EUROPEAN
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Community research

# PAMINA
# Performance Assessment Methodologies in Application to Guide the Development of the Safety Case

(**Contract Number: FP6-036404**)

# COMPARISON OF REGULATORY EXPECTATIONS AND USE OF SAFETY AND PERFORMANCE INDICATORS BY PAMINA PARTICIPANTS
# MILESTONE (N°: M3.4.19)


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Date of issue of this report : **07/08/2009**

Start date of project : **01/10/2006** Duration : 36 Months


| **Project co-funded by the European Commission under the Euratom Research and Training Programme on Nuclear Energy within the Sixth Framework Programme (2002-2006)** | | |
|---|---|---|
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| **PU** | Public | X |
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| **CO** | Confidential, only for partners of the [PAMINA] project | |

## Foreword

The work presented in this report was developed within the Integrated Project PAMINA: **P**erformance **A**ssessment **M**ethodologies **IN** **A**pplication to Guide the Development of the Safety Case. This project is part of the Sixth Framework Programme of the European Commission. It brings together 25 organisations from ten European countries and one EC Joint Research Centre in order to improve and harmonise methodologies and tools for demonstrating the safety of deep geological disposal of long-lived radioactive waste for different waste types, repository designs and geological environments. The results will be of interest to national waste management organisations, regulators and lay stakeholders.

The work is organised in four Research and Technology Development Components (RTDCs) and one additional component dealing with knowledge management and dissemination of knowledge:

- In RTDC 1 the aim is to evaluate the state of the art of methodologies and approaches needed for assessing the safety of deep geological disposal, on the basis of comprehensive review of international practice. This work includes the identification of any deficiencies in methods and tools.
- In RTDC 2 the aim is to establish a framework and methodology for the treatment of uncertainty during PA and safety case development. Guidance on, and examples of, good practice will be provided on the communication and treatment of different types of uncertainty, spatial variability, the development of probabilistic safety assessment tools, and techniques for sensitivity and uncertainty analysis.
- In RTDC 3 the aim is to develop methodologies and tools for integrated PA for various geological disposal concepts. This work includes the development of PA scenarios, of the PA approach to gas migration processes, of the PA approach to radionuclide source term modelling, and of safety and performance indicators.
- In RTDC 4 the aim is to conduct several benchmark exercises on specific processes, in which quantitative comparisons are made between approaches that rely on simplifying assumptions and models, and those that rely on complex models that take into account a more complete process conceptualization in space and time.

The work presented in this report was performed in the scope of RTDC 3.

All PAMINA reports can be downloaded from http://www.ip-pamina.eu.

Milestone M3.4.19
Version 1

# PAMINA WP3.4 Task 19: Comparison of Regulatory Expectations and Use of Safety and Performance Indicators by PAMINA Participants

August 2009

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Milestone M3.4.19
Version 1

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# Comparison of Regulatory Expectations and Use of Safety and Performance Indicators by PAMINA Participants

**Report History**

This document has been prepared by Galson Sciences Limited (GSL) as part of the European Commission Project PAMINA FP6-036404.

| **PAMINA WP3.4 Task 19: Comparison of Regulatory Expectations and Use of Safety and Performance Indicators by PAMINA Participants** | | | | |
|---|---|---|---|---|
| Version: | Date: | Lead Author:<br>J.E. Morris | Reviewed by:<br>R.D. Wilmot | Approved by:<br>D.A. Galson |
| M3.4.19<br>Version 1 | 7 August 2009 | Sign<br>……......................<br>Date<br>….…..................... | Sign<br>........................…<br>Date<br>........................… | Sign<br>........................…..<br>Date<br>........................….. |

# Executive Summary

This document reports on activities performed within Task 19 of PAMINA WP3.4 by Galson Sciences Limited (**GSL**). The aim of WP3.4 is to achieve a common understanding of the role of safety and performance indicators, establish indicators for all types of host rocks, and test performance/function indicators. The aim of Task 19 is to provide a regulatory viewpoint on safety and performance indicators by reviewing existing regulations and international guidance, and to compare these regulatory expectations with the approach undertaken by the PAMINA participants within WP3.4.

A performance indicator provides a measure of performance to support the development of system understanding and to assess the quality, reliability or effectiveness of a disposal system as a whole or of particular aspects or components of a disposal system. A safety indicator is a special type of performance indicator and is used to assess calculated performance in terms of overall safety. Safety indicators are measures that provide an indication of the safety of the disposal system as a whole. Because measures of the performance of sub-systems may not be directly related to overall safety in this way, it is usual to refer to *sub-system performance indicators* for all examples of sub-system performance, however derived.

Regulators establish criteria for primary safety indicators, such as dose rate or risk. International guidance recommends the use of complementary safety indicators to support calculations of dose rate and/or risk indicators in the safety case. However, few national regulations or guidance documents specifically address this issue, notable exceptions being Finland, the UK and the US (for the Waste Isolation Pilot Plant (WIPP) project).

Only in the US have regulations for sub-system performance indicators been developed. However, generic prescriptive sub-system performance measures, such as those in US regulations for geological disposal (10 CFR Part 60), can result in a sub-optimal system design. These regulations do not apply to the WIPP or Yucca Mountain projects.

All PAMINA participants in WP3.4 consider radiological dose rate as the primary safety indicator. A range of complementary safety indicators and sub-system performance indicators have been used in the programmes reviewed. The participants are, therefore, exceeding the regulatory requirements on the use of safety and performance indicators.

Prescriptive regulatory values are difficult to determine for safety indicators other than dose rate and risk. Site-specific reference values are needed due to differences in host rock type and background radiation. Similarly, sub-system performance indicators will be disposal concept-specific. Therefore, suitable design-specific and site-specific reference values should be proposed by developers/operators and agreed with regulators.

