

Report on the OPERA Safety Case structure

OPERA-PU-NRG2111

Radioactive substances and ionizing radiation are used in medicine, industry, agriculture, research, education and electricity production. This generates radioactive waste. In the Netherlands, this waste is collected, treated and stored by COVRA (Centrale Organisatie Voor Radioactief Afval). After interim storage for a period of at least 100 years radioactive waste is intended for disposal. There is a world-wide scientific and technical consensus that geological disposal represents the safest long-term option for radioactive waste.

Geological disposal is emplacement of radioactive waste in deep underground formations. The goal of geological disposal is long-term isolation of radioactive waste from our living environment in order to avoid exposure of future generations to ionising radiation from the waste. OPERA (OnderzoeksProgramma Eindberging Radioactief Afval) is the Dutch research programme on geological disposal of radioactive waste.

Within OPERA, researchers of different organisations in different areas of expertise will cooperate on the initial, conditional Safety Cases for the host rocks Boom Clay and Zechstein rock salt. As the radioactive waste disposal process in the Netherlands is at an early, conceptual phase and the previous research programme has ended more than a decade ago, in OPERA a first preliminary or initial safety case will be developed to structure the research necessary for the eventual development of a repository in the Netherlands. The safety case is conditional since only the long-term safety of a generic repository will be assessed. OPERA is financed by the Dutch Ministry of Economic Affairs, Agriculture and Innovation and the public limited liability company Electriciteits-Produktiemaatschappij Zuid-Nederland (EPZ) and coordinated by COVRA. Further details on OPERA and its outcomes can be accessed at www.covra.nl.

This report concerns a study conducted in the framework of OPERA. The conclusions and viewpoints presented in the report are those of the author(s). COVRA may draw modified conclusions, based on additional literature sources and expert opinions. A .pdf version of this document can be downloaded from www.covra.nl.

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Summary

This report presents the OSCAR project-team's views and recommendations on: (1) the structure of the OPERA Safety Case and consequently (2) the structure of the OPERA Safety Case documentation. The IAEA structure and the use of the IAEA MASC matrix are recommended for the Dutch safety case structure and development. However, it is also recognized that other structures have been and could be successful and, in this respect, there is a need to be flexible in the development of any safety case.

Samenvatting

Dit rapport presenteert ideeën en aanbevelingen van het OSCAR projectteam over (1) de structuur van de OPERA Safety Case en daarmee ook voor (2) de structuur van de OPERA Safety Case documentatie. Aanbevolen wordt om de IAEA structuur over te nemen en voor de Nederlandse Safety Case structuur en verdere ontwikkeling daarvan de IAEA MASC matrix te gebruiken. Tevens wordt echter erkend dat ook andere structuren succesvol zijn geweest en dat ook in dit geval zouden kunnen zijn, en dat bij de ontwikkeling van elke safety case flexibiliteit in dit opzicht noodzakelijk is.

1. Introduction

1.1. Background

The five-year research programme for the geological disposal of radioactive waste - OPERA- started on 7 July 2011 with an open invitation for research proposals. In these proposals, research was proposed for the tasks described in the OPERA Research Plan (Verhoef, 2011a; Section I, p.20,21), including this task - recommendation of a safety case structure.

1.2. Objectives

Based on the work performed by the OSCAR project-team concerning WP2 *Safety Case*, Task 2.1.1 *Structure of the Safety Case* of the Research Plan (Verhoef, 2011a; Section II, p.7) this report presents views and recommendations on (1) the structure of the OPERA Safety Case and consequently (2) the structure of the OPERA Safety Case documentation.

1.3. Realization

In Task 2.1.1 the safety case structures of the NEA, IAEA, a representative sample of national programs, and the Dutch CO₂ program were compared. An important conclusion of that evaluation is that there is no universal format for the presentation of a safety case but there is an international consensus on the main components of a safety case. As the IAEA and the NEA have defined and accepted the language of the safety case and represent international consensus, their structures have been compared in more detail in the present report.

1.4. Explanation of contents

Chapter 2 presents an overview of the comparison of safety case structures as outlined by the IAEA and the NEA and in selected national programmes. Chapter 3 compares the safety case structures in more detail, resulting in the proposal in Chapter 4 to adopt the IAEA structure and use the IAEA MASC matrix for the Dutch safety case structure and development of any safety case.

2. Structures of the Safety Case

“The safety case is 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” (IAEA, 2012; p.1). This is a general formulation of the operational definition in the OPERA research plan (Verhoef, 2011a' p. 5): "The Safety case means a collection of arguments in support of the long-term safety of the repository."

The OPERA Safety Case (OSC) will be captured in a report, or a set of reports, presenting the generic Safety Case for disposal in clay. The OSCAR consortium is proposing a structure for the OSC based on the evaluation of existing international safety cases, safety reports, and license applications. The components of existing safety cases that are best suited for the Dutch program and the OSC have been identified and an overall safety case structure for the Dutch program is proposed.

