Defence in Depth (DiD) and/or Robustness”:

- In the Draft WENRA report on SRL’s [47]:
  - SRL 2.1.2: Multiple safety functions, including use of multiple barrier and controls.
  - SRL 2.1.6: The licensee shall provide for isolation and containment during normal evolution and shall ensure robustness of the disposal system.
- In IAEA SF-1 [55] P8 § 3.31 & 3.32 : Defence in Depth justification of facilities and activities
- IAEA GSR Part3 [56] alinea 3.40: Defence in Depth in R15 on Prevention and mitigation of accidents
- In IAEA SSR-5 [2] R7: Multiple safety functions

IAEA SSR-5 [2] R7 mentions that the host environment shall be selected and facility designed and operated to ensure that safety is provided by multi safety functions, containment and isolation shall provide a number of physical and engineered barriers, overall performance shall not be dependent on a single safety function, individual physical elements and safety function combined together shall be demonstrated in the Safety Case, including what measures will be put in place if it does not function correctly.

Draft WENRA SRL 2.1.2 states that the licensee shall ensure that the host environment is selected, the engineered components are designed and the facility is operated so as to ensure that safety is provided by means of multiple safety functions, including use of multiple barrier and controls. The performance of these barriers shall be achieved by diverse physical and chemical means. The overall performance of the disposal system shall not be unduly dependent on a single safety function. This appears to be in line with the IAEA requirement SSR-5 R7.

4.5.2 Common points and differences between existing guides

Regarding national technical guidance, only two mention the notion of defence in depth. The principle of defence in depth (DiD) is defined in [22] as the involvement of the deployment of successive lines of defence capable of preventing the occurrence or, where applicable, of minimizing the consequences of technical, human or organizational failures likely to lead to accidents that could adversely affect human health or the environment. The multiple barriers system is defined in [12].

4.5.3 Needs for dialogue, development and harmonization

As current DiD is based on Nuclear Power Plants it is suggested to first hold discussions with regulators & TSOs on the terminology , as part of the future SITEX platform, to obtain a common understanding of the DiD principle for geological repositories for radioactive waste (complementarity, independence, role of controls, …). It will also be important to discuss on the practical implementation of this principle as well as on the verification that this principle and associated requirements have been adequately implemented throughout the repository development process. These discussions may lead the conclusion that further guidance needs to be developed.

4.6 PASSIVE MEANS

4.6.1 Requirements

The following safety requirements are associated with the “safety topic” “passive means”:

- In the Draft WENRA report [47] SRL 2.1.3 : The licensee shall ensure that post-closure safety be achieved by passive means
- In IAEA SSR-5 [2] R5 on Passive means for the safety of the disposal facility
- In EC directive 2011/70/Euratom [3]: Article 4.3c on the principles, on which national policies shall be based, that spent fuel and radioactive waste shall be safely managed, including in the long term with passive safety features;

The IAEA SSR-5 R5 states that safety is ensured by passive means to the fullest extent possible and the need evaluate actions that need to be taken after closure. It further states the passive means need to be identified at the beginning (siting and conceptual design) and need to be evaluated throughout lifecycle of disposal facility. The operators are responsible and need to minimize responsibilities passed on to future generations. It also notes that there is a difference between geological and surface facilities. It also refers to the institutional controls which are discussed separately in IAEA SSR-5 Requirements 21 and 22.

SRL 2.1.3 also indicated that the licensee shall ensure passive means in post-closure, but does not re-enforce the need to look at in the early stages such at IAEA SSR-5 R5.

4.6.2 Common points and differences between existing guides

Passive means are addressed in the national technical guidance [22,12,18], but at the post-closure timing. One states that passive means do not require activities on site, which is in regards to institutional controls [18]. This topic is further analysed in § 11 of the present report. Another national guidance promotes “passively functioning natural and engineered barriers” [18].

4.6.3 Needs for dialogue, development and harmonization

No needs were identified for this topic.

4.7 GOOD ENGINEERING PRACTICE, PROVEN TECHNIQUES AND FEASIBILITY

4.7.1 Requirements

The following safety requirements are associated with the "safety topic" "Good engineering practice, proven techniques and feasibility":

- In the Draft WENRA report on SRL's [47]:
  - SRL 2.3.1: on the design of the disposal facility that shall provide safety with due consideration of the characteristics of the wastes to be disposed of, the feasibility of the technical options and the characteristics of the selected site.
  - SRL 2.3.7 on the design of the disposal facility that shall be based on applicable standards, appropriately proven techniques and the use of appropriate materials to ensure that the safety requirements will be met, throughout the foreseeable operational phase including closure, as well as after closure.
  - SRL 2.5.1 on the construction of the disposal facility that shall be in accordance with the design as described in the safety case and by application of appropriately proven techniques.

- In IAEA GSR Part 3 [56], alinea 3.39: Good engineering practice in R15 on Prevention and mitigation of accidents

- In EC directive 2011/70/Euratom [3]: Article 11.2 on the regular update of national programme, taking into account technical and scientific progress as appropriate as well as recommendations, lessons learned and good practices from peer reviews.

4.7.2 Common points and differences between existing guides

Regarding national technical guides, only one guide [22] mentions the need to demonstrate the feasibility in order to ensure that the expected performance of the disposal system components will be attained in light of the reasonably foreseeable disturbances to which the disposal system may be exposed.

4.7.3 Needs for dialogue, development and harmonization

As part of the future SITEX platform, it is suggested to first hold discussions with regulators & TSOs on the terminology to obtain a common understanding of:

- Good engineering practices;
- Feasibility;
- Proven Techniques and
- Demonstrability.

It will also be important to discuss on the practical implementation of these requirements as well as on the verification that there have been adequately implemented throughout the repository development process.

These discussions may lead the conclusion that further guidance needs to be developed.

4.8 ISOLATION AND CONTAINMENT

4.8.1 Requirements

The following safety requirements are associated with the "safety topic" "Isolation and Containment":

- In the Draft WENRA report on SRL's [47]:
  - SRL 2.1.5: general requirement on containment and isolation of the disposal facility for a period of time suited to its hazardous properties.
  - SRL 2.1.6: general requirement on isolation and containment during normal evolution, ensuring robustness of the disposal system.
  - SRL 2.3.5: on the safety functions to be fulfilled by the disposal facility during the operational phase and with among them the containment and isolation of radioactive material;.

- In IAEA SSR-5 [2]:
  - R8 : Containment of radioactive waste
  - R9: Isolation of radioactive waste

In general, the existing international requirements mention containment and indicated that objective for containment was to contain the waste in engineered barriers and host rock designed and guidance indicated that a period of time requirement to reduce risk. For isolation, the main points were for the repository to be sited away from humans and the environment. There was more information on containment then on isolation.

The draft WENRA SRL also mentions the lifecycle concept – looking at isolation and containment throughout each phase of a repository decommission and closure and based on the period of time that it will be hazardous.

4.8.2 Common points and differences between existing guides

In general, the existing national technical guides [12, 18, 23, 22] refer containment and indicated that the purpose of containment is to contain the radioactive waste. This is a common point. The majority of the guidance indicated that there was a need for multi-barriers and there is a period of time that is needed to be demonstrated to reduce hazard/risk. For isolation, this term was not as commonly mentioned as containment was. The majority of the technical guides mentioned to keep from humans and the biosphere.

4.8.3 Needs for dialogue, development and harmonization

In the accessible national guidance, the majority of countries included the concept of containment, however the concept of isolation was not found as frequently.

As part of the future SITEX platform, it is suggested to first hold discussions with regulators & TSOs on the terminology to obtain a common understanding of isolation and containment in their national guidance. These discussions may lead the conclusion that further guidance needs to be developed.

4.9 REVERSIBILITY/RETRIEVABILITY VS. SAFETY

4.9.1 Requirements

The following safety requirements are associated with the “safety topic” “reversibility/retrievability vs. safety”:

- In the Draft WENRA report on SRL’s [47] , SRL 2.1.7: The licensee shall ensure that any provisions to facilitate reversal of disposal operations, or retrieval of waste packages disposed of, have no unacceptable adverse effects on post-closure safety.

- In IAEA SSR-5 [2]:
    - alinea 1.20, 1.22 on possible reversibility and retrievability in the step by step approach within the development of the disposal facility.
    - alinea 1.25 on the no relaxation of safety standards or requirements because of possible retrievability

Requirements from WENRA and IAEA are focusing on the fact that provisions to facilitate reversibility or retrievability should not have unacceptable adverse effect.

4.9.2 Common points and differences between existing guides

IAEA Safety Guide SSG-23 references definitions from the NEA for retrievability and reversibility. It also states that retrievability and reversibility need to take into account at the very beginning during the siting and conceptual stage. Furthermore, it indicates that delay in closing and sealing the facility increases the risk, unless duly taken into account within a managed framework of reversibility.

Regarding national technical guides, information on reversibility and retrievability is found in [12,21,22,24] . France and Switzerland had information. However, France mainly focused on reversibility.

France has the “reversibility principle” stated in law and defines a reversibility phase. In the national guidance for France [22], reversibility is needed to be looked at in the conceptualization of the disposal and thus to be considered from the site selection. It shall as well be taken into account in the surveillance programme. The measures to ensure reversibility of disposal must not compromise either operational safety or post-closure safety of the repository.

The strategic note for Belgium FANC-NS [21] and the Belgian position paper FANC-RRR [24] provides definitions of reversibility and retrievability and also includes a definition for flexibility [21]. It mentions that reversibility starts with the emplacement of the first radioactive waste packages and terminates once a gallery or module is sealed. After that, the possibility of taking back the waste is called retrievability. Regarding when to consider reversibility and retrievability, the Strategic Note does specify that these should be considered during siting or conceptual phase. It mentions furthermore that, once there is no more regulatory control, any decision by future generations to retrieve waste placed in a repository must result in an intervention, within the radiological meaning of the term [21]. Furthermore it is stated that flexibility, reversibility and retrievability may not, in any event and at any time, threaten the operational safety and/or the long-term safety of the final disposal facility.

4.9.3 Needs for dialogue, development and harmonization

It could be useful for a future SITEX platform for regulators and TSO to first hold discussions on:

- terminology/ common understanding of retrievability and reversibility.
- benefits and potential adverse effects on safety
- time-frames associated with the level of retrievability & reversibility for each step of the facility develop ent

These discussions may lead the conclusion that further guidance needs to be developed.

4.10 GRADED APPROACH IN THE DEVELOPMENT OF A RADIOACTIVE WASTE DISPOSAL

4.10.1 Requirements

The following safety requirements are associated with the "safety topic" "Graded approach" in the development of a radioactive waste disposal:

- In the Draft WENRA report on SRL's [47]:
    - SRL 1.1.4: The licensee shall be responsible for implementing programmes and procedures necessary to maintain safety during operation, decommissioning and closure and to achieve post-closure safety. These programmes and procedures shall be proportionate to the hazards presented by the waste.
    - SRL 2.1.1: on the application of the ALARA principle in the development of disposal facility and the adoption of a graded approach depending on the hazard presented by the waste
- In IAEA GSR Part 3 [56] R6: Graded approach. The basic safety requirements in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the magnitude and likelihood of the exposures.
- In EC directive 2011/70/Euratom [3]: Article 4.3d stating that national policies on spent fuel and radioactive waste management shall follow a graded approach in the implementation of design measures to keep the generation of radioactive waste to the minimum which is reasonable.

4.10.2 Common points and differences between existing guides

Graded approach is dealt consistently through the existing guides. Graded approaches is proportionated to the hazard presented by the waste and the complexity of the installation.

4.10.3 Needs for dialogue, development and harmonization

No needs were identified for this topic.

4.11 STEPWISE APPROACH

4.11.1 Requirements

No SRL from the Draft WENRA report [47] is being proposed for the “safety topic”: “Stepwise approach”.
Following international safety requirements, associated with this topic are:

- In IAEA SSR-5 [2] R11: Step by step development and evaluation of disposal facilities

In the IAEA SSR-5 [2] requirement R11, the stepwise approach to the development of a disposal facility refers to the steps that are imposed by the regulatory body and by political decision making processes. Further the international standard develops many safety requirements on the step by step implementation of the planning measures that are necessary for safety and to assist in developing confidence in the safety of disposal facilities.

Although there are no WENRA SRL specifically dedicated to the stepwise approach, it is recalled in the context (Part II) of the Draft WENRA report [47] it refers to many IAEA requirements that are explicitly related to step by step development of a disposal facility.

4.11.2 Common points and differences between existing guides

IAEA documents SSG-14 [25] and SSG-23 [4] are more a restatement of SSR5-R11 than a guide describing how to this requirement should be implemented.

The EPG report [1] sets out what the regulator body expects from the safety case at each step of the project and how the regulator will evaluate the elements of the safety case. The steps considered in the EPG report provide a broad description of the progressive development of a repository and of its safety case. As such, these steps have to be considered as a generic framework to identify the expectations of the regulatory body.

At national level, most countries (e.g.: [13], [26], [27]) define the licensing steps in laws or decree. National guides mainly reaffirm elements developed in IAEA guides without adding additional guidance to implement the requirement.

4.11.3 Needs for dialogue, development and harmonization

The EPG report can be considered as the reference for this topic (when e.g. reviewing safety cases). Although the following need has been identified on:

- Prelicensing process (having the regulator involved early before a license application is submitted, including dealing with request of the public)

4.12 CONCURRENT ACTIVITIES

4.12.1 Requirements

The following safety requirements are associated with the “safety topic” “Concurrent activities”:

- In the Draft WENRA report on SRL’s [47] SRL 2.1.9: If construction, operation, decommissioning or closure activities take place concurrently, the licensee shall perform the works so that they will not have an unacceptable adverse effect on operational or post-closure safety.
- In IAEA SSR-5 [2] alinea 4.34 in R17 on Construction of a disposal facility: overlapping of construction and operational activities has to be planned and carried out so as to ensure safety, both in operation and after closure.

The requirement in the Draft WENRA report [47] focuses on the need to work against any unacceptable adverse effect on operational or post-closure safety, but does not mention any possible co-activity.

4.12.2 Common points and differences between existing guides

In several guides, the concurrent activities of excavation and waste emplacement are considered regarding:

- long term safety, in the ENSI-G03 guide from Switzerland [12] (§5,1,3,d);
- possible negative effects for long term safety of monitoring as in the ASN guide from France [22] (§5.6) or in [12] (§2,1), of recovering or retrieval in the BMU-2010 guide from Germany [11] (§8,6) and of driving the pilot facility in the ENSI-G03 guide from Switzerland [12] (§5,1,5).
- conducting co-activity in accordance with the requirements for radiation protection, excavation safety and industrial safety in IAEA SSG-14 [25] (IAEA SSG-14 [25], §6.45 and §6.51);
- the separation of mining and construction activities from waste emplacement activities as a way to optimize the radiation protection in IAEA SSR-5 [2] (§2.8) and in the German BMU guide[11] (§8.4)

4.12.3 Needs for dialogue, development and harmonization

The GEOSAF Companion report [63], in the chapter entitled “Need for future work”, underlines the need to exchange on <u>co-activity</u> between the nuclear (emplacement of waste packages, handling…) and non-nuclear (mining, civil engineering…) processes.

Two needs were identified within the SITEX project:

- The practical approach to manage concurrent activities should be developed, such as for example, the implications for the management system or the implication on design.
- The possible effects of concurrent activities on post-closure safety should also be discussed.

4.13 SAFETY POLICY & SAFETY STRATEGY

4.13.1 Requirements

The following safety requirements are associated with the "safety topic" "Safety Policy & Strategy":

- In the Draft WENRA report on SRL's [47]
    - SRL 1.1.3 on the establishment and implementation of a safety policy
    - SRL 1.2.1 on the establishment of an organizational structure in accordance with to the safety policy
    - SRL 1.3.5 on the management system that among others documents the safety policy.
    - SRL 2.1.10 on the integrated approach to safety, security and accounting and the assurance that safety is not unacceptably affected by measures for any other purpose.
    - Expectations about the description of the safety strategy in the safety case as asked in Draft WENRA SRL 4.1.5 are found in annex 3 of the Draft WENRA SRL document.

- In IAEA GSR-Part 4 [48] R22 & R23 : The safety assessment management and use of the safety assessment for it.

- In IAEA SSR-5 [2] R4 on the importance of safety in the process of development and operation of a disposal facility

4.13.2 Common points and differences between existing guides

4.13.2.1 INTERNATIONAL GUIDES

The NEA report on Post-closure Safety Cases for Geological Repositories [28], the IAEA guide SSG-23 [4] on the safety case and safety assessment [4] and The EPG report [1] address the requirements identified in §1. There are relatively consistent with each other regarding the scope and the understanding of the term "safety strategy" although each of them develops specific aspects more in details.

These guides define the safety strategy as the high-level approach adopted for achieving safe disposal including an overall management strategy, a siting and design strategy and an assessment strategy. This refers to the approach that will be taken to comply with the safety objectives, principles and criteria, to comply with regulatory requirements and to ensure that good engineering practice has been adopted and that safety and protection are optimized.

The overall management strategy must ensure the effective conduct of the activities required for repository planning and implementation. It includes the approach for implementing the optimization of protection principle. The siting and design strategy aims at developing a reliable and robust system and is generally based on principles that favour robustness and minimise uncertainty, including the use of the multi-barrier concept. The assessment strategy must ensure that safety assessments capture, describe and analyse uncertainties that are relevant to safety, and investigate their effects.

The safety strategy should address a number of key elements namely: the provision of multiple safety functions and defence in depth, containment and isolation of the waste, the adoption of passive safety features, robustness of the disposal system, demonstrability of safety related features and aspects and interdependencies with the predisposal management of the waste. It should also address the approach that will be taken to management of uncertainties with a view to ensuring that the approach to safety will be respected.

The early development and adoption of a strategy for safety is a key point in the development of the safety case. The safety strategy should remain consistent during the different phases of disposal facility development. Fundamental aspects of the strategy are not, in general, expected to change over the course of the project; however, they may evolve to take into account experience, technical developments, societal inputs, and new national and international standards and guidance. As the project develops the safety strategy should be continually validated and any changes to it should be justified in the safety case. Any evolution of the safety strategy should be carefully recorded.

4.13.2.2 National guides

Except for the Belgian guide [23], existing national guides [22, 29, 11] do not mention the safety strategy explicitly but address specific elements of the safety strategy as defined in international guidance.

The Belgian guide defines the safety strategy as the strategy describing the processes and the methods that will ensure that the disposal facility meets the safety objective. It repeats most of the elements described in the international guides and considers that the safety strategy is the reference for the iterative process of developing a repository. The safety concept is identified as an outcome of the safety strategy (see Figure 3).

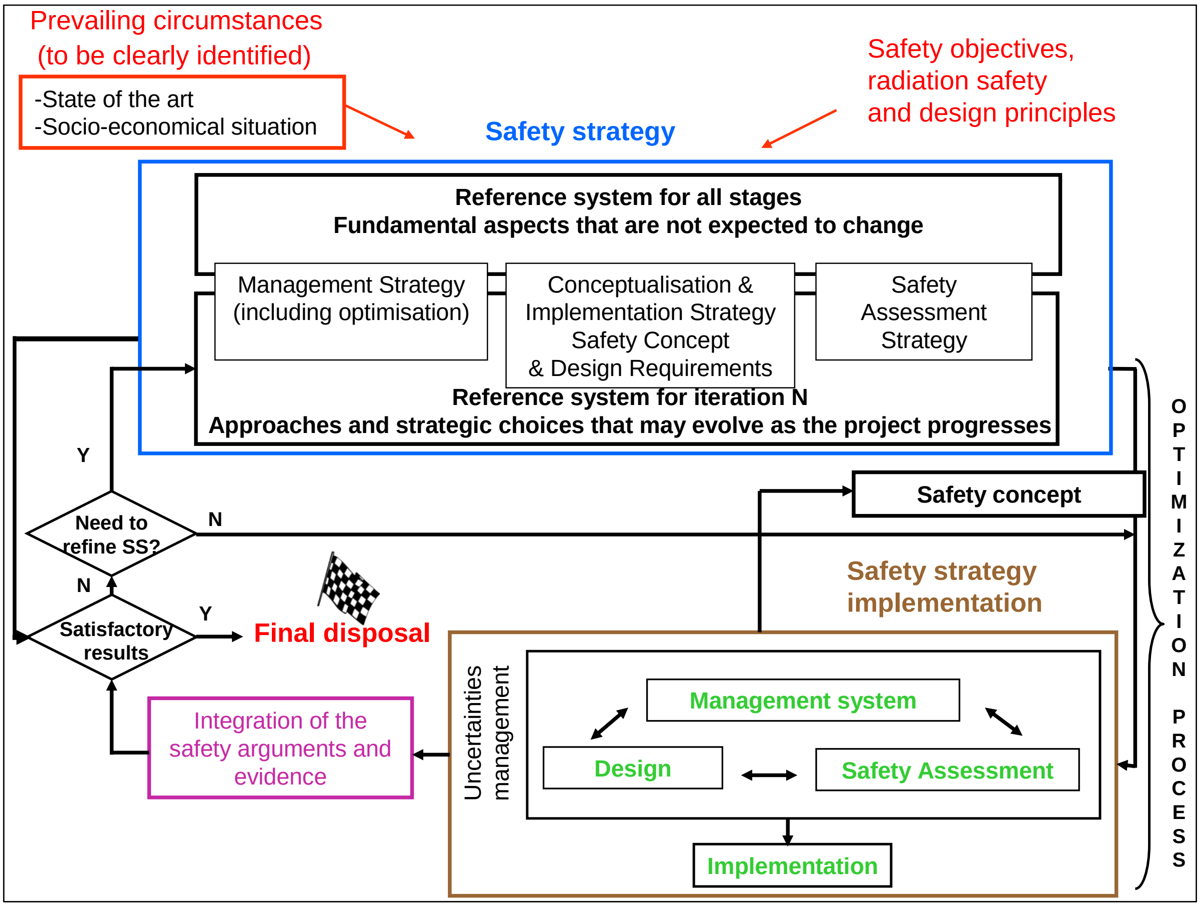

Figure 3. Safety strategy and its implementation through the step wise process to develop and implement a radioactive waste disposal.

4.13.3 Needs for dialogue, development and harmonization

The existing international guides [28, 4, 1] are consistent with each other and give a clear view of the expectations related to the safety strategy. However most existing national guides do not explicitly mention the safety strategy. Therefore it should be at least necessary to know if regulatory bodies consider the existing international safety guides as the reference when developing guide or reviewing safety cases.

Needs for dialogue and/or harmonization on the following issues have also been identified:

- Terminology: clarification of the understanding/scope of the terms « safety strategy» and « safety policy »
- Identification/clarification of the different elements of the safety strategy/policy

5 Management

5.1 INTRODUCTION

The implementer should establish, document, maintain, assess and continuously update a management system during all the activities to be carried out from site characterization to closure of the facility and, as required by the regulator, post-closure activities. This important "safety topic" is the subject of the IAEA GS-R-3 on Management for facilities and activities [57] and is well developed in EPG draft report [1].

The objectives of the management system are in particular:

- To ensure and demonstrate the commitment and responsibilities of the management.
- to ensure that the implementer has set up an appropriate organization (including staffing, skills, experience and knowledge) and processes to address any requirement or recommendation resulting from the regulations, from regulatory assessment of the project and/or from peer review;
- to ensure that the implementer competently undertakes all relevant activities required to be implemented and to ensure the quality of the deliverables;
- to ensure that R&D programmes are appropriately focussed on safety-relevant issues and adequate for the management of uncertainties;
- to take into account international feedback from similar facilities elsewhere;
- to ensure that key information, data and their provenance are recorded and preserved.
- to ensure that the management determines and provides the amount of resources (individuals, infrastructure, working environment, information and knowledge material and financial) necessary to carry out the activities.

The safety case should contain information about the implementation of the management system with particular emphasis on long project timescales considerations and the iterative nature of the project over these timescales. In particular, the implementer will be expected to present activities to be carried out and targets to be reached prior moving to the next step.

The implementer's management system needs progressively to improve and adapt so that it is suitable for each stage when that stage is reached. The implementer should substantiate that the allocation of appropriate resources is being updated and that needs for the next phase will be satisfied. In order to ensure that this is achieved, necessary adaptations need to be formulated in advance. In the early stages the regulator should be satisfied that the implementer will allocate and commit appropriate resources to the project. The long timescale for the process requires confidence in the stability of the implementing organization such that the safety strategy and safety relevant information will be preserved irrespective of potential future changes in organizations or responsibilities.

5.2 REQUIREMENTS

Many safety requirements are associated with the “safety topic” “management”:

- In the Draft WENRA report on Radioactive Waste Disposal Facilities SRLs [47]:
    - SRL 1.1.1 about responsibility for ensuring and demonstrating that the facility is safe before and after closure
    - SRL 1.1.2 about responsibility for commitment for maintaining safety using experience feedback and continuous safety improvement.
    - SRL 1.1.3 about responsibility to establish and implement a safety policy in line with national and international standards.
    - SRL 1.1.4 about responsibility for implementing programmes and procedures necessary to maintain safety and to achieve post-closure safety.
    - SRL 1.1.5 about responsibility to ensure that the timely availability of necessary resources when they are needed.
    - SRL 1.1.6 about responsibility for surveillance of the facility/activity and for any remedial action that might be required.
    - SRL 1.1.7 about responsibility to ensure that all activities are performed and controlled according to appropriate quality standards.
    - SRL 1.1.8 about responsibility to ensure that interfaces between organisations are clearly defined, agreed and documented.
    - SRL 1.2.1 about establishing an appropriate organizational structure to enable its safety policy to be properly implemented.
    - alinea 1.2.2: about adapting its organization.
    - SRL 1.2.3: about defining necessary qualification, experience and skills for all staff involved.
    - SRL 1.2.4 about implementing training programs and ensuring that personnel are appropriately trained.
    - SRL 1.2.5 about retaining capability to assess the adequacy of the contractor’s resources and skills.
    - SRL 1.3.1 about responsibility to and continuously improve its management system.
    - SRL 1.3.2 about ensuring that the management system covers normal operation conditions, anticipated operational occurrences and possible accidents.
    - SRL 1.3.3 about ensuring that its management system encompasses all activities related to safety in all stages of facility development.

- SRL 1.3.4 about ensuring that the management system encompasses processes to ensure compliance with waste acceptance criteria.
- SRL 1.3.5 about the documentation of the management system
- SRL 1.3.6 about ensure necessary documents (e.g.: operational procedures, instructions) have been prepared before beginning that activity
- SRL 1.3.7 about establishing and conducting an experience feedback programme
- SRL 2.6.14 about preparing adequate implementation arrangements before commissioning of the disposal facility and start of operation
- SRL 2.7.1 : about establishing and maintaining records of waste receipt inventory and emplacement, combined with information on waste acceptance
- SRL 2.7.2 about ensuring that knowledge and records important to safety are kept up to date and retained

- In IAEA SF-1 [55] Fundamental Safety principles
  - Principle 1: Responsibility for safety (paragraphs 3.3 – 3.7)
  - Principle 3: Leadership and management for safety (paragraphs 3.12 – 3.17)
- IAEA GS-R-3 [57] The Management System for Facilities and Activities (whole document)
- In IAEA GSR Part 3 [56]:
  - R4: Responsibilities of the protection and safety (paragraphs 2.39 – 2.46)
  - R5: Management for protection and safety (paragraphs 2.47 – 2.52)
  - R9: Responsibilities of registrants and licensees in planned exposure situations (paragraphs 3.13 - 3.15)
  - R21: Responsibilities of employers, registrants and licensees for the protection of workers (paragraphs 3.74 – 3.82)
  - R22: Compliance by workers: Workers shall fulfil their obligations and carry out their duties for protection and safety (paragraphs 3.83 – 3.84)
  - R23: Cooperation between employers and registrants and licensees (paragraphs 3.85 – 3.87)
  - R24: Arrangements under the radiation protection programme (paragraphs 3.88 - 3.98)
  - R30: Responsibilities of relevant parties specific to public exposure (paragraphs 3.125 – 3.130)

- In IAEA GSR Part 4 [48] Safety Assessment for Facilities and Activities:
  - R3 : Responsibility for the safety assessment

    - R22-24: Management, use and maintenance of the safety assessment (paragraphs 5.1 - 5.10)

- In IAEA SSR-5 [2] Disposal of Radioactive Waste:
    - R2: Responsibilities of the regulatory body (paragraphs 3.8 – 3.11)
    - R3: Responsibilities of the operator (paragraphs 3.12 – 3.16)
    - R25: Management systems (paragraphs 5.22 – 5.26)

- In EC directive 2011/70/Euratom [3] Article 7 on responsibilities, Management, financial and human resources and in particular Article 7.4: Establishment and implementation of an integrated management system including quality assurance by the licence holders to be verified by the competent regulatory authority

The IAEA Fundamental Safety Principles [55] provides for the overarching principles for addressing management also for disposal of radioactive waste. Likewise, IAEA GSR Part 3 [56] provides for some high-level principle requirements to be applied for radioactive waste management activities/facilities, including disposal.

The IAEA GS-R-3 [57] is a central reference in the IAEA suite of safety standards as regards management of facilities and activities and provides for basic requirements on establishing, implementing and assessing and continually improving a management system for any nuclear facility.

The IAEA SSR-5 [2] provides for requirements in general on disposal of radioactive waste, including management aspects and IAEA GSR Part 4 [48] addresses to some extent management aspects related to safety assessment activities.

The Draft WENRA SRL report for disposal [47] provides in SRLs 1.1.1 – 1.1.8 (Responsibility) 1.2.1 – 1.2.5 (Organizational structure), 1.3.1 – 1.3.5 (Management system) and 2.7.2 (Records and knowledge keeping) supplementary safety requirements as defined by WENRA. These requirements are, however, strongly linked to the IAEA Safety Requirements and provides limited added value to what exists in the IAEA Safety Standards.

5.3 COMMON POINTS AND DIFFERENCES BETWEEN EXISTING GUIDES

Management of activities, based on establishment of management systems, is a subject very general in context. Basic standards on management systems have been established by the International Organization for Standardization (ISO). The basic ISO-standards form the basis for the development of guidance for specific areas e.g. nuclear activities and disposal of radioactive waste. Approaches for developing management (systems) approaches for nuclear activities, including radioactive waste disposal, has since long been part of the work programme of the IAEA.

The current suite of IAEA Safety Standards builds on the fundamental principles [55] that are expanded/elaborated into more detailed specific and concretized requirements in the IAEA

Safety Requirements document GS-R-3, The Management System for Facilities and Activities [57] and further detailed in IAEA SSR-5, Disposal of Radioactive Waste [2].