Regulatory decisions on the acceptability of a disposal system are unlikely to be based on safety assessment calculations alone, due to the very long timescales involved. It is likely that complementary lines of reasoning that demonstrate an understanding of the performance of compartments or barriers during the evolution of the disposal system will also be required. Sub-system performance indicators allow developers/operators to demonstrate a detailed understanding of the disposal system, and their inclusion in the safety case will therefore assist the regulatory decision-making process.

# Contents

**Executive Summary ........ i**

**1 Introduction ........ 1**
1.1 Definitions ........ 1
1.2 Objective and Scope ........ 3
1.3 Methodology and Report Structure ........ 4

**2 Regulatory Expectations for Safety and Performance Indicators ........ 5**
2.1 Safety Indicators ........ 5
2.1.1 Primary Safety Indicators in National Regulations ........ 5
2.1.2 Complementary Safety Indicators in National Regulations ........ 11
2.2 Sub-system Performance Indicators ........ 15

**3 Safety and Performance Indicators Studied by Participants in WP3.4 ........ 17**
3.1 Safety Indicators ........ 17
3.2 Sub-system Performance Indicators ........ 20

**4 Summary ........ 25**

**5 References ........ 27**

# PAMINA WP3.4 Task 19: Comparison of Regulatory Expectations and Use of Safety and Performance Indicators by PAMINA Participants

## 1 Introduction

PAMINA (**P**erformance **A**ssessment **M**ethodologies **IN** **A**pplication to Guide the Development of the Safety Case) is an Integrated Project funded by the Sixth Framework Programme of the European Commission (EC). The work is organised in four Research and Technology Development Components (RTDCs) and one additional component dealing with knowledge management and dissemination of knowledge. RTDC-3 aims to develop methodologies and tools for integrated performance assessment (PA) for various geological disposal concepts. It consists of four Work Packages (WPs): the development of PA scenarios (WP3.1), the PA approach to gas migration processes (WP3.2), the PA approach to radionuclide source term modelling (WP3.3), and safety and performance indicators (WP3.4).

WP3.4 aims to achieve a common understanding of the role of safety and performance indicators, establish indicators for all types of host rocks, and test performance/function indicators with formations other than granite (which was assessed during a previous EC project on Testing of Safety and Performance Indicators (SPIN)). It consists of 23 tasks, each of which will result in one or more Milestone reports; this document is the Galson Sciences Ltd. (**GSL**) report on activities performed within Task 19, which compares regulatory expectations on the use of safety and performance indicators with the approach adopted by PAMINA participants within WP3.4.

### 1.1 Definitions

There are a range of definitions for the terms *safety indicator* and *performance indicator*. The International Atomic Energy Agency (IAEA) defines these terms in the "IAEA Safety Glossary" (IAEA, 2007) and in the publication "Safety indicators for the safety assessment of radioactive waste disposal" (IAEA, 2003). The Nuclear Energy Agency (NEA) of the Organisation for Economic Co-operation and Development (OECD) also provides definitions for safety indicators (NEA, 2001). For the purposes of the present report, alternative definitions were agreed upon by the participants in PAMINA WP3.4 and documented in PAMINA report D3.4.1 (Becker and Wolf, 2008).

A broad definition of a performance indicator is (IAEA, 2007):

> "*A characteristic of a process that can be observed, measured or trended to infer or directly indicate the current and future performance of the process, with particular emphasis on satisfactory performance for safety.*"

A performance indicator provides measures of performance to support the development of system understanding and to assess the quality, reliability or effectiveness of a disposal system as a whole or of particular aspects or components of a disposal system (IAEA, 2003). For the purposes of PAMINA WP3.4, a performance indicator is defined as "*a quantity, calculable by means of appropriate models, that provides a measure for the performance of a system component, several components or the whole system in comparison with each other*" (Becker and Wolf, 2008).

A safety indicator is a special type of performance indicator which is used to assess calculated performance in terms of overall safety. A broad definition of a safety indicator is (IAEA, 2007):

> "*A quantity used in assessments as a measure of the radiological impact of a source or practice, or of the performance of protection and safety provisions, other than a prediction of dose or risk. Such quantities are most commonly used in situations where predictions of dose or risk are unlikely to be reliable, e.g. long term assessments of repositories. They are normally either: (a) Illustrative calculations of dose or risk quantities, used to give an indication of the possible magnitude of doses or risks for comparison with criteria; or (b) Other quantities, such as radionuclide concentrations or fluxes, that are considered to give a more reliable indication of impact, and that can be compared with other relevant data.*"

An indicator was defined by the IAEA (2003) as "*any characteristic or consequence of a disposal system that has a bearing on the ability of the system to perform its safety functions*", whereas a safety indicator is used to assess calculated performance in terms of overall safety. For the purposes of PAMINA WP3.4, a safety indicator is defined as "*a quantity, calculable by means of suitable models, that provides a measure for the total system performance with respect to a specific safety aspect, in comparison with a reference value quantifying a global or local level that can be proven, or is at least commonly considered, to be safe*" (Becker and Wolf, 2008).

Illustrative calculations of dose rate and risk are widely used as *primary* safety indicators for assessing the safety of radioactive waste disposal. Safety indicators other than dose rate and risk are generally referred to as *complementary (or secondary) safety indicators*.