The OPERA Meerjarenplan (Verhoef, 2011; p.4) describes an incrementally developed and evolving Safety Case. An evolving safety case allows for: 1) safety arguments to evolve through site selection, site characterization, design, and continuing research, as well as to adapt to political and societal demands that change with time; and 2) provide a sound and documented basis for interim decisions during the life of facility development. In the meantime, the work in OPERA will focus on a generic site and a generic design. In this generic stage, the OSC can be used to present preliminary Safety Arguments that describe the emerging safety requirements, the interpretation of these requirements, and points forward to the claims that need to be made about the system and type and degree of evidence that will be needed to support these claims. By evolving from a generic safety case to a site specific safety case, the OSC can continually help to identify the key arguments needed to support the long-term safety of the disposal system.

The following sections provide a general description of safety case structures that were described in detail and evaluated by the OSCAR consortium (Hart, 2014) as potential structures to be used for the Dutch OSC. The reviewed safety case structures include the international consensus safety case structures defined by the NEA and IAEA, safety case structures defined or implied by existing geologic disposal programs, and a safety case structure used in carbon sequestration. The following sections provide only a general overview of each safety case structure reviewed. For details the reader is directed to the previous OSCAR report (Hart, 2014).

2.1. The NEA's Proposed Structure For a Post-Closure Safety Case For Geological Repositories (NEA, 2004)

In 2004, specialists from six Waste Management Organizations (supported by NEA editors) and based on their experience in preparing safety cases and safety assessments, published the definition, purpose, and general contents of safety cases for geological repositories for long-lived radioactive waste (NEA, 2004). The NEA description of the safety case was the main building block of the OPERA Research Plan (Verhoef, 2011a). The relation of the NEA-defined safety case components¹ to their safety case structure is shown in Figure 2-1.

¹ The NEA report uses the term "element" rather than "component".

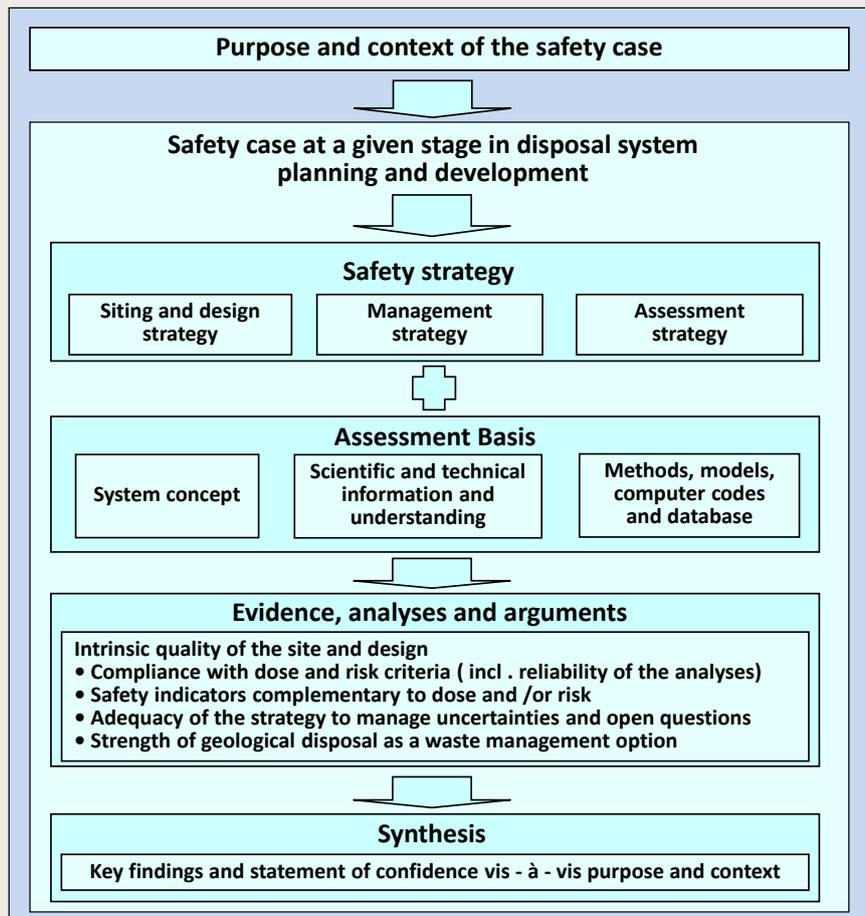


Figure 2-1 Components and structure of the NEA safety case (NEA, 2004 - Figure 1. "An overview of the relationship between different elements of a safety case")

In their text (NEA, 2004; p.8,9), the NEA defines the same general components of a safety case for geologic disposal as shown in Figure 2-1 but lists different sub-components:

- The Safety Strategy
 - Informing principles
 - Robustness and the multi-barrier principle
 - Characterizing and managing uncertainties
- The Assessment Basis
 - Components of the assessment basis
 - Presentation of the assessment basis and support for its quality and reliability
- Evidence, Analyses, And Arguments, And Their Synthesis In A Safety Case
 - Types of evidence, arguments, and analyses
 - Emphasis placed on different lines of evidence, arguments, and analyses when presenting a safety case
 - Synthesis of evidence, analyses, arguments, and a statement

2.2. Revised NEA safety case structure (NEA, 2013)

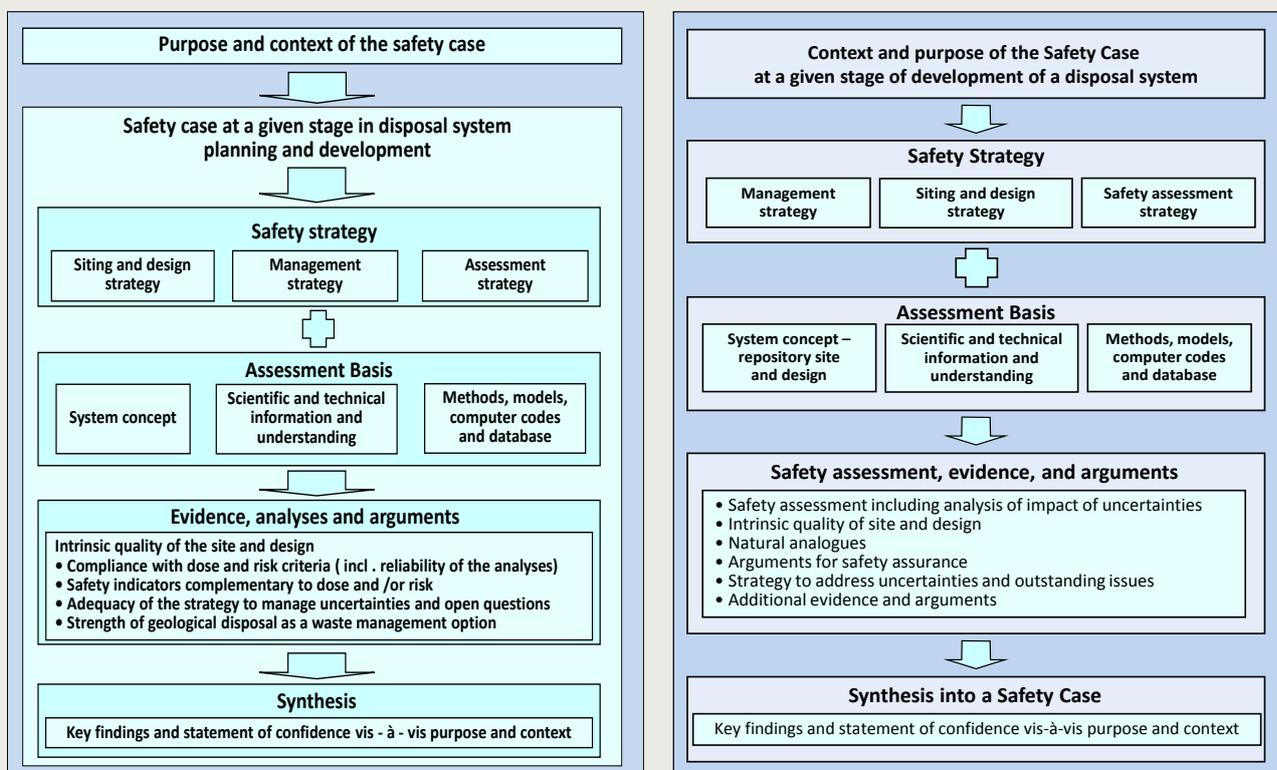
In 2013, specialists from two Waste Management Organizations, two research organizations, and two governmental departments (supported by NEA editors) updated the 2004 report to create a more useful reference for those involved in the development of safety cases and

for those with responsibility for, or interest in, decision making in radioactive waste management (NEA, 2013).

Since the OPERA research plan was developed using the NEA 2004 report, a brief overview of the changes and additions in the update of this NEA report.

The chapter titles and content in (NEA, 2013) and (NEA, 2004) are almost identical. The exception is addition of Chapter 5, Safety Assessment and the Compilation of the Safety Case and Chapter 6, the Synthesis of Evidence, Analyses and Arguments and Statement of Confidence in (NEA, 2013).