The following guidance documents have been developed by the IAEA to provide for more detailed guidance associated with the topic "management":

- IAEA GS-G-3.1, Application of the Management System for Facilities and Activities [58]
- IAEA GS-G-3.4, The Management System for Disposal of Radioactive Waste [49]
- IAEA GS-G-3.5, The Management System for Nuclear installations [59]
- IAEA SSG-14, Geological Disposal Facilities for Radioactive Waste [25]
- IAEA SSG-23, The Safety Case and Safety Assessment for The Disposal of Radioactive Waste [4]

IAEA GS-G-3.1 [58] functions as a sort a general guidance for how to implement the basic requirements in IAEA GS-R-3 [57]. IAEA GS-G-3.5 [59] provides for specific guidance for nuclear installations in general whereas IAEA GS-G-3.4 [49] provides for even further elaborated guidance for facilities for disposal of radioactive waste. It is worth mentioning that [49] contains two specific appendices addressing specificities for disposal facilities:

- Appendix I: Aspects of management systems specific to the phases of operation, closure and post-closure active institutional control for disposal facilities for radioactive waste
- Appendix II: Guidance on controlling the computer modelling of disposal facilities for radioactive waste

Both IAEA SSG-14 and SSG-23 provides for specific guidance related to disposal facilities for radioactive waste. IAEA SSG-14 [25] is general guidance for how to implement the basic requirements in IAEA SSR-5 [2] and paragraphs 6.77-6.84 contains specific guidance on management systems for geological disposal of radioactive waste. IAEA SSG-23 [4] provides for specific guidance on the (management of the) safety case and safety assessment (including management system aspects) for disposal of radioactive waste.

International projects have also been launched to look into specific subjects related to the topic management. One such example is the project Preservation of Records, Knowledge and Memory (RK&M) across Generations, an initiative of the OECD/NEA Radioactive Waste Management Committee (RWMC), running from 2011 to2014 [75] **.**

Specific national guidance on management (systems) for disposal of radioactive waste has not been identified. National guidance in legislation, ordinances or regulations does in general not specifically address management systems (or quality assurance systems) except in a general sense, i.e. specifying that a quality management program should address certain elements at a certain stage in the establishment of a nuclear practice [12, 27, 31, 61]. One could conclude that the topic "management (system)" is not something that is specific for disposal of radioactive waste but rather an obvious element in most activities. Thus, when dealing with disposal of radioactive waste (or any other specific activity), it is essential to adapt the management (system) to the specificities of that specific activity.

5.4 NEEDS FOR DIALOGUE, DEVELOPMENT AND HARMONIZATION

Existing international guidance seem to be more or less satisfactory. Also, national regulations/guidance seems to appropriately address the main issue of management (systems).

Thus, no specific need for development of further guidance for this topic has been identified although some specific issues were identified as having a potential for further discussions on possible development, e.g.:

- Allocation of responsibilities in general, clarification of extent of responsibilities
- until termination of the license
- interfaces as regards responsibilities of the licensee of a disposal facility and the organisations responsibility for the waste before sending to the repository
- Assessment of compliance with requirements associated with available resources (i.e. organisational structure, staffing, skills, experience and knowledge, training/recruitment programs for the life-cycle of a DGR, infrastructure, subcontractors, financial resources, …)
- Principle and means of preservation of records and knowledge

6 Site Selection

6.1 REQUIREMENTS

No SRL's from Draft WENRA report [47] is being proposed for the "safety topic" "Site selection".

Nonetheless, several IAEA safety requirements are associated with this topic:

- In IAEA SSR-5 [2]:
  - R4: on the importance of safety in the process of development and operation of a disposal facility where the understanding of the relevance and the implications for safety of the siting options among the other available options shall be developed with the purpose of providing an optimized level of safety ;
  - R7 on the use of multiple safety functions to ensure safety and overall performance of the disposal in, among others, the selection of the host environment;
  - R8 on the containment of radioactive waste, which has to be provided by the host environment and the engineered barriers.;
  - R9 on the isolation of radioactive waste from people and the accessible biosphere, which has to be provided by the siting, design and operations of the disposal facility..

6.2 COMMON POINTS AND DIFFERENCES BETWEEN EXISTING GUIDES

National guidance typically requires that one or several safety functions are attributed to the host rock. Besides, several guides describe the factors that need to be taken into account when selecting a site to ensure that these functions will be fulfilled (e.g. [34, 33]).

The following siting criteria are typically considered in guidance documents:

- The stability or robustness of the geological formation is an important aspect underlined in all guidance documents.
- Avoidance of natural resources in order to limit intrusion is a common requirement of all guides. However the definition of natural resources varies from one document to another. Some guides recommend explicitly to take drinkable water into consideration; more generic definitions such as "raw materials deposit that are workable for present day" are also used.
- Depth is commonly identified as a key factor. An a priori minimum depth is provided in one of the guides [22]. The repository should be located deep enough to avoid (or minimize) external disturbances from its environment (such as erosion, intrusion,…).

- The thickness of the layer is sometimes mentioned (e.g. [34, 32]). The thickness of the layer should be thick enough to host on one hand the repository and on the other hand to ensure that the minimum level of performance required from the host rock will be reached.
- Avoiding geological discontinuities is a recurring theme in several guidance documents (e.g. [34,33]).

An appropriate characterisation of the site is a common requirement in most guides and detailed guidance on characterization is provided in several documents (e.g. [22,25]). The importance of the investigation scale that should be at least consistent with the scale of the repository is also underpinned [22,34].

Some countries clearly state in their guidelines that site selection should be the result of an optimisation process (e.g. [34,11]) while others may have more generic optimisation requirements without specification of the step(s) of repository development to which optimisation applies (e.g. [30]). Factors that need to be taken into consideration in site optimisation may also be specified (e.g. [34,25]).

The different stages of site selection and the procedures associated with these stages are also provided in one guidance document SFOE-SP [31].

6.3 NEEDS FOR DIALOGUE, DEVELOPMENT AND HARMONIZATION

The need for developing guidance on site selection method and criteria has been identified. In particular, dialogue and/or developments on the weighting of criteria when applying optimisation to site selection (as discussed in safety requirement IAEA SSR5 R4 [2] and in ICRP publication 122 [62]) are felt useful.

7 Design

7.1 REQUIREMENTS

The following safety requirements are associated with the “safety topic” “design”:

- In the Draft WENRA report on SRL’s [47]: SRLs 2.3.1 to 2.3.14 related to the design of the disposal facility and system

- In IAEA SSR-5 [2]:
    - R7 on the use of multiple safety functions to ensure safety and overall performance of the disposal;
    - R8 on the containment of radioactive waste, which has to be provided by the host environment and the engineered barriers;
    - R9 on the isolation of radioactive waste from people and the accessible biosphere, which has to be provided by the siting, design and operations of the disposal facility.
    - R16 on the Design of a disposal facility

The general message is as follows. Operational and post-closure safety should be provided.
The licensee shall design the facility on the basis of normal conditions, as well as for possible accidents conditions. The licensee shall define and document the design basis.
The following safety functions should be fulfilled during the operational phase:

- Control of the exposure of operating personnel, the general public and the environment;
- Containment and isolation of radioactive material;
- Control of sub-criticality, if applicable
- Heat or gas removal, if applicable.

These safety functions shall be achieved during normal operation, and during anticipated operational occurrences and possible accidents.
The design of the facility should be based on applicable standards, appropriately proven techniques and the use of appropriate materials. The engineered components should be compatible with each other, the waste and the host environment. Provisions are made for maintenance, testing, inspection and monitoring of SSCs, addressing also their ageing, for monitoring the host environment and to enable surveillance.
Passive operational safety features should be applied into the design of the disposal facility as far as reasonably practicable and the handling equipment is designed to take account of radiation protection aspects, ease of maintenance, and minimization of the probability and consequences of anticipated operational occurrences and possible accidents during handling.

7.2 COMMON POINTS AND DIFFERENCES BETWEEN EXISTING GUIDES

Common points (found in most of the guides)

- Criticality must always be avoided.
- Radiological monitoring will be foreseen.
- Containment can be achieved through a robust design based on multiple barriers and on the defence-in-depth principle, in order to prevent significant inflow of water as far as possible.
- Underground structures are to be designed and maintained in such a way that their safe operation is assured until final closure of the repository.
- When designing the geological repository, attention has to be paid to the thermal output of heat-producing waste and its compatibility with the engineered and natural barriers.
- During design attention has to be paid to the effectiveness of safety functions during accidents.
- Wherever possible, safety functions must be implemented in accordance with the principles of redundancy and diversity.
- Preference should be given to passive rather than to active safety functions.
- There should be a spatial separation between radioactive waste handling areas (operation work) and mining work areas (construction work).

Differences

- The level of detail concerning accidents and operational failures differ from one country to another.
- Differences concerning retrievability of the radioactive waste: in some countries post-closure retrievability is required and therefore sets boundary conditions to the repository design (e.g. Germany, see below).

Country specific guidelines

Some more specific design guidelines are mentioned in national guides:

ENSI (Switzerland)

- Safety functions must be automated so that, in the event of malfunctions, no safety-relevant interventions by personnel are required during the first 30 minutes following the initiating event.
- The expected ambient dose rate in areas that are entered routinely has to be kept low by designing facility components with a view to accommodating appropriate fixed or movable shielding.
- The repository must be designed so that it can be closed within a period of several years.

GRS (Germany)

- Every effort must be made to minimise the number of holes in the isolating rock zone and they should be executed in a manner designed to cause minimum damage to the rock.
- Handing of the waste containers must be guaranteed for a period of 500 years in case of recovery from the decommissioned and sealed final repository.

IRSN/ASN (France)

France has more detailed requirements in order to take into account long-term safety of the repository:

- The design of the repository must take into account the influence of present air volumes or gas production.
- The maximum temperature between the waste packages and the engineered barriers must be limited to 100°C

Furthermore, the IAEA document SSG-14 [25] considers that the design should meet the precept of simplicity. This recommendation is not mentioned in national guides. Guidance on technical feasibility is not systematically provided in national guides dealing with the repository design, whereas it is generally a main requirement.

7.3 NEEDS FOR DIALOGUE, DEVELOPMENT AND HARMONIZATION

Some specific issues that could be subject for development have been identified:

- Development of the “design basis” including:
    - Design giving due consideration of characteristics of radioactive waste and of the site
    - Consideration of normal operational conditions, anticipated operational occurrences and possible accidents
    - Design giving due consideration to disturbing features, events and processes and disturbances during operation whose consequences may affect post-closure safety
- Development process of design requirements & specifications
- Design of underground access structures (design to prevent significant inflow of surface water and to meet the requirements relating to normal operation and to management of incidents or accidents).
- Consideration of stakeholder requirements regarding design.

8 Construction

8.1 REQUIREMENTS

The following safety requirements are associated with the "safety topic" "construction":

- In the Draft WENRA report on SRL's [47]:SRLs 2.5.1 to 2.5.4 on construction of the disposal facility

- In IAEA SSR-5 [2] R17 on Construction of a disposal facility

The general message is as follows. The disposal facility shall be constructed in accordance with the design as described in the safety case and by application of appropriately proven techniques and in such a way as to preserve the post-closure safety functions of the host environment.

During the construction, the licensee shall gather information in particular to improve the knowledge of the properties of the host environment and refine the assumptions of the safety case and of the geomechanical response of the host environment to, and the effect on geochemical and hydrogeological conditions of, the perturbations induced by the facility. The licensee shall plan, assess, document, review, and implement any modifications of design, construction procedures and methods using arrangements consistent with the importance to safety of the modification. These arrangements shall ensure that the modifications will not have an unacceptable effect on operational and post-closure safety.

8.2 COMMON POINTS AND DIFFERENCES BETWEEN EXISTING GUIDES

The existing international guides as IAEA SSG-14 [25], IAEA SSG-23 [4] and EPG [1]) are consistent with each other.

The international guides IAEA SSG-14 [25], EPG [1] and IAEA SSG-23 [4] cover the draft WENRA SRL 2.5.1, 2.5.2, 2.5.3 and 2.5.4 and the IAEA SSR-5 requirement 17. However, additional guidance may be developed on the following aspects.

- The main areas on which information should be gathered by the operator during the construction phase (draft WENRA SRL 2.5.3 gives more details on this topic than the safety guides). This point may equally be developed in a safety guide devoted to the monitoring programme.
- The approach to deal with the design modifications that may occur during the construction phase (draft WENRA SRL 2.5.4).

According to the answers to the questionnaire WP2.1, there are no national guides specifically devoted to the construction phase of a geological disposal However, the construction phase is partially covered by the national documents listed in section 2. IAEA SSR-5 requirement 17 and the 2 following draft WENRA SRL are principally covered by these documents:

- SRL 2.5.2 is covered by ENSI-G03 in Switzerland [12] and “Safety Requirements Governing the Final Disposal of Heat-Generating Radioactive Waste” in Germany [11];
- SRL 2.5.3 is covered by the French guide “Safety guide for final disposal of radioactive waste in geological formations” [22].

8.3 NEEDS FOR DIALOGUE, DEVELOPMENT AND HARMONIZATION

Since no participating countries have developed specific guidance on the construction phase of a geological disposal and considering that the international guides only partially cover the construction phase, the development of a safety guide devoted to the construction phase of geological disposal facilities is needed.

The new safety guide should particularly address:

- the implication of constraints associated with nuclear safety on the management of construction activities (including construction procedures, quality control,…)
- the main areas on which information should be gathered by the operator during the construction phase (monitoring programme);
- the approach to deal with the design modifications (assessment, review, documentation,…) that may occur during the construction phase.

9 Operation

9.1 GENERAL ASPECTS

9.1.1 Requirements

The following safety requirements are associated with the general "safety topic" "Operation":

- In the Draft WENRA report [47] SRL 2.6.1: general requirement on operation
- In IAEA SSR-5 [2] R18: Operation of a disposal facility

The Draft WENRA report [47], SRL 2.6.1 and IAEA SSR-5 [2], R18, both indicate that the licensee shall operate the facility in accordance with the conditions of the licence and the relevant regulatory requirements so as to maintain safety during the operational phase, and so as to establish and preserve the post-closure safety functions claimed in the safety case.

9.1.2 Common points and differences between existing guides

The common points and differences between existing guides regarding operation are developed below for each of the identified subtopics.

9.1.3 Needs for dialogue, development and harmonization

The SITEX participants have identified the need for additional developments on the way to operate in accordance with the conditions of licence and regulatory requirements.

9.2 INVESTIGATIONS AND FEEDBACK OF INFORMATION ON OPERATING EXPERIENCE

9.2.1 Requirements

The following safety requirements are associated with the subtopic "Investigations and feedback of information on operating experience":

- Draft WENRA report [47] SRL 2.6.2: general requirement on detection and response to anticipated operational occurrence

- IAEA GSR-Part3 [56] R16: Investigations and feedback of information on operating experience

The two developed requirements focus on respectively the need to detect and respond to anticipated operational occurrences and possible accidents so as not to jeopardize post closure safety, SRL 2.6.2 [47] and the need to carry out investigations on operational occurrences, accidents and abnormal events and to disseminate information that is significant for protection of safety, R16 in the GSR Part 3 [56].

9.2.2 Common points and differences between existing guides

Two aspects developed in international guides are:

- the radiation protection programme, given that it includes training and use of mock-ups as well as feedback of experience in TECDOC 630 [36] (§4.6);
- feedback of experience and technologies from operating of other nuclear facilities in SSG-14 [25] (§4.6). This aspect in also developed in the NEO national guide from Switzerland [27] (Article 33.1-b).

9.2.3 Needs for dialogue, development and harmonization

The following topics need to be developed:

- how to investigate the specificities of operation of an underground nuclear facility (fire protection, ventilation…), by collecting feedback and develop specific studies;
- how to ensure post-closure safety during operation.

9.3 OPERATIONAL LIMITS AND CONDITIONS

9.3.1 Requirements

The following safety requirements are associated with the subtopic “Operational limits and conditions”:

- In Draft WENRA Report [47] SRL 2.6.3 on operational limits and conditions, which have to be established, substantiated, documented and implemented by the licensee.

- In IAEA GSR Part 3 [56], §3.123a: the registrants or licensees shall use the operational limits and conditions as the criteria for demonstration of compliance after the beginning of operation of a source.

- In IAEA SSR-5 [2]
    - R3: Operation of a disposal facility, § 3.14: the operator has to establish technical specifications that are justified by safety assessment, to ensure that the disposal facility is developed in accordance with the safety case. This has to include waste acceptance criteria (see Requirement 20) and other controls and limits to be applied during construction, operation and closure.

- R18: The disposal facility shall be operated in accordance with the conditions of the licence and the relevant regulatory requirements so as to maintain safety during the operational period and in such a manner as to preserve the safety functions assumed in the safety case that are important to safety after closure. (§ 4.35 to 4.37).
- In particular § 4.35: all operations and activities important to the safety of a disposal facility have to be subjected to limitations and controls and emergency plans have to be put in place. […] Additional facility specific criteria may be established by the regulatory body or by the operator.

Although operational limits and conditions, as explained in IAEA GSR Part 3 [56] and IAEA SSR-5 [2] have to be established by the regulatory body in the framework of the license application and this is seen as a responsibility of the government and regulatory body, it is asked to the licensee to provide controls and limits to be applied during construction, operation and closure and further to meet the limits and conditions as defined in the license application. IAEA GSR Part 3 [56] requirements in § 3.123 on what to consider in the establishment of these OCLs, are also firstly addressed to regulatory body. However requirements on aspects as e.g. the definition of dose below the dose limits, the consideration of optimization of protection and safety, the use of good practice, the operational flexibility and the potential radiological environmental impact assessment (see § 3.123b to e) should also apply to the licensee.

9.3.2 Common points and differences between existing guides

This topic is developed in international and national guidance.

In IAEA SSG-14 [25], it is highlighted that the use OLCs for geological disposal facilities is quite different than that for other nuclear facilities (1.7) for which the safety mainly focus on the operational phase
IAEA SSG-14 [25] recalls that the facility should be operated in accordance with the terms and conditions of the operating licence and relevant regulatory requirements to provide for adequate radiation protection of workers, the public and the environment (§ 6.48). It specifies some elements of obtaining approval for operation in the license process as : the adequacy of the facility structures, systems, components, services, functions and procedures for the safe receipt, emplacement and, if necessary, retrieval of waste packages, including for off-normal events and emergency conditions (§ 6.47).

Even if this topic appears well developed in international guidance, this guidance is mainly developed for the safety of nuclear installations having their core mission during the operational phase. It follows that technical guidance is not completely adapted to the geological disposal facilities.

In national guides, the need to counter any deviations from normal operation as well as considerations on malfunctions and measures to prevent and mitigate the consequences of abnormal releases is specified in the Swiss Nuclear Energy Ordinance (CH_NEO) [27] (§7, Article 7).

9.3.3 Needs for dialogue, development and harmonization

Developments are required on the way how to establish and substantiate OLCs, how to maintain OLCs to ensure compliance with end-state, how to meet OLCs and assure that they are being met, and finally on the feedback from other nuclear facilities.

This is also emphasized in the GEOSAF Companion report [63], which indicates that: "*The definition of normal operation (normal operation envelope) and anticipated operational occurrences (incidents and accidents), and the associated set of safety margins and limits to get from one state to the other, is an area of knowledge that needs to be developed. As few experience feedback is available from existing geological disposal facilities, efforts could be made to gain as much as possible experience from other (nuclear) facilities*".

9.4 MODIFICATIONS

9.4.1 Requirements

The following safety requirements are associated with the specific subtopic "Modifications":

- In the Draft WENRA report on SRL's [47] :
  - SRL 2.6.6 on the modifications to the disposal facility during operation that may not have unacceptable effect on operational and post-closure safety.
  - SRL 2.6.7 on the planning and documentation of any modifications of design, waste acceptance criteria, structures, system and components, operational limits and conditions (OLCs) and operational procedures.

9.4.2 Common points and differences between existing guides

The considerations on maintenance, refurbishment or replacement of equipment presented in SSG-14 [25] (§6.52) may be added to this topic.

This topic is considered in the NEO national guide from Switzerland [27] (Article 33), indicating that when assessing the impact of modifications to the facility, systematic safety and security assessment has to be carried out and *"each risk assessment must incorporate an up-to-date, plant-specific probabilistic safety assessment (PSA)…"*.

The question of the effects of anticipated operational occurrences (incidents and accidents) on the operational or the post-closure safety is also underlined by GEOSAF in the Companion report [63].

9.4.3 Needs for dialogue, development and harmonization

These requirements have to be gathered and developed in a same guide, in particular the modifications of design, waste acceptance criteria, structures, SSCs (systems and components), OLCs (operational limits and conditions) and operational procedures and methods.

9.5 EMERGENCY PREPAREDNESS AND RESPONSE

9.5.1 Requirements

Several safety requirements are developed on the subtopic "Emergency preparedness and response":

- In the Draft WENRA report on SRL's [47]:
    - SRL 2.6.8 on the preparation and implementation of an Emergency plan proportionate to the consequences of possible accidents considered;
    - SRL 2.6.9 on the objectives of the Emergency plan;
    - SRL 2.6.10 on the organizational structure to be established and implemented for Emergency preparedness and response, with appropriate trained and qualified personnel, facilities and equipment;
    - SRL 2.6.11 on the submission of the Emergency plan to the regulatory body, its testing by emergency exercises and its review

- In IAEA SF-1 [55] P9 (§3.34 to 3.38): Emergency preparedness and response
- In IAEA GSR Part3 [56]:
    - alinea R15, 3.43 and 3.44 on Emergency preparedness and response
    - R43: Emergency management system
    - R44: Preparedness and response to an emergency
    - R45: Arrangements for controlling the exposure of emergency workers
    - R46: Arrangements for the transition from an emergency exposure situation to an existing exposure situation

- The IAEA GS-R-2 Standard on "Preparedness and Response for a Nuclear or Radiological Emergency" [64].

9.5.2 Common points and differences between existing guides

Several IAEA guides develop this subject for any nuclear facility as in RS-G-1.1 [38] (§ 6) and GS-G-2.1 [65].

However, neither these one nor the above SRLs consider the particularity of the underground facilities as for geological disposals, and the associated complexity of emergency. The existing guides dedicated to safety of geological disposal facilities do not develop this issue.

9.5.3 Needs for dialogue, development and harmonization

The need to discuss on emergency and preparedness and in particular on collecting experience feedback from the emergency plans existing in exploitation mines, tunnels and other non-nuclear underground facilities.

9.6 MAINTENANCE, PERIODIC TESTING AND INSPECTION

9.6.1 Requirements

The following safety requirements are associated with the subtopic “Maintenance, periodic testing and inspection”:

- Three requirements indicate the role of licensees for maintenance, periodic testing and inspection in the WENRA draft report [47]:
    - SRL 2.6.12: on the establishment and implementation of programmes for maintenance, periodic testing and inspection
    - SRL 2.6.13: on recording and assessing the results of maintenance, periodic testing and inspection
    - SRL 2.6.14: on reviewing and revising programmes of maintenance, periodic testing and inspection

- The IAEA SSR-5 [2] R10 on Surveillance and control of passive safety features addresses the topic.

9.6.2 Common points and differences between existing guides

Some issues are developed in the NEO guide [27] from Switzerland (§4, Article 32).
Additional considerations are developed in this document about monitoring ageing of equipment and structures [27] (§4, Article 35).

No developed guidance exists on records required in the SRL 2.6.13 [47]. The same way, no guidance develops the SRL 2.6.18 [47] on programmes for maintenance, periodic testing, and inspection.

9.6.3 Needs for dialogue, development and harmonization

Following issues that could be subjected for development have been identified:

- ageing of equipment and structures during the operational phase
- programmes and records

9.7 OCCUPATIONAL EXPOSURE

9.7.1 Requirements

The "Occupational exposure" is addressed

- only indirectly in the Draft WENRA report on SRL's [47] through the following generic SRL's:
    - SRL 2.3.5 on the disposal facility that has to be designed to fulfil safety functions during the operational phase and among them the control of the exposure of operating personnel, the general public and the environment;
    - SRL 4.2.1: on the operational safety assessment that has to consider both occupational and public exposures resulting from normal operation, and anticipated operational occurrences and possible accidents

The Draft WENRA report has indeed not taken into account the conventional occupational health and safety, physical protection, which are considered to be covered by other regulatory requirements.

- Several IAEA safety requirements are developed, mainly in the GSR Part 3 [56] on this topic:
    - R 19 on Responsibilities of the regulatory body specific to occupational exposure to ensure that protection and safety is optimized, and enforce compliance with dose limits for occupational exposure;
    - R 21 on responsibilities of employers, registrants and licensees for the protection of workers against occupational exposure and for its optimization;
    - R 23: Cooperation between employers and registrants and licensees for compliance by all responsible parties with the requirements for protection and safety;
    - R 24: Organization between employers, registrants and licensees for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace, in a radiation protection programme for occupational exposure;
    - R 25: Assessment of occupational exposure and workers' health surveillance;
    - R 26: Information, instruction and training of workers by employers, registrants and licensees.

9.7.2 Common points and differences between existing guides

The International guide IAEA RS-G-1.1 [38], is dedicated to Occupational Radiation Protection. It develops complete chapters on framework for occupational radiation protection (§2), dose limitation (§3) and optimization of radiation protection for practices (§4). Many developments are particularly dedicated to exposure to natural sources such as radon and thoron, for installations and facilities such as mines and mills, processing radioactive ores and radioactive waste management facilities.

As is asked in IAEA GSR Part 3 [56], occupational exposure is also formulated in the guide [38] in terms of responsibilities among the registrants, licensees, employers and workers (respectively, in §2.33 to 2.35, 2.36 to 2.39, 2.40 to 2.42 and 5.33)

The other existing guides for disposals, as IAEA-TECDOC-630 [36] or for geological disposal SSG-14 [25] do not provide additional requirements with these ones.

9.7.3 Needs for dialogue, development and harmonization

This topic does not require additional development in the frame of the SITEX platform.

9.8 PUBLIC EXPOSURE

9.8.1 Requirements

- As for Occupational exposure the subtopic "Public exposure" is only indirectly addressed in the Draft WENRA report on SRL's [47] in:
    - SRL 2.3.5 on the disposal facility that has to be designed to fulfil safety functions during the operational phase and among them the control of the exposure of operating personnel, the general public and the environment;
    - SRL 4.2.1: on the operational safety assessment that has to consider both occupational and public exposures resulting from normal operation, and anticipated operational occurrences and possible accidents

Several IAEA safety requirements are developed, mainly:

- In the GSR Part 3 [56] on this topic:
    - R 30 on the responsibilities of the relevant parties to apply the system of protection and safety to protect members of the public against exposure;
    - R 31 on the responsibilities of the relevant parties to ensure that radioactive waste and discharges of radioactive material to the environment are managed in accordance with the authorization.
- In IAEA SSR-5 [2], (§2.11) about radiological protection during the operational period, stating that no release, or only very minor releases, of radionuclides may be expected.

9.8.2 Common points and differences between existing guides

Requirements dedicated to public exposure are scarce in international references for geological disposal facilities. The guides are more developed on workers' exposure:

- General requirements on occupational Radiation Protection for workers in RS-G-1.1 [38] must also be applied to members of the public (justification of practices, optimization, information and training…);
- Irradiation from the excavated rock brought to the surface should not be treated as background radiation, but rather as an additional radiation source resulting from repository operations in IAEA-TECDOC-630 [36] (§2.1);
- The radiation protection programme for the facility should include: controlling public access to areas of operational sensitivity; monitoring of off-site environments to detect possible excessive radiation or releases of radioactive material; informing the public on the general aspects of radiation hazards and repository operations; development of appropriate emergency plans, also in IAEA-TECDOC-630 [36] (§2.2).

9.8.3 Needs for dialogue, development and harmonization

This topic thus does not require additional development in the frame of the SITEX platform.

9.9 RECEIVING, HANDLING AND EMPLACEMENT OF WASTE

9.9.1 Requirements

The following safety requirements are associated with the subtopic "Receiving, handling and emplacement of waste":

- In the Draft WENRA report on SRL's [47]:
    - SRL 2.3.13: on the design of the handling equipment to take account of radiation protection aspects, ease of maintenance, and minimization of the probability and consequences of anticipated operational occurrences and possible accidents during handling.
    - SRL 2.6.4 on the planning, assessment, reviewing and implementation arrangement before commissioning of the disposal facility and start of the operation including arrangement for receiving, handling and emplacement waste

9.9.2 Common points and differences between existing guides

International IAEA-TECDOC-630 [36] provides guidance on operation during receipt of the waste (3.2), buffer storage (3.3), waste package preparation (3.4), transfer of waste from surface to underground (3.5) and emplacement of waste (3.6).

9.9.3 Needs for dialogue, development and harmonization

The requirements on receiving, handling and emplacement of waste need to be developed, possibly by proposing a revised version of the IAEA-TECDOC-630 [36].

10 Closure & decommissioning

10.1 REQUIREMENTS

The following safety requirements are associated with the “safety topic” “closure and decommissioning”:

- In the Draft WENRA report on SRL’s [47]:
  - SRL 2.6.5 on planning for closure decommissioning and post-closure activities before starting the operational phase;

  On the closure of the disposal facility:
  - SRL 2.8.1: so as to provide for the safety function required after closure;
  - SRL 2.8.2: dismantling and decommissioning the structures, systems and components that are not needed after closure as required;
  - SRL 2.8.3: defining the appropriate programme;
  - SRL 2.8.4: in accordance with the conditions of the licence and relevant regulatory requirements so as to maintain safety during decommissioning and closure, and so as to establish and preserve the post-closure safety functions claimed in the safety case;
  - SRL 2.8.5: planning, assessing, documenting and implementing any modifications in the authorized procedures and methods and
  - SRL 2.8.6: documenting after the closure operations, through a report, the state of the disposal system as built

- In IAEA SSR-5 [2] R19: on the Closure of a disposal facility

- The IAEA WS-R-5 [91] on “Decommissioning of Facilities Using Radioactive Material”

The general message is as follows. Before starting the operational phase, the licensee shall plan for closure, decommissioning and post-closure activities. The licensee shall close the disposal system in such a way as to provide for the safety functions required after closure. The licensee shall ensure that structures, systems and components that are not needed after closure are safely dismantled and decommissioned as required.

Before starting decommissioning and closure, the licensee shall define the corresponding programme so that it takes into account the state of the facility, dismantling and removal of operational equipment, remaining backfilling and sealing, decommissioning of auxiliary structures, environmental remediation as required, programmes for surveillance, security and safeguards, plans for preserving knowledge and records about the waste disposed of and the disposal system.