The NEA defines primary and secondary safety indicators as follows (NEA, 2001):

> *"Primary safety indicators should provide some measure of indication of radiological impact on human health and the environment. The indicators should be possible to assess against, or compare with, criteria or references*

*independent of the safety assessment itself. These criteria or reference values should have a similar general validity as dose or risk."*

*"Secondary safety indicators are those which can be assessed against sub-system criteria, or references, derived from safety assessments based on dose or another primary safety indicator. Examples from this category are fluxes through engineered barriers and release rates from waste forms."*

Under this definition, secondary safety indicators can apply to one or more sub-systems within the disposal system, but their validity is dependent on these indicators being derived from primary safety indicators. Because measures of the performance of sub-systems may not be directly related to overall safety, it is usual to refer to *sub-system performance indicators* for all examples of sub-system performance, however derived.

## 1.2 Objective and Scope

The aim of this document is to provide a regulatory viewpoint on safety and performance indicators by reviewing existing regulations and international guidance, and to compare these regulatory expectations with the approach undertaken by the PAMINA participants within WP3.4.

The review of current regulations and international guidance on safety and performance indicators covers 15 countries, including three non-European countries (Canada, Korea and the United States).

Information on the approach adopted by participants within WP3.4 was compiled from the following organisations:

- Belgium:
  - SCK•CEN - National Nuclear Research Centre.
- Czech Republic:
  - NRI - Nuclear Research Institute.
- Germany:
  - GRS - Company for Plant and Reactor Safety.
- The Netherlands:
  - NRG - Nuclear Research and Consultancy Group.
- Spain:
  - Amphos21.

## 1.3 Methodology and Report Structure

Section 2 provides a review of existing regulations and international guidance on safety and performance indicators. Most national regulations specify criteria for the primary safety indicators of dose rate and/or risk. This information was mainly compiled from the following two sources:

- A review of existing criteria in the regulations, undertaken as part of PAMINA Deliverable 1.1.1 (Becker, 2008).
- A publication by the NEA on regulating the long-term safety of geological disposal (NEA, 2007).

Examples from the UK and Finland are provided to illustrate the consideration of complementary safety indicators in regulation. Only in the US do regulations include requirements on sub-system performance indicators; these are also presented and discussed.

Section 3 reviews and discusses the safety and sub-system performance indicators studied by PAMINA participants in WP3.4.

Section 4 summarises the regulatory perspective and considers the safety and sub-system performance indicators studied by PAMINA participants in WP3.4 in this light.

Section 5 lists the references used in the report.

# 2 Regulatory Expectations for Safety and Performance Indicators

This section outlines the regulatory expectations for primary and complementary safety indicators (Section 2.1) and sub-system performance indicators (Section 2.2).

## 2.1 Safety Indicators

Most regulations only specify values (or criteria) for the main or primary safety indicator of dose rate and/or risk. The existing regulatory criteria for dose rate and risk were reviewed in PAMINA Deliverable 1.1.1 (Becker, 2008) and by the Nuclear Energy Agency (NEA, 2007), and are described in Section 2.1.1.

The international consensus is that additional (secondary or complementary) safety indicators should be used to support dose rate and/or risk indicators to strengthen the safety case. However, few national regulations or regulatory guides specifically address this issue. Notable exceptions are regulations in Finland, the UK and for the US Waste Isolation Pilot Plant (WIPP). The regulatory guidance on complementary safety indicators is summarised in Section 2.1.2.

### 2.1.1 Primary Safety Indicators in National Regulations

The radiological impact of a geological disposal facility is regulated on the basis of compliance with the fundamental objective of protection of humans and the environment. Estimates of dose rates due to the future migration of radionuclides from a geological disposal facility are therefore used as indicators of the degree of protection provided by the facility (IAEA, 2006). The International Commission on Radiological Protection (ICRP) considers that the principal means of protecting the public from exposures in the long periods involved is through a process of constrained optimisation, taking account of the ICRP's recommended upper value for the dose rate constraint of 0.3 mSv per year or its risk equivalent of around $10^{-5}$ per year (ICRP, 1998).

Dose rate and risk are primary safety indicators, and regulations always establish at least one safety indicator for which a dose rate or risk criterion is assigned. The dose rate and/or risk criteria established by the regulators in eight European countries were reviewed within the PAMINA project (Deliverable 1.1.1, Part 4; Becker, 2008); also, NEA (2007) reviewed the regulations for 17 countries, including Canada and the US.

Table 2.1 summarises the primary safety indicators used to regulate the geological disposal of radioactive waste. Three levels of regulatory standards are included in Table 2.1 (Wilmot, 2005):

- Limits. A limit provides a value (e.g. for effective dose rate) that *must* not be exceeded.

- Constraints. A constraint provides a value (e.g., for site-related or source-related dose rate) that *should* not be exceeded.

- Target or Guidance level. A target provides a numerical criterion against which information can be assessed. A target is sometimes termed an optimisation level and indicates the standard of safety that the regulator expects, but does not suggest that there is an absolute requirement for this level to be met.

In some cases, national constraints are applied to specific sites in conjunction with international limits set for the purpose of protection of human health and the environment. For example, the IAEA Safety Requirements for the "Geological Disposal of Radioactive Waste" (IAEA, 2006) state that:

> *"The dose limit for members of the public from all practices is an effective dose of 1 mSv in a year, and this or its risk equivalent is considered a criterion not to be exceeded in the future. To comply with this dose limit, a geological disposal facility (considered as a single source) is designed so that the estimated average dose or average risk to members of the public who may be exposed in the future as a result of activities involving the disposal facility does not exceed a dose constraint of not more than 0.3 mSv in a year or a risk constraint of the order of $10^{-5}$ per year."*

The dose rate criteria specified in Table 2.1 range from 0.1 to 0.3 mSv/y and the risk criteria from $10^{-5}$ to $10^{-6}$/y. Regulations also differ with respect to the timeframes over which the criteria are applied. The regulatory criteria in the countries reviewed in NEA (2007) are based on:

- Acceptability of the levels of risk.
- Comparison with numerical radiological protection criteria used for current practices.
- Comparison with existing levels of natural radiation, or a combination of the above.