The overall NEA safety case structure of the approach has not been changed, although in some instances formulations and emphasis are different. To illustrate this, the overviews of 2004 and 2013 safety case structures are shown in Figure 2-2 below.



a) NEA, 2004; Figure 1

b) NEA, 2013: Figure 2.1:

Figure 2-2 Comparison of the NEA 2004 and 2013 overview of the safety case components²

Broadly, the safety case components are the same, but note that the 2013 document refers to "safety assessment" where the 2004 document refers to "analyses" and "synthesis" has been changed into "synthesis into a safety case" in 2013.

Chapter 5 of NEA (2013) describes the building blocks of the safety assessment. These building blocks are very similar to the ISAM scheme in the OPERA Research Plan (Verhoef, 2011a; Section I, p.12).

² The NEA reports use the term "element" rather than "component"

2.3. IAEA's Structure for the Safety Case and Safety Assessment for the Disposal of Radioactive Waste (IAEA, 2012)

The IAEA Specific Safety Guide SSG-23 (IAEA, 2012) provides guidance and recommendations on meeting safety requirements in light of a safety case and supporting safety assessment for the disposal of radioactive waste. SSG-23 covers:

- Demonstrating The Safety Of Radioactive Waste Disposal
- Safety Principles And Safety Requirements
- The Safety Case For Disposal Of Radioactive Waste
- Radiological Impact Assessment For The Period After Closure
- Specific Issues
- Documentation And Use Of The Safety Case
- Regulatory Review Process

The IAEA Safety Case consists of the eight components shown in Figure 2-3 below.

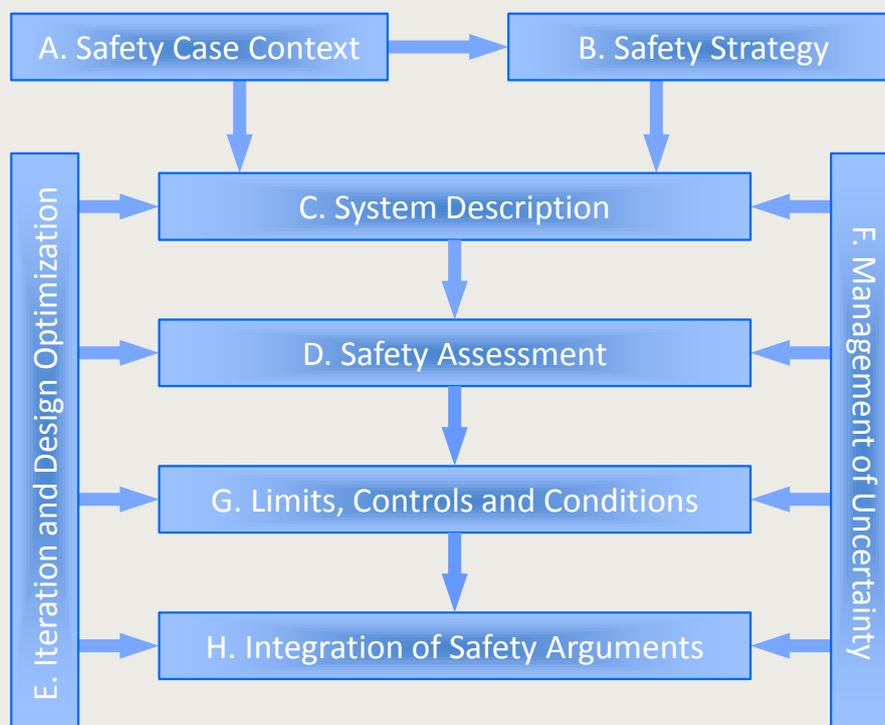


Figure 2-3 The IAEA Safety Case Structure (IAEA, 2012 - FIG. 2. "Components of the safety case")

The purpose of each safety case component is described in the IAEA SSG-23 report (IAEA, 2012). IAEA went further in their PRISM project (IAEA, 2012b) and developed the Matrix of Arguments for the Safety Case that related the components of the safety case to each major decision in the development of a radioactive waste repository.

2.4. Screening of various national safety assessment reports

In Task 2.1.1 of the OSCAR project (Hart, 2014) the safety case developments and status of safety cases of national repository programs from the following representative sample of countries were collected and summarized:

- Belgium

- Finland
- France
- Germany
- Sweden
- Switzerland
- United States

In addition, an evaluation of the Dutch Safety Case for the underground storage of CO₂ was included as the intent of CO₂ storage is essentially the same as geologic disposal of radioactive waste - isolation in geologic media and a different perspective of isolation could be of value for the OPERA Safety Case structure.

The selected disposal programs for spent fuel, TRU, and HLW were reviewed and summarized in Chapters 2 to 8 of the OSCAR report (Hart, 2014) with an emphasis on key components of a safety case including:

- General nuclear profile and waste inventory;
- Institutional arrangements - including legal, regulatory, and funding frameworks;
- Site screening, selection, and characterization, if applicable;
- Repository design concepts;
- Stakeholder involvement, licensing and decision making processes;
- Methodology to perform safety assessments; and
- Program status and maturity.