The licensee shall perform decommissioning and closure activities in accordance with the conditions of the licence and the relevant regulatory requirements.
The licensee shall plan, assess, document and implement any modifications in the authorized decommissioning and closure procedures and methods using arrangements consistent with the importance to safety of the modifications.
After completion of the closure operations, the licensee shall prepare a report that documents the state of the disposal system including as built records of the means of closure as actually implemented.
Availability of the necessary technical and financial resources to achieve closure and decommissioning has to be assured.

10.2 COMMON POINTS AND DIFFERENCES BETWEEN EXISTING GUIDES

Common points (found in most of the guides)

- A (preliminary) decommissioning plan or plan for the monitoring period and the closure of the facility should be submitted in order to obtain a general/construction license. The level of detail depends on the country.
- This decommissioning plan has to be kept up to date throughout the lifecycle of a disposal facility.
- Documentation about the repository should be kept, and will be handed over to the supervisory authorities after decommissioning. There is a requirement for long-term retention and method of retention of records.
- When closing a deep geological repository, its owner must backfill all still open areas of the repository and seal the sections important for long-term safety and security. The most important safety function of this backfilling and sealing is to limit the release of radionuclides (radionuclide containment).
- Granting a license for the closure/decommissioning of a repository is a federal/national matter.
- Adequate financing will be available for the repository closure and decommissioning phase and for the proper management of the resulting radioactive waste.
- An agreement exists about the fact that finally a passive state should be reached.

Differences

- Different time indications are mentioned, e.g. for the update of the decommissioning plan: every 5 years for Canada (indicated in questionnaire), while in most other countries this is every 10 years.
- Some countries mention a period within which sealing/closure must be achieved (e.g. Switzerland Nuclear Energy Act [26]: “A deep geological repository must be designed to ensure that it can be closed within a period of several years).

- Although the clearance of material deriving from the decommissioning phase is considered in the IAEA safety guides (e.g. IAEA WS-G-5.2 [40]), there is currently no consensus among the partners on this option (e.g. France, no clearance).
- Some countries consider the release of the site for unlimited use (e.g. Czech Republic), while other countries consider restricted use (e.g. Switzerland Nuclear Energy Ordinance [27]: a definitive protection zone must be defined for a deep geological repository).

10.3 NEEDS FOR DIALOGUE, DEVELOPMENT AND HARMONIZATION

Some specific issues that could be subject for development have been identified:

- Programme of closure and decommissioning (including timeframes, formal procedures,…)
- Report after completion of the closure
- Clearance of material derived from repository decommissioning

11 Period after closure and institutional controls

11.1 REQUIREMENTS

The following safety requirements are associated with the “safety topic” “Period after closure and institutional controls”:

- In the Draft WENRA report on SRL's [47]:
  - SRL 1.1.6: After closure and until termination of the licence, the licensee shall remain responsible for surveillance of the disposal system in accordance with the safety case and for any remedial action that might be required.
  - SRL 2.1.1: The licensee shall design, construct, operate and decommission a disposal facility, ensure closure and, as appropriate, carry out post-closure surveillance so as to fulfil the objective of protecting people and the environment according to the ALARA principle. A graded approach shall be adopted proportionate to the hazard presented by the waste.
  - SRL 2.6.5: Before starting the operational phase, the licensee shall plan for closure, decommissioning and post-closure activities.
  - SRL 2.9.1: After closure and until termination of the licence, the licensee shall implement an appropriate post-closure surveillance programme. In the event that surveillance demonstrates the need for remedial actions, the licensee shall implement such actions in accordance with the licence.
  - SRL 2.9.2: Before the licensee is relieved of further responsibility (i.e., by termination of the licence and any other permits the licensee holds), the licensee shall:
    - Demonstrate that the results of surveillance programme are consistent with the assumptions of the safety case, to the satisfaction of the regulatory body;
    - Propose any restrictions on land use, suggest and substantiate the way they shall be implemented, or any other measures deemed appropriate for the post-licensing phase.

- In IAEA SSR-5 [2]:
  - R10: Surveillance and control of passive safety features
  - R21: Monitoring programmes at a disposal facility
  - R22: The period after closure and institutional controls

- In EC directive 2011/70/Euratom [3], Article 5.1d: The national framework shall provide for a system of appropriate control, a management system, regulatory inspections, documentation and reporting obligations for radioactive waste and spent fuel management activities, facilities or both, including appropriate measures for the post-closure periods of disposal facilities;

Note that requirements specific on the use of passive means are addressed at § 4.6: "passive means" of the present report. Only the link between the period after closure and institutional control with the passive means is stressed here.

Note as well that requirements addressing the demonstration of compliance of safety requirements for the period after closure and institutional controls, which has to be documented in the safety case, are treated in in §14.2 of the present report.

11.2 COMMON POINTS AND DIFFERENCES BETWEEN EXISTING GUIDES

Institutional controls can include both active measures and passive means (IAEA SSG-23 [4], CNSC-G-320 [18]). A claim for active institutional control will need to be supported by detailed forward planning of organisational arrangements and a suitable demonstration of funding arrangements as explained in UK_EA and NIEA guide [66].

The long term safety (after license release) does not rest on institutional controls because isolation and confinement safety function are fulfilled by the passive means (EPG [1], IAEA SSG-23 [4], NEA-6923-MeSA [50], ENSI-G03 [12], SÚJB-2004 [29], UK_EA-NIEA-GD [66], FANC-GEN [23]). However, for political or societal reasons some arrangements for institutional control may be defined and applied for an extended period. The possibility of remedial actions after license release should not form part of a safety case.

It is also generally stressed that during the post-closure no monitoring or other actions should be undertaken that could undermine isolation and containment.
For further aspects post-closure monitoring on refers to the "safety topics" dedicated to it in see § 13 of this report.

11.3 NEEDS FOR DIALOGUE, DEVELOPMENT AND HARMONIZATION

The issues that need to be further discussed and harmonized are:

- Planning for post-closure activities (before starting the operational phase)
- Implementation of post-closure surveillance programme
- Expectations on what is required to release a DGR site from licensing
- Activities before termination of licence
- Passive institutional controls
- Requirements for marking of a geological repository
- Rationale for the duration of institutional controls
- Common understanding of the different used terms (monitoring, control, surveillance)

12 Waste Acceptance

12.1 REQUIREMENTS

The following safety requirements are associated with the “safety topic” “Waste acceptance”:

- In the Draft WENRA report on SRL’s [47]:
  - SRL 2.7.1: The licensee shall establish and maintain records of waste receipt, inventory and emplacement, combined with the information on waste acceptance.
  - SRL 3.1.1: The licensee shall contribute to the safe management of the waste by establishing preliminary waste acceptance criteria at the earliest opportunity. The licensee shall update such preliminary waste acceptance criteria to reflect the development of the disposal project.
  - SRL 3.1.2: Prior the start of waste emplacement, the licensee shall specify waste acceptance criteria so as to ensure the conformity of the waste to the safety case and other aspects of the disposal arrangements. The waste acceptance criteria shall be consistent with the operational and post-closure safety case.
  - SRL 3.1.3: The licensee shall establish and implement, as necessary, limits on important parameters such as radionuclides inventories and activity concentrations in individual waste packages, in specific parts of the facility and in the disposal facility as a whole.
  - SRL 3.1.4: The licensee shall specify criteria to ensure that waste accepted for disposal is physically and chemically stable and compatible with other components of the disposal facility.
  - SRL 3.1.5: The licensee shall ensure that waste acceptance criteria as a minimum specify:
    - limits on raw waste composition
    - limits on the waste form
    - limits on the waste container for packaged waste
    - limits on the waste package (where relevant)
  - SRL 3.2.1: The licensee shall report changes to waste acceptance criteria to the regulatory body, for approval if appropriate. The licensee shall substantiate the consistency of any changes with the assumptions made in the safety case.
  - SRL 3.3.1: The licensee shall check that the waste accepted for disposal conforms to waste acceptance criteria. A conformity check shall be

performed in accordance with written arrangements which include administrative procedures, inspections and/or tests.
  - SRL 3.3.2: The licensee shall ensure that each waste package consigned for disposal is traceable by a unique means of identification.
  - SRL 3.3.3: The licensee shall review the quality of information supplied by the organization responsible for the waste together with its management system so as to provide an adequate level of assurance that the waste characteristics conform to the waste acceptance criteria. The licensee's arrangements for this may include audits and checks on operations and processes at other facilities.
  - SRL 3.3.4: The licensee shall establish procedures for dealing with waste packages that do not conform to waste acceptance criteria, and shall not accept such waste packages unless acceptability with regard to safety has been demonstrated on a case by case basis.

- In IAEA SSR-5 [2], R20: Waste acceptance in a disposal facility: Waste packages and unpackaged waste accepted for emplacement in a disposal facility shall conform to criteria that are fully consistent with, and are derived from, the safety case for the disposal facility in operation and after closure.

These requirements relate to the necessity to establish and implement limits on important parameters regarding waste and packaging and the use of these waste acceptance criteria in the safety case for both operational and post-closure phase. They also require process in order to ensure the traceability, the checking operations and the way to deal with non-compliant waste and changes in the waste acceptance criteria, in accordance with the safety case.

12.2 COMMON POINTS AND DIFFERENCES BETWEEN EXISTING GUIDES

Several international documents address the "waste acceptance criteria" as IAEA SSG-14 [25] and EPG report [1], or have developed procedure and specifications related to it as in IAEA-TECDOC-1129 [68] (but for near surface disposal) or in IAEA-TECDOC-1515 (§5.5) [69]. Most of the existing national guides address the subject of waste acceptance criteria (CNSC-G-320 [18] (§6.0), CSA 286.05 [70], to be replaced soon by CSA 286.12 [71], ÚJD-30/2002 Coll. [72], ENSI-G03 [12], BMU-2010 [11] (§7.5-7.6), ASN-RFIII-2 [22] (§5.2) and SÚJB 2003 [73] (§5.6)).

There are no significant contradiction between them. All the requirements are not considered in each national guide, and some subjects are more detailed than others.

The terminology used in existing guides addressing the issue of waste acceptance criteria are mostly the same but the terms “emplacement conditions” and “waste data” are also used [11]

The more developed subject is the establishment of waste acceptance criteria [44, 18, 11, 22], usually with a non-prescriptive approach. The operator of the final repository is expected to determine the acceptance criteria.
There are some differences in the description of the way to derive the acceptance criteria :

- both from regulatory requirements, objectives and benchmarks specified in guidelines and performance expectations that relate to safety [11, , 22] or only from the safety analyses [11],
- with or without list of parameters

IAEA-TECDOC-1515 [69] proposes a detailed table of criteria, with distinction between waste prior to packaging and packaged waste.

This aspect is the less harmonised one between the different guides. Nonetheless, a common trend in most guides is the importance of radiological parameter, and waste acceptance criteria seems mainly to be developed for packaged waste.

The level of uncertainty and conservatism in the definition of waste acceptance criteria are also discussed with more or less details in some of the guides [18,22].

The checking operations are developed for different steps :

- the waste acceptance criteria definition has to be submitted to the regulator [12, 11, 22]
- the emplacement of waste packages in the repository can require a clearance by the regulator, relating to individual waste packages or to waste package types (see [12])
- the checking operations during the operational phase can result of operator’s checking [12] or of inspections before, during or after the packaging

There are few information in the guides regarding the way to deal with non-compliant waste (see [12,22]).

12.3 NEEDS FOR DIALOGUE, DEVELOPMENT AND HARMONIZATION

The following needs for guidance development related to the requirements of §1 have been identified:

- Preliminary waste acceptance criteria
- How the waste is checked to ensure conformity with waste acceptance criteria ?
- How to deal with waste packages that do not conform to waste acceptance criteria

13 Monitoring

13.1 REQUIREMENTS

The focus of this section is on monitoring for disposal system performance (e.g. effectiveness of the barrier systems, provide information to support the confirmation of safety assessment) and radiation protection of the public and the environment. Monitoring for occupational radiation protection is not directly addressed in this chapter. Occupational radiation protection is discussed in chapter 5.2 (radiation protection) and chapter 10 operation.

The following safety requirements are associated with the “safety topic” “Monitoring”.

- In the Draft WENRA report on SRL’s [47]:
    - SRL 2.1.8: The licensee shall define and implement an appropriate programme (e.g. through R&D, investigations, modelling, testing and monitoring activities) to improve and confirm the understanding of the evolution of the disposal system.
    - SRL 2.2.2: on the conduct of site characterisation to among others establish baseline conditions for the site and the environment.
    - SRL 2.3.10: The licensee shall make provisions for maintenance, testing, inspection and monitoring of structures, systems and components (SSCs), addressing also their ageing.
    - SRL 2.3.11: The licensee shall establish appropriate provisions for monitoring the host environment.
- Further in § 2.4.1 on Information gathering and monitoring:
    - SRL 2.4.1: Before starting construction, the licensee shall establish a baseline state of the environment both for supporting the monitoring programme and for evaluating the impact of the facility on the environment.
    - SRL 2.4.2: Before starting construction, the licensee shall define and document a systematic monitoring programme to be implemented during construction, operation, decommissioning and closure, and as appropriate after closure.
    - SRL 2.4.3: on the objectives of the monitoring programme to:
        - Contribute to demonstration of adequate protection of people and environment and compliance with requirements and licence conditions;
        - Confirmation of expected behaviour and evolution of the disposal system;

        - Identify any deviations from the expected behaviour of the disposal system;
        - Contribute to confirmation and refining key assumptions
        - Enhance understanding of the environmental conditions and of the functioning of the disposal system
        - Provide data for supporting decision-making and;
        - Provide background information for any post-closure surveillance programme.
- In § 2.5 on safety issue: construction
    - SRL 2.5.3. During construction, the licensee shall gather information in particular to improve the knowledge of:
        - The properties of the host environment and to refine the assumptions of the safety case;
        - The geomechanical response of the host environment, and the effect on geochemical and hydrogeological conditions of the perturbations induced by the disposal facility.

Further the following international safety requirements associated with "Monitoring" are identified:

- In IAEA GSR Part 3 [56]:
    - R14 Registrants and licensees and employers shall conduct monitoring to verify compliance with the requirements for protection and safety and in particular:
        - alinea 3.38. a) conduct of monitoring and measurements of parameters as necessary for verification of compliance b) with suitable equipment and implementation of verification procedures c) with traceable maintenance, tests and calibrations at appropriate intervals d) with records of the results of monitoring and with e) required sharing of the results with the regulatory body
    - R32: The regulatory body and relevant parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available. In particular:
        - alinea 3.137: on the a) & f): establishment by the registrants and licensees of monitoring programmes including external exposure from sources, discharges, radioactivity in the environment and public exposure; on c), d) & e): the reporting of the results and deviations to the regulatory body on g): verification of assumptions in the safety assessments and h) publication of results

- In IAEA GSR Part 4 [48] R24 Maintenance of the safety assessment:
    - alinea 5.2 : updating of the safety assessment to provide baseline for the future evaluation of monitoring data and performance indicators;

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- In IAEA SSR-5 [2]
    - R10: An appropriate level of surveillance and control shall be applied to protect and preserve the passive safety features, to the extent that this is necessary, so that they can fulfil the functions that they are assigned in the safety case for safety after closure.
    - R21: A programme of monitoring shall be carried out prior to, and during, the construction and operation of a disposal facility and after its closure, if this is part of the safety case. This programme shall be designed to collect and update information necessary for the purposes of protection and safety. Information shall be obtained to confirm the conditions necessary for the safety of workers and members of the public and protection of the environment during the period of operation of the facility. Monitoring shall also be carried out to confirm the absence of any conditions that could affect the safety of the facility after closure.

13.2 COMMON POINTS AND DIFFERENCES BETWEEN EXISTING GUIDES

The IAEA is developing a detailed technical Safety Guide on “Monitoring and Surveillance of Disposal Facilities” (see IAEA DS 357 [46]). The objective of the drafted guide is to provide guidance for monitoring and surveillance of radioactive waste disposal facilities such as near surface disposal facilities, geological disposal facilities and disposal facilities for uranium and thorium mine waste during their entire lifetime. The focus of the drafted guide is on monitoring for disposal system performance and radiation protection of the public and the environment. This draft specifies monitoring for geological repository at different phases of repository and responsibilities of the implementer and the regulator regarding a monitoring programme. Specific objectives of monitoring for a deep geological repository are to demonstrate compliance with the regulatory constraints and licence conditions, to verify that the disposal system is functioning as expected, to strengthen understanding of aspects of system behaviour, to accumulate an environmental database for future decisions that are part of a stepwise programme according to this draft. Design of monitoring programme should be an iterative process, allowing for periodic changes to the programme. In addition the draft addresses the use of monitoring information and how to deal with deviations from expected results.

Prior to the draft an IAEA Monitoring TECDOC-1208 was published [45] and discusses the possible purposes for monitoring of geological repositories at the different stages of a repository programme, starting from surface exploration up to the post closure phase. It also discusses the use that may be made of the information obtained and the techniques that might be applied. It establishes general points of importance to the monitoring of geological repositories.

A follow-up project was carried out on the topic "Monitoring Developments for Safe Repository Operation and Staged Closure (MoDeRn)", within the Seventh European Atomic Energy Community Framework Programme (Euratom FP7/2007-2011). The focus of the research project was the repository monitoring for deep geological disposal of long lived radioactive waste and/or spent nuclear fuel. Within this project a Monitoring Reference Framework was developed and published as guidance for the development of a geological disposal monitoring programme (see [MoDeRn D-1.2]. [74]). It addresses the design of monitoring systems to implement such a programme; the use of monitoring results and their contribution to the governance of a stepwise disposal process; and the progressive updating of the monitoring programme within that stepwise process. It presents the MoDeRn partners' conclusions on development of monitoring objectives

In several national guides monitoring of a disposal facility for radioactive waste is included as e.g. Belgian guide FANC-GEN [23] , Canadian Regulatory Guide CNSC-G-320 [18], Czech Republic SÚJB-2004 [29], French Guide ASN-RFIII-2 [22] , German BMU-2010 [11], Swiss ENSI-G03 [12] and Sweden SE_SSMFS 2008:21 [30]. In general, the international high level requirements and technical documents are addressed in the national guides; however the level of detail for monitoring requirements and approaches varies in the national guides. For example, the Swiss regulation differs between specific compartments for monitoring such as test areas (underground laboratory at the site) and a pilot facility. In addition it specifies that monitoring may not compromise the passive safety barriers. The French guidelines ASN-RFIII-2 [22] also address monitoring to inform reversible disposal management . The German Guide BMU-2010 [11], calls for a monitoring programme including a certain period after decommissioning which, in addition to surface-based environmental monitoring, is able to provide information about the thermo-hydro-mechanical response of the host rock due to the heat generating waste.

In the international documents as IAEA DS 357 [46], IAEA-TECDOC—1208 [45] and MoDeRn D1-2 [74], it is widely accepted that the long term safety of geological disposal should not rely on a continued capability to monitor a repository after it has sealed and closed. The system should be designed to be intrinsically and passively safe. Key purposes of monitoring a deep geological repository are in the period up to repository closure:

- to provide information for making management decisions in a stepwise programme
- operational safety
- to strengthen understanding of some aspects of system behaviour used in developing the safety case of the repository development and strengthen confidence, that the repository is having no undesirable impacts on human health and the environment
- to accumulate an environmental database on the repository site and its surroundings that may be of use future decision makers (baseline information related to the "undisturbed" conditions)

- to address the requirement to maintain nuclear safeguards, should the repository contain fissile material such as spent fuel or plutonium-rich waste

13.3 NEEDS FOR DIALOGUE, DEVELOPMENT AND HARMONIZATION

The following needs for dialogue and possibly development of further guides were identified:

- Expectations for an environmental baseline programme and the starting point of an environmental monitoring programme;
- Monitoring programme including programme specific to construction phase;
- Guidance on a quality assurance programme for the lifecycle of a safety case of a deep geological repository to confirm and refine assumptions.

14 Safety Case and Safety Assessment

14.1 INTRODUCTION

As defined in IAEA SSG-23 [4] and based on IAEA glossaries, the term “Safety Case”, used within the SITEX project, designs “*the collection of scientific, technical, administrative and managerial arguments and evidence in support of the safety of a disposal facility, covering the suitability of the site and the design, construction and operation of the facility, the assessment of radiation risks and assurance of the adequacy and quality of all of the safety related work associated with the disposal facility. The Safety Case may relate to a given stage of development of the disposal facility.*
Safety assessment, an integral part of the safety case, is driven by a systematic assessment of radiation hazards and is an important component of the safety case. The latter involves quantification of radiation dose and radiation risks that may arise from the disposal facility for comparison with dose and risk criteria, and provides an understanding of the behaviour of the disposal facility under normal conditions and disturbing events, considering the time frames over which the radioactive waste remains hazardous. The safety case and supporting safety assessment provide the basis for demonstration of safety and for licensing. They will evolve with the development of the disposal facility, and will assist and guide decisions on siting, design and operations. The safety case will also be the main basis on which dialogue with interested parties will be conducted and on which confidence in the safety of the disposal facility will be developed.”

Many requirements are related to the “Safety case and Safety Assessment”. Within the safety assessment, requirements can be grouped in “safety topics” according to whether one considers the operational phase or the post-operational phase or according to the type of analyses performed within the assessment as the assessment of the performances of the geological disposal or of the radiological impact on human and environment. Other “safety topics” are rather related to the assessment basis on which the assessment rely, i.e. characterisation, knowledge and understanding of the repository system and its evolution as well as the safety assessment methodology. These “safety topics” defined for the safety case and safety assessment are analysed in the subsequent sections.

One refers as well to WP4.1 of SITEX [97] for more details on the scope and content of a safety case and on the review process by the regulatory of the Safety Case.

14.2 OBJECTIVES SCOPE AND CONTENT OF THE SAFETY CASE AND SAFETY ASSESSMENT VS. REGULATORY DECISION STEPS

14.2.1 Requirements

The following safety requirements are associated with the "safety topic" "Objectives, scope and content of Safety Case/ Safety Assessment *versus* regulatory decision steps":

- in § 4.1on the Scope and content of a the safety case, in Draft WENRA report [47]:
    - SRL 4.1.1: substantiation of compliance;
    - SRL 4.1.2: including a safety assessment and an evaluation of the technical feasibility of the design and the construction, operation, decommissioning, closure and post-closure activities;
    - SRL 4.1.3: content of the safety assessment;
    - SRL 4.1.4: updating and submission of the safety case to the regulator before each major regulatory decision;
    - SRL 4.1.5: typical content of the safety case, including reference to the Annex 3 of the draft WENRA report;
    - SRL 4.1.6: clear understanding of the safety arguments, comprehensiveness and level of detail appropriate to the step reached in the disposal facility development to be provided;
    - SRL 4.1.7: clarity, substantiation and traceability of the assumptions, choices and decisions made;
    - SRL 4.1.8: factors that influence safety and their significance;
    - SRL 4.1.9: uncertainties;
    - SRL 4.1.10: demonstration that design, engineering and operational choices and decisions are derived from a process of optimization;
    - SRL 4.1.11: programmes, plans and provisions for closure of the disposal facility and for post-closure activities and their revision and updates;
    - SRL 4.1.12: management system;
    - SRL 4.1.13: multiple lines of reasoning, graded approach and level of confidence reached;
    - SRL 4.1.14 : content of the updating of the safety case and
    - SRL 4.1.15: use of safety case for assessing the safety implications of changes

- in IAEA GSR Part 3 [56], R13 dedicated to safety assessment, alinea 3.3: Documentation and review of the safety assessment

- in IAEA GSR Part 4 [48]
    - R1: Graded approach in the safety assessment

- R2: Scope of the safety assessment
- R4: Purpose of the safety assessment
- R5: Preparation for the safety assessment
- R14: Scope of the safety analysis
- R20: Documentation of the safety assessment

- in IAEA SSR-5 [2]
  - alinea 4.6 to 4.11: The Safety Case and Safety Assessment in R11 on the step by step development and evaluation of disposal facilities
  - R12: Preparation, approval and use of the safety case and safety assessment for a disposal facility
  - R13: Scope of the safety case and safety assessment
  - R14: Documentation of the safety case and safety assessment

- in EC directive 2011/70/Euratom [3]
  - Article 7.2.: regular assessment, verification and improvement of the safety of the radioactive waste and spent fuel management facility or activity through an appropriate safety assessment, other arguments and evidence.
  - Article 7.3: Scope and extent of the safety demonstration

14.2.2 Common points and differences between existing guides

International guides

Existing international guides as IAEA SSG-23 [4] and EPG draft report on SC review [1] address the requirements identified in §1. They provide an overview of the role and content of the safety case at each steps. They are relatively consistent with each other.

The safety case will provide the information needed to make these key regulatory decisions. The safety arguments will develop and mature as the project progresses and the supporting information and assessments will become more substantial. It will be important to maintain a historical record of the developing safety arguments so that how and why they have changed can be traced and understood.

The level of detail in the safety case at each stage will depend on the type of facility, the technology to be used and other factors, and should be determined in accordance with a graded approach.
The safety case should be updated progressively to incorporate information gained during the different phases of the project. This will include:

- The growing body of data about the geological environment of the disposal facility;
- Information about the facility as actually built and the waste as actually emplaced, as opposed to the prior intent;

- New developments and operating practices, such as emplacement techniques and materials of encapsulation, buffer materials or construction materials;
- Any other advances in understanding.

If new information arises that is potentially significant in terms of its effect on the safety case, the implementer should review, and if necessary revise, the safety case to take the new information into account. Any substantial change to the disposal system design motivated by feedback from operational activities or monitoring should be documented in the safety case and submitted to the regulator for approval.

National guides

The evolution of the Safety Case/ Safety Assessment content vs regulatory decision steps are only little described in national guides as in the ENSI-G03 [12] and the CNSC-G-320 [18].

14.2.3 Needs for dialogue, development and harmonization

Dialogue and/or harmonization on the following issues have been identified, which could be based on or further developed from those identified documents:

- Assessment of technical feasibility
- How often SC should be refined/updated ?
- Table of content of a SC for each important step of disposal facility development
- Developed planning of the SC
- Traceability and transparency of a SC (helpful for public to understand as well)
- Verification that design, engineering and decisions on the disposal system derive from a process involving optimization of radiological protection

14.3 CHARACTERIZATION, KNOWLEDGE AND SYSTEM UNDERSTANDING

14.3.1 Generalities

14.3.1.1 Requirements

The following safety requirements are associated with the "safety topic" "Characterization, knowledge and system understanding" in general. Specific requirements are developed in the subsequent sections.

- In the Draft WENRA report on SRL's [47] :
    - SRL 2.1.8 : the definition and implementation of an appropriate program (R&D, monitoring…) to improve and confirm the understanding of the evolution of the disposal system;
    - SRL 4.1.6 : clear understanding of the safety arguments, comprehensiveness and level of detail appropriate to the step reached in the disposal facility development to be provided;
    - SRL 4.1.8: factors that influence safety and their significance adequately reflected in the safety case;

- In IAEA SSR-5 [2]
    - R4, (alinea 3.17–3.20): Importance of safety in the process of development and operation of a disposal facility including the development of an understanding of the relevance and the implications for safety of the available options for the facility throughout its development and operation.
    - R6, (alinea 3.26–3.31): Understanding of a disposal facility and confidence in safety with the development of an adequate understanding of the features of the facility and its host environment and of the factors that influence its safety after closure over suitably long time periods.

14.3.1.2 Common points and differences between existing guides

The topics developed in international guidance are related to the following issues:

- importance to determine the basic characteristics of the host rock and surrounding environment as well as those of the potential construction materials of the engineered components as e.g. explained in EPG report [1].
- definition of a R&D program in SSG-14 [25] (§6.2);
- importance of safety in the process of development and operation in SSG-14 [25] (§4.3-4.7).

- understanding of a disposal facility and confidence in safety in SSG-14 (§5.25, 5.26) [25].

14.3.1.3 Needs for dialogue, development and harmonization

The need to detail the content of the programme to improve and confirm the understanding of the disposal system evolution has been identified, as well as the level of knowledge and understanding required in the Safety Case at each stage of the disposal development and associated programme steps. About the needed development of knowledge, the gas production and transport in deep geological repositories has been identified.

14.3.2 Waste

14.3.2.1 Requirements

- Besides the requirements associated with the "safety topic" "Characterization, knowledge and system understanding" in general, following additional safety requirements from the Draft WENRA report [47] address the subtopic "Waste" in particular:
    - SRL 2.7.1: Establishment and maintenance records of waste receipt, inventory and emplacement, combined with the information on waste acceptance, as part of record and knowledge keeping;

In the framework of waste acceptance:

- SRL 3.3.1.: conformity check of the accepted waste in accordance with written arrangements which include administrative procedures, inspections and/or tests;
- SRL 3.3.3.: Review of the quality of information and management system so as to provide an adequate level of assurance that the waste characteristics conform to the waste acceptance criteria. The licensee's arrangements for this may include audits and checks on operations and processes at other facilities

14.3.2.2 Common points and differences between existing guides

These requirement are also developed in SSG-23 [4] (§4.35). Few other connected topics are developed:

- a description of the expected safety functions of waste packages in the French ASN guide [22] (§5.2), and the need for fulfilment of the safety functions by the waste form and packaging with regard to long term safety in SSG-14 [25] (§6.36) as well as to engineered components and host rock in the French ASN guide [22] (§5.2);
- the track of inventory during reception and emplacement for approval of facility closure in SSG-14 [25] (§6.37).

14.3.2.3 Needs for dialogue, development and harmonization

The need for development on the characterization of the source term (including review of vector of nuclides) has been identified.

14.3.3 Engineered components

14.3.3.1 Requirements

Besides the safety requirements identified for the general "safety topic" "Characterization, knowledge and system understanding" no additional safety requirements were identified for the "Engineered components" in particular.

14.3.3.2 Common points and differences between existing guides

Concerning the engineered components, the EPG report [1] report states that the implementer should establish the state-of-the-art knowledge on the properties of component materials (generally metal, clay or concrete) important for the safety of the disposal facility. The implementer have to substantiate the main technical choices (layout of the disposal facility, excavation and construction techniques, waste emplacement, materials, safety functions complementarity, access to disposal, sealing and backfilling options …) and the feasibility of their implementation (including reversibility issues if required). He has to define performance targets for the engineered components and the associated specifications (including the characteristics of materials used). He has to determine the safety margins in order to strengthen confidence in the design. He has also to define a R&D program related to the performance of engineered components of the system, considering all envisaged forms of loading on these components (thermal load, mechanical load, chemical, radiation…) representative of the operational and post-closure periods.

14.3.3.3 Needs for dialogue, development and harmonization

It is recommended to have a unique guide developing the definition, functions and performances of engineered components in geological disposal facilities, including backfilling and seals but also all the other components with retaining or circulation functions. This need is considered to be linked with the "safety topic" "design" addressed in § 7.