In some countries, dose rate criteria apply to high-probability (normal evolution) scenarios and risk criteria apply to lower-probability scenarios (Table 2.1).

The Environment Agency and NIEA (2009) expect the developer/operator of a geological disposal facility to provide quantitative assessments of the radiological risk from the facility to a person representative of those at greatest risk for comparison with a risk guidance level of $10^{-6}$/y. However, the risk guidance level does not apply to human intrusion. The regulator assumes that unintentional human intrusion into a geological disposal facility is unlikely, and recommends that the consequences of human intrusion should therefore be explored through stylised scenarios.

**Table 2.1:** Examples of primary safety indicators used to regulate the geological disposal of radioactive waste (from Becker, 2008; Environment Agency and NIEA, 2009; NEA, 2007). Note that the existing national regulations are currently being revised in Belgium, Canada, France, Germany, Korea, Slovakia and Spain.

| Country | Primary Safety Indicator (dose rate or risk value given is for impact to most exposed individual) | Comments on Application of Indicator | Comments on Treatment of Uncertainty |
|---|---|---|---|
| Belgium | Dose constraint: 0.1 to 0.3 mSv/y.<br>Risk constraint: $10^{-5}$/y.<br>(Working values, as there are currently no specific regulations for the disposal of radioactive waste – maximum dose limits of 1 mSv/y for members of the public and 20 mSv/y to workers still apply). | Dose constraint is relevant to high-probability scenarios and risk constraint is relevant to lower-probability scenarios. | |
| Canada | Under development.<br>Interim dose constraint of up to 0.3 mSv/y for design optimisation. | Guidance on timescales, institutional control and other indicators is also under development. A public dose criterion of 1 mSv/y is used to evaluate human intrusion scenarios. | Under development. |
| Czech Republic | Dose constraint: 0.25 mSv/y. | A dose constraint of 1 mSv/y is applied to less probable ‘emergency scenarios’. | Scenarios with probabilities $< 10^{-6}$/y do not need to be considered in the safety analysis. |
| Finland | Dose limit: 0.1 mSv/y for normal evolution scenarios.<br>For unlikely events, impacts assessed against a risk equivalent of the dose limit. | Dose or risk limits apply for several thousand years.<br>For long timeframes beyond adequate predictability, constraints for the average release of specific radionuclides apply. | Unlikely events should be assessed quantitatively where practicable, otherwise by qualitative discussion. Deterministic, conservative analyses with assessment of implications of uncertainties. |

| Country | Primary Safety Indicator (dose rate or risk value given is for impact to most exposed individual) | Comments on Application of Indicator | Comments on Treatment of Uncertainty |
|---|---|---|---|
| France | Dose limit: 0.25 mSv/yr for normal evolution scenarios. | The dose limit applies for 10,000 years and is a reference value for later periods.<br>For altered scenarios, the impact is assessed according to the likelihood, the nature of potential exposures, and the degree of pessimism in the assumptions made. | Random, unanticipated events are subjected to case-by-case judgement, including glaciations after 50,000 years. |
| Germany | Dose limit: 0.3 mSv/y.<br>(Official guideline as currently no regulations for long-term safety assessment). | The dose rate should be evaluated out to 10,000 years. | A safety case containing uncertainty analysis is required for licensing.<br>Human intrusion is assumed not to occur within 500 years of closure. |
| Hungary | Dose limit: 0.1 mSv/y.<br>Risk limit: $10^{-5}$/y, for the impact of individual disruptive events. | The consequences of individual disruptive events shall be evaluated using probabilistic analysis. | Events with a likelihood of occurrence < $10^{-7}$/y do not need to be considered. |
| Netherlands | Dose limit: 0.1 mSv/y.<br>(Optimisation goal for normal evolution is 0.04 mSv/y).<br>Risk limit: $10^{-6}$/y. | Specific dose limits apply for different scenarios and groups of people (adults/children). | |
| Republic of Korea | Dose limit: 0.1 mSv/y for normal evolution.<br>Risk limit: $10^{-6}$/y for disruptive events, using probabilistic analysis. | A dose limit of 1 mSv/y is applied to human intrusion scenarios. | Under development. |

| Country | Primary Safety Indicator (dose rate or risk value given is for impact to most exposed individual) | Comments on Application of Indicator | Comments on Treatment of Uncertainty |
|---|---|---|---|
| Slovakia | Dose limit: 0.1 mSv/y for normal evolution scenarios for LLW and SL-ILW.<br>Dose limit: 1 mSv/y for human intrusion scenarios, for LLW and SL-ILW.<br>(Limits are under development for LL-ILW and HLW.) | The following acronyms are defined:<br>LLW: Low-Level radioactive Waste<br>SL-ILW: Short-Lived Intermediate-Level radioactive Waste<br>LL-ILW: Long-Lived Intermediate-Level radioactive Waste<br>HLW: High-Level radioactive Waste | |
| Spain | Dose constraint: 0.1 mSv/y.<br>Risk limit: $10^{-6}$/y.<br>(Under revision). | Dose constraint is relevant to high-probability scenarios and the risk limit to lower-probability scenarios. | |
| Sweden | Risk limit: $10^{-6}$/y (Dose/risk conversion factor of 0.073 $Sv^{-1}$ to be used). | Quantitative assessment is required for the first 1,000 years. Beyond 1,000 years, consideration of various scenarios is required. A safety assessment shall cover at least 10,000 years, or as long as barrier functions are required. | Uncertainties must be reported and sensitivity analysis used to show how uncertainties affect the analysis of consequences to human health and the environment. |
| Switzerland | Dose constraint: 0.1 mSv/y.<br>Risk target: $10^{-6}$/y. | The dose constraint is relevant to high-probability scenarios and the risk target to lower-probability scenarios, with no time limit.<br>Complete containment of the radionuclides is required for 1,000 years. | |