All of the programs documented their safety cases adequately for their purposes, but because these programs were well underway before the NEA and IAEA reports were published, the structure of the documents are different from the structures proposed by NEA or IAEA. In fact, most of the documents are not referred to as (or part of a) safety case. However, the majority of these programs did address the major components of a safety case as defined by the NEA and the IAEA.

The fact that these programs are successful while not following the format of either the NEA or the IAEA reveals that the choice of a safety case structure is less important than assurance that all of the safety case components are present and that flexibility in constructing the safety case is provided for.

2.5. Discussion

An important conclusion of the evaluation of the NEA, IAEA, existing repository programs, and the CO₂ program is that there is no universal format for the presentation of a safety case but there is an international consensus on the main components of a Safety Case. As the IAEA and the NEA have defined and accepted the language of the Safety Case and represent international consensus, we believe the choice for the Dutch safety case structure should be between these two.

In general, the IAEA and the NEA structures for the safety case are very similar (see Figure 2-4). The main difference is that the NEA includes the "assessment basis" which is not an obvious component of the IAEA structure.

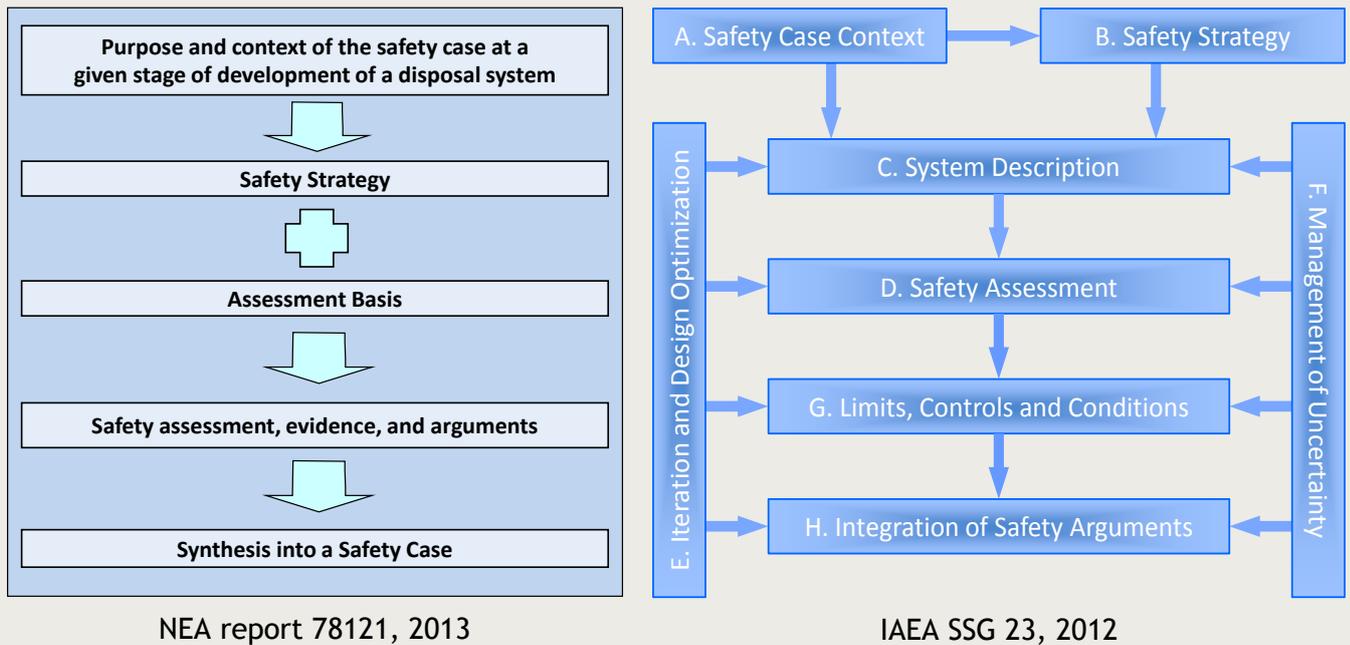


Figure 2-4 Top-level presentation of the components (NEA - left) and components (IAEA- right) Safety Case structures

The NEA describes a process: a number of steps are taken, and the results to be synthesized into a safety case. In the NEA document, a safety case is a formal compilation of evidence, analyses and arguments. For the OPERA Safety Case, this compilation is interpreted as a report or a collection of reports. The synthesis will contain results supporting each of the components of the safety case.

That said, a safety case produced in accordance with the NEA scheme could be compiled following the IAEA structure by mapping the components of the process (described by NEA) to the components (described by IAEA). The mapping of the element "assessment basis" involves splitting this element into its sub-components (1) "System concept - repository site and design", (2) "Scientific and technical information and understanding" and (3) "Methods, models, computer codes and database" and associating sub-element (1) and (2) to the component "System Description" and sub-element (3) to "Safety Assessment".