14.3.4 Site

14.3.4.1 Requirements

Besides the requirements associated with the "safety topic" "Characterization, knowledge and system understanding" in general or of all components of the disposal system, following additional safety requirements address the subtopic "Site" in particular.

- In Draft WENRA Report on SRL's [47]:
  - SRL 2.2.1 : Preparation and implementation of a program for site characterization of the selected site, providing the data to support the safety case in
  - SRL 2.2.2 : Conduct of site characterisation to establish baseline conditions for the site and the environment, to support understanding of the normal evolution, identification of possible disturbing features, events and processes (FEPs) as well as understanding their impact on safety.
  - SRL 2.5.3: gathering of information during construction to improve knowledge on the properties of the host environment, and on its geomechanical, geochemical and hydrogeological conditions induced by the disposal facility.

- In IAEA GSR Part 4 [48] R8: Assessment of site characteristics relating to the safety of the facility or activity.

- In IAEA SSR-5 [2]
  - R15: Site characterization for a disposal facility at a level of detail sufficient to support a general understanding of both the characteristics of the site and how the site will evolve over time, including present condition, probable natural evolution, possible natural events, and also human plans and actions in the vicinity that may affect the safety of the facility over the period of interest. It shall also include a specific understanding of the impact on safety of features, events and processes associated with the site and the facility. Further recommendations are provided in the following alinea of R15:
    - 4.26: on the quality of the site characterisation
    - 4.27, 4.29 on specific investigation activities to include in the geological and surface environment characterisations as geodynamics, structures, seismicity; volcanism, geotechnics, mineralogy, hydrogeology, surface characteristics, climate, local population…
    - 4.28 on the graded approach that has to be adopted to the site characterization, depending on the hazard potential of the waste, the complexity of the site and disposal design.

14.3.4.2 Common points and differences between existing guides

Existing guides are consistent. The requirement related to characterisation of the selected site is recalled in SSG-23 [4] (§3.8) and detailed in SSG-14 [25] (stages in the siting process, objectives and tools), followed by the detailed program for site characterization and understanding of its evolution (§6.4-6.23).

In addition, the following topics are developed in existing international and national guidance:

- the quality of the site characterization in IAEA SSG-14-[25] (§6.18), IAEA SSG-23 [4] (§4.55) and in the German BMU guide [11] (§7.7);
- the geological and other aspects to develop (geodynamics, structures, seismicity; volcanism, geotechnics, mineralogy, hydrogeology, surface characteristics, climate, local population…) in SSG-23 [4] (§4.54) and in the French ASN guide [22] (§A1-2);
- the identification of the site conditions to be monitored (and required level of measurements) during the pre-construction, construction and operational phases, to ensure a suitable baseline record of the site natural systems in the IAEA SSG-14), [25] (§6.16), as well as the decision on post-closure monitoring in [25] (§6.17);

the development of an environmental impact assessment in conjunction with the site characterization in [25] (§6.24).

14.3.4.3 Needs for dialogue, development and harmonization

The need to develop the programme for site characterization, including the transferability issues, has been identified.

14.3.5 Use of operating experience & monitoring data

14.3.5.1 Requirements

Besides the requirements associated with the “safety topic” “Characterization, knowledge and system understanding” in general or of all components of the disposal system, following additional safety requirements address the subtopic “Use of operating experience & monitoring data” in the safety case and safety assessment in particular:

- In the Draft WENRA report [47]
  - SRL 2.4.3 : Objectives of the monitoring programme, including among others the refining of the key assumptions and models of the safety case and enhancement of the understanding of the environmental conditions and functioning of the disposal system.
  - SRL 4.3.2: Evaluation of among others operational experience with equipments, structures, systems and components, their maintenance, inspections and controls; anticipated operational occurrences, possible accidents and corrective actions; modifications of the facility, of the operational procedures and of the organization as part of the Periodic Safety Review

- In IAEA GSR-Part 4 [48] R19: Use of operating experience data. Data on operational safety performance shall be collected and assessed including records of incidents such as human errors, the performance of safety systems, radiation doses, and the generation of radioactive waste and effluents and in accordance with a graded approach.
- In IAEA SSR-5 [2] alinea 5.4 on the purposes of the monitoring within R21 on Monitoring programmes at a disposal facility.

14.3.5.2 Common points and differences between existing guides

Several developments exist in international guides, as IAEA-TECDOC-630 [36], SSG-14 [25], IAEA-TECDOC-1208 [45] and DS 357 [46] on the use of monitoring data.

This topic is also developed in several national guides as in the CNSC-G-320 guide from Canada [18], the ASN guide from France [22], NEO guide from Switzerland [27] and BMU-2010 guide from Germany [11].

The use of operating experience is less developed but national guide CNSC-G-320 [18] addresses the topic and more specifically the need for collecting and assessing data on operational safety performance.

The following objectives are identified from international and national guides:

- to re-evaluate the preliminary performance criteria for each components of the disposal system in an iterative process, as additional information and analyses on the design and performance of the repository systems are progressively provided during the operation stage ([36] §4; [22] §5.6);
- to provide information for making management decisions in a stepwise programme of repository construction, operation and closure ([45] §3.1, 3.4, 3.6; [46]; [22] §5.6; [11] §7.4);
- to strengthen understanding of some aspects of system behaviour used in developing the safety case for the repository and to allow further testing of models predicting those aspects, as well as confirmation that actual conditions are consistent with the assumptions ([25] §6.60; [45] §3.2; [46]; [18] §7.3.2; [22] §5.6);
- to demonstrate compliance with the regulatory requirements and licence conditions for operation, including compliance with safety requirements for environmental and radiation protection ([25] §6.62; [22] §5.6, [27] §4, Article 36; [11] §7.4);
- to evaluate impact of an extended operating period (facility remaining open a long time after waste emplacement has ceased) on post-closure ([25] §6.55);
- to provide information to give society at large the confidence to take decisions on the major stages of the repository development programme ([45] §3.3;[46]).

14.3.5.3 Needs for dialogue, development and harmonization

Although no major inconsistency has been identified in existing guides, the use of operating experience in safety assessment is a poorly developed topic and thus would deserve developments.

14.4 SAFETY ASSESSMENT METHODOLOGIES, APPROACHES & TOOLS

14.4.1 Timescales and timeframes

14.4.1.1 Requirements

The following safety requirements are associated with the "safety topic" "Timescales and timeframes":

- In the Draft WENRA report on SRL's [47]
  - SRL 4.2.4: The licensee shall substantiate in the safety case the timescale over which the safety assessment is carried out
- In IAEA GSR Part4 [48]:**-** Requirement 12: The safety assessment shall cover all the stages in the lifetime of a facility or activity in which there are possible radiation risks.
- In ICRP 81 [76] Doses and risks, as measures of health detriment, cannot be forecast with any certainty for periods beyond around several hundreds of years in future. Instead, estimates can be made for longer periods, but they must not be regarded as predictions of future health detriment. Calculated doses are viewed not as predictions but rather as indicators.
- In ICRP 122 [62], Dose and risk concepts § 4.3 are explained according to exposure situations as well as relevant timeframes. Timeframes are defined in § 3.3.2 according to the phases of a disposal facility as in § 3.3.1 and oversight.

14.4.1.2 Common points and differences between existing guides

A common trend in most guides is the necessity to argue important time intervals of the repository. Basically, assessments of the future impact may arise from the radioactive waste are expected to include the period of time during which the maximum impact is predicted to occur.

In number of international documents (NEA-4435 [78], NEA-6405 [80] and IAEA SSG-23 [4]) the issue of timescales and timeframes is widely discussed. Probably some conclusions of these discussions is included in [4] with formulations given in paragraphs § 6.43 – 6.51.

There are some differences between existing national guides concerning timescales and timeframes, but it seems that these differences are most likely related to formulation of the requirement details. It is required to argue the time intervals of a repository used in the assessment and the hypotheses related to these intervals as it is the case in e. g. the Belgian FANC-SAR [51] or Canadian CNSC-G-320 [18].

It is also required that the assessment timeframe is large enough to encompass the maximal doses (IAEA SSG-23 [4], Canadian Guides CNSC-P-290 [16], CNSC-G-320 [18], Swedish Guide SSMFS 2008:37 [19], Belgian FANC-SAR [51], Swiss ENSI-G03 [12]).
Some countries specify an assessment timeframe of 1 million of years (BMU-2010 [11], ENSI-G03 [12], SSMFS 2008:37 [19]).

14.4.1.3 Needs for dialogue, development and harmonization

The need identified for this topic is on compliance for the very long time frames.

14.4.2 Assessment of the possible radiation risks

14.4.2.1 Requirements

Note that this "Safety topic" is dedicated to the "possible radiation risks" as it is defined in IAEA GSR Part 4 [48] i.e. "*the maximum possible radiological consequences that could occur when radioactive material is released from the facility or in the activity, with no credit being taken for the safety systems or protective measures in place to prevent this*".

Note as well that the "Safety topic" related to the radiological impact assessment is addressed in in §14.7 of the present report.

Based on this definition of the "possible radiation risks" no SRL from the draft WENRA report [47] is explicitly dedicated to the "safety topic" "Assessment of the possible radiation risks". Although some SRL's suggest implicitly that the possible radiation risks has to be assessed as e.g. in the framework of the design development, establishment and implementation of the programmes and demonstration of safety that have to be commensurate to the hazards associated with the waste being disposed of (see e.g. SRL 1.1.4, 2.1.1, 2.1.5, 4.1.1…).

The following safety requirements are associated with the "safety topic" "Assessment of possible radiation risk":

- In IAEA GSR Part 4 [48]
    - R6, § 4.19 The possible radiation risks associated with the facility or activity include the level and likelihood of radiation exposure of workers and the public, and of the possible release of radioactive material to the environment, that are associated with anticipated operational occurrences or with accidents that lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation.

As for draft WENRA report on SRL's requirements that stipulate specifically that an assessment of the "possible radiation risks" has to be performed and provided are not found in IAEA SSR-5 [2], however it is implicitly addressed by the requirements on design and development of the disposal facility that have to be appropriate to the potential hazards of the waste. Requirements on graded approach stress in particular on development effort and on the assessment that have to be commensurate with the potential hazards.

14.4.2.2 Common points and differences between existing guides

As mentioned in § 4.10, existing guides are addressing the graded approach in the development of the disposal and the safety assessment, which implicitly necessitates the assessment of the "possible radiation risks". However, only little information on the way to assess these risks is given. ENSI-G03 [12] specifies e.g. that a description of the evolution with time of the radiotoxicity of the emplaced waste has to be provided in the safety assessment and FANC-SAR [51] requires that robustness of the disposal system and its components is evaluated against the evolution of possible risks associated to the waste. It specifies that the assessment of this possible risks should be done by considering penalising assumptions on the performance of the disposal.

14.4.2.3 Needs for dialogue, development and harmonization

The identified need is how to assess "possible radiation risks" as defined by IAEA.

14.4.3 Uncertainties

14.4.3.1 Requirements

The following safety requirements are associated with the "safety topic" "Uncertainties":

- In Draft WENRA report on SRL's [47], SRL 4.1.9 The licensee shall identify all uncertainties significant to safety and shall demonstrate that these uncertainties are adequately taken into account in the safety case. The licensee shall describe a programme for uncertainties management.

- In IAEA GSR Part 4 [48],
    - R17 Uncertainty and sensitivity analysis shall be performed and taken into accounting the results of the safety analysis and the conclusions drawn from it.
        - alinea 4.58 The safety analysis incorporates, to varying degrees, predictions of the circumstances that will prevail in the operational or post-operational stages of a facility or activity. There will always be

uncertainties associated with such predictions that will depend on the nature of the facility or activity and the complexity of the safety analysis. These uncertainties have to be taken into account in the results of the safety analysis and the conclusions drawn from it.

- alinea 4.59. Uncertainties in the safety analysis have to be characterized with respect to their source, nature and degree, using quantitative methods, professional judgement or both. Uncertainties that may have implications for the outcome of the safety analysis and for decisions made on that basis are to be addressed in uncertainty and sensitivity analyses. Uncertainty analysis refers mainly to the statistical combination and propagation of uncertainties in data, whereas sensitivity analysis refers to the sensitivity of results to major assumptions about parameters, scenarios or modelling.

- In IAEA SSR-5 [2],
  - R6: Understanding of a disposal facility and confidence in safety
    - alinea 3.26 Confidence has to be assured by the results of safety assessment for a disposal facility. The features of the facility and its host environment that provide for safety have to be identified, in addition to those factors that might be detrimental. It has to be demonstrated that these features and factors are sufficiently well characterized and understood. Any uncertainties have to be taken into consideration in the assessment of safety.
    - alinea 3.31 In establishing these regulatory requirements, it has to be recognized that there are various types and components of uncertainty inherent in modelling complex environmental systems. It also has to be recognized that there are, inevitably, significant uncertainties associated with projecting the performance of a disposal system over time.
  - R11: Step by step development and evaluation of disposal facilities:
    - alinea 4.7, At any step in the development of a disposal facility, the safety case also has to identify and acknowledge the unresolved uncertainties that exist at that stage and their safety significance, and approaches for their management.
    - alinea 4.10 *[…]* Safety assessment has to include quantification of the overall level of performance, analysis of the associated uncertainties and comparison with the relevant design requirements and safety standards […].
  - R13: Scope of the safety case and safety assessment:

- alinea 4.17 With regard to safety after closure, the expected range of possible developments affecting the disposal system and events that might affect its performance, including those of low probability, have to be considered in the safety case and supporting assessment by the following means: […] d) By identifying and presenting an analysis of the associated uncertainties.
- alinea 4.19 The performance of the disposal system […] has to be analysed in the safety assessment. […] If necessary, sensitivity analyses and uncertainty analyses would be undertaken to gain an understanding of the performance of the disposal system and its components under a range of evolutions and events.

- In Council Directive 2011/70/EURATOM [3], article 7.3 on a.o. the approach used in the safety demonstration, which shall identify and reduce uncertainties.

14.4.3.2 COMMON POINTS AND DIFFERENCES BETWEEN EXISTING GUIDES

Uncertainty of safety assessment of deep geological repository has been comprehensively discussed in a number of international documents as e.g. IAEA SSG-23 [4], EPG [1], NEA-6405 [80], NEA-6923-MeSA [50].

Section 3.6.1 of EPG report [1] is dedicated to the management of uncertainties involving issues as uncertainty strategy, uncertainties in the assessment bases, uncertainty in the performance assessment and the irreducible uncertainties.

The outcome of the NEA MeSA (Methods for Safety Assessment of Geological disposal) Initiative provides an analyses of the treatment of uncertainties used in safety assessment for radioactive waste disposal facilities in various national waste management programmes.
It discusses the strategy in treating the uncertainties, mathematical techniques and the perspectives of the regulatory body (chapter 8 in NEA-6923-MeSA [50]). NEA-6923-MeSA distinguishes scenario uncertainties, model uncertainties, and data and parameter uncertainties. Further regardless of its classification he uncertainties can be of reducible (epistemic) or irreducible (aleatory) nature.
The MeSA programme stresses on the need to integrate the safety assessment in an uncertainty management strategy.
concludes that strategies of treating uncertainties within the safety assessment are well established, generally falling into the following 5 categories of strategies:

1) Demonstrating that the uncertainty is irrelevant to the safety assessment
2) Addressing the uncertainty explicitly – for examples through a probabilistic approach or through a series of sensitivity studies

3) Bounding the uncertainty – for example by making a simplifying assumptions taking a conservative view
4) Ruling out the uncertain event or process – for example on the basis of very low probability
5) Using an agreed stylised approach to avoid addressing the uncertainty explicitly, e.g. biosphere uncertainties.

It indicates that mathematical methods for assessing quantitatively the influence of uncertainties on the calculated indicators are available. Concerning regulatory perspectives, regulators expect uncertainties to be identified, to the extent possible quantitatively characterised or bounded, and their impact on safety clearly articulated in the safety case. Moreover, the way uncertainties are treated and propagated in the safety assessment should be traceable and substantiated. Complementary strategies like scoping and bounding assessments, deterministic and probabilistic approaches, realistic best estimates, conservative estimates, and alternate lines of evidence may be prescribed by regulations for specific assessment objectives. Uncertainties connected to the assessment results can be placed into an understandable context that enhances the ability to evaluate its importance by reference to multiple lines of evidence either as a complement to the entire safety assessment or to parts of it.

Most of the national guides ask to include an analysis of the uncertainties within the safety assessment as e.g. FANC-GEN [23], FANC-SAR [51], CNSC-G-320 [18], ENSI-G03 [12], SÚJB 2004 [29], ASN Guide [22] and BMU-2010 [11] The uncertainties have to be identified and their relevance for safety have to be assessed.

Few guides specify that uncertainty management and strategy has to be established [23, 51, 11, 18] but several guides specify that for each uncertainty the source of uncertainty, which can be in the input data, the knowledge on processes involved or on future events or human activities, the conceptual model and mathematical methods, has to be identified and presented in the safety assessment [18, 12, 22]. In case of uncertainty in the input data, it is asked to provide the results with the range of uncertainty [29, 22] or to base the assessment on the most pessimistic values [22]. Deterministic or probabilistic calculations, appropriate for the purpose of the assessment are used to reflect data uncertainty [18] (this topic is further developed in following section 14.4.4).
The uncertainties have to be reduced as far as possible and where uncertainties remain, the maximum radiological consequences have to be estimated by calculating envelope variants or by making conservative assumptions [12].

14.4.3.3 Needs for dialogue, development and harmonization

The need to detail the regulatory expectations over the programme on uncertainties management by the licensee has been identified.

14.4.4 Deterministic vs. probabilistic approaches

14.4.4.1 Requirements

No SRL from the draft WENRA report [47] is explicitly dedicated to the "safety topic" "Deterministic vs. probabilistic approaches".

The following international safety requirements are associated with the topic "Deterministic versus Probabilistic Approaches".

- In IAEA GSR Part 4 [48]:
  - R15 Both deterministic and probabilistic approaches shall be included in the safety analysis.
    - alinea 4.53 Deterministic and probabilistic approaches have been shown to complement one another and can be used together to provide input into an integrated decision making process. The extent of the deterministic and probabilistic analyses carried out for a facility or activity has to be consistent with the graded approach.
    - alinea 4.54 The aim of the deterministic approach is to specify and apply a set of conservative deterministic rules and requirements for the design and operation of facilities or for the planning and conduct of activities. When these rules and requirements are met, they are expected to provide a high degree of confidence that the level of radiation risks to workers and members of the public arising from the facility or activity will be acceptably low. This conservative approach provides a way of compensating for uncertainties in the performance of equipment and the performance of personnel, by providing a large safety margin.
    - alinea 4.55 The objectives of a probabilistic safety analysis are to determine all significant contributing factors to the radiation risks arising from a facility or activity, and to evaluate the extent to which the overall design is well balanced and meets probabilistic safety criteria where these have been defined. In the area of reactor safety, probabilistic safety analysis uses a comprehensive, structured approach to identify failure scenarios. It constitutes a conceptual and mathematical tool for deriving numerical estimates of risk. The probabilistic approach uses realistic assumptions whenever possible and provides a framework for addressing many of the uncertainties explicitly. Probabilistic approaches may provide insights into system performance, reliability, interactions and weaknesses in the design, the application of defence in depth, and risks, that it may not be possible to derive from a deterministic analysis.

- alinea 4.56 Improvements in the overall approach to safety analysis have permitted a better integration of deterministic and probabilistic approaches. With increasing quality of models and data, it is possible to develop more realistic deterministic analysis and to make use of probabilistic information in selecting accident scenarios. Increasing emphasis is being placed on specifying probabilistically how compliance with the deterministic safety criteria is to be demonstrated, for example, by specifying confidence intervals and how safety margins are specified.

14.4.4.2 COMMON POINTS AND DIFFERENCES BETWEEN EXISTING GUIDES

International guide IAEA SSG-23 [4] provides an analysis of advantage and disadvantages of deterministic and probabilistic approaches in safety analyses and recommends to use both approaches, because deterministic and probabilistic approaches have been shown to complement one another and can be used together to provide input into an integrated decision making process.

The outcome of the MeSA analysis in NEA-6923-MeSA [50] confirms that in many national programmes both approaches are applied and seen as complementary. They might be used in parallel to increase the confidence in the results obtained.

The use of these approaches is strongly related to the analysis of the uncertainty.

In assessing parameter uncertainties probabilistic analyses can be performed, using probability density function (PDF) of the parameter. This general procedure is however not yet internationally established [50].

Probabilistic analysis is explicitly asked for the operational safety assessment in BMU-2010 [11] and in ENSI-G03 [12]. SÚJB 2004 [29] requires the use of probabilistic approach in the analysis of alternative scenario involving abnormal or extreme situations. For long-term safety assessment BMU-2010 [11] mentions the use of deterministic calculations based on the most realistic modelling possible, using best estimates but 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.
Other national guides mention the use of both approaches (CNSC-G-320 [18]).

However with exception of guide CNSC-G-320 [18], the way to use the probabilistic analyses is not developed in national guides of participant countries.

14.4.4.3 NEEDS FOR DIALOGUE, DEVELOPMENT AND HARMONIZATION

An identified need is the determination of roles and methods associated with both deterministic and probabilistic approaches.

14.4.5 Conservative & realistic assessments

14.4.5.1 Requirements

- There are no explicit requirements concerning the "safety topic" "Conservative & realistic assessments" in the Draft WENRA report on SRL's [47].

- IAEA GSR-Part 4 [48]
    - R15 on deterministic and probabilistic approaches in the safety analysis address realistic assessment:
        - alinea 4.55: the probabilistic approach uses realistic assumptions whenever possible and provides a framework for addressing many of the uncertainties explicitly;
        - alinea 4.56: with increasing quality of models and data, it is possible to develop more realistic deterministic analysis and to make use of probabilistic information for example, by specifying confidence intervals and how safety margins are specified.

14.4.5.2 Common points and differences between existing guides

The use of conservative & realistic calculations is developed in EPG report [1] and IAEA SSG-23 (§ 5.15 – 5.19, 5.67)[4].

In IAEA SSG-23 [4], following recommendations are provided:
- alinea 5.15. A realistic assessment is aimed at providing an indication of the most likely behaviour of the disposal system. In a conservative assessment the ability of the disposal system to provide protection is deliberately underestimated. If a conservative approach is taken, the assessment should describe the justification for labelling certain parameter values or assumptions as conservative and quantitative estimates of the degree of conservatism should be provided, if possible.
- alinea 5.16. Both conservative and realistic calculations might be necessary in radiological impact assessment for the period after closure, and both approaches can be used to increase confidence in the safety of the disposal facility. For example, conservative models can be used, especially in early phases of assessment, to assess quickly the performance of part of or the entire disposal system. Simple conservative models may also be used to increase confidence in results obtained with more complex models Conservative models are also necessary to deal with uncertainties that are not amenable to quantification. Conservative estimates may be used in the assessment for some parameters, whilst realistic values based on detailed characterization and/or more realistic models may be used for others.

- alinea 5.17. The decision to use a conservative approach, a realistic approach, or both will depend on a number of factors such as the nature and objective of the assessment, regulatory requirements, the availability of data and scientific understanding, the complexity of the site and the facility, and available resources.
- alinea 5.18. For optimization of the design of the facility or in order to demonstrate a detailed understanding of the behaviour of the disposal system, the assessment should be as realistic as is possible, depending on the availability of data with which to parameterize the models. A realistic assessment may, however, necessitate complex calculations involving a large number of parameters, and significant resources may be required to demonstrate that the data and models used do in fact lead to a realistic representation of the performance of the disposal system.
- alinea 5.19. In order to demonstrate compliance with a numerical measure or standard of performance, it may be appropriate to undertake a conservative analysis based on relatively simple models. Such an approach will be feasible if there is a large margin of safety. Caution is necessary, however, because, if misused, results from overly conservative or worst case representations of the disposal system may lead to poor decision making that is based on assessment results that bear little resemblance to the actual performance of the facility. In addition, the use of an overly conservative approach can raise concerns of interested parties about manipulation of results, if later assessments adopt a more realistic (or less conservative) approach to demonstrate compliance with regulatory requirements. In order to avoid such situations, the choice of a conservative approach or a realistic approach, and the reasons for modifying the approach if this is done, should be clearly documented and communicated.
- alinea 5.67. Another commonly used approach to treat uncertainties is to use conservative (cautious) assumptions. For example, when simplifying the models used, a conservative view can be taken. Another example is to assign conservative values to model parameters. This approach has several advantages, in particular for demonstration of compliance with regulatory criteria. However, in some cases such conservative assumptions may lead to assessments representing situations that are extremely unrealistic or impossible and, therefore, difficult to interpret and communicate. Also, when conservative values are assigned to several parameters, the results of the calculations might be overly conservative and would provide a poor basis for decision making. Another important consideration is that an assumption that is conservative in one scenario, or for one nuclide, might not be so for another; for example, an assumption that overestimates migration of radionuclides from a facility may underestimate the long term risk from intrusion. The conservatism of the assumptions should be justified in relation to their impact on the assessment endpoints.

It seems to be agreement that conservative approach should be used in the case of lack of information or uncertainties in order to ensure that the calculated dose will not be underestimated (FANC-SAR [51] , CNSC-G-320 [18], ENSI-G03 [12], SÚJB 2004 [29], ASN Guide [22]).

In Belgian FANC-SAR [51] it is mentioned that the level of realism will depend on the objective of the analysis (e.g.: performance assessment versus radiological impact). It states that a minimum of realism is required in calculations to ensure good understanding of the system behaviour and involved processes, provide confidence in the used conceptual model, appraise the level of conservatism and to be able to compare different options. Canadian CNSC-G-320 [18] warns on the use upper or lower limits of input data that are not necessarily leading to conservative response of the models and in the case of realistic best estimate assessment, on the required use of real site and as-built facility data, site-specific scenarios, and accurate models of the processes. In BMU-2010 [11] the deterministic calculations should be based on the most realistic possible modelling.

14.4.5.3 Needs for dialogue, development and harmonization

The need identified is to provide guidance on the approach to use (conservative or realistic) versus the objective of the assessment.

14.4.6 Scenarios

14.4.6.1 Requirements

Based on IAEA glossary on radioactive waste management [92], IAEA GRS Part 4 [48] and Draft WENRA report on SRL's [47], a scenario can be defined as follows:
A scenario is a postulated or assumed set or sequence of conditions and/or features, events and processes (FEPs) leading to possible future situations and time histories.
A set of scenarios is devised in the safety assessment for the purpose of illustrating the range of future behaviours and states of a disposal system and its surrounding after closure. They may be particularly useful if there is uncertainty or lack of knowledge about what assumptions are appropriate.

The following safety requirements are associated with the "safety topic" "Scenarios":

- in the Draft WENRA report of SRL's [47]:
  - SRL 2.3.3: The licensee shall design the disposal facility giving due consideration to both normal evolution of the disposal system after closure and scenarios involving disturbing features, events and processes.
  - SRL 4.1.8: The licensee shall ensure that the safety case adequately reflects the factors that influence safety and their significance.
  - SRL 4.2.2: The licensee shall present in the post-closure safety assessment a scenario analysis that considers the possible features, events and processes

that might affect the performance of the disposal system, including events of low probability and human actions.

- In IAEA GSR Part 4 [48] alinea 4.51 of R14 on the scope of the safety analysis: The features, events and processes to be considered in the safety analysis are to be selected on the basis of a systematic, logical and structured approach, and justification has to be provided that the identification of all scenarios relevant for safety is sufficiently comprehensive.

- In IAEA SSR-5 [2], R13 on Scope of the safety case and safety assessment:
    - alinea 4.19: The performance of the disposal system under expected and less likely evolutions and events, […] has to be analysed in the safety assessment. A judgement of what is to be considered the expected evolution and less likely evolutions has to be discussed between the regulatory body and the operator. If necessary, sensitivity analyses and uncertainty analyses would be undertaken to gain an understanding of the performance of the disposal system and its components under a range of evolutions and events
    - alinea 4.20: The consequences of unexpected events and processes may be explored to test the robustness of the disposal system. In particular, the resilience of the disposal system has to be assessed. Quantitative analyses have to be undertaken, at least over the time period for which regulatory requirements apply. However, the results from detailed models for safety assessment purposes are likely to be more uncertain for timescales extending into the far future.

14.4.6.2 COMMON POINTS AND DIFFERENCES BETWEEN EXISTING GUIDES

In IAEA SSG-14 [25], alinea 5.12 it is mentioned that the safety case for the period after closure, should address scenarios for the more likely evolutions of the geological disposal facility and its regional setting over very long time periods (e.g. a time period comparable to that over which the waste remains hazardous) and the less likely events that might affect the performance of the facility. For geological disposal facilities, to meet the requirements of IAEA SSR-5 (e.g. R13) [2], it is necessary that the safety case and the supporting assessments:

- (a) present evidence that the key features, events and processes that might significantly affect geological disposal system are sufficiently well understood that scenarios of possible evolutions are properly generated;
- (b) provide estimates of the performance of the geological disposal system regarding compliance with all the relevant safety requirements;
- (c) identify and present an analysis of the associated uncertainties.

Further explanation and recommendations in developing and analysing scenarios are provided in Appendix II of [25].

IAEA SSG-23 [4] describe the methodology to apply in the development of scenarios (Sections 5.35 – 5.46, 6.11) and the use of Feature Events and Processes (FEPs) lists. These aspects are also developed in several international reports as a. o. NEA on the post-closure safety case for geological disposal (§ 2.4, 4.2, 5.1) [85], [28], NEA-MeSA (§ 5.1-5.6, 13, 17.7) [50], EPG report (§3.2, 4.1.2.1, 4.1.2.5, 4.2.2.3, 4.3.2.3, 5.) [1].
Safety assessment scenarios are commonly used in the national programmes and addressed in the corresponding guides as FANC-SAR [51], CNSC-G-320 (§ 2.0, 7.5) [18], ENSI-G03 [12], SÚJB 2004 (4.2, 4.3, 4.4) [29], ASN Guide [22] and BMU-2010 (§ 5.2, 7.2) [11], SSMFS 2008:21 (Appendix 1, § 9) [30], EA and NIEA Guidance (Requirement R7, Section 7.2.8) [66].

The analysis of the normal evolution and altered evolutions of the disposal site and disposal system are required both in international and national guidelines. Therefore, a scenario development has to be performed where potential futures relevant to safety assessment of radioactive waste repositories are identified and described. The scenario development should consider the possible features, events and processes that might affect the safety of the disposal system in the post closure phase (FANC-SAR [51], ENSI-G03 [12], BMU-2010 [11], SÚJB 2004 [29], CNSC-G-320 [18], SSMFS 2008:21 [30], EA and NIEA 2009 [66]).
There is a broad range of used terms in existing guides for scenarios or evolution e.g. normal evolution, expected evolution, main scenario, base scenario, reference scenario, altered scenario, disturbed scenario and less likely scenario.