| Country | Primary Safety Indicator (dose rate or risk value given is for impact to most exposed individual) | Comments on Application of Indicator | Comments on Treatment of Uncertainty |
|---|---|---|---|
| UK (excluding Scotland) | Dose constraint: 0.3 mSv/y (recommended 0.15 mSv/y for members of the public).<br>Risk guidance level: $10^{-6}$/y (using dose/risk conversion factor of 0.06 $Sv^{-1}$). | The dose constraint applies to the period before institutional control is withdrawn, and the risk guidance level applies after the period of authorisation.<br>Human intrusion is considered to be highly unlikely to occur, so the risk guidance level is not applied to human intrusion scenarios. Measures to reduce this likelihood should be taken. The potential consequences of human intrusion should be assessed.<br>The safety case is required to show that radionuclide releases are unlikely to lead to significant increases of radioactivity in the accessible environment. | |
| US<br>(40 CFR Part 197 and 10 CFR Part 63 for Yucca Mountain) | Dose limit: 0.15 mSv/y for normal evolution scenarios.<br>Dose limit: 0.15 mSv/y for human intrusion scenarios at or before 10,000 years after closure. | Restrictions of radionuclide concentrations in groundwater apply for 10,000 years. Quantitative assessment is required for the first 10,000 years, with a requirement to calculate the peak dose rate if this occurs between 10,000 and 1,000,000 years. | Events or scenarios with a likelihood of occurrence < $10^{-8}$/y do not need to be considered. |
| US<br>(40 CFR Parts 191 and 194 for WIPP) | Dose limit: 0.15 mSv/y<br>Cumulative release limit: Specified in terms of limitations on the probability of exceeding specified quantities of particular radionuclides. | Dose limit applies to undisturbed performance over 10,000 years.<br>Cumulative release limit applies to all scenarios over 10,000 years. | |

Dose rate and risk have uncertainties associated with assumptions about the future state of the biosphere and conditions in the near-surface, which tend to increase in magnitude with the period under consideration. The ICRP recognises the problems of estimating collective dose rate, since the size and distribution of future populations is uncertain over extended periods (ICRP, 1997, 1998): "*Both the individual doses and the size of the exposed population become increasingly uncertain as time increases. Furthermore, the current judgements about the relationship between dose and detriment may not be valid for future populations*". For the far future, safety indicators other than dose rate and individual risk may be appropriate, and the use of complementary safety indicators such as concentrations and fluxes of naturally-occurring radionuclides, or bounding analyses, can be considered (IAEA, 2006).

### 2.1.2 Complementary Safety Indicators in National Regulations

Due to the inherent uncertainties in the calculation of dose rate and risk in the far future, the robustness of the safety case is strengthened by the use of "*multiple lines of evidence leading to complementary safety arguments that can compensate for shortcomings in any single argument*" (NEA, 2004). Dose rate or risk criteria may be combined with assumed human exposure pathways and dose-response relationships into another unit of measure, such as the total flux of radionuclides across a boundary (NAS, 1995).

If regulatory criteria are specified for complementary safety indicators, they are likely to be back-calculated by the regulators from the criteria for dose rate or risk. This calculation requires the regulator to develop generic, stylised biosphere assumptions. In this case, the developer/operator does not need to model the biosphere to demonstrate compliance with the regulatory criteria. As an alternative, the regulator may specify that the developer/operator should use site-specific stylised biosphere assumptions or bounding scenarios to back-calculate a particular complementary safety indicator, for comparison with the results of safety assessment calculations.

Whether the regulator or the developer/operator calculates the criteria for complementary safety indicators, the assumptions relating to future populations and biosphere environments are inherent, but are presented separately from the safety assessment calculations. Although complementary safety indicators have been or will be used in several countries (e.g., Belgium, Finland, Germany, Spain and Sweden), national regulatory guidance on this topic is not well developed. Notable exceptions are Finland, the UK and the US (WIPP).

### Finland

In Finland, regulatory guidance from the Radiation and Nuclear Safety Authority (STUK, 2001) states that:

> "*The average quantities of radioactive substances over long time periods, released from the disposed waste and migrated to the environment, shall remain below the nuclide specific constraints defined by the Radiation and Nuclear Safety Authority. These constraints shall be defined so that:*
>
> *1. At their maximum, the radiation impacts arising from disposal can be comparable to those arising from natural radioactive substances; and*
>
> *2. On a large scale, the radiation impacts remain insignificantly low.*"

The radionuclide-specific constraints for the activity releases to the environment are given in Table 2.2. STUK considers that these constraints will apply to activity releases arising from the expected evolution scenarios, which may enter the environment after several thousands of years. These activity releases can be averaged over 1000 years at the most. The sum of the ratios between the nuclide specific activity releases and the respective constraints shall be less than one.