3. Proposed Structure of the OPERA Safety Case

In this chapter, the OSCAR consortium describes the proposed safety case structure, how the present OPERA research fits in this structure and how future OPERA reports can fit in this structure.

3.1. Proposed OPERA Safety Case structure

To structure the OPERA Safety Case, the consortium proposes to use the components and their relations as described in IAEA SSG-23 (IAEA, 2012).

IAEA SSG-23 provides a structure for the safety case by defining the components and their relationship³. These components are:

- A. Safety Case context
- B. Safety Strategy
- C. System Description
- D. Safety Assessment
- E. Iteration and Design Optimization
- F. Management of Uncertainties
- G. Limits, Controls and Conditions
- H. Integration of Safety Arguments

The consortium proposes to use the IAEA structure for the OPERA Safety Case for the following reasons:

- IAEA SSG-23 helps in developing a safety case by elaborating at a relatively high level these components and their relationships;
- The IAEA provides a structure for the safety case that fits well in the overall well-defined IAEA safety framework (IAEA, 2012);
- IAEA specific safety guides are regarded as having more authority than NEA reports.
- NEA reports 3679 and 78121 presents a very useful description of the process of developing a safety case, rather than the safety case itself. IAEA SSG-23 gives a much clearer description of the Safety Case.

In addition, the IAEA has provided the MASC matrix to relate the safety case components to decision making.

3.2. The structure of the OPERA Research Program

The contents of the components of the OSC depends on the results of the OPERA R&D projects. The basis for this research, the OPERA Research Plan (Verhoef, 2011a) was carefully developed following the logic of NEA report 3679 (NEA, 2004). At that time IAEA SSG-23 (IAEA, 2012) and NEA report 78121 (NEA, 2013) were not available.

Since the "components of the Safety Case" from NEA 3679 are very similar to the components defined by IAEA SSG-23 (see Section 2.5) it is relatively easy to map the tasks defined in the OPERA research plan on the IAEA components, even though the Research Plan is based on NEA reports 3679.

In Appendix 1 the tasks of the OPERA Research Plan have been mapped onto the safety case components defined in SSG-23 (IAEA, 2012) showing that all tasks are correlated to

³ A structure is the way in which the components of a system are arranged or organized.

one of the IAEA safety case components. Note that the majority of the tasks connect to the components "System description" and "Safety Assessment". Also note that the links between the OPERA R&D tasks and the component "safety assessment" is treated in more detail in (Grupa, 2013).

As the Dutch Safety Case evolves, the IAEA MASC matrix (IAEA, 2012b) can be used to assure that all components of the safety case are addressed in support of each decision supporting repository development.

3.3. Structure of the OSC documentation

The safety case structure provides fundamentally more than an outline for the Safety Case report(s). Nevertheless, it makes good sense, to base the outline of the documentation on the structure chosen for the safety case."

Our review of the national safety assessment reports (Hart, 2014) found that the safety case documentation should clearly present the safety concept and a complete compilation of all technical data and analyses. In addition, a short, higher-level document with only a minimum of technical details may be desirable for the less technically oriented stakeholders. In fact, the NEA mentions that: "*Multiple levels of documentation may thus be required, but these products must remain consistent amongst one another*" (NEA, 2004; p.10).

With respect to a specific format, the IAEA states that: "*There are many possible ways of structuring and documenting the safety case and important components of the safety case are briefly discussed in the following paragraphs* (IAEA, 2012; p.92)

- *Executive summary (...)*
- *Introduction and the context for the safety case (...)*
- *Strategy for safety (...)*
- *Synthesis and conclusions (...)*
- *Follow-up programmes and actions (...)*"

The reports that will be produced in the various OPERA projects, defined on the basis of the OPERA Research Plan, are R&D reports. This is a consequence of the early stage of the Dutch disposal process. In later stages of the disposal process, these reports will be replaced or supplemented by site specific data reports, reports providing in detailed design of the disposal system and components, results of test programs, and demonstrations.

Each research report will address one or more research or technological issues. However, research reports support a safety case and the sequence of research reports cannot be read as a continuing story. The safety case, on the other hand, includes at its heart a safety assessment based on general science, site-specific information, design, and the research results. Therefore a synthesis of reports, along with the safety assessment, will be necessary to compile a coherent safety case (see Figure 2-2).

As an example of a safety case report, the previous Dutch programs can be considered. The OPLA-1 document structure consisted of a high level executive summary ("Samenvatting OPLA-rapportage 'geologische opberging'"), a top-level final report ("Eindrapport fase 1"; OPLA, 1989), two synthesis reports ("Eindrapport Fase 1, Bijlages 1 en 2") and 26 R&D reports (OPLA deelstudies). The components of the OPLA-document structure were actually based on "science disciplines", i.e. there were components on Geology, Geohydrology, Rock Mechanics, etc.