Only few guides include requirements regarding a structured and comprehensible approach of scenario development. In CNSC-G-320 [18], it is asked that the safety assessment presents and justifies the techniques and criteria used to develop the scenarios that are analysed. Scenarios should be developed in a systematic, transparent, and traceable manner through a structured analysis of relevant features, events, and processes (FEPs) that are based on current and future conditions of site characteristics, waste properties, and receptor characteristics and their lifestyles. The approach to scenario development should be consistent with the rigor of the assessment, taking into consideration the purpose of the assessment, the hazard of the waste, and the nature of the decision for which the assessment is being undertaken. Accordingly, scenario development can range from "brainstorming" to formal analysis of FEPs and extrapolation of current lifestyle information.

There are pretty different approaches how to provide human intrusion scenarios and how to deal with human intrusion in the safety case. In some guides it is acknowledged that future human actions are unpredictable and therefore respective scenarios cannot be developed in a systematic way like scenarios that take natural phenomena and waste induced phenomena into account. For this reason the issue of human intrusion is often treated separately from the systematic scenario development (MeSA -2012 [50]).

14.4.6.3 Needs for dialogue, development and harmonization

Further following needs for dialogues and harmonization were identified on:

- possible features, events and processes that have to be considered
- consideration of human actions (including the treatment of human intrusion in the SC)
- scenario development methods (how to ensure completeness, structured and comprehensible approach,…)
- common understanding of the different used terms in scenario development

14.4.7 Models

14.4.7.1 Requirements

The following safety requirements are associated with the “safety topic” “Models”:

- In the Draft WENRA report on SRL’s [47]:
  - SRL 2.4.3: on the contribution of monitoring to the confirmation and refinement of models;
  - SRL 4.1.7: on the clarity, substantiation and traceability of the assumptions, choices and decisions made .
  - SRL 4.2.6: On the use of models and computer codes that have undergone verification and, to the extent possible, validation in the safety assessment;

- In IAEA GSR Part 4 [48] R18: Any calculational methods and computer codes used in the safety analysis shall undergo verification and validation.

14.4.7.2 Common points and differences between existing guides

Several existing guides address the requirements on the verification and validation of models and computer codes identified in §1 (IAEA GSG-G 3.4 [49], NEA-6923-MeSA [50], FANC-SAR [51], V&V [52], CNSC-G-320 [18]). These guides are relatively consistent with each other. Verification and validation are commonly seen as two important processes aimed at building confidence in models. However, the need for verification and validation is not explicitly mentioned in all guides (see e.g. ENSI-G03 [12], ASN-RFIII-2 [22 and SÚJB-2004 [29]). Nonetheless, a common trend in most guides is the necessity to substantiate that a model adequately represents the system or subsystem and is adequate for the application i.e. fit for the given purpose, as explained in IAEA SSG-23 [4] and [49, 50, 51, 52, 12]).

Guidance on verification usually includes the objectives and steps or activities associated with the verification process [49, 50, 51, 18]. The model verification process should demonstrate that the computer code or numerical model correctly implements the mathematical model for the conditions under consideration using e.g. model comparison studies. In some cases, verification may also include the demonstration that the model and/or the corresponding computer program is a proper mathematical representation of the conceptual model [49, 51].

Guidance on validation always includes an explanation of the objectives of the validation process [49, 50, 51, 52, 18]. Validation is usually aimed at demonstrating that the model provides a good representation of the real processes that they are supposed to represent through comparisons with field or laboratory data or with natural systems. It is also recognized in most guides that complete comparison between model predictions and data from real systems cannot be done for models used in post-closure safety assessment. Validation is therefore focused on the testing of specific key model features in order to increase confidence in model results.

Besides verification and validation, additional activities or elements contributing to building confidence in models are also identified and developed in most guides. Some of these activities are related to Draft WENRA SRLs 2.4.3 and 4.1.7 or have to be carried out as part of the quality assurance process. Additional activities include:

- System understanding including the identification and understanding of key processes and events [51,18,22], the correlation between theory and experiments and extrapolation from natural analogues as necessary and as feasible [49],…;
- Data selection (e.g. [50,18]);
- Identification and analysis of uncertainties (e.g. [49,18]);
- Sensitivity analyses (e.g. [49,18]);
- Justification of assumptions, parameter values, probability distributions, limitations, simplifications as well as of considered and discarded phenomena [49,4,50,51,52,18,12,22];
- Ensuring that there is a suitable linking of models of different parts of the waste disposal system [49,51];
- Demonstrating consistency of model results with complementary scoping and bounding assessments [18];
- Ensuring the traceability of the model development process through an appropriate record keeping and documentation (e.g. [49,4,51,29]). This includes the quality control of data and parameter values (e.g. [49,4,50]);
- Peer reviews [50,18];
- Model review and updates owing to increasing knowledge and lessons learned (e.g. [49,4]);
- …

The level of accuracy, realism, conservatism and complexity reached in a model as well as the level of confidence in a model that should be achieved are also discussed in some of the guides [4,51,18].

The terminology used in existing guides addressing the issue of modelling is of importance. Several guides provide definitions of the different model types or components (conceptual model, mathematical model, computer code,…) (see e.g. [49,4,50,51]). The term qualification is also used in [50] as the overall process aimed at demonstrating that the model is fit for the given purpose.

14.4.7.3 NEEDS FOR DIALOGUE, DEVELOPMENT AND HARMONIZATION

Although no major inconsistency has been identified in existing guides, differences in the types of activities that need to be carried out to substantiate that a model is "fit for a given purpose" are observed. Hence, needs for dialogue, guidance development and/or harmonization on the following issues related to the requirements associated with the topic "Models", have been identified:

- Activities and arguments needed to build confidence in models: Sensitivity analyses, peer reviews, justification of choices and hypotheses, benchmark calculations,…;
- Validation strategy of computer codes over long timeframes (lifecycle) of the repository: Roles of monitoring & controls in model validation,…
- Modelling of gas production and transport in a deep geological repository has also been identified.

14.5 INDICATORS & CRITERIA

14.5.1 Requirements

No WENRA SRL is being proposed for the “safety topic” “Indicators & criteria” except that in the content of the safety case the establishment of respectively performance indicators are asked in the assessment of performance and robustness and safety indicators in the assessment of radiological and non-radiological impact assessment (see Annex 3 of Draft WENRA report [47]).

Several ICRP publications are dealing with requirements on the radiological indicators and criteria as a.o. ICRP 101a [93]and ICRP 103 [54] but most of the requirements are recalled as well in the ICRP publication specific to geological disposal ICRP 122 [62], and developed in ICRP 108 [86] in case of environmental protection.

- In ICRP 122 [62], in § 4.3 on dose and risks concept:
    - alinea (45): on the use of the effective dose for demonstrating compliance with dose limits or protection standards or for comparing with dose constraints or reference levels.
    - alinea (46): in case of potential exposure, resulting from an event, the risk associated with such an event is a function of the probability of an unintended event causing a dose, and the probability of detriment due to that dose. The Commission recommends a risk constraints of 2 10^{-4} $year^{-1}$ for worker and 1 10^{-5} $year^{-1}$ for the public.

- in § 4.4 in alinea (49) on protection in the operational phase: The annual dose limit for workers of 20 mSv $year^{-1}$, averaged over a 5-year period, is applied with the requirement of optimising protection below dose constraints. The recommended dose constraint for the public is 0.3 mSv $year^{-1}$ for each source.

- in § 4.5 on protection in the post-operational phase:
    - alinea (54): for the expected evolution of a geological disposal facility in the distant future Commission recommends a dose constraint of 3 mSv $year^{-1}$ [54] (or no more than 0.3 mSv $year^{-1}$ according to ICRP 103 [54]) or, in case of potential exposure, an annual risk constraint of 1 10^{-5} from the emplaced waste. Two approaches may be considered: (1) aggregation of risk by combining doses and probabilities, and comparing the result with the risk constraint; or (2) for each exposure, presenting the dose and its corresponding probability of occurrence separately, and comparison with the dose constraint supplemented by consideration of the probability that the doses would be incurred.

  - ICRP notes that although regulatory control of a geological disposal facility is not envisaged to continue indefinitely, the dose criteria for clearance do not apply.
- in § 4.6 on protection in particular circumstances:
  - alinea (58) for natural events that are included in the design-basis evolution, the Commission recommends application of the risk constraint or the dose constraint as for planned exposure situations.
  - alinea (59) The potential impact of severe disruptive events may be estimated at the design stage using stylised or simplified calculations. If this approach was adopted, the appropriate reference levels would be those for an existing exposure situation, or for an emergency exposure situation, depending on the specific scenario.
  - alinea (61) long-lasting exposures resulting from natural disruptive events should be referred to as 'existing exposure situations', and the recommended reference level for optimising protection strategies ranges between 1 and 20 mSv $year^{-1}$. A reference level should be selected in the lower part of the band (e.g. in the range of a few mSv per year).
  - alinea (65) in the distant future, if indirect oversight has ceased, the occurrence of human intrusion cannot be excluded. At the planning stage, the results of the stylised or simplified calculations can be used as indicators of system robustness by comparing them with numerical values of dose. If this approach is taken, the application of the reference levels defined for emergency and/or existing exposure situations is recommended.
- in § 4.7. Summary of relevant exposure situation according to oversight
- in § 5 On the concept of representative person (based on ICRP 101a [93])
  - alinea (91) […]exposures should be assessed on the basis of the annual dose to the representative person.
  - alinea (93) […] for the purpose of protection of the public, the representative person corresponds to an individual receiving a dose that is representative of the more highly exposed individuals in the population.

- In IAEA GSR Part 4 [48] following requirements related to the operational safety are:
  - R16, alinea 4.57: Criteria shall be defined for the safety analysis, for judging safety and for assessing compliance with safety objective and fundamental principles and requirements of the designer, operating organization and regulatory body. They include risk criteria that relate to the likelihood of anticipated operational occurrences or of accidents giving rise to significant radiation risks.

- R19 alinea 4.61 […]. For complex facilities, data are to be collected on the basis of a set of safety performance indicators that have been established for the facility.

- In IAEA SSR-5 [2]
  - R9, alinea 3.47 […]For such long time periods after closure, indicators of safety other than estimates of dose or individual risk may be appropriate, and their use has to be considered .
  - R13, alinea 4.21. For timescales extending into the far future, arguments may be needed to illustrate safety, on the basis, for example, of complementary safety indicators, such as concentrations and fluxes of radionuclides of natural origin in the geosphere and biosphere and bounding analyses. While such assessments cannot yield precise levels of possible doses or risks, the results may provide a tool to indicate the level of safety and verify that no alternative design would have obvious advantages

  In the context on protection of the environment:
  - alinea 2.23. Additional indicators and comparisons, such as estimates of concentrations and fluxes of contaminants and their comparison with concentrations and fluxes of radionuclides of natural origin within the geosphere or biosphere, may also prove valuable in indicating a level of overall environmental protection that is independent of assumptions about the habits of people. Other factors to be considered may include the need for protection of groundwater resources and the ecological sensitivity of the environment into which contaminants might be released.

Note that IAEA GSR-4 Part 4 [48] focus more on safety indicators to be used in the framework of operation safety and on the use of complementary indicators as e.g.. Safety Performance Indicators commonly used for Nuclear Power Plants. These indicators are of a measurable, operational type (e.g. number of outages in the reporting period) and are often used to show continuous improvement.
Requirements related to the use of safety indicators and criteria in the framework of the post-closure safety assessment of a geological disposal are more developed in IAEA SSR5 [2].

14.5.2 Common points and differences between existing guides

Several international reports and guidelines exist on indicators used in the safety assessment related to geological disposal. They are mostly related to the post-operational safety assessment. However for the operational period, experience can also be used from the Nuclear Power Plants safety to define Safety Performance Indicators as recommended in IAEA GSR Part 4. An overview is provided e.g. in IAEA-TECDOC-1141 [95].

Guidelines are provided in IAEA-TECDOC-1372 [82] and IAEA-TECDOC-1464 [83]. An overviews of safety indicators for the post-operational period is given in e.g. the NEA report on indicators by the Integrated Group on the Safety Case (IGSC) [84]. It is based on previous compilations with among them the deliverable D3.4.2 of PAMINA project [96]. It is as well developed in §7 of NEA-MeSA report [50]. Discussions and guidance are provided in [84, 50] a.o. on the types of safety indicators and possible classifications, on the consideration of timescale, on the yardstick against which indicators can be compared and on their transferability between repository concepts and sites.

In all national guides analysed within WP2.1 dose and risk are considered as the primary safety indicators used to verify compliance with dose and risk limits (see FANC-RPC-POP [94], CNSC-G-320 [18], ENSI-G03 [12], SÚJB 2004 [29], ASN Guide [22], BMU-2010 [11], SSMFS 2008:37 [19]).
Dose constraints and risk constraints are mentioned as well but their use can vary as a criteria for compliance in radiologic impact assessment, for assessment of the performances of the disposal or optimization.

Differences might be also observed between countries concerning the values of the criteria especially for the very long term assessments with low probable evolutions and are related to the conservatism of the assessment imposed through the safety assessment scenarios.

Complementary indicators are recommended in different context, depending on the country (see e.g. in FANC-RPC-POP [94], CNSC-G-320 [18], ASN Guide [22], SSMFS 2008:37 [19]) but their type and the corresponding criteria are not always specified, leaving the option to the applicant. They are recommended for increasing confidence in calculated risks as for the period up to 100 000 years in SSMFS 2008:37 [19]. They must be used to assess the radiological impact for the period extending beyond a few thousand years when the dose and risk constraints become reference values or when the individual risk associated with a potential exposure cannot be quantified in FANC-RPC-POP [94].

Activity fluxes and concentrations estimated at various locations in the repository are examples of complementary indicators proposed for performance assessment in ASN Guide [22]. Environmental concentrations are used as safety indicators and model parameters can be used as performance indicators in CNSC-G-320 [18]. Environmental radiotoxicity or radioactivity must be assessed comparing them to natural values or drinking water criteria or without necessarily associating any reference values or criteria in case of alternative assessment scenario as described in FANC-RPC-POP [94].

The first regulatory authority that specified complementary indicators and criteria was STUK in Finland that included a constraint on the amount of activity that may be released from the repository to the accessible environment.

Differences in national requirements and guidelines relate finally to the practical implementation of indicators, but these differences are not expected to lead to significant differences in required performance of the disposal system.

14.5.3 Needs for dialogue, development and harmonization

Although several international guides or overview exist on the possible use of indicators the WP2.1 recommend further development and common view on the use of indicators complementary to the effective dose and risk, in the national regulation guides in the context of the very long-term assessment, the robustness assessment and environmental protection assessment.

Following specific needs are identified :

- Criteria for radiological protection of the environment
- Criteria for non-radiological protection of the environment
- Criteria for non-radiological protection of humans
- Indicators & criteria for very long time-frames
- Reference values for complementary indicators
- Indicators & criteria for performance/robustness assessment

14.6 OPERATIONAL SAFETY ASSESSMENT

14.6.1 Requirements

The following safety requirements are associated with the “safety topic” “Operational safety assessment”:

- In the Draft WENRA on SRL’s report [47]:
  - SRL 4.2.1: consideration of both occupational exposure and public exposure resulting from normal operation, and anticipated operational occurrences and possible accidents in the assessment;
  - SRL 4.2.3: assessment of the defence in depth whether provided, as appropriate, through a combination of several layers of protection that would have to fail or to be bypassed before there could be any consequences for people or the environment;

- In IAEA GSR Part 4 [48]
  - R7: specification and assessment of all safety functions associated with a facility or activity ;
  - R9: determination if whether adequate measures are in place to protect people and the environment from harmful effects of ionizing radiation.
  - R10: verification that a facility or activity uses SSCs of robust and proven design);
  - R11: consideration of the human interactions with the facility or activity in the safety assessment, and assessment of the procedures and safety measures that are provided for all normal operational activities, in particular those that are necessary for implementation of the operational limits and conditions
  - R13: Determination in the assessment of defence in depth whether adequate provisions have been made at each of the levels of defence in depth.

- In IAEA SSR-5 [2] R13: the safety case and supporting safety assessment shall demonstrate the level of protection of people and the environment provided and shall provide assurance to the regulatory body and other interested parties that safety requirements will be met ; in particular:
  - alinea 4.15: Consideration of all aspects of operation relevant to safety including both occupational exposure and public exposure resulting from conditions of normal operation and anticipated operational occurrences over the operating lifetime of the disposal facility.

- alinea 4.16: Consideration of accidents of a lesser frequency, but with significant radiological consequences, with regard to both their likelihood of occurrence and the magnitude of possible radiation doses and of the adequacy of the operational features, in the assessment.

14.6.2 Common points and differences between existing guides

The existing guides develop topics on:

- the differences between safety assessments for the operational period and for the post-closure period: during the entire operational period, the facility is subject to regulatory inspection and radiation monitoring and it will rely on active and passive measures (see SSG-14 [25] §5.9);
- the safety case, which should address all aspects of operation relevant to radiation exposure for the operational period of a geological disposal facility (waste emplacement, any underground construction work carried out during emplacement and backfilling, sealing and closing of the facility) and include considerations on the replacement of equipment and demonstration of safely retrievability while the facility is open (see SSG-14 [25], §5.10);
- the case of accidents of less frequency is also tackled in SSG-14 [25],§5.11.

In addition, this topic is well-develop in the Swiss ENSI-G03 guide [12] on the content of the safety report, which must contain:

- a description of all structures, facilities and installations at surface and underground that are relevant for safety;
- the measures taken for radiation protection during normal operations as well as expected radiation exposure of personnel and local population;
- accident analysis;
- details on assumptions regarding the course of incidents or accidents, their possible radiological consequences and their impact on the long-term safety of a closed repository.
- a probabilistic safety analysis has to be carried out for the operational phase.

14.6.3 Needs for dialogue, development and harmonization

The need to develop aspects of the operational safety assessment specific to geological disposal has been underlined but not by all organizations. This is probably because many organizations are in the first stage of development of the geological disposal project in which operational safety does not play the dominant role.

A specific concerns is, as identified within the GEOSAF Companion report [12], how to deal with the hazard assessment of a geological disposal facility being constructed and operated over a significant time period and thus how to take account for a continuously changing facility in a changing environment. It is also recommended to provide more guidance, in the impact assessment, on scenario development involving incidents, accidents, failures of safety systems or controls and their modelling specific to the geological disposal facility and the use of specific indicators and criteria (temperature, pressure, size, position…).

14.7 L-T SAFETY ASSESSMENT

14.7.1 Requirements

The following safety requirements are associated with the "safety topic" "Long-term safety assessment".

- In the Draft WENRA Report on SRL's: [47]:
  - SRL 4.1.3. The licensee shall include in the safety assessment:
    - a) An evaluation of the performance and robustness of the disposal facility and system and its components;
    - b) An evaluation of the radiological impact.
  - SRL 4.1.6 . The licensee shall ensure that the safety case provides a clear understanding of the safety arguments, is comprehensive and documented with a content and level of detail appropriate to the step reached in the disposal facility development.
  - SRL 4.1.10 The licensee shall ensure that the safety case shows that design, engineering and operational choices and decisions on the disposal system derive from a process involving optimization of radiological protection.
  - SRL 4.1.13 The licensee shall include in the safety case, subject to a graded approach, a synthesis of multiple lines of reasoning regarding post-closure safety and an evaluation of the level of confidence reached.
  - SRL 4.2.3. The licensee shall determine in the assessment whether adequate defence in depth has been provided, as appropriate, through a combination of several layers of protection (i.e. physical barriers, systems to protect the barriers, and administrative procedures) that would have to fail or to be bypassed before there could be any consequences for people or the environment.
  - SRL 4.2.5. If nuclear criticality cannot be ruled out due to long-term uncertainties, the licensee shall substantiate that in case of nuclear criticality occurring after closure, there would be no unacceptable adverse effect on post-closure safety.

- In IAEA GSR Part 4 [48]:
  - R7: All safety functions associated with a facility or activity shall be specified and assessed.
  - R9 on the assessment of the provisions for radiation protection. It shall be determined in the safety assessment of a facility or activity whether adequate measures are in place to protect people and environment from harmful effects of ionizing radiation. Normal operation of the facility or

activity, anticipated operational occurrences and accident conditions have to be addressed.

- R10 on the assessment of engineering aspects i.e. whether a facility or activity uses, to the extent practicable, structures, systems and components of robust and proven design.
- R12: Assessment of the possible radiation risks: The possible radiation risks associated with the facility or activity shall be identified and assessed.
- R13 on the assessment of defence in depth whether adequate provisions have been made at each of the levels of defence in depth. In particular:
  - alinea 4.45. to address deviations from expected evolution and to mitigate their consequences on safety;
  - alinea 4.46 to identify all necessary layers of protection, including physical barriers to confine and the necessary supporting administrative controls;
  - alinea 4.47 to determine if it has been adequately implemented by giving priority to reducing the number of challenges to the integrity of the layers of protection and physical barriers; using independent layers of protection and physical barriers; paying special attention to the simultaneous failures; implementing measures to ensure reliability and effectiveness of the required defence in depth;
  - alinea 4.48 to determine whether there are adequate safety margins in the design and operation of the facility. Safety margins are typically specified in codes and standards as well as by the regulatory body.
- R15 Both deterministic and probabilistic approaches shall be included in the safety analysis.
- R17: Uncertainty and sensitivity analysis shall be performed and taken into account in the results of the safety analysis and the conclusions drawn from it.
- R21: Independent verification: The operating organization shall carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body

- In IAEA SSR-5 [2]
  - R7 on the use of multiple safety functions. The capability of the individual barriers and controls together with that of the overall disposal system to perform as assumed in the safety case shall be demonstrated. The overall performance of the disposal system shall not be unduly dependent on a single safety function.

- R8 on the containment of radioactive waste, which has to be provided by the host environment and the engineered barriers and the demonstration of it through safety assessment.
- R9 on the isolation of radioactive waste and the demonstration of it through safety assessment.
- R13: The safety case and supporting safety assessment shall demonstrate the level of protection of people and the environment provided and shall provide assurance to the regulatory body and other interested parties that safety requirements will be met. In particular:
  - alinea 4.17. With regard to safety after closure, the range of possible developments affecting the disposal system and events that might affect its performance have to be considered in the safety assessment using means as evidence of sufficient understanding of the disposal system, demonstration of feasibility and implementation of the design, estimates of performance of the disposal, demonstration of the compliance of safety requirements and optimization and identification and analysis of the uncertainties.
  - alinea 4.18. The safety case may include the presentation of multiple lines of reasoning
  - alinea 4.19. The performance of the disposal system under expected and less likely evolutions and events, which can be outside the design performance range of the disposal facility, has to be analysed.
  - alinea 4.20. The consequences of unexpected events and processes may be explored to test the robustness of the disposal system. In particular, the resilience of the disposal system has to be assessed. Quantitative analyses have to be undertaken, at least over the time period for which regulatory requirements apply…
  - alinea 4.21. For timescales extending into the far future, arguments may be needed to illustrate safety or to verify that no alternative design would have obvious advantages, on the basis, for example, of complementary safety indicators such as concentrations and fluxes of radionuclides of natural origin in the geosphere and biosphere and bounding analyses.

Among these requirements many are related respectively to the assessment of the performance of the disposal facility and system and its components and to the assessment of the radiological impact as asked in SRL 4.1.3.
Other requirements concern the long-term safety assessment in general and several concern the integration of analyses, arguments & evidence, presented as subtopic in the Table 1 in Appendix A1.

14.7.2 Common points and differences between existing guides

Several international documents and guides exist on the long-term safety assessment, published in the European framework or by NEA as e.g. NEA-6923-MeSA [50]. The IAEA SSG-23 guide [4] being dedicated to the safety case and to the safety assessment provides many recommendations on how to implement expectations on long-term safety assessment.

Note that the long-term safety assessment is called in the IAEA SSG-23 guide [4]: "Assessment of the post-closure radiological impact". Considered as the core of a safety case for a waste disposal it involves qualitative and quantitative analyses of the evolution of the disposal system and its environment, possible challenges to the safety functions and the resulting potential radiological impacts (4.44). It is, in other words, as explained in (5.1) a process of evaluating the performance of a disposal system and quantifying its potential impact on human health and the environment (5.1).

- In assessing the evolution of the disposal system and its environment, IAEA SSG-23 [4] recommends to provide (4.45): sufficient demonstration of the adequacy of the site and engineering components; reasonable assurance of compliance with the relevant safety principles and requirements;
- Assurance that the safety strategy set out for the facility is fulfilled

The guide [4] specifies the favourable characteristics or properties of natural barriers and the engineered barriers that have to be assessed in particular, as passive safety, multiple safety functions, defence in depth and robustness (4.47-4.51).
More details on what to consider in the performance assessment of the geological disposal are provided in (e.g. 6.5, 6.6, 6.10) as well as how to address the assessment of defence in depth (6.29-6.33) and robustness (6.38-6.41).

The assessment of the radiological impact *sensu stricto* i.e. in terms of dose and risks to human and environment is developed in §5 of [4] with focus on the safety assessment approach.

In § 7.10 of IAEA SSG-23 [4] it is recommended to dedicate a section of the safety case on synthesis and conclusions that:

- draws the key findings from the safety assessment
- highlights the main evidence, analyses and arguments that quantify and support the claim that the disposal facility is safe
- present an evaluation of uncertainties and unresolved issues with the planned steps to resolve them
- describe complementary evidence for safety
- presents statements of confidence

All guides require an assessment of the performance of the disposal system and an assessment of the radiological impact on human and environment FANC-SAR [51], CNSC-G-

320 [18], ENSI-G03 [12], SÚJB 2004 [29], ASN Guide [22], BMU-2010 [11] and SSMFS 2008:37 [19].

Differences are observed in the terminology used in their recommendations and on the way the safety assessment is organized in the safety case.

Several other elements of the safety assessment are required in the various guides but already discussed in the other sections of this present report (see § 14.2 to 14.5).

14.7.3 Needs for dialogue, development and harmonization

The following needs were identified:

- Performance and robustness assessment (assessment of safety functions, methodology,…)
- Assessment of defence in depth
- Multiple lines of reasoning & evaluation of the level of confidence
- Assessment of criticality after closure

14.8 PERIODIC SAFETY REVIEW

14.8.1 Requirements

The following safety requirements are associated with the "safety topic" "Periodic Safety Review":

- In Draft WENRA report on SRL's [47]:
    - SRL 4.3.1: Review of the operational and post-closure at regular intervals of which the frequency shall be established by the national regulatory framework. (e.g. every ten years);
    - SRL 4.3.2: Definition and substantiation of the scope and submission of it to the regulator with at least following considerations:
        - evaluation of operational experience
        - review of radiological protection aspects (with occupational dose, public doses and environmental survey results)
        - review of waste acceptance and waste quality controls
        - review of experience with aspects influencing post-closure safety.
        - review of compliance with the current regulatory

  A guide of the content is given in the annex 4 of draft WENRA Report [47];
    - SRL 4.3.3: Documentation of the result and preparation and implementation of an action plan for all reasonably practicable improvements;

- In IAEA GSR Part 4 [48] R24: The safety assessment shall be periodically reviewed and updated and in particular:

- alinea 5.2: the SA has to be updated to reflect changes and evolution of the facilities and activities, to take account for advances in the knowledge and understanding, to provide baseline for future evaluation of monitoring and safety assessments and appropriate records of references with regard to future use of the site.
- alinea 5.10: Periodic review and update at predefined intervals to take into account for: a) changes that may significantly affect safety, b) significant development in knowledge and understanding, c) emerging safety issue due to regulatory concern or significant incident and d) significant changes in computer codes or changes in input data.

- In IAEA SSR-5 [2], Disposal of Radioactive Waste: Requirement 11, paragraph 4.5: Periodic reviews also have to be undertaken during the operation of the facility and following closure, up to termination of the facility license.

14.8.2 Common points and differences between existing guides

Overall safety assessments are normally required as a basis for a regulatory/governmental decision to grant an authorisation for (change of status for) an activity or facility (i.e. siting, construction, commissioning, trial operation, routine operation, decommissioning, etc.).
Periodic safety review (PSR) could be considered as a specific application of an overall safety assessment of an activity or a facility with regards to the aspect of timing only, i.e. to make sure that overall safety assessments are carried out at regular intervals, independently from any authorisation process for a change in the status of the facility. Thus, the requirements for the scope, objective and methodology do not differ from other authorisation driven safety assessments.

The following documents has been developed by the IAEA to provide for more detailed guidance associated also with the topic “periodic safety review”:

- IAEA SSG-25, Periodic Safety Review for Nuclear Power Plants [87]
- IAEA GSG-3, The Safety Case and Safety Assessment for the Predisposal Management of Radioactive Waste [60]

Although IAEA SSG-25 addresses nuclear power reactors, the main principles and approaches are applicable also for other facilities including disposal facilities.

Specific national guidance on periodic safety review for disposal facilities for radioactive waste has not been identified. National guidance on periodic safety review is generally part of a national approach for requiring periodic safety reviews for any nuclear facility with a periodicity not exceeding typically ten years ENSI-G03 [12].

14.8.3 Needs for dialogue, development and harmonization

Existing international guidance seem to be more or less satisfactory. Also, national regulations/guidance seems to appropriately address the main issue of periodic safety reviews. Thus, no specific need for development of further guidance for this topic has been identified although some specific issues were identified as having a potential for further discussions on possible development in relation to disposal of radioactive waste, e.g. ;

- Frequency of PSR
- Elements to be taken into account in a PSR
- Identification and evaluation of safety significance of differences
- Documentation of PSR and implementation of an action plan

14.9 INDEPENDENT VERIFICATION

14.9.1 Requirements

There seems not to be a draft WENRA SRL addressing explicitly the conduction of an "independent verification" but following international safety requirements are associated with this "safety topic":

- In IAEA GSR Part4 [48]:
  - R20, alinea 4.64 The safety report has to document the safety assessment in sufficient scope and detail to support the conclusions reached and to provide an adequate input into independent verification and regulatory review.
  - R21 (alinea 4.66 to 4.71): Independent verification. The operating organization shall carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body
- In IAEA SSR-5 [2], R14: Documentation of the safety case and safety assessment: The safety case and supporting safety assessment for a disposal facility shall be documented to a level of detail and quality sufficient to inform and support the decision to be made at each step and to allow for independent review of the safety case and supporting safety assessment. Important consideration in documenting the safety case and supporting safety are justification, traceability and clarity as mentioned in alinea 4 and further developed in alinea 4.24 and 4.25.