**Table 2.2**: Radionuclide-specific constraints for the activity releases to the environment from a geological disposal facility (STUK, 2001).

| Radionuclide(s) | Radionuclide-specific constraint for activity released to the environment (GBq/y) |
|---|---|
| Long-lived, α-emitting isotopes of Ra, Th, Pa, Pu, Am and Cm. | 0.03 |
| $^{79}$Se, $^{129}$I and $^{237}$Np | 0.1 |
| $^{14}$C, $^{36}$Cl and $^{135}$Cs and long-lived isotopes of U. | 0.3 |
| $^{94}$Nb and $^{126}$Sn | 1 |
| $^{99}$Tc | 3 |
| $^{93}$Zr | 10 |
| $^{59}$Ni | 30 |
| $^{107}$Pd and $^{151}$Sm | 100 |

The activity release constraints in Table 2.2 are expressed as nuclide-specific activity fluxes across the geosphere-biosphere interface and are defined such that (i) at their maximum, the radiation impacts arising from disposal can be comparable to those arising from natural radioactive substances, and (ii) on a large scale, the radiation impacts will remain insignificantly low.

**UK**

The recently updated regulatory guidance contains specific requirements to consider complementary safety indicators but does not specify quantitative criteria (Environment Agency and NIEA, 2009). The environment agencies consider that environmental safety can only be assured over very long timescales through multiple lines of reasoning based on a variety of evidence (Environment Agency and NIEA, 2009, Section 7.3.7):

> "*Examples of environmental safety indicators that might be used to strengthen the environmental safety case include radiation dose, radionuclide flux, radionuclide travel times, environmental concentration and radiotoxicity. The developer/operator should provide a wide range of information relating to such indicators, for example:*
>
> - *Assessments of radionuclide release characteristics from the waste and from the various barriers that make up the disposal system.*
> - *Assessments of the concentrations in the accessible environment of radionuclides released from the disposal system and comparison of these with naturally occurring levels of radioactivity in the environment.*
> - *If appropriate, assessment of collective radiological impact (as a measure of how widespread any significant increase in risk may be as a result of radioactivity released into the accessible environment).*
> - *Unifying statements that aim to place in context the different items of information that contributes to assuring environmental safety.*"

**US (WIPP)**

The WIPP is used for the disposal of transuranic (TRU) radioactive waste from defence programs of the US Department of Energy (DOE). It is certified by the US Environmental Protection Agency (EPA) through generic radioactive waste disposal standards (40 CFR Part 191; EPA, 1993) and WIPP-specific criteria (40 CFR Part 194; EPA, 1998).

The generic standards in 40 CFR Part 191 contain three requirements, including primary and complementary safety indicators. The requirements are:

- **Containment Requirements** "*Disposal systems for spent nuclear fuel or high-level or transuranic radioactive wastes shall be designed to provide a reasonable expectation, based upon performance assessments, that the cumulative releases of radionuclides to the accessible environment for 10,000 years after disposal from all significant processes and events that may affect the disposal system shall:*
  (1) *Have a likelihood of less than one chance in 10 of exceeding the quantities calculated according to [Table 2.3]; and*
  (2) *Have a likelihood of less than one chance in 1,000 of exceeding ten times the quantities calculated according to [Table 2.3].*"

- **Individual Protection Requirement** "*Disposal systems for waste and any associated radioactive material shall be designed to provide a reasonable expectation that, for 10,000 years after disposal, undisturbed performance of the disposal system shall not cause the annual committed effective dose, received through all potential pathways from the disposal system, to any member of the public in the accessible environment, to exceed 15 millirems (150 μSv).*"
- **Groundwater Protection Requirement** "*Disposal systems for waste and any associated radioactive material shall be designed to provide a reasonable expectation that 10,000 years of undisturbed performance after disposal shall not cause the levels of radioactivity in any underground source of drinking water, in the accessible environment, to exceed the limits specified in 40 CFR part 141 as they exist on January 19, 1994.*"

**Table 2.3**: Release limits for containment requirements from 40 CFR Part 191, as applied to the WIPP (EPA, 1993). The cumulative releases to the accessible environment for 10,000 years after disposal are listed by radionuclide.

| Radionuclide | Release limit per 1,000 metric tons of heavy metal (MTHM) or other unit of waste (Bq) | Release limit per 1,000 MTHM or other unit of waste (Curies) |
|---|---|---|
| $^{241}Am$ or $^{243}Am$ | $3.7 \times 10^{12}$ | 100 |
| $^{14}C$ | $3.7 \times 10^{12}$ | 100 |
| $^{135}Cs$ or $^{137}Cs$ | $3.7 \times 10^{13}$ | 1,000 |
| $^{129}I$ | $3.7 \times 10^{12}$ | 100 |
| $^{237}Np$ | $3.7 \times 10^{12}$ | 100 |
| $^{238}Pu$, $^{239}Pu$, $^{240}Pu$, or $^{242}Pu$ | $3.7 \times 10^{12}$ | 100 |
| $^{226}Ra$ | $3.7 \times 10^{12}$ | 100 |
| $^{90}Sr$ | $3.7 \times 10^{13}$ | 1,000 |
| $^{99}Tc$ | $3.7 \times 10^{14}$ | 10,000 |
| $^{230}Th$ or $^{232}Th$ | $3.7 \times 10^{11}$ | 10 |
| $^{126}Sn$ | $3.7 \times 10^{13}$ | 1,000 |
| $^{233}U$, $^{234}U$, $^{235}U$, $^{236}U$, or $^{238}U$ | $3.7 \times 10^{12}$ | 100 |
| Any other α-emitting radionuclide with a half-life greater than 20 years | $3.7 \times 10^{12}$ | 100 |
| Any other radionuclide with a half-life greater than 20 years that does not emit α-particles | $3.7 \times 10^{13}$ | 1,000 |

## 2.2 Sub-system Performance Indicators

While sub-system performance indicators have been widely adopted by developer/operators, most countries do not have specific regulatory requirements on sub-system performance indicators to be considered as part of the safety case. The notable exception is the US, in a regulation of mainly historical interest.