The CORA document structure consisted of a high level executive summary (“Populaire samenvatting van het wetenschappelijke onderzoek”), one final report (CORA, 2001), containing the executive summary and the synthesis, and 21 R&D reports.

For the OPERA Safety Case reports a similar leveled structure is proposed in Figure 3-1. There will be an OPERA report or brochure providing the high level, non-technical summary, there will be one or more OPERA synthesis reports, and there will be about 40 OPERA R&D reports.

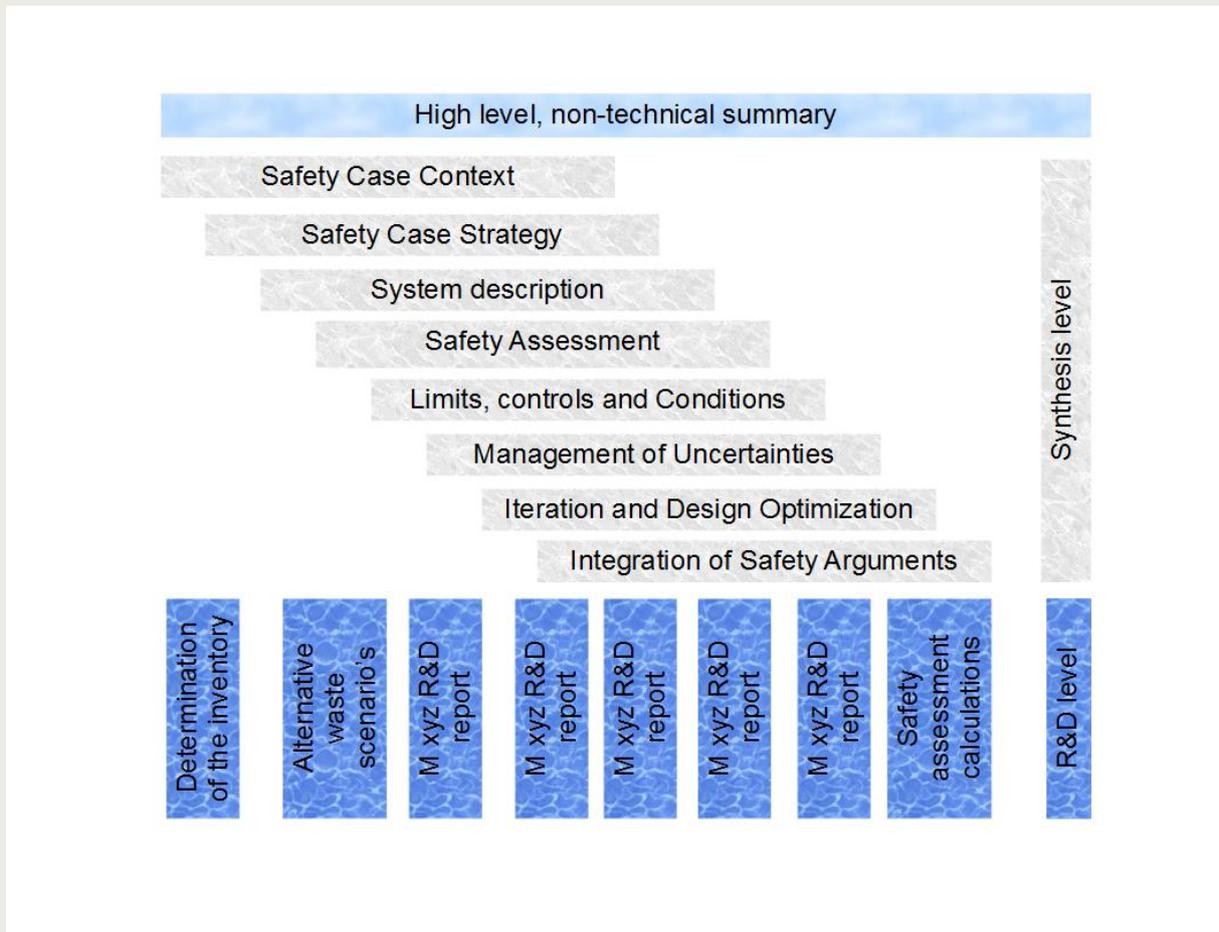


Figure 3-1 Relation between the proposed OPERA safety case components, the synthesis level and the safety case and research and development reports

The OPERA R&D reports are defined as milestones in the OPERA Research Plan and, as such, are fixed. For the synthesis level it is recommended to follow the component structure described in the IAEA SSG-23 (IAEA, 2012). Finally, it is recommended to summarize the OPERA research program with a high-level, non-technical summary report.