14.9.2 Common points and differences between existing guides

14.9.2.1 International guides

IAEA Specific Safety Guide SSG-23 [4] addresses the topic "independent verification" (3.14) to meet the requirement 14 of IAEA SSR-5 [2] or R20 of GSR Part 4 [48] It recommends the use of Peer Reviews from the early stages as an active part leading to the development of a safety case (4.93). With this aim, it is recommended to consider how they will be conducted in the safety strategy (4.36). SSG-23 proposes assessing reproducibility and peer review as element of good practice in the safety assessment (4.52). They are mentioned to play an important role in building confidence and should entail a formally documented examination of a technical programme by one or more qualified experts that have not been directly involved in the development of the safety case and have no direct interest (e.g. financial or political interest) in the outcome (4.92). The use of international Peer Reviews to focus on specific topics or to evaluate the entire safety case are recommended as well (4.94). NEA guidelines [89] and questionnaire for Peer Reviews are referenced in this context [90].

14.9.2.2 National guides

Few of the existing national guides addressing this safety topic were identified (see CNSC-G-320 [18] (§ 4.3.3), ENSI-G03 [12], art. L542-10-1 in French Programme Act L2006-739 [88]) They mainly focus on the documentation of the safety case that has to be adequate and sufficient to allow its evaluation. CNSC-G-320 [18] specifies that details should be sufficient to allow independent calculations confirming assessment results. As a way to build confidence in the assessment it recommends the use of independent predictions based on different assessment strategies and computing tools. It recommends publication in open literature to allow scientific peer reviews. The use of peer reviews is as well suggested as support for the regulatory review.

As for the international guide IAEA SSG-23 [4], they do not explicitly mention that an independent verification of the safety assessment shall be organised by the operating organisation.

14.9.3 Needs for dialogue, development and harmonization

National guides address the subject of independent verification. A sharing of experiences or questions about independent verification could be useful for the development of harmonized practices and more specifically on the following aspects:

- Common understanding of “independent verification” (terminology).
- Feedback on already requested 3rd party verification (purpose, how should it be conducted, do some countries have requested the NEA/IAEA to conduct a third party review ?, …) ?

15 Needs for Dialogue and Guidance Development

15.1 PRIORITIZATION OF NEEDS IDENTIFIED BY NSAs AND TSOs

Needs for discussion, additional guidance or harmonization have been identified by NSAs and TSOs for each of the “safety topics” and subtopics, as presented in the subsections of chapters 4 to 14.
As explained in section 2.4 the identification was performed, having the IGD-TP vision [102] in mind and they are the result of answers to questionnaires, analyses of existing guides and discussion between partners of the SITEX project.
This WP2.1 exercise leaded to the identification of almost hundreds of needs, which are summarized according to the “safety topics” in Table A4.1 of Appendix A4.

Note that a need for discussion, additional guidance or harmonization was identified concerning the interactions between operational and long term safety and concern several “safety topics” of the list in chapter 3. It can be related to “concurrent activities”, “design”, “management”, “operational safety assessment”, “long-term safety assessment”, etc. It is therefore presented separately in a generic topic called “safety” of Table A4.1.

It is worth to note as well that several initiatives were referenced with regards to the safety topics although they could not always be integrated in the analysis of existing guides from the beginning of the SITEX project. They concern recently launched projects of still running projects for which conclusions still have to be drawn or made available.
Among them IAEA project as HIDRA, GEOSAF II, MODARIA, DRiMa are mentioned as well as the European projects EPG on WAC and MoDeRn.
They are considered very relevant for the “safety topic” and we recommend to take account for their outcomes in future development of the SITEX platform.

The list of needs was used in a second questionnaire addressed to the partners of WP2.1 to classify them according to :

- the importance given by them on the need
    - L: Lowest (dialogue/development not really or at all needed)
    - M: Medium (dialogue/development would be « nice to have »)
    - H: Highest
- the priority for them to develop guidance or enhance dialogue on it (considering the time-frames associated with the decision-making process):

- L = Low priority (after 2020).
- M = Medium priority (before 2020);
- H = High priority (before 2016);

The level of priority or "urgency" to develop the needs has been determined considering:

- the importance for safety;
- the IGD-TP vision statement that "by 2025, the first geological disposal facilities for spent fuel, high-level waste, and other long-lived radioactive waste will be operating safely in Europe" [102] and the associated time-frames related to the decision-making process.

Four SITEX partners provided an answer: Bel V, FANC, CNSC and GRS and the four answers were used to assign a final "average" score on importance and priority of the needs.

With the exception of 5 issues, in general all issues that were identified with a high level interest were also identified with a high level of urgency. The results are discussed hereafter per groups of "safety topics" (ST).

"Governing principles, safety policy and safety strategy" (ST1 to ST12)

Needs identifies for "Safety topics" on "Optimisation", "Defence in depth and robustness" and "Isolation & confinement" were identified both with high level of interest and urgency. Even if these principles are accepted as safety principles, a need for guidance have been identified. Indeed, these principles when applied to geological disposal ask to take into account specificities related to the long term safety of geological disposal. For examples, when applied to geological disposal, defence in depth may not rest on active measure at long term and optimisation has to be understood in the broadest sense as an iterative, systematic, and transparent evaluation of options for enhancing the capabilities of the system and for reducing impact.

Some safety topics for which the principles are clearly transposed in each country's regulation, as it was the case for topics on "limitation or risk" and the "protection of the environment" did not lead to recommendations of additional development of guidance or harmonization. Several needs on the related safety topic "indicators and criteria" are however defined and concern the non-radiological protection, the environmental protection or the very long term.

The need to discuss time-frames associated to reversibility and retrievability were identified both with high level of interest and urgency. In different countries retrievability becomes indeed a legal or societal requirements that have to be considered early in the development of a repository.

The use of the graded approach is generally considered in the development of a geological disposal and do not require additional developments or discussion. It follows from the analysis as well that there is no need to discuss principle of using passive means in the geological disposal but it is referred to the safety topic on “isolation and containment” for which it is recommended to discuss the common understanding of isolation and containment and therefore indirectly the use of passive means.

The need to discuss the pre-licensing process was identified both with high level of interest and urgency. The need include the role of the regulatory body at important decision steps (e.g. sitting) and the Civil Society involvement.

Needs for the “safety topic” on “Safety policy & strategy” were identified with a medium level of interest. However the scopes of the safety policy and of the safety strategy are often subject to discussions at the international level. Since, the early development and adoption of a policy and a strategy for safety is a key point in the development of the safety case the topic as identified with a high level of urgency.

“Management”(ST 13)

Some specific issues were identified as having a potential for further discussions on possible development e.g.: responsibilities and assessment of compliance with requirements associated with available resources.

The need on principle and means of preservation of records and knowledge was identified with a high degree of urgency since this principle should be applied from the beginning of the development of the repository.

“Repository development” (ST 14 to ST19)

Followings needs were identified both with high level of interest and urgency:

- The interpretation of ICRP 122 [62] regarding the radiation protection principles applied to geological disposal and the weighting of criteria when applying optimization to site selection
- Programme for site characterisation
- Possible Features Events & Processes that have to be considered in scenarios
- Development of the “design basis”
- characteristics of radioactive waste and of the site
- normal and anticipated operational conditions, possible accidents

- disturbing FEPs during operation whose consequences may affect post-closure safety
- hazards linked to concurrent activities and specificities of operation

These issues have indeed to be discussed with a high priority since site characterisation and selection as well the development of the design basis constitutes the first steps of development of a repository.

The need to clearly define the terms monitoring, control and surveillance was also identified was identified both with high level of interest and urgency.

Waste acceptance and monitoring (ST20, ST21)

The need to discuss on “preliminary waste acceptance criteria” was identified both with high level of interest and urgency. The preliminary waste acceptance should indeed be established at the earliest opportunity. This issue is not straightforward since the final design is not yet known at the moment the criteria are defined.

The needs related to the “safety topic” “monitoring” were identified both with high level of interest and urgency. Monitoring is indeed quite important to confirm that the repository system behaves has foreseen in the safety case and have to be considered quite early in the development of a repository.

Safety case and safety assessment (ST22 to ST35)

The need to discuss on the content of a safety case for each important step of repository development was identified both with high level of interest and urgency. A clear position of regulatory bodies on this issue constitute an important input for the licensee when developing the safety case.

Most of needs related to “Characterisation, Knowledge & System understanding”, “Time scales and time frames”, “Uncertainties”, “Deterministic vs probabilistic approaches”, “Scenarios”, “Models”, “Indicators & criteria” and “Long term safety assessment” were identified both with high level of interest and urgency. Clear expectations of regulatory bodies on these issues are indeed important in the frame of the IGD-TP vision and constitute therefore a priority.

15.2 NEEDS OF WMOS

In order to verify if the needs and priorities of WMOs are sufficiently addressed within WP2.1 or should be adapted, it was proposed to IGD-TP members, at the 3rd exchange forum of IGD-TP held on the 29 of November 2012 in Paris, to answer a questionnaire on the needs of the experts involved in the implementation of disposal programmes (i.e. implementing function) for technical dialogue and guidance at the European level. Examples of questions of the questionnaire for each "safety topic" were:

- Do you think it is necessary to develop or further develop guidance on this issue?
- What are the topics that should be covered in particular by the guidance?
- What are the requirement(s) that should be addressed by the guidance?
- What is the level of priority of this development?
- Should the guidance address specific programme phase(s)?

One member (ONDRAF/NIRAS) completed the questionnaire but it was specified during the 4rd exchange forum of IGD-TP held on the 29-30 of October 2013 in Praha that the answers should not be considered as representative of all IGD-TP members.

Given no representative opinion was made available through the questionnaire, we limited our analysis by checking needs and priorities on the basis of the IGD-TP's Strategic Research Agenda 2011 [53] & Deployment Plan 2011-2016 [103]. It appeared that several topics identified are directly related to requirements and "safety topic" addressed in WP2.1, e.g.:

- Increase confidence in, and testing and further refinement of the tools (concepts, definition of scenarios and computer codes) used in safety assessment;
- Technical feasibility and long-term performance of repository components ;
- Methodologies for adaptation and optimisation during the operational phase and
- Monitoring.

It was concluded from this analysis that the list of needs and priorities identified by NSAs and TSOs as presented in previous section and summarized in Table A4.1 of Appendix A4 covers the needs by the WMOs.

15.3 NEEDS OF CIVIL SOCIETY

This section presents the outcomes of the Senec SITEX workshop discussions that took place In Slovakia, in the framework of WP5 [99] on interaction between civil society and expertise function.

A specific roundtable on “Decision making process and needs of stakeholders for expertise, background of knowledge” was dedicated to the WP2 issue.

During the roundtable, following questions were also debate:

- What time, stage to enter the decision making process?
- What are the necessary conditions for allowing mutual understanding between the expertise function and the civil society ?
- What would be the most suitable way(s) of identifying the needs of the public society ?

As a result from the discussions it appears that development is needed on how and when should civil society enter the decision making process and on a clear identification of the role of the civil society. Stakeholder’s expectation is to take part to the decision making at the earliest stage, even before conceptual phase, when energy strategy is prepared. To ask civil society to cooperate only at the final stage of the nuclear energy cycle without interaction in earlier stages of project development often lead to an impasse.

In general it can be noted that early interaction with expertise function should forego any decision making process. Interaction with the public during early stages is needed on any topic related to waste management, including decommissioning and legacy waste management. More flexibility should be given to enable the public to interact with the decision-making process when he feels appropriate.

Implementing transparency in the context of Radioactive Waste Management makes it necessary to create conditions for the public to have an effective access to a relevant and reliable information as well as to have an access to independent sources of expertise and as a minimum requirement to the expertise function of the public authorities. Representatives of civil society commonly do not have sufficient knowledge and resources to enter discussions on an equal footing with the proponents of the projects. There is a need for clarification regarding the principle of independency of the expertise function. It is also understood that, in the reality, no expert or scientists can be absolutely independent because of the necessary cooperation in research areas, or as result of a lack of available researchers in nuclear sector in each country.

Mutual understanding is therefore required to guarantee a continuous dialogue between the civil society and the expertise function. If there is no common understanding of fundamental issues, it is not possible to discuss more detailed aspects of each stage of the decision-making. The most important topics to be discussed were identified by stakeholders during the SITEX workshop as follows :

- Fundamental aspects of waste management background in each national context
- Decision process, history and rational of already done decisions, subsequent strategic decisions ;
- Norms and standards determining certain decisions and waste management itself ;
- Safety principles & requirements ;
- Position of regulator and regulatory body's experts;
- Regular update on the R&D programme of the expertise function;
- Regular update on the Safety Case review progress; (i.e. Safety concept; Safety strategy adopt by the implementer).

During these discussions no needs were expressed to develop guidance on specific "safety topics" within WP2.1 but it is clear that the concerns of the CS encourage to make documents (position papers and technical guides) available to facilitate the interpretation and understanding of safety requirements guiding the development of repositories and to help mutual understanding and involvement of the public society.

16 Conclusions

The SITEX project "Sustainable network of Independent Technical EXpertise for radioactive waste disposal", coordinated by IRSN was launched in 2012 for a period of two years with the aim of establishing the conditions to build a network of technical expertise independently from the operators to support the regulatory bodies in its activities of regulating, authorizing and verifying the compliance of geological repositories for radioactive waste.

SITEX work packages were defined to provide support to this final objective and as concluding work package, WP6 defines the conditions to develop such network of expertise [101].

As part of the expertise function, technical guidance explaining how regulatory expectations or requirements can be met in practice and how compliance should be substantiated by the implementing function are needed to ensure that regulatory expectations are clearly interpreted and communicated. Work package WP2.1 on "Overview of Existing Technical Guides and Further Development" was developed in this context.

The main objective of WP2.1 is to identify the areas where development of such guidance, harmonization, common positions or dialogue is needed in priority, considering the IGD-TP vision that "by 2025, the first geological disposal facilities for spent fuel, high-level waste, and other long-lived radioactive waste will be operating safely in Europe" [102].

The WP2.1's deliverable D2-1 provides an overview of existing and available technical guides, within the SITEX consortium, addressing "safety topics" to consider in the development of a geological disposal and submission of a safety case. It identifies the common points and differences between these guides and finally identifies and prioritize the needs for further development, harmonization and dialogue.

Almost hundreds of needs are identified. Thirty-five of them are of both high level of interest and high priority. As is reasonably logical to expect, most of these priority needs are associated with the first steps of development of a repository (namely site selection and characterisation; development of the design basis and monitoring programme); with the content of the safety case and with the safety assessment (namely treatment of uncertainties, scenarios, models and timeframes).

WP2.1 contributes, with this deliverable, to the general objective of SITEX and presents one of the basis on which WP6.2 relies on to define the functions of the Future Expertise Network [101]. It might be as well one of the starting points for defining potential actions that could be undertaken by this Future Expertise Network.

The work performed in the framework of WP2.1 constitutes a valuable input for the future SITEX activities aiming to share national experience and prospective views on:

- the interpretation and implementation of the "high level" international requirements;
- practices to verify that the recommendations are effectively implemented;
- the dialog and interaction with WMOs during the pre-licensing and licensing phases.
- the communication and interaction with the Civil Society

The structured list of "safety topics' developed within WP2.1, which covers most of the high-level requirements to be considered in the development of a geological disposal facility and submission of a safety case and which makes the link with available international and national guides, constitutes as well a useful base for knowledge management and a reference for building competences within the future Expertise Network. It should be further improved and regularly updated according to future developments.

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Appendix A1. Requirements and technical guides associated with the list of "Safety Topics"

Table A1.1 Safety Topics and requirements associated with the governing principles, safety policy and safety strategy.

SAFETY TOPICS considered in WP2.1	WENRA SRLs	IAEA Principles & Requirements	EC directive 2011/70/Euratom ICRP Recommendations
Governing principles			Article 4.3
*** Radiation protection**		GSR Part3 R1 GSR Part3 R19 GSR Part3 R29	ICRP 103 Ch5 ICRP 103 Ch6
- **Justification**		SF-1, P4 GR Part3 R10	
- **Optimisation of protection**	SRL 2.1.1 SRL 2.1.4	SF-1 P5 GSR Part3 R11 SSR-5 R4, §2.9, 2.18	Article 5.1e Article 7.2 ICRP 101b ICRP 103 ICRP 122
- **Limitation of risks to individuals**		SF-1 P6 GSR Part3 R12	
+ Operational period		SSR-5 §2.7-14	
+ Post-closure period		SSR-5 §2.15-19	ICRP 103 art. 43-251; ICRP 122 art: 44, 45-48
*** Protection of present and future generations**		SF-1 P7	(Article 1.1)
*** Protection of the environment**		SSR-5 §2.21-23	
*** Defence in depth & Robustness**	SRL 2.1.2 SRL 2.1.6	SF-1 P8 GSR Part3 R15, §3.40 SSR-5 R7	
*** Passive Means**	SRL 2.1.3	SSR-5 R5	Article 4.3c
*** Good engineering practice, proven techniques & feasibility**	SRL 2.3.1 SRL 2.3.7 SRL 2.5.1	GSR Part3 R15, §3.39	Article 11.2
*** Isolation & Containment**	SRL 2.1.5 SRL 2.1.6 SRL 2.3.5	SSR-5 R8 SSR-5 R9	
*** Reversibility/Retrievability vs. Safety**	SRL 2.1.7		
*** Graded approach**	SRL 2.1.1	GSR Part3 R6	Article 4.3d
*** Stepwise approach**		SSR-5 R11	
*** Concurrent activities**	SRL 2.1.9	SSR-5 R17, §4.34	
Safety policy & strategy *** Safety assessment strategy** *** Management strategy** *** Design and implementation strategy**	SRL 1.1.3 SRL 1.2.1 SRL 1.3.5 SRL 2.1.10 Appendix 3	GSR Part4 R23 SSR-5 R4 GSR Part4 R22	

Table A1.2 Safety Topics and requirements associated with the Management

SAFETY TOPICS considered in WP2.1	WENRA SRLs	IAEA Principles & Requirements	EC directive 2011/70/Euratom ICRP Recommendations
Management		SF-1 P3 GSR Part3 R5 GSR Part3 R24 GS-R-3	Article 7
*** Responsibilities**	SRL 1.1.1 SRL 1.1.2 SRL 1.1.3 SRL 1.1.4 SRL 1.1.5 SRL 1.1.6 SRL 1.1.7 SRL 1.1.8	SF-1 P1 GSR Part3 R4 GSR Part3 R9 GSR Part3 R21 GSR Part3 R22 GSR Part3 R30 GSR Part4 R3 SSR5 R3	Article 7.1
*** Organisational structure**	SRL 1.2.1 SRL 1.2.2 SRL 1.2.3 SRL 1.2.4 SRL 1.2.5 SRL 2.6.14	GSR Part3 R23 GR-R-3 Section5	
*** Management system**	SRL 1.3.1 SRL 1.3.2 SRL 1.3.3 SRL 1.3.4 SRL 1.3.5 SRL 1.3.6 SRL 1.3.7	GR-R-3 Section5 GSR Part4 R22 SSR-5 R25	Article 7.4
*** Records & knowledge keeping**	SRL 2.7.2		

Table A1.3 Safety Topics and requirements associated with the different stages of repository development

SAFETY TOPICS considered in WP2.1	WENRA SRLs	IAEA Principles & Requirements	EC directive 2011/70/Euratom ICRP Recommendations
Site selection		SSR-5 R4 SSR-5 R7 SSR-5 R8 SSR-5 R9	
Design	SRL 2.3.1 SRL 2.3.2 SRL 2.3.3 SRL 2.3.4 SRL 2.3.5 SRL 2.3.6 SRL 2.3.7 SRL 2.3.8 SRL 2.3.9 SRL 2.3.10	SSR-5 R7 SSR-5 R8 SSR-5 R9 SSR-5 R16	

SAFETY TOPICS considered in WP2.1	WENRA SRLs	IAEA Principles & Requirements	EC directive 2011/70/Euratom ICRP Recommendations
	SRL 2.3.11 SRL 2.3.12 SRL 2.3.13 SRL 2.3.14		
Construction	SRL 2.5.1 SRL 2.5.2 SRL 2.5.3 SRL 2.5.4	SSR-5 R17	
Operation	SRL 2.6.1	SSR-5 R7 SSR-5 R8 SSR-5 R9 SSR-5 R18	
*** Investigations and feedback of information on operating experience**	SRL 2.6.2	GSR Part3 R16	
*** Operational limits and conditions**	SRL 2.6.3	GSR Part3 §3.123a SSR-5 R3	
*** Modifications**	SRL 2.6.6 SRL 2.6.7		
*** Emergency preparedness and response**	SRL 2.6.8 SRL 2.6.9 SRL 2.6.10 SRL 2.6.11	SF-1 P9 GSR Part3 R15 GSR Part3 R43-46 GS-R-2	
*** Maintenance, periodic testing and inspection**	SRL 2.6.12 SRL 2.6.13 SRL 2.6.14	SSR-5 R10	
*** Occupational exposure**	SRL 2.3.5 SRL 4.2.1	GSR Part3 R19 GSR Part3 R24 GSR Part3 R25 GSR Part3 R26	
*** Public exposure**	SRL 2.3.5 SRL 4.2.1	GSR Part3 R29 GSR Part3 R30 GSR Part3 R31	
*** Receiving, handling and emplacement of waste**	SRL 2.3.13 SRL 2.6.4		
Closure & Decommissioning	SRL 2.6.5 SRL 2.8.1 SRL 2.8.2 SRL 2.8.3 SRL 2.8.4 SRL 2.8.5 SRL 2.8.6	SSR-5 R19 WS-R-5	
Period after closure and institutional controls	SRL 1.1.6 SRL 2.1.1 SRL 2.6.5 SRL 2.9.1 SRL 2.9.2	SSR-5 R10 SSR-5 R21 SSR-5 R22	Article 5.1d

Table A1.4 Safety Topics and requirements associated with waste acceptance and mmonitoring

SAFETY TOPICS considered in WP2.1	WENRA SRLs	IAEA Principles & Requirements	EC directive 2011/70/Euratom ICRP Recommendations
Waste acceptance	SRL 2.7.1 SRL 3.1.1 SRL 3.1.2 SRL 3.1.3 SRL 3.1.4 SRL 3.1.5 SRL 3.2.1 SRL 3.3.1 SRL 3.3.2 SRL 3.3.3 SRL 3.3.4	SSR-5 R20	
Monitoring	SRL 2.1.8 SRL 2.2.2 SRL 2.3.10 SRL 2.3.11 SRL 2.4.1 SRL 2.4.2 SRL 2.4.3 SRL 2.5.3	GSR Part3 R14 GSR Part4 R24 SSR-5 R10 SSR-5 R21	
*** Occupational exposure**			
*** Public exposure**		GSR Part3 R32	

Table A1.5 Safety Topics and requirements associated with the Safety Case and Safety Assessment

SAFETY TOPICS considered in WP2.1	WENRA SRLs	IAEA Principles & Requirements	EC directive 2011/70/Euratom ICRP Recommendations
Safety case and assessment		GSR Part3 R13, §3.34	Article 7.2
*** Objectives and scope**	SRL 4.1.1 SRL 4.1.2	GSR Part4 R2 GSR Part4 R4 GSR Part4 R14 SSR-5 R13	
*** Graded approach**	SRL 4.1.13	GSR Part4 R1	Article 7.3
*** Safety Case/ Safety Assessment content vs regulatory decision steps**	SRL 4.1.3 SRL 4.1.4 SRL 4.1.5 SRL 4.1.6 SRL 4.1.7 SRL 4.1.10 SRL 4.1.11 SRL 4.1.12 SRL 4.1.14 SRL 4.1.15	GSR Part4 R5 SSR-5 R11 SSR-5 R12 GSR Part4 R20 SSR-5 R14	Article 7.3

SAFETY TOPICS considered in WP2.1	WENRA SRLs	IAEA Principles & Requirements	EC directive 2011/70/Euratom ICRP Recommendations
*** Characterization, knowledge and system understanding**	SRL 2.1.8 SRL 4.1.6 SRL 4.1.8	SSR-5 R4 SSR-5 R6	
- **Waste**	SRL 2.7.1 SRL 3.3.1 SRL 3.3.3		
- **Engineered components**			
- **Site**	SRL 2.2.1 SRL 2.2.2 SRL 2.5.3	GSR Part4 R8 SSR-5-R15	
- **Use of operating experience & monitoring data**	SRL 2.4.3 SRL 4.3.2	GSR Part4 R19 SSR-5 R21, §5.4	
*** Safety assessment methodologies, approaches & tools**			
- **Timescales and timeframes**	SRL 4.2.4	GSR Part4 R12	ICRP 81 ICRP 122 § 3.3.2
- **Assessment of the possible radiation risks**		GSR Par4 R4, §4.5 GSR Part4 R6 GSR Par4 R12, §4.43	
- **Uncertainties**	SRL 4.1.9	GSR Part4 R17 SSR-5 R6, §3.26, 3.31 SSR-5 R11 §4.7, 4.10 SSR-5 R13 §4.17, 4.19	Article 7.3
- **Deterministic vs. probabilistic approaches**		GSR Part4 R15, §4.53-4.56	
- **Conservative & realistic assessments**		GSR Part4 R15, §4.55-4.56	
- **Scenarios**	SRL 2.3.3 SRL 4.1.8 SRL 4.2.2	GSR Part4 R14, §4.51 SSR-5 R13, §4.19-4.20	
- **Models**	SRL 2.4.3 SRL 4.1.7 SRL 4.2.6	GSR Part4 R18	
*** Indicators & criteria**		GSR Part4 R16, §4.57 GSR Part4 R19, §4.61 SSR-5 § 2.15, 2.16, 2.23,A.4 SSR-5 R9 §3.47 SSR-5 R13 §4.21	ICRP 101 ICRP 103 ICRP 122
*** Operational Safety assessment**	SRL 4.2.1 SRL 4.2.3	GSR Part4 R7 GSR Part4 R9 GSR Part4 R10 GSR Part4 R11 GSR Part4 R13 SSR-5 R13, §4.15-16	
*** L-T Safety assessment**	SRL 4.1.3	GSR Part4 R15 GSR Part4 R17 GSR Part4 R21 SSR-5 R13 §4.17-21	

SAFETY TOPICS considered in WP2.1	WENRA SRLs	IAEA Principles & Requirements	EC directive 2011/70/Euratom ICRP Recommendations
- **Performance, defence in depth and robustness assessment**	SRL 4.1.3 SRL 4.2.3	GSR Part4 R7 GSR Part4 R10 GSR Part4 R13, §4.17, 4.19-4.21 SSR-5 R7 SSR-5 R8 SSR-5 R9 SSR-5 R13, §4.19-20	
- **Assessment of the radiological impact**	SRL 4.1.3	GSR Part4 R9 GSR Part4 R12	
- **Integration of analyses, arguments & evidences**	SRL 4.1.6 SRL 4.1.10 SRL 4.1.13 SRL 4.2.5	SSR-5 R13, §4.18	
*** Periodic safety review**	SRL 4.3.1 SRL 4.3.2 SRL 4.3.3	GSR Part4 R24 SSR-5 R11, §4.5	
*** Independent verification**		GSR Part4 R20, §4.64 GSR Part4 R21, §4.66-4.71	

Appendix A2. List of international and national regulation documents

Table A2.1 List of international and national regulation documents and guides identified in the framework of WP2.1

Abbreviation	Date (draft)	Title of the document	[#]	Link to internet page (March 2014)
International Regulation documents				
EC-2011/70/Euratom	2011	COUNCIL DIRECTIVE 2011/70/EURATOM of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.	3	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:199:0048:0056:EN:PDF
EUR_WENRA-WD-1.4	(2012)	Draft Report on Radioactive waste disposal facilities safety reference levels (Draft version V1.4.2 of 20121118 after Stockholm meeting of 16/10/2012)	47	http://www.wenra.org/media/filer_public/2012/11/19/v0_draft_disposal_report.pdf
ICRP 81	1998	ICRP Publication 81: Radiation protection recommendations as applied to the disposal of long-lived solid radioactive waste. Annals of the ICRP, 28(4), 1–2.	76	http://www.sciencedirect.com/science/article/pii/S0146645399000172
ICRP 101a	2006	ICRP Publication 101a: Assessing dose of the representative person for the purpose of radiation protection of the public.	93	http://www.icrp.org/publication.asp?id=ICRP%20Publication%20101a
ICRP 101b	2006	ICRP Publication 101b: The optimisation of radiological protection--broadening the process.	77	http://www.icrp.org/publication.asp?id=ICRP%20Publication%20101b
ICRP 103	2007	ICRP Publication 103: The 2007 Recommendations of the International Commission on Radiological Protection	54	http://www.icrp.org/docs/ICRP_Publication_103-Annals_of_the_ICRP_37%282-4%29-Free_extract.pdf
ICRP 122	2013	ICRP Publication 122: Radiological Protection in Geological Disposal of Long-lived Solid Radioactive Waste	62	http://www.icrp.info/article/S0146-6453%2813%2900002-X/abstract?elsca1=etoc&elsca2=email&elsca3=0146-6453_201306_42_3&elsca4=elsevier
ICRP 108	2008	ICRP Publication 108: Environmental Protection: the Concept and Use of Reference Animals and Plants.	86	http://www.icrp.org/publication.asp?id=ICRP%20Publication%20108
IAEA SF-1	2006	Fundamental Safety Principles	55	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1273_web.pdf
IAEA GSR Part3	(2011)	Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards INTERIM EDITION : General Safety Requirements Part 3 (Interim)	56	http://www-pub.iaea.org/MTCD/publications/PDF/p1531interim_web.pdf
IAEA GSR Part4	2009	Safety Assessment for Facilities and Activities : General Safety Requirements Part 4	48	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1375_web.pdf
IAEA GS-R-2	2002	Preparedness and Response for a Nuclear or Radiological Emergency: Safety Requirements N° GS-R-2.	64	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1133_scr.pdf
IAEA GS-R-3	2006	The Management system for Facilities and Activities: Safety Requirements N° GS-R-3.	57	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1252_web.pdf
IAEA-NEA_WS-R-5	2006	Decommissioning of Facilities using Radioactive Material. Safety Requirement WS-R-5.	91	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1274_web.pdf