In the US, the performance objective for the geological disposal system as a whole is set by the US EPA; however, the US Nuclear Regulatory Commission (NRC) has responsibility for implementing the EPA standards and making licensing decisions for facilities containing non-defence wastes. Generic sub-system performance criteria have been specified by the NRC in regulations for the geological disposal of high-level radioactive waste (10 CFR Part 60; NRC, 1988). Numerical values for expected performance are placed on the waste packages, the engineered barrier system and the natural environment to ensure redundancy in the multi-barrier system. In particular, 10 CFR Part 60 specifies (NRC, 1988):

1. Substantially complete containment of radionuclides within the waste package for 300 – 1,000 years, during the period when radiation and thermal conditions in the engineered barrier system are dominated by fission product decay.
2. A release rate of any radionuclide from the engineered barrier system to the geological setting of less than one part in 100,000 per year of the inventory of that radionuclide calculated to be present at 1,000 years following closure of the disposal facility.
3. A pre-emplacement groundwater travel time of at least 1,000 years between the disturbed zone and the accessible environment.

The sub-system performance criteria reflected a defence-in-depth approach, which was designed to provide reasonable assurance that the overall system would meet the EPA system performance objective (40 CFR Part 191, see Section 2.1.2). The third criterion was intended to drive the US Department of Energy (DOE) to select sites that can compensate for the increasing uncertainties in near-field performance with time. The NRC stated that the numerical values specified in 10 CFR Part 60 could be varied on a case-by-case basis, as long as the EPA's overall performance objective was met.

Although the principle of a multi-barrier approach to waste isolation is widely supported, the establishment of generic numerical values for sub-system performance criteria was criticised because the values specified by the NRC do not guarantee that the EPA standard will be met, and the appropriate performance of particular barriers is dependent upon site-specific design features and site characteristics. Thus, generic regulator-specified sub-system performance measures can result in a sub-optimal overall system.

These detrimental aspects are the main reason that specification of sub-system performance indicators has not been taken further by other regulators, and are now of mainly historical interest in the US. 10 CFR Part 60 is a generic regulation for geological disposal that dates from the 1980s. By the mid-1990s, it was realised in the

US that this regulation was not appropriate for the proposed geological disposal facility at Yucca Mountain (and it was not used for the WIPP). A review of the technical bases for the Yucca Mountain standards was conducted by the US National Academy of Sciences (NAS, 1995). Consequently, both the EPA (at 40 CFR Part 197; US EPA, 2008) and the NRC (at 10 CFR Part 63; NRC, 2004) developed new site-specific regulations for Yucca Mountain; 10 CFR Part 63 states that:

> "*EPA has established standards for Yucca Mountain that consider risk to a hypothetical individual and are to be the only such standards for the post-closure performance of the repository. This approach differs from that taken in the existing generic criteria, which relies on quantitative sub-system performance standards.*"

In June 2008, the US DOE submitted a license application to the NRC for the proposed geological disposal facility at Yucca Mountain ( US DOE, 2008). As per the new site-specific regulations, this included an assessment of the mean annual dose to a reasonably maximally exposed individual (RMEI) for the 10,000-year period after repository closure, and the median of the total expected annual dose to the RMEI for the post-10,000-year period ending at 1,000,000 years after disposal.

# 3 Safety and Performance Indicators Studied by Participants in WP3.4

This section outlines and discusses, from a regulatory viewpoint, the safety indicators (Section 3.1) and sub-system performance indicators (Section 3.2) studied by the PAMINA participants within WP3.4.

## 3.1 Safety Indicators

The following four safety indicators have been studied by PAMINA participants within WP3.4:

- Dose rate or risk (primary safety indicator).
- Concentration of radiotoxic and chemotoxic elements in the biosphere.
- Radiotoxicity flux from the geosphere to the biosphere.
- Contribution to the power density in groundwater.

Table 3.1 provides more information on the safety indicators, including on their methods of calculation and their reference values. All of the PAMINA participants in WP3.4 consider radiological dose rate to a representative person as the primary quantitative safety indicator, often in relation to a regulatory dose rate constraint. Intermediate quantities, such as radiotoxicity fluxes to the biosphere or concentrations in the biosphere, can be used as complementary safety indicators. We note the following:

- The concept of radiotoxicity is used to compare the combined effects of different radionuclides on human health, in the form of a complementary safety indicator. Dose factors for the ingestion of individual radionuclides can be used as a weighting factor which is related to the potential radiological risk. Radiotoxicity flux (units: $Sv/km^2$) is determined by multiplying the dose factor and activity of individual radionuclides to calculate a weighted sum over all radionuclides (SCK•CEN, 2009).

- Power density provides an approximate measure of the impact of radiation on biota and is independent of assumptions about future human populations (GRS, 2009a).

Interestingly, the quantitative complementary safety indicator that has been established in regulation in the US (40 CFR 191; US EPA, 1993) was not considered within the PAMINA project. As discussed in Section 2, this indicator is expressed in terms of cumulative release of radionuclides to the accessible environment over 10,000 years.