The level of detail can only be determined by the achievements in the OPERA R&D projects, which are limited by available resources and expertise. When the syntheses are being prepared, the level of detail of the various topics can be balanced, and omissions can be identified. These omissions can be taken into account when the section "*Follow-up programmes and actions*" is prepared at synthesis level.

3.4. Discussion

Eventually, after completion of the research program, the published documents will be regarded as the OPERA Safety Case. These documents, however, are presently not available, and it is not known what they will contain. In order to provide a structure now, we need to have an abstract concept of the OPERA Safety Case in mind. Some would even argue that the safety case will always be an abstract concept, and the documents published are a presentation of this concept.

The variability in the precise meaning of Safety Case shows in some quotes taken from IAEA 2012:

- "Documentation of the safety case" implies that the safety case and its documentation are different entities.
- "Section 4 elaborates on the concept of the safety case." implies it is a concept
- "The safety case and supporting safety assessment shall be submitted to the regulatory body for approval." implies it is a (set of) documents.
- "(...) the safety functions assumed in the safety case (...)" implies that the safety case is a line of reasoning.

and from NEA 2013

- Figure 2."An overview of the relationship between the different elements of a safety case" contains an element "Synthesis into a safety case". This implies that "safety case" has at least two meanings.

To get a grip on this, we propose to consider using "safety case" as an abstract concept, and regarding the documentation, the research contained in the safety case and the lines of reasoning as different but valid 'presentations' of this abstract concept. As a consequence, the structure proposed for the safety case should be reflected in the research as well as in the documentation of the safety case.

4. Conclusion

This document presents views and recommendations of the OSCAR project-team with respect to (1) the structure of the OPERA Safety Case and consequently (2) the structure of the OPERA Safety Case documentation. We recommend the adoption of the IAEA structure and use of the IAEA MASC matrix for the Dutch safety case structure and development. However we also recognize that the other structures have been and could be successful and, in this respect, there is a need to be flexible in the development of any safety case.

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Appendix 1 Relation between the OPERA R&D tasks and the IAEA safety case components

Safety Case Components	OPERA Task	Short Description of OPERA R&D Tasks
Safety Case Development	2.1.1.B	Safety Case structure
	2.1.2.B	Guideline OPERA reporting
	2.2.1	Repository design rock salt
Safety Case Context	1.2.1	Stakeholder Analysis
	1.2.4	Stakeholder involvement
	1.2.2	Legal requirements
Safety Strategy	7.1.1	Scenario development
System Description		
Waste Characteristics	1.1.1	Radionuclide Inventory
	1.1.2	Alternative waste scenarios
Facility design	3.1.1	Feasibility reference design
	3.2.1	Design modifications
EBS Characteristics	5.1.1	HLW matrix corrosion
	5.1.2	LILW degradation
	5.1.3	Metal corrosion
	5.1.4	Cementitious degradation
	5.1.5	Microbiological effects
Near Field Characteristics	4.2.1	Near field boundary conditions
	5.2.1	Geochemical properties Boom Clay
	5.2.2	Geochemical interactions Boom Clay
	5.2.3	Geochemical/THM evolution Boom Clay
	6.1.1	Fundamental sorption aspects
	6.1.2	Modelling of sorption
	6.1.3	Modelling of diffusion
	6.1.4	Mobility and presence colloids
	6.1.5	Non-diffusive transport
	6.1.6	Gas migration
Far Field Characteristics	4.1.1	Geo(hydro)logical properties
	4.1.2	Future evolution geological properties
	6.2.1	Modeling hydraulic transport
	6.2.2	Modeling nuclide migration
Biosphere Characteristics	6.3.1	Modeling biosphere process
Safety Assessment	2.1.2.A	Safety assessment methodology
System Conceptualization	7.2.1	Performance Assessment Boom Clay model
	7.2.2	Performance Assessment model aquifer migration
	7.2.3	Performance Assessment model biosphere
	7.2.4	Integrated Safety Assessment model
	7.2.5	Model parameterization
Definition of Scenarios	2.1.2.C	FEPs
	7.1.1	Scenario development
	7.1.2	Scenario representation
Treatment of Uncertainty	7.3.2	Methodology uncertainty analyses
Performance of Calculations	7.3.3	Safety assessment calculations

Safety Case Components	OPERA Task	Short Description of OPERA R&D Tasks
Evaluation	7.3.1	Safety Assessment indicators methodology
Iteration and design optimization	3.1.1	Feasibility reference design
	3.2.1	Design modifications
Management of Uncertainty	7.3.2	Methodology uncertainty analyses
	1.1.2	Alternative waste scenarios
Limits, controls & conditions	1.2.2	Legal requirements
	1.2.3	Retrievability
Integration of safety arguments	2.1.1.C	Safety statements
	1.3.1	Communicating Safety Case results

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