Abbreviation	Date (draft)	Title of the document	[#]	Link to internet page (March 2014)
IAEA SSR-5	2011	Disposal of radioactive waste : Specific Safety Requirements N° SSR-5.	2	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1449_web.pdf
IAEA_RW-GLO	2003	Radioactive Waste Management Glossary. 2003 Edition.	92	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1155_web.pdf
International Guides				
IAEA GSG-2	2011	Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency : General Safety Guide N° GSG-2	37	http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1467_web.pdf
IAEA GSG-3	2013	The Safety Case and Safety Assessment for the Predisposal Management of Radioactive Waste: General Safety Guide N° GSG-3.	60	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1576_web.pdf
IAEA GS-G-1.1	2002	Organization and staffing of the regulatory body for nuclear facilities : safety guide N° GS-G-1.1	7	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1129_scr.pdf
IAEA GS-G-1.2	2002	Review and assessment of nuclear facilities by the regulatory body: Safety Guide N° GS-G-1.2	8	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1128_scr.pdf
IAEA GS-G-1.3	2002	Regulatory inspection of nuclear facilities and enforcement by the regulatory body : safety guide N° IAEA GS-G-1.3	5	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1130_scr.pdf
IAEA GS-G-2.1	2007	Arrangements for Preparedness for a Nuclear or Radiological Emergency : safety guide N° GS-G-2.1	65	http://www-pub.iaea.org/mtcd/publications/pdf/pub1265_web.pdf
IAEA GS-G-3.1	2006	Application of the management system for facilities and activities. Safety Guide N°GS-G-3.1.	58	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1253_web.pdf
IAEA GS-G-3.4	2008	The Management System for the Disposal of Radioactive Waste. Safety guide N° GS-G-3.4	49	http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1330_web.pdf
IAEA GS-G-3.5	2009	The Management System for Nuclear Installations : Safety Guide N°GS-G-3.5	59	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1392_web.pdf
IAEA SSG-14	2011	Geological disposal facilities for radioactive waste : Specific Safety Guide N° SSG-14	25	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1483_web.pdf
IAEA SSG-23	2012	The Safety Case and Safety Assessment for the Disposal of Radioactive Waste : Specific Safety Guide N° SSG-23.	4	http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1553_web.pdf
IAEA SSG-25	2013	Specific Safety Guide N° SSG-25: Periodic Safety Review for Nuclear Power Plants	87	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1588_web.pdf
IAEA RS-G-1.1	1999	Occupational Radiation Protection. Safety Guide RS-G-1.1.	38	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1081_web.pdf
IAEA WS-G-5.1	2006	Release of Sites from Regulatory Control on Termination of Practices : safety guide N° WS-G-5.1.	39	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1244_web.pdf
IAEA WS-G-5.2	2008	Safety Assessment for the Decommissioning of Facilities Using Radioactive Material. Safety Guide N° WS-G-5.2. Safety Standards Series.	40	http://www-pub.iaea.org/MTCD/publications/PDF/Pub1372_web.pdf
IAEA DS357	(2011)	DRAFT of Safety Guide: Monitoring and Surveillance of Radioactive Waste Disposal Facilities. DS357.	46	-
IAEA-TECDOC-0630	1991	Guidelines for the Operation and Closure of Deep Geological Repositories for the Disposal of High Level and Alpha Bearing Wastes	36	http://www-pub.iaea.org/MTCD/publications/PDF/te_630_web.pdf
IAEA-TECDOC-1077	1999	Critical groups and biospheres in the context of radioactive waste disposal. Fourth report of the Working Group on Principles and Criteria for Radioactive Waste Disposal.	78	http://www-pub.iaea.org/MTCD/publications/PDF/te_1077_prn.pdf
IAEA-TECDOC-1129	2000	IAEA-TECDOC-1129: Inspection and Verification of Waste Packages for Near Surface Disposal.	68	http://www-pub.iaea.org/MTCD/publications/PDF/te_1129_prn.pdf

Abbreviation	Date (draft)	Title of the document	[#]	Link to internet page (March 2014)
IAEA-TECDOC-1141	2000	IAEA-TECDOC-1141: Operational safety performance indicators for nuclear power plants	95	http://www-pub.iaea.org/MTCD/publications/PDF/te_1141_prn.pdf
IAEA-TECDOC-1208	2001	IAEA-TECDOC-1208: Monitoring of geological repositories for high level radioactive waste.	45	http://www-pub.iaea.org/MTCD/publications/PDF/te_1208_web.pdf
IAEA-TECDOC-1372	2003	IAEA-TECDOC-1372: Safety indicators for the safety assessment of radioactive waste disposal : sixth report of the working group on principles and criteria for radioactive waste disposal.	82	http://www-pub.iaea.org/MTCD/publications/PDF/te_1372_web.pdf
IAEA-TECDOC-1464	2005	IAEA-TECDOC-1464: Natural activity concentrations and fluxes as indicators for the safety assessment of radioactive waste disposal. Results of a coordinated research project .	83	http://www-pub.iaea.org/MTCD/publications/PDF/te_1464_web.pdf
IAEA-TECDOC-1515	2006	IAEA-TECDOC-1515: Development of Specifications for Radioactive Waste Packages.	69	http://www-pub.iaea.org/MTCD/publications/PDF/te_1515_web.pdf
IAEA_GEOSAF-OP-Comp	2012	REPORT of the GEOSAF Working Group on Operational Safety. (GEOSAF. The International Intercomparison and Harmonisation Project on Demonstrating the safety of Geological Disposal)	63	http://www-ns.iaea.org/downloads/rw/projects/geosaf/companion-report-on-operational-safety.pdf
EUR_EPG-SC-Rev	(2010)	Report on the European Pilot Study on the Regulatory Review of a Safety Case for Geological Disposal of Radioactive Waste	1	
EUR_EPG-WAC	(2010)	Report on the European Pilot Study on WAC EPG. (2010). Draft Report WAC: The development of Waste Acceptance Criteria (§4) (No. Draft version of 19/2/2010).	44	
PAMINA-D3.4.2-indicators	2009	PAMINA Performance Assessment Methodologies in Application to Guide the Development of the Safety Case. Safety Indicators and Performance Indicators. DELIVERABLE (D-N°:3.4.2)	96	http://www.ip-pamina.eu/downloads/pamina3.4.2.pdf
MoDeRn_D-2.1	2013	MoDeRn Monitoring Reference Framework report - Deliverable D-1.2. MoDeRn Partners, European Commission Euratom Research and Training Programme 7 th Framework Programme (2007-2013).	74	http://www.modern-fp7.eu/fileadmin/modern/docs/Deliverables/MoDeRn_D1.2_MoDeRn_MonitoringReferenceFrameworkReport.pdf
NEA_RegR&D-WD	2011	Regulatory Research for Waste Disposal - Objectives and International Approaches	6	https://www.oecd-nea.org/rwm/docs/2010/rwm-rf2010-4.pdf
NEA-3679-Post-Closure	2004	Post-closure safety case for geological repositories : Nature and purpose (Vol. NEA n° 3679). Issy-les-Moulineaux: Nuclear Energy Agency, Organisation for Economic Co-operation and Development. *(superseded)*	85	http://www.oecd-nea.org/rwm/reports/2004/nea3679-closure.pdf
NEA-4435-Timescale	2004	The handling of timescales in assessing post-closure safety : lessons learnt from the April 2002 workshop in Paris, France.	79	http://www.oecd-nea.org/rwm/reports/2004/nea4435-timescales.pdf
NEA-6082-PR-Guid	2005	International Peer Reviews for Radioactive Waste Management. General Information and Guidelines - Revues internationales par des pairs pour la gestion des déchets radioactifs. Informations générales et lignes directrices.	89	http://www.oecd-nea.org/rwm/reports/2005/nea6082-peer-review.pdf
NEA-PR-Quest	2005	Revues internationales par des pairs dans le domaine des déchets radioactifs. Questionnaire sur les principes et bonnes pratiques concernant les dossiers de sûreté internationaux. - Peer Reviews in the Field of Radioactive Waste. Questionnaire on Principles and Good Practice for Safety Cases.	90	http://www.oecd-nea.org/rwm/docs/2005/rwm-peer2005-2.pdf

Abbreviation	Date (draft)	Title of the document	[#]	Link to internet page (March 2014)
NEA-6405-Reg-GD	2010	Regulation and Guidance for the Geological Disposal of Radioactive Waste Review of the Literature and Initiatives of the Past Decade (Vol. NEA-6405). Paris	80	https://www.oecd-nea.org/rwm/reports/2010/nea6405-regulation-guidance-ENG.pdf
NEA-6424-Timescale	2009	Considering timescales in the post-closure safety of geological disposal of radioactive waste.	67	http://www.oecd-ilibrary.org/nuclear-energy/considering-timescales-in-the-post-closure-safety-of-geological-disposal-of-radioactive-waste_9789264060593-en
NEA-6923-MeSA	2012	Methods for Safety Assessment of Geological Disposal Facilities for Radioactive Waste. Outcomes of the NEA MeSA Initiative.	50	https://www.oecd-nea.org/rwm/reports/2012/nea6923-MESA-initiative.pdf
NEA_Indicators	2012	Indicators in the Safety Case A report of the Integrated Group on the Safety Case (IGSC)	84	http://www.oecd-nea.org/rwm/docs/2012/rwm-r2012-7.pdf
NEA-78121-Post-closure	2013	The Nature and Purpose of the Post-closure Safety Cases for Geological Repositories. NEA n° 78121	28	http://www.oecd-nea.org/rwm/reports/2013/78121-rwn-sc-brochure.pdf
NEA_RK&M-ProgRep	2013	Progress Report of the Project on Preservation of Records, Knowledge and Memory (RK&M) Across Generations. (March 2012 - March 2013)	75	http://www.oecd-nea.org/rwm/rkm/documents/rwm_rkm_2013_1_progress-2012-2013.pdf
National Regulation documents and Guides - Belgium				
BE_FANC-NS	2009	Facilities for final disposal of radioactive waste. Policy and guidelines for assessing licence applications.	21	
BE_FANC-GEN	(2010)	Guide tecnique générique dépôts	23	
BE_FANC-GEO	(2011)	Guide technique dépôt géologique (déchets de type B&C)	34	
BE_FANC-SAR	(2012)	Projet de guide technique "Analyse de la sûreté post-fermeture des établissements de stockage définitif de déchets radioactifs"	51	
BE_FANC-RPC-OP	2012	Guide on the radiological protection during the operational period of a facility for the disposal of radioactive waste	20	
BE_FANC-RPC-POP	2011	Technical guide "Radiation Protection Criteria for Post-Operational Safety Assessment for Radioactive Waste Disposal"	94	
BE_FANC-BIO	(2012)	Safety assessment: biosphere		
BE_FANC-SEC	2009	Protection physique dans le cadre de la sécurité nucléaire des projets de gestion à long terme des déchets radioactifs en Belgique: orientations AFCN.		
BE_FANC-PSR-Cl1	(2010)	Approche pour les prochaines révisions périodiques de sûreté des établissements de classe I. - Aanpak met betrekking tot de toekomstige periodieke veiligheidsherzieningen van inrichtingen van klasse I.		
BE_FANC-Mod-Cl1	2008	Richtlijn van het FANC voor de behandeling van aangiften van wijzigingsontwerpen in het kader van artikel 12 van het algemeen reglement op de bescherming van de bevolking, van de werknemers en het leefmilieu tegen het gevaar van de ioniserende stralingen (ARBIS), voor de inrichtingen van klasse I. - Directive de l'AFCN pour le traitement des déclarations de projets de modifications dans le cadre de l'article 12 du Règlement général de la protection de la population des travailleurs et de l'environnement contre le danger des rayonnements ionisants (RGPRI), pour les établissements de classe I.		

Abbreviation	Date (draft)	Title of the document	[#]	Link to internet page (March 2014)
BE_FANC-RRR	2012	Reflections on Flexibility, Reversibility, Retrievability and Recoverability by the Belgian nuclear safety authority. In Reversibility and Retrievability in Planning for Geological Disposal of Radioactive Waste. Proceedings of the "R&R" International Conference and Dialogue 1 4-17 December 2010, Reims, France.	24	http://www.oecd-nea.org/rwm/docs/2012/6993-proceedings-rr-reims.pdf
BE_Bel V-V&V	2011	Exigences en matière de Validation et Vérification d'outils de modélisation et de calcul utilisés dans le cadre d'études de Sureté. Concepts, Définitions, Méthodes	52	
BE_AVN-GEO-ARG	2005	Regulatory guidance for the geologic disposal of radioactive waste: « A minima requirements on argillaceous sedimentary formations »	32	
National Regulation documents and Guides - Canada				
CA_RW-Policy-FWK	1996	Canada's Radioactive Waste Policy Framework		http://nuclearsafety.gc.ca/eng/waste/index.cfm#Policy
CA_NSCA_EN	1997	Nuclear Safety and Control Act - Loi sur la sûreté et la réglementation nucléaires.	13	http://laws-lois.justice.gc.ca/eng/acts/N-28.3/
CA_NSCR_SOR2000-202	2009	General Nuclear Safety and Control Regulations - Règlement général sur la sûreté et la réglementation nucléaires (SOR/2000-202).		http://laws-lois.justice.gc.ca/PDF/SOR-2000-202.pdf
CA_Cl1_SOR2000-204	2009	Class I Nuclear Facilities Regulations (SOR/2000-204) - Règlement sur les installations nucléaires de catégorie I.	14	http://laws-lois.justice.gc.ca/PDF/SOR-2000-204.pdf
CA_RPR_SOR2000-203	2009	Radiation Protection Regulations (RPR) (SOR/2000-203) - Règlement sur la radioprotection.	15	http://laws-lois.justice.gc.ca/PDF/SOR-2000-203.pdf
CA_CNSC-P-223	2001	Protection of the environment. P-223. Ottawa, Ontario, Canada: Canadian Nuclear Safety Commission.		http://nuclearsafety.gc.ca/pubs_catalogue/uploads/P-223_e.pdf
CA_CNSC-P-290	2004	Managing Radioactive Waste. Regulatory Policy P-290	16	http://nuclearsafety.gc.ca/pubs_catalogue/uploads/P290_e.pdf
CA_CSA-N294-09	2009	CSA N294-09 - Decommissioning of facilities containing nuclear substances	41	http://www.scc.ca/en/standardsdb/standards/25436
CA_CSA-N286-05	2005	CSA N286-05 - Management System Requirements for Nuclear Power Plants. Mississauga, Ontario, Canada	70	http://www.techstreet.com/products/1276605
CA_CSA-N286-12	2012	CSA N286-12 - Management system requirements for nuclear facilities.	71	http://www.techstreet.com/products/1836900
CA_CNSC-G-228	2001	Regulatory Guide G-228: Developping and Using Action Levels.		http://nuclearsafety.gc.ca/pubs_catalogue/uploads/G228_e.pdf
CA_CNSC-G-129	2004	Regulatory Guide G-129, Rev1: Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)."	17	http://nuclearsafety.gc.ca/pubs_catalogue/uploads/G129rev1_e.pdf
CA_CNSC-G-225	2001	Regulatory Guide G-225: Emergency Planning at Class I Nuclear Facilities and Uranium Mines and Mills.		http://www.cnsc-ccsn.gc.ca/pubs_catalogue/uploads/G225_e.pdf
CA_CNSC-G-219	2000	Regulatory Guide G-219: Decommissioning Planning for Licensed Activities.	43	http://nuclearsafety.gc.ca/pubs_catalogue/uploads/G219_e.pdf
CA_CNSC-G-206	2000	Regulatory Guide G-206: Financial Guarantees for the Decommissioning of Licensed Activities.	42	http://nuclearsafety.gc.ca/pubs_catalogue/uploads/G206_e.pdf
CA_CNSC-G-320	2006	Regulatory Guide G-320: Assessing the long term safety of radioactive waste management.	18	http://nuclearsafety.gc.ca/pubs_catalogue/uploads/G-320_Final_e.pdf
CA_AECB-R-72	1987	Regulatory Document R-72: Geological Considerations in Siting a Repository for Underground Disposal of High-Level Radioactive Waste	33	http://nuclearsafety.gc.ca/pubs_catalogue/uploads/R-72e.pdf

Abbreviation	Date (draft)	Title of the document	[#]	Link to internet page (March 2014)
CA_Joint-Review-Process	?	Joint Regulatory Review Process	35	
National Regulation documents and Guides - Switzerland				
CH_NEA	2003	Nuclear Energy Act (NEA) 732.1	26	http://www.admin.ch/opc/en/classified-compilation/20010233/200901010000/732.1.pdf
CH_RPA	1991	Radiological Protection Act (RPA) 814.50	9	http://www.bfe.admin.ch/energie/00558/00593/index.html?lang=en
CH_NEO	2004	Nuclear Energy Ordinance (NEO) 732.11	27	http://www.admin.ch/opc/en/classified-compilation/20042217/201205010000/732.11.pdf
CH_RPO	1994	Radiological Protection Ordinance (RPO) 814.501	10	http://www.admin.ch/opc/en/classified-compilation/19940157/201401010000/814.501.pdf
CH_ENSI-G03	2009	G03 Specific design principles for deep geological repositories and requirements for the safety case - – ENSI-G03/e	12	http://static.ensi.ch/1314022023/g-003_e.pdf
CH_SFOE-SP	2008	Sectoral Plan for Deep Geological Repositories. Conceptual Part (p. 89).	31	http://www.bfe.admin.ch/php/modules/publikationen/stream.php?extlang=en&name=en_821844489.pdf&endung=Sectoral%20Plan%20for%20Deep%20Geological%20Repositories%20-%20Conceptual%20Part
National Regulation documents and Guides – Czech Republic				
CZ_18/2002_AEA	(2002)	Atomic Act *(not found)*		
CZ_18/1997_AEA	1997	Act N°18/1997 Coll. on Peaceful Utilisation of Nuclear Energy and Ionising Radiation (the Atomic Act) and on Amendments and Alterations to Some Acts.		http://www.sujb.cz/fileadmin/sujb/docs/legislativa/zakony/Act-18-1997_Eng_preklad_final.pdf
CZ_100/2001_EIA	2001	Act N°100/2001 Coll. on Environmental Impact Assessment.		http://www.mzp.cz/ris/vis-legcz.nsf/4C2B64C81B7D0323C1256DE40060892E/$file/2001100Sb_kv.pdf
CZ_SÚJB-307/2002	2002	REGULATION No. 307/2002 Coll. of the State Office for Nuclear Safety of 13 June 2002 on Radiation Protection.	81	http://www.sujb.cz/fileadmin/sujb/docs/legislativa/vyhlasky/R307_02.pdf
CZ_SÚJB-132/2008	2008	Decree No. 132/2008 Coll. on Quality Assurance System in Performing and Ensuring Activities Related to the Utilisation of Nuclear Energy and Radiation Activities, and on Quality Assurance of Selected Equipment with Regard to their Ranking into Safety Classes.	61	www.sujb.cz/fileadmin/sujb/docs/legislativa/V1322008.doc
CZ_SÚJB-144/1997	1997	REGULATION No. 144/1997 Coll. of the State Office for Nuclear Safety on Physical Protection of Nuclear Material and Nuclear Facilities and their Classification.		https://www.sujb.cz/fileadmin/sujb/docs/legislativa/vyhlasky/R144_97.pdf
CZ_SÚJB-145/1997	1997	REGULATION No. 145/1997 Sb. of the State Office for Nuclear Safety on Accounting for and Control of Nuclear Material and their Detailed Specification.		https://www.sujb.cz/fileadmin/sujb/docs/legislativa/vyhlasky/R145_97.pdf
CZ_SÚJB-1999	1999	unknown		
CZ_SÚJB-2003	2003	unknown	73	
CZ_SÚJB-2004	2004	Procedure for preparation of a safety report for issue of a licence for siting radioactive waste repositories (§ 4.3). Abridged and adapted translation of Czech regulatory body (SÚJB) guide.	29	
CZ_SÚJB???		Decision document of SÚJB on operation of repositories under approved conditions		
National Regulation documents and Guides - Germany				
DE_BMU-2010	2010	Safety Requirements Governing the Final Disposal of Heat-Generating Radioactive Waste	11	http://www.bmub.bund.de/fileadmin/bmu-import/files/english/pdf/application/pdf/si

Abbreviation	Date (draft)	Title of the document	[#]	Link to internet page (March 2014)
				cherheitsanforderungen_endlagerung_en_bf.pdf
National Regulation documents and Guides - France				
FR_L2006-739-RW	2006	Programme Act No. 2006-739 of 28 june 2006 - ASN.	88	http://www.french-nuclear-safety.fr/References/Regulations/Programme-Act-No.-2006-739-of-28-june-2006
FR_ASN-RFIII-2	2008	Guide de sûreté relatif au stockage définitif des déchets radioactifs en formation géologique profonde	22	http://www.asn.fr/Media/Files/guide_RFSIII_2_fV1_2_
National Regulation documents and Guides - Sweden				
SE_SSMFS 2008:37	2009	SSMFS 2008:37 The Swedish Radiation Safety Authority's Regulations Concerning the Protection of Human Health and the Environment in Connection with the Final Management of Spent Nuclear Fuel and Nuclear Waste.	19	http://www.stralsakerhetsmyndigheten.se/Global/Publikationer/Forfattning/Engelska/SSMFS-2008-37E.pdf
SE_SSMFS 2008:21	2009	SSMFS 2008:21 The Swedish Radiation Safety Authority's regulations concerning safety in connection with the disposal of nuclear material and nuclear waste.	30	https://www.stralsakerhetsmyndigheten.se/Global/Publikationer/Forfattning/Engelska/SSMFS-2008-21E.pdf
National Regulation documents and Guides – Slovak Republic				
SK_ÚJD-30/2002	2012	Decree of the Nuclear Regulatory Authority of the Slovak Republic 30/2012 Coll. laying down details of requirements for the handling of nuclear materials, nuclear waste and spent nuclear fuel.	72	http://www.ujd.gov.sk/files/legislativa/Vyhlasky/30_eng.pdf
National Regulation documents and Guides – United Kingdom				
UK_EA-NIEA-GD-2009	2009	Geological Disposal Facilities on Land for Solid Radioactive Wastes. Guidance on Requirements for Authorisation.	66	http://www.environment-agency.gov.uk/business/sectors/99322.aspx

Table A2.2 List of international and national guides and documents used in WP2.1 for the "Safety Topics" on governing principles, safety policy and safety strategy.

Abbreviation	Justification	Optimisation of protection	Limitation of risks to individuals (Op & Post-op)	Protection of present and future generations	Protection of the environment	Defence in depth & Robustness	Passive means	Good engineering practice, proven techniques & feasibility	Isolation & Containment	Reversibility/Retrievability vs. Safety	Graded approach	Stepwise approach	Concurrent activities	Safety policy & strategy
	ST1a	ST1b	ST1c	ST2	ST3	ST4	ST5	ST6	ST7	ST8	ST9	ST10	ST11	ST12
IAEA SSG-14												X	X	
IAEA SSG-23												X		X
EUR EPG-SC-Rev														X
NEA-78121-Post-closure														X
BE FANC-NS										X				
BE FANC-GEN									X					
BE FANC-RPC-OP			X											
BE FANC-RRR										X				
CA NSCA		X										X		
CA NSCR SOR2000-202														
CA CI1 SOR2000-204		X												
CA RPR SOR2000-203		X	X											
CA CNSC-P-290				X										
CA CNSC-G-129		X	X											
CA CNSC-G-320		X	X		X	X	X		X					
CH NEA				X								X		
CH RPA	X	X												
CH NEO												X		
CH RPO	X													
CH ENSI-G03		X	X	X	X	X	X		X	X			X	
CZ SÚJB-2004														X
DE BMU-2010	X	X	X	X	X								X	X
FR ASN-RFIII-2						X	X	X	X	X			X	X
SE SSMFS 2008:37		(X)												

Table A2.3 List of international and national guides and documents used in WP2.1 for the “Safety Topics” on Management and on the development of a geological disposal.

Abbreviation	Management	Site selection	Design	Construction	General aspect on operation	Investigations and feedback of information on operating experience	Operational limits and conditions	Modifications	Emergency preparedness and	Maintenance, periodic testing and inspection	Occupational exposure	Public exposure	Receiving, handling and emplacement of waste	Closure & Decommissioning	Period after closure and institutional
	ST13	ST14	ST15	ST16	ST17a	ST17b	ST17c	ST17d	ST17e	ST17f	ST17g	ST17h	ST17i	ST18	ST19
IAEA GSG-2									X						
IAEA GS-G-2.1									X						
IAEA GS-G-3.1	X														
IAEA GS-G-3.4	X														
IAEA GS-G-3.5	X														
IAEA SSG-14	X	X	X	X		X	X	X			X			X	
IAEA SSG-23	X			X											X
IAEA RS-G-1.1									X		X	X			
IAEA WS-G-5.1														X	
IAEA WS-G-5.2														X	
IAEA-TECDOC-0630						X					X	X		X	
IAEA GEOSAF-OP-Comp							X	X							
EUR EPG-SC-Rev				X											X
EUR EPG-WAC	X														
NEA-6424-Timescale															X
NEA-6923-MeSA															X
NEA-78121-Post-closure															X
NEA RK&M-ProgRep	X														
BE FANC-NS															X
BE FANC-GEN															X
BE FANC-GEO		X	X												
BE AVN-GEO-ARG		X													
CA NSCA				(X)											
CA Cl1 SOR2000-204			X											X	
CA CNSC-P-290														(X)	
CA CSA-N294-09-Decom														X	
CA CNSC-G-129														(X)	
CA CNSC-G-219														X	
CA CNSC-G-320															X
CA Joint-Review-Process			X												
CH NEA														X	X
CH NEO	X		X	(X)		X	X	X		X				X	
CH ENSI-G03	X		X	X											X
CH SFOE-SP-CP	X			(X)											
CZ SÚJB-132/2008	X														
CZ SÚJB-2004			X			(X)								X	X
CZ SÚJB???															
DE BMU-2010		X	X	X										X	X
FR ASN-RFIII-2		X	X	X										X	

Abbreviation	Management	Site selection	Design	Construction	General aspect on operation	Investigations and feedback of information on operating experience	Operational limits and conditions	Modifications	Emergency preparedness and	Maintenance, periodic testing and inspection	Occupational exposure	Public exposure	Receiving, handling and emplacement of waste	Closure & Decommissioning	Period after closure and institutional
	ST13	ST14	ST15	ST16	ST17a	ST17b	ST17c	ST17d	ST17e	ST17f	ST17g	ST17h	ST17i	ST18	ST19
SE SSMFS 2008:21		X													X
UK EA-NIEA-GD-2009															X

Table A2.4 List of international and national guides and documents used in WP2.1 for the "Safety Topics" on Waste Acceptance, Monitoring, Periodic safety Review and independent verification

Abbreviation	Waste acceptance	Monitoring (Occup. & Public exp.)	Abbreviation	Periodic safety review	Independent verification
	ST20	ST21		ST34	ST34
IAEA SSG-14	X		IAEA GSG-3	X	
IAEA DS357		X	IAEA SSG-23		X
IAEA-TECDOC-1129	X		IAEA SSG-25	X	
IAEA-TECDOC-1208		X	NEA-6082-PR-Guid		X
IAEA-TECDOC-1515	X		NEA-PR-Quest		X
EUR EPG-WAC	X		CA CNSC-G-320		X
MoDeRn D-2.1		X	CH ENSI-G03		X
BE FANC-GEN		X			
CA CSA-N286-05-MST	X				
CA CSA-N286-12-MST	X				
CA CNSC-G-320	X	X			
CH ENSI-G03	X	X			
CZ SÚJB-2004		X			
DE BMU-2010	X	X			
FR ASN-RFIII-2	X	X			
SE SSMFS 2008:21		X			
SK ÚJD-30/2002	X				

Table A2.5 List of international and national guides and documents used in WP2.1 for the "Safety Topics" on Safety Case and Safety Assessment

	Safety case & safety assessment	Characterization, knowledge and system understanding					Safety assessment methodologies, approaches & tools									
Abbreviation	Objectives and scope, Graded approach, content vs regulatory decision steps	general aspects	Waste	Engineered components	Site	Use of operating experience & monitoring data	Timescales and timeframes	Assessment of the possible radiation risks	Uncertainties	Deterministic vs. probabilistic approaches	Conservative & realistic assessments	Scenarios	Models	Indicators & criteria	Operational Safety assessment	L-T Safety assessment
	ST22	ST23a	ST23b	ST23c	ST23d	ST23e	ST24	ST25	ST26	ST27	ST28	ST29	ST30	ST31	ST32	ST33
IAEA GSG-2													G			
IAEA GS-G-2.1		G	G	G	G	G						G			G	
IAEA GS-G-3.1	G		G		G		G	G	G	G	G	G	G			G
IAEA GS-G-3.4						G										
IAEA GS-G-3.5				G		G										
IAEA SSG-14														G		
IAEA SSG-23						G										
IAEA RS-G-1.1														G		
IAEA WS-G-5.1														G		
IAEA WS-G-5.2	G								G		G	G				
IAEA-TECDOC-0630														G		
IAEA GEOSAF-OP-Comp												G				
EUR EPG-SC-Rev							G		G							
EUR EPG-WAC							(G)									
NEA-6424-Timescale							(G)		G	G		G	G			G
NEA-6923-MeSA														G		
NEA-78121-Post-closure												G				
NEA RK&M-ProgRep							G	(G)		G	G	G	G			G
BE FANC-NS								G								
BE FANC-GEN														G		
BE FANC-GEO													G			
BE AVN-GEO-ARG							G									
CA NSCA	G			(G)		G	G		G	G	G	G	G	G		G
CA CI1 SOR2000-204				G		G										
CA CNSC-P-290	G			G			G	G	G	G	G	G	G		G	G
CA CSA-N294-09-Decom														G		
CA CNSC-G-129								G								
CA CNSC-G-219									G	G	G	G	G	G		G
CA CNSC-G-320					G	G	G		G	G	G	G		G		G
CA Joint-Review-Process			G	G	G	G			(G)	G	G	G	G	G		
CH NEA							G					G		G		G
CH NEO							(G)									
CH ENSI-G03												G				
CH SFOE-SP-CP													G			
CZ SÚJB-132/2008		G	G	G	G	G						G			G	
CZ SÚJB-2004	G		G		G		G	G	G	G	G	G	G			G

	Safety case & safety assessment	Characterization, knowledge and system understanding					Safety assessment methodologies, approaches & tools									
Abbreviation	Objectives and scope, Graded approach, content vs regulatory decision steps	general aspects	Waste	Engineered components	Site	Use of operating experience & monitoring data	Timescales and timeframes	Assessment of the possible radiation risks	Uncertainties	Deterministic vs. probabilistic approaches	Conservative & realistic assessments	Scenarios	Models	Indicators & criteria	Operational Safety assessment	L-T Safety assessment
	ST22	ST23a	ST23b	ST23c	ST23d	ST23e	ST24	ST25	ST26	ST27	ST28	ST29	ST30	ST31	ST32	ST33
CZ SÚJB???						G										
DE BMU-2010				G		G										
FR ASN-RFIII-2														G		
SE SSMFS 2008:21						G										
UK EA-NIEA-GD-2009														G		

Appendix A3. IAEA safety requirements and principles associated to the list of key "Safety Topics"

Fundamental Safety Principles (SF-1)
Series No.SF-1, published Tuesday, November 07, 2006
http://www-pub.iaea.org/MTCD/publications/PDF/Pub1273_web.pdf

- **Principle 1: Responsibility for safety:** The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks.
- **Principle 3: Leadership and management for safety** (See also management system)**:** Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks.
- **Principle 4: Justification of facilities and activities:** Facilities and activities that give rise to radiation risks must yield an overall benefit.
- **Principle 5: Optimization of protection:** Protection must be optimized to provide the highest level of safety that can reasonably be achieved.
- **Principle 6: Limitation of risks to individuals:** Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.
- **Principle 7: Protection of present and future generations:** People and the environment, present and future, must be protected against radiation risks.
- **Principle 8: Prevention of accidents** (includes the « defence in depth » principle)**:** All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.
- **Principle 9: Emergency preparedness and response:** Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.
- **Principle 10: Protective actions to reduce existing or unregulated radiation risks:** Protective actions to reduce existing or unregulated radiation risks must be justified and optimized.

Preparedness and Response for a Nuclear or Radiological Emergency Safety Requirements (GS-R-2)
Series No.GS-R-2, published Wednesday, November 06, 2002
http://www-pub.iaea.org/MTCD/publications/PDF/Pub1133_scr.pdf

The Management System for Facilities and Activities Safety Requirements (GS-R-3)
Series No.GS-R-3, published Friday, July 21, 2006
http://www-pub.iaea.org/MTCD/publications/PDF/Pub1252_web.pdf

- Section 2: Management system
- Section 3: Management responsibility
- Section 4: Resource management
- Section 5: Process implementation
- Section 6: Measurement, assessment and improvement

Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards - Interim Edition (GSR Part3)
Series No.GSR Part 3 (Interim), published Thursday, November 03, 2011
http://www-pub.iaea.org/MTCD/publications/PDF/p1531interim_web.pdf

General requirements for protection and safety

- **Requirement 1: Application of the principles of radiation protection:** Parties with responsibilities for protection and safety shall ensure that the principles of radiation protection are applied for all exposure situations.
- **Requirement 4: Responsibilities for protection and safety:** The person or organization responsible for facilities and activities that give rise to radiation risks shall have the prime responsibility for protection and safety. Other parties shall have specified responsibilities for protection and safety.
- **Requirement 5: Management for protection and safety:** The principal parties shall ensure that protection and safety is effectively integrated into the overall management system of the organizations for which they are responsible.
  - Protection and safety elements of the management system
  - Safety Culture
  - Human factors

Planned exposure situations

- **Requirement 6: Graded approach:** The application of the requirements of these Standards in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the magnitude and likelihood of the exposures.
- **Requirement 9: Responsibilities of registrants and licensees in planned exposure situations:** Registrants and licensees shall be responsible for protection and safety in planned exposure situations.
- **Requirement 10: Justification of practices:** The government or the regulatory body shall ensure that only justified practices are authorized.

- **Requirement 11: Optimization of protection and safety:** The government or regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized.
- **Requirement 12: Dose limits:** The government or the regulatory body shall establish dose limits for occupational exposure and public exposure, and registrants and licensees shall apply these limits.
- **Requirement 13: Safety assessment:** The regulatory body shall establish and enforce requirements for safety assessment, and the person or organization responsible for a facility or activity that gives rise to radiation risks shall conduct an appropriate safety assessment of this facility or activity.
- **Requirement 14: Monitoring for verification of compliance:** Registrants and licensees and employers shall conduct monitoring to verify compliance with the requirements for protection and safety.
- **Requirement 15: Prevention and mitigation of accidents:** Registrants and licensees shall apply good engineering practice and shall take all practicable measures to prevent accidents and to mitigate the consequences of those accidents that do occur.
    - Good engineering practice
    - Defence in depth
    - Accident prevention
    - Emergency preparedness and response
- **Requirement 16: Investigations and feedback of information on operating experience:** Registrants and licensees shall conduct formal investigations of abnormal conditions arising in the operation of facilities or the conduct of activities, and shall disseminate information that is significant for protection and safety.

Occupational exposure

- **Requirement 19: Responsibilities of the regulatory body specific to occupational exposure:** The government or regulatory body shall establish and enforce requirements to ensure that protection and safety is optimized, and the regulatory body shall enforce compliance with dose limits for occupational exposure.
- **Requirement 20: Requirements for monitoring and recording of occupational exposure:** The regulatory body shall establish and enforce requirements for the monitoring and recording of occupational exposures in planned exposure situations.
- **Requirement 21: Responsibilities of employers, registrants and licensees for the protection of workers:** Employers, registrants and licensees shall be responsible for the protection of workers against occupational exposure. Employers, registrants and licensees shall ensure that protection and safety is optimized and that the dose limits for occupational exposure are not exceeded.

- **Requirement 22: Compliance by workers:** Workers shall fulfil their obligations and carry out their duties for protection and safety.
- **Requirement 23: Cooperation between employers and registrants and licensees:** Employers and registrants and licensees shall cooperate to the extent necessary for compliance by all responsible parties with the requirements for protection and safety.
- **Requirement 24: Arrangements under the radiation protection programme:** Employers, registrants and licensees shall establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace, in a radiation protection programme for occupational exposure.
    - Classification of areas (controlled and areas)
    - Local rules and procedures and personal protective equipment
    - Monitoring of the workplace
- **Requirement 25: Assessment of occupational exposure and workers' health surveillance:** Employers, registrants and licensees shall be responsible for making arrangements for assessment and recording of the occupational exposure and for workers' health surveillance.
    - Occupational exposure assessment
    - Records of occupational exposure
    - Workers' health surveillance
- **Requirement 26: Information, instruction and training:** Employers, registrants and licensees shall provide workers with adequate information, instruction and training for protection and safety.

Public exposure

- **Requirement 29: Responsibilities of the government and the regulatory body specific to public exposure:** The government or the regulatory body shall establish the responsibilities of relevant parties that are specific to public exposure, shall establish and enforce requirements for optimization, and shall establish, and the regulatory body shall enforce compliance with, dose limits for public exposure.
- **Requirement 30: Responsibilities of relevant parties specific to public exposure:** Relevant parties shall apply the system of protection and safety to protect members of the public against exposure.
    - General considerations
    - Visitors
    - External exposure and contamination in areas accessible to members of the public

- **Requirement 31: Radioactive waste and discharges:** Relevant parties shall ensure that radioactive waste and discharges of radioactive material to the environment are managed in accordance with the authorization.
    - Radioactive waste
    - Discharges
- **Requirement 32: Monitoring and reporting:** The regulatory body and relevant parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available.

Emergency exposure situations
Generic requirements

- **Requirement 43: Emergency management system:** The government shall ensure that an integrated and coordinated emergency management system is established and maintained.

Public exposure

- **Requirement 44: Preparedness and response to an emergency:** The government shall ensure that protection strategies are developed, justified and optimized at the planning stage, and that emergency response is undertaken through their timely implementation.

Exposure of emergency workers

- **Requirement 45: Arrangements for controlling the exposure of emergency workers:** The government shall establish a programme for managing, controlling and recording the doses received in an emergency by emergency workers.

Transition from an emergency exposure situation to an existing exposure situation

- **Requirement 46: Arrangements for the transition from an emergency exposure situation to an existing exposure situation:** The government shall ensure that arrangements are in place and are implemented as appropriate for the transition from an emergency exposure situation to an existing exposure situation.

Safety Assessment for Facilities and Activities General Safety Requirements (GSR Part4)

Series No.GSR Part 4, published Tuesday, May 19, 2009.
http://www-pub.iaea.org/MTCD/publications/PDF/Pub1375_web.pdf

Graded approach to safety assessment

- **Requirement 1: Graded approach:** A graded approach shall be used in determining the scope and level of detail of the safety assessment carried out in a particular State for any particular facility or activity, consistent with the magnitude of the possible radiation risks arising from the facility or activity.

Safety assessment

Overall requirements

- **Requirement 2: Scope of the safety assessment:** A safety assessment shall be carried out for all applications of technology that give rise to radiation risks; that is, for all types of facilities and activities.
- **Requirement 3: Responsibility for the safety assessment:** The responsibility for carrying out the safety assessment shall rest with the responsible legal person; that is, the person or organization responsible for the facility or activity.
- **Requirement 4: Purpose of the safety assessment:** The primary purposes of the safety assessment shall be to determine whether an adequate level of safety has been achieved for a facility or activity and whether the basic safety objectives and safety criteria established by the designer, the operating organization and the regulatory body, in compliance with the requirements for protection and safety as established in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources [4], have been fulfilled.

Specific requirements

- **Requirement 5: Preparation for the safety assessment:** The first stage of carrying out the safety assessment shall be to ensure that the necessary resources, information, data, analytical tools as well as safety criteria are identified and are available.
- **Requirement 6: Assessment of the possible radiation risks:** The possible radiation risks associated with the facility or activity shall be identified and assessed.
- **Requirement 7: Assessment of safety functions:** All safety functions associated with a facility or activity shall be specified and assessed.
- **Requirement 8: Assessment of site characteristics:** An assessment of the site characteristics relating to the safety of the facility or activity shall be carried out.
- **Requirement 9: Assessment of the provisions for radiation protection:** It shall be determined in the safety assessment for a facility or activity whether adequate measures are in place to protect people and the environment from harmful effects of ionizing radiation.
- **Requirement 10: Assessment of engineering aspects:** It shall be determined in the safety assessment whether a facility or activity uses, to the extent practicable, structures, systems and components of robust and proven design.
- **Requirement 11: Assessment of human factors:** Human interactions with the facility or activity shall be addressed in the safety assessment, and it shall be determined whether the procedures and safety measures that are provided for all normal

operational activities, in particular those that are necessary for implementation of the operational limits and conditions, and those that are required in response to anticipated operational occurrences and accidents, ensure an adequate level of safety.

- **Requirement 12: Assessment of safety over the lifetime of a facility or activity:** The safety assessment shall cover all the stages in the lifetime of a facility or activity in which there are possible radiation risks.

Defence in depth and safety margins

- **Requirement 13: Assessment of defence in depth:** It shall be determined in the assessment of defence in depth whether adequate provisions have been made at each of the levels of defence in depth.

Safety analysis

- **Requirement 14: Scope of the safety analysis:** The performance of a facility or activity in all operational states and, as necessary, in the post-operational phase shall be assessed in the safety analysis.
- **Requirement 15: Deterministic and probabilistic approaches:** Both deterministic and probabilistic approaches shall be included in the safety analysis.
- **Requirement 16: Criteria for judging safety:** Criteria for judging safety shall be defined for the safety analysis.
- **Requirement 17: Uncertainty and sensitivity analysis:** Uncertainty and sensitivity analysis shall be performed and taken into account in the results of the safety analysis and the conclusions drawn from it.
- **Requirement 18: Use of computer codes:** Any calculational methods and computer codes used in the safety analysis shall undergo verification and validation.
- **Requirement 19: Use of operating experience data:** Data on operational safety performance shall be collected and assessed.

Documentation

- **Requirement 20: Documentation of the safety assessment:** The results and findings of the safety assessment shall be documented.

Independent verification

- **Requirement 21: Independent verification:** The operating organization shall carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body.

Management, use and maintenance of the safety assessment

- **Requirement 22: Management of the safety assessment:** The processes by which the safety assessment is produced shall be planned, organized, applied, audited and reviewed.
- **Requirement 23: Use of the safety assessment:** The results of the safety assessment shall be used to specify the programme for maintenance, surveillance and inspection; to specify the procedures to be put in place for all operational activities significant to safety and for responding to anticipated operational occurrences and accidents; to specify the necessary competences for the staff involved in the facility or activity and to make decisions in an integrated, risk informed approach.
- **Requirement 24: Maintenance of the safety assessment:** The safety assessment shall be periodically reviewed and updated.

Decommissioning of Facilities Using Radioactive Material Safety Requirements (WS-R-5)
Series No.WS-R-5, published Wednesday, October 18, 2006
http://www-pub.iaea.org/MTCD/publications/PDF/Pub1274_web.pdf

Disposal of Radioactive Waste Specific Safety Requirements (SSR-5)
Series No.SSR-5, published Thursday, May 05, 2011
http://www-pub.iaea.org/MTCD/publications/PDF/Pub1449_web.pdf

Radiation protection in the operational period (§2.7-2.14)
Radiation protection in the post-closure period (§2.15-2.19)
Environmental and non-radiological concerns (§2.21-2.23)

Planning for the disposal of radioactive waste
Safety approach

- **Requirement 4: Importance of safety in the process of development and operation of a disposal facility**: Throughout the process of development and operation of a disposal facility for radioactive waste, an understanding of the relevance and the implications for safety of the available options for the facility shall be developed by the operator. This is for the purpose of providing an optimized level of safety in the operational stage and after closure.
- **Requirement 5: Passive means for the safety of the disposal facility:** The operator shall evaluate the site and shall design, construct, operate and close the disposal facility in such a way that safety is ensured by passive means to the fullest extent possible and the need for actions to be taken after closure of the facility is minimized.
- **Requirement 6: Understanding of a disposal facility and confidence in safety:** The operator of a disposal facility shall develop an adequate understanding of the features of the facility and its host environment and of the factors that influence its

safety after closure over suitably long time periods, so that a sufficient level of confidence in safety can be achieved.

Design concepts for safety

- **Requirement 7: Multiple safety functions:** The host environment shall be selected, the engineered barriers of the disposal facility shall be designed and the facility shall be operated to ensure that safety is provided by means of multiple safety functions. Containment and isolation of the waste shall be provided by means of a number of physical barriers of the disposal system. The performance of these physical barriers shall be achieved by means of diverse physical and chemical processes together with various operational controls. The capability of the individual barriers and controls together with that of the overall disposal system to perform as assumed in the safety case shall be demonstrated. The overall performance of the disposal system shall not be unduly dependent on a single safety function.
- **Requirement 8: Containment of radioactive waste:** The engineered barriers, including the waste form and packaging, shall be designed, and the host environment shall be selected, so as to provide containment of the radionuclides associated with the waste. Containment shall be provided until radioactive decay has significantly reduced the hazard posed by the waste. In addition, in the case of heat generating waste, containment shall be provided while the waste is still producing heat energy in amounts that could adversely affect the performance of the disposal system.
- **Requirement 9: Isolation of radioactive waste:** The disposal facility shall be sited, designed and operated to provide features that are aimed at isolation of the radioactive waste from people and from the accessible biosphere. The features shall aim to provide isolation for several hundreds of years for short lived waste and at least several thousand years for intermediate and high level waste. In so doing, consideration shall be given to both the natural evolution of the disposal system and events causing disturbance of the facility.
- **Requirement 10: Surveillance and control of passive safety features:** An appropriate level of surveillance and control shall be applied to protect and preserve the passive safety features, to the extent that this is necessary, so that they can fulfil the functions that they are assigned in the safety case for safety after closure.

Development, operation and closure of a disposal facility
Framework for disposal of radioactive waste

- **Requirement 11: Step by step development and evaluation of disposal:** Facilities Disposal facilities for radioactive waste shall be developed, operated and closed in a series of steps. Each of these steps shall be supported, as necessary, by iterative evaluations of the site, of the options for design, construction, operation and management, and of the performance and safety of the disposal system.

The safety case and safety assessment

- **Requirement 12: Preparation, approval and use of the safety case and safety assessment for a disposal facility:** A safety case and supporting safety assessment shall be prepared and updated by the operator, as necessary, at each step in the development of a disposal facility, in operation and after closure. The safety case and supporting safety assessment shall be submitted to the regulatory body for approval. The safety case and supporting safety assessment shall be sufficiently detailed and comprehensive to provide the necessary technical input for informing the regulatory body and for informing the decisions necessary at each step.
- **Requirement 13: Scope of the safety case and safety assessment:** The safety case for a disposal facility shall describe all safety relevant aspects of the site, the design of the facility and the managerial control measures and regulatory controls. The safety case and supporting safety assessment shall demonstrate the level of protection of people and the environment provided and shall provide assurance to the regulatory body and other interested parties that safety requirements will be met.
- **Requirement 14: Documentation of the safety case and safety assessment:** The safety case and supporting safety assessment for a disposal facility shall be documented to a level of detail and quality sufficient to inform and support the decision to be made at each step and to allow for independent review of the safety case and supporting safety assessment.

Steps in the development, operation and closure of a disposal facility

- **Requirement 15: Site characterization for a disposal facility:** The site for a disposal facility shall be characterized at a level of detail sufficient to support a general understanding of both the characteristics of the site and how the site will evolve over time. This shall include its present condition, its probable natural evolution and possible natural events, and also human plans and actions in the vicinity that may affect the safety of the facility over the period of interest. It shall also include a specific understanding of the impact on safety of features, events and processes associated with the site and the facility.
- **Requirement 16: Design of a disposal facility:** The disposal facility and its engineered barriers shall be designed to contain the waste with its associated hazard, to be physically and chemically compatible with the host geological formation and/or surface environment, and to provide safety features after closure that complement

those features afforded by the host environment. The facility and its engineered barriers shall be designed to provide safety during the operational period.

- **Requirement 17: Construction of a disposal facility:** The disposal facility shall be constructed in accordance with the design as described in the approved safety case and supporting safety assessment. It shall be constructed in such a way as to preserve the safety functions of the host environment that have been shown by the safety case to be important for safety after closure. Construction activities shall be carried out in such a way as to ensure safety during the operational period.
- **Requirement 18: Operation of a disposal facility:** The disposal facility shall be operated in accordance with the conditions of the licence and the relevant regulatory requirements so as to maintain safety during the operational period and in such a manner as to preserve the safety functions assumed in the safety case that are important to safety after closure.
- **Requirement 19: Closure of a disposal facility:** A disposal facility shall be closed in a way that provides for those safety functions that have been shown by the safety case to be important after closure. Plans for closure, including the transition from active management of the facility, shall be well defined and practicable, so that closure can be carried out safely at an appropriate time.

Assurance of safety

- **Requirement 20: Waste acceptance in a disposal facility:** Waste packages and unpackaged waste accepted for emplacement in a disposal facility shall conform to criteria that are fully consistent with, and are derived from, the safety case for the disposal facility in operation and after closure.
- **Requirement 21: Monitoring programmes at a disposal facility:** A programme of monitoring shall be carried out prior to, and during, the construction and operation of a disposal facility and after its closure, if this is part of the safety case. This programme shall be designed to collect and update information necessary for the purposes of protection and safety. Information shall be obtained to confirm the conditions necessary for the safety of workers and members of the public and protection of the environment during the period of operation of the facility. Monitoring shall also be carried out to confirm the absence of any conditions that could affect the safety of the facility after closure.
- **Requirement 22: The period after closure and institutional controls:** Plans shall be prepared for the period after closure to address institutional control and the arrangements for maintaining the availability of information on the disposal facility. These plans shall be consistent with passive safety features and shall form part of the safety case on which authorization to close the facility is granted.

- **Requirement 23: Consideration of the State system of accounting for, and control of, nuclear material:** In the design and operation of disposal facilities subject to agreements on accounting for, and control of, nuclear material, consideration shall be given to ensuring that safety is not compromised by the measures required under the system of accounting for, and control of, nuclear material.
- **Requirement 24: Requirements in respect of nuclear security measures:** Measures shall be implemented to ensure an integrated approach to safety measures and nuclear security measures in the disposal of radioactive waste.
- **Requirement 25: Management systems:** Management systems to provide for the assurance of quality shall be applied to all safety related activities, systems and components throughout all the steps of the development and operation of a disposal facility. The level of assurance for each element shall be commensurate with its importance to safety.

Existing disposal facilities

- **Requirement 26: Existing disposal facilities:** The safety of existing disposal facilities shall be assessed periodically until termination of the licence. During this period, the safety shall also be assessed when a safety significant modification is planned or in the event of changes with regard to the conditions of the authorization. In the event that any requirements set down in this Safety Requirements publication are not met, measures shall be put in place to upgrade the safety of the facility, economic and social factors being taken into account.

IAEA Requirements not included in the list

The following requirements identified by IAEA as applying to radioactive waste disposal facilities were not included in the list:

- Governmental, Legal and Regulatory Framework (SF-1 – P2, GSR Part 1, GSR Part3 – R2-3 & SSR-5 – R1-R3)
- Predisposal Management of Radioactive Waste General Safety Requirements (GSR Part 5)
- Remediation of Areas Contaminated by Past Activities and Accidents Safety Requirements (WS-R-3)
- Notification and authorization (GSR Part3 – R7)
- Exemption and clearance (GSR Part3 – R8)
- Radiation generators and radioactive sources (GSR Part3 – R17)
- Human imaging (GSR Part3 – R18)
- Conditions of service & Special arrangements for workers (GSR Part3 – R27-28)
- Consumer products (GSR Part3 – R33)
- Medical exposure (GSR Part3 – R34-42)

- Detailed requirements for existing exposure situations (GSR Part3 – R47-52)
- Non-radiological concerns (SSR-5 - §2.20 & §2.24)

Appendix A4. Needs of NSAs and TSOs

Table A4.1: List of identified needs for further development, dialogue or harmonization, related to the Safety Topic (ST) analysed within WP2.1

ST	Topic/subtopic	N	Identified needs	U	I
ST1a	Justification	0			
ST1b	Optimisation	1	Interpretation of new ICRP 122	M	H
ST1b		2	Implementation of the principle (factors, existing circumstances, weighting criteria, …)	H	H
ST1c	Limitation of risks to individuals	0			
ST2	Protection of present and future generations	1	Discussion on common understanding on "undue burden" and "future generation"	L	L
ST3	Protection of environment	0			
ST4	DiD/Robustness	1	Practical implementation of DiD principles for geological disposal (complementarity, independence, role of controls,…) (as mainly NPP focused)	H	H
ST5	Passive Means	0			
ST6	Good engineering practice, proven techniques & feasibility	1	Terminology/common understanding: - Good engineering practices - Feasibility - Proven techniques - Demonstrability	M	M

ST	Topic/subtopic	N	Identified needs	U	I
ST7	Isolation & Containment	1	Clarification of terminology/Common understanding	H	H
ST8	Reversibility/retrievability vs. safety	1	Common understanding on Reversibility & Retrievability		
ST8		2	Benefits and potential adverse effects on safety	M	M
ST8		3	Time-frames associated with retrievability and reversibility (level of retrievability for each step of the facility development,…)	H	H
ST9	Graded approach	0			
ST10	Stepwise approach	1	Pre-licensing process (having the regulator involved early before a licence application submitted, including dealing with requests of the public)	H	H
ST11	Concurrent activities	1	Practical approach to manage concurrent activities (implications for the management system, design,...)	M	M
ST11		2	Possible effects of concurrent activities on post-closure safety	M	M
ST12	Safety Strategy & Policy	1	Common understanding on Safety Policy versus Safety Strategy		
ST12		2	Elements of safety strategy & policy	H	M
ST13	Management	1	Assessment of compliance with requirements associated with available resources (i.e. organisational structure, staffing, skills, experience and knowledge, training/recruitment programs for the life-cycle of a DGR, infrastructure, subcontractors, financial resources,…)	M	M
ST13		2	Preservation of records and knowledge	M	H
ST13		3	Responsibilities, e.g.: - Responsibilities until termination of the license - Interfaces between the responsibility of the licensee of a disposal facility and the organisations responsible for the waste before sending to the repository	M	M

ST	Topic/subtopic	N	Identified needs	U	I
ST14	Site selection	1	Site selection method and criteria	H	H
ST14		2	Weighting of criteria when applying optimisation to site selection	H	H
ST15	Design	1	Development of the "design basis" including: ·- Design giving due consideration of characteristics of radioactive waste and of the site - Consideration of normal operational conditions, anticipated operational occurrences and possible accidents - Design giving due consideration to disturbing features, events and processes and disturbances during operation whose consequences may affect post-closure safety	H	H
ST15		2	Development process of design requirements & specifications	H	H
ST15		3	Design of underground access structures (design to prevent significant inflow of surface water and to meet the requirements relating to normal operation and to management of incidents or accidents)	M	M
ST15		4	Consideration of stakeholder requirements regarding design	M	M
ST16	Construction	1	Implication of constraints associated with nuclear safety on the management of construction activities (including construction procedures, quality control,…)	M	M
ST16		2	Information that shall be gathered during construction	M	M
ST16		3	Approach to deal with design modifications that may occur during construction	M	M
ST17	Operation	1	Operation in accordance with the conditions of the license and regulatory requirements	M	M
ST17		2	Specificities of operation of an underground nuclear facility (including aspects such as fire protection, ventilation,…)	M	M
ST17		3	Waste handling and emplacement	M	M
ST17		4	Maintenance, periodic testing and inspection • ageing of equipment and structures during the operational phase	M	M

ST	Topic/subtopic	N	Identified needs	U	I
			• programmes and records		
ST17		5	Operating limits and conditions (OLCs): How to establish and substantiate OLCs, how to maintain OLCs to ensure compliance with end-state, how to meet OLCs and assurances that they are being met (especially if operations are not as expected), feedback from other (nuclear) facilities,…	M	M
ST17		6	Modifications of design, waste acceptance criteria, structures, systems and components (SSCs), operational limits and conditions (OLCs) and operational procedures and methods	M	M
ST17		7	Emergency preparedness (feedback from emergency plans existing in mines, tunnels and other non-nuclear underground facilities,…)	M	M
ST17		8	Ensuring post-closure safety during operation	M	M
ST18	Closure & Decommissioning	1	Programme of closure and decommissioning (including timeframes, formal procedures,…)	M	M
ST18		2	Report after completion of the closure	L	L
ST18		3	Clearance of material derived from repository decommissioning	L	L
ST19	Period after Closure & Institutional Controls	1	Planning for post-closure activities (before starting the operational phase)	M	M
ST19		2	Implementation of post-closure surveillance programme	M	M
ST19		3	Expectations on what is required to release a DGR site from licensing	M	M
ST19		4	Activities before termination of licence	M	M
ST19		5	Passive institutional controls	L	M
ST19		6	Requirements for marking of a geological repository	L	M
ST19		7	Rationale for the duration of institutional controls	M	H
ST19		8	Common understanding of the different used terms (monitoring, control,	H	H

ST	Topic/subtopic	N	Identified needs	U	I
			surveillance)		
ST20	Waste acceptance	1	Preliminary waste acceptance criteria	H	H
ST20		2	How the waste is checked to ensure conformity to waste acceptance criteria	M	M
ST20		3	Dealing with waste packages that do not conform to waste acceptance criteria	M	M
ST21	Monitoring	1	Expectations for baseline program (timing,…)	H	H
ST21		2	Monitoring programme (including programme specific to construction phase)	H	H
ST21		3	QA program/monitoring to confirm and refine assumptions (including traceability)	H	H
ST22	Objective & Scope, Graded Approach & SC/SA content vs. Regulatory decision steps	1	Assessment of technical feasibility	H	H
ST22		2	How often SC should be refined/updated ?	M	M
ST22		3	Table of content of a SC for each important step of disposal facility development	H	H
ST22		4	Developed planning of the SC	M	M
ST22		5	Traceability and transparency of a SC (helpful for public to understand as well)	M	H
ST22		6	Verification that design, engineering and decisions on the disposal system derive from a process involving optimization of radiological protection	M	M
ST23	Characterization, Knowledge & System Understanding	1	Programme concerning the understanding of the evolution of the disposal system	M	M
ST23		2	Programme for site characterisation (including transferability issues)	H	H
ST23		3	Level of knowledge and understanding vs. Programme step	M	M
ST23		4	Characterization of the source term (including review of vector of nuclides)	H	H
ST23		5	Characterisation during operation	M	M
ST23		6	Gas production and transport in a deep geological repository	H	H
ST24	Timescales and	1	Compliance for (very) long timeframes	H	H

ST	Topic/subtopic	N	Identified needs	U	I
	timeframes				
ST25	Assessment of the possible radiation risks	1	How to assess possible radiation risks (as defined by IAEA)	M	M
ST26	Uncertainties	1	Programme for uncertainty management	H	H
ST27	Deterministic vs. probabilistic approaches	1	Roles and methods associated with both approaches	H	H
ST28	Conservative & realistic assessments	1	Approach vs. objective of the assessment	H	H
ST29	Scenarios	1	Possible features, events and processes that have to be considered	H	H
ST29		2	Consideration of human actions (including the treatment of human intrusion in the SC)	H	H
ST29		3	Scenario development methods (how to ensure completeness, structured and comprehensible approach,…)	H	H
ST29		4	Common understanding of the different used terms in scenario development	H	H
ST30	Models	1	How to validate computer codes over long timeframes (lifecycle) of the repository (roles of monitoring & controls in model validation,…)	H	H
ST30		2	Activities and arguments needed to build confidence in models (sensitivity analyses, peer reviews, justification of choices and hypotheses, benchmark calculations,…)	H	H
ST30		3	Modelling of gas production and transport in a deep geological repository	H	H
ST31	Indicators & Criteria	1	Criteria for radiological protection of the environment	H	H
ST31		2	Criteria for non-rad. protection of the environment	M	M
ST31		3	Criteria for non-rad. protection of humans	M	M
ST31		4	Indicators & criteria for very long time-frames *(see also the issue "timescales &*	H	H

ST	Topic/subtopic	N	Identified needs	U	I
			timeframes")		
ST31		5	Reference values for complementary indicators	M	M
ST31		6	Indicators & criteria for performance/robustness assessment	M	M
ST32	Operational Safety Assessment	1	Aspects specific to geological disposal	M	M
ST33	L-T Safety Assessment	1	Performance and robustness assessment (assessment of safety functions, methodology,…)	H	H
ST33		2	Assessment of defence in depth	H	H
ST33		3	Multiple lines of reasoning & evaluation of the level of confidence	H	H
ST33		4	Assessment of criticality after closure	M	M
ST34	Periodic Safety Review	1	Guidance on frequency of PSR	M	M
ST34		2	Elements to be taken into account in a PSR	M	M
ST34		3	Identification and evaluation of safety significance of differences	M	M
ST34		4	Documentation of PSR and implementation of an action plan	M	M
ST35	Independent Verification	1	Definition of the term "independent verification"	M	M
ST35		2	Feedback on independent "3rd party" verification (purpose, is it done?, how should it be conducted ?,…)	M	M
	Safety (globally)		Interactions between operational and long term safety	M	M

U: Urgency; possible answers: L = Low (after 2020) - M= Medium (before 2020) - H = High (before 2016)
I: Interest; possible answers: L = Lowest (dialogue/development not really or at all needed) - M = Medium (dialogue/development would be « nice to have ») - H = Highest (dialogue/development « highly » needed)