**Table 3.1**: Safety indicators studied by PAMINA participants in WP3.4.

| Safety Indicator | Participant | Method of calculation | Reference Values | Comment | Reference |
|---|---|---|---|---|---|
| **Dose Rate** | All | Based on regulatory limit – see Table 2.1. | See Table 2.1. | Primary safety indicator, specified by regulators (Section 2.2). | |
| **Concentration of Radiotoxic and Chemotoxic Elements in the Biosphere** | NRI | Based on measurements of surface and groundwater activity. | Surface water: 0.16 mSv/m$^3$ Groundwater: 0.05 mSv/m$^3$ (min) 17 mSv/m$^3$ (max) | Converted into dose per cubic metre of water consumed. | NRI, 2008 |
| | Amphos21 | Based on geochemical properties, radiological/ toxicological impact, and availability of data. | Cd, Cr, Ni, K, Ra, Rn, Rb, Se, Th, and U in natural waters. | | Amphos21, 2009 |
| | GRS | Reference value ~one-third of background concentration of naturally-occurring radionuclides in the upper groundwater system. | $2\times10^{-6}$ Sv/m$^3$ | Radiotoxicity concentration in biosphere water (salt host rock). | GRS, 2009a |
| | NRG | Assuming that geosphere flux is discharged into a river, activity concentrations are calculated by dividing the mass release to biosphere by the annual river discharge. | $2\times10^{-5}$ Sv/m$^3$ | Radiotoxicity concentration in biosphere water. Indicator is dependent on assumptions about dilution in the biosphere. | NRG, 2008 |
| | SCK•CEN | Calculated by the SPIN project. Applied to radiotoxicity in biosphere water above Boom Clay. | $2\times10^{-5}$ Sv/m$^3$ | Can be defined without a biosphere model, but is affected by uncertainty in dilution factors. | SCK•CEN, 2009; Storck and Becker, 2004 |

| Safety Indicator | Participant | Method of calculation | Reference Values | Comment | Reference |
|---|---|---|---|---|---|
| **Radiotoxicity Flux from the Geosphere to the Biosphere** | NRI | Minimum and maximum groundwater radionuclide concentrations are multiplied by groundwater run-off rate. | 0.8 Sv/y/km$^2$ (min)<br>5,500 Sv/y/km$^2$ (max) | Uncertainties related to the rate of groundwater run-off. | NRI, 2008 |
| | Amphos21 | Based on geochemical properties, radiological/ toxicological impact and the availability of data. | Cd, Cr, Ni, K, Ra, Rn, Rb, Se, Th, and U in natural waters. | | Amphos21, 2009 |
| | GRS | Reference value ~one-third of flux of naturally occurring radionuclides in upper groundwater system. | 0.1 Sv/y | | GRS, 2009a |
| | SCK•CEN | Derived from the application of phosphate fertilisers in Flanders, range between 2.5 and 15 Sv/km$^2$. | Assuming a facility with an area of 1 km$^2$, the radiotoxicity flux ~10 Sv/y. | Flux can be defined without using dilution in aquifers or rivers; the estimation of relevant reference values introduces uncertainties. | SCK•CEN, 2009 |
| **Contribution to the Power Density in Groundwater** | GRS | Measured activity concentration of every radionuclide (Bq/m$^3$) multiplied by its decay energy (MeV). The reference value is one third of the sum of the power densities of the $^{238}$U, $^{235}$U and $^{232}$Th decay chains. | 25 MeV/(s.m$^3$) | Radiological consequences of the radiation can not be assessed by this indicator. It provides an approximate measure of the impact of radiation on biota. | GRS, 2009a |
| | NRG | Power density in biosphere water, calculated as above. | 80 MeV/(s.m$^3$) | | NRG, 2008 |

In general, reference values are difficult to determine for safety indicators other than dose rate, and the usefulness of such complementary safety indicators should be assessed in the light of whether justified reference values are available (GRS, 2009b). Site-specific and design-specific reference values would normally be needed due to differences in environment, host rock type, design, and background radiation levels.

## 3.2 Sub-system Performance Indicators

In addition to indicators that evaluate the overall safety of a disposal system, some indicators may be determined for the performance of sub-systems. For instance, radionuclide concentrations can be calculated for each engineered barrier or each model compartment (e.g., facility, aquifer, biosphere), and radionuclide fluxes may be calculated through barriers or between compartments. Compartments are design-specific, but tend to be either concentric or serial (along the travel path), and might include waste matrix, waste package, buffer, host formation, aquifer and biosphere.

Unlike safety indicators, the definition of sub-system performance indicators does not require a reference value to be established. Instead, such indicators are used to compare performance of the different compartments, or barriers, of the disposal system, or to make comparisons between design options.

The sub-system performance indicators studied by the PAMINA participants within WP3.4 are as follows:

- Activity in compartments.
- Radiotoxicity inventory in different compartments.
- Radiotoxicity flux from compartments (e.g. from the disposal facility to the geosphere).
- Integrated radiotoxicity fluxes from compartments.
- Time to closure.
- Containment factor.
- Transport time through compartments.

These are described in more detail in Table 3.2. The definition of sub-system performance indicators based on multiple safety functions, as opposed to a multi-barrier system, is discussed by SCK•CEN (2009). Indicators based on "released fractions" were defined for the safety functions that were identified to contribute to the confinement of the radionuclides in the disposal system: containment; limitation of release; and retardation due to migration through buffer and host formation. Sub-system performance indicators based on safety functions were not studied by the other participants in WP3.4 and have not been included in Table 3.2.

In general, safety indicators enable the level of safety of the total system to be assessed, but do not provide information about how the system works. The performance of a disposal system is provided by the individual barriers or compartments of the multi-barrier system, and sub-system performance indicators are quantities describing the behaviour of radionuclides in and between these individual compartments.

Table 3.2 shows that a wide range of sub-system performance indicators is being considered by the participants of WP3.4. The indicators are based on radionuclide activities and concentrations, fluxes, time to closure, containment factor, and travel times within and across model compartments (or components of the disposal system). Indicators of "concentration" can be calculated at different locations within the disposal system and compared with measured natural data. Indicators of "flux" calculated within the disposal system may provide useful information about the effectiveness of the barrier system, especially if compared at different locations, different times, or when comparing the performance of different possible barrier systems. Normalising activities to initial inventories and integrating fluxes over time can give an indication of containment. Note that the PAMINA participants have not made direct use of the only available regulatory-defined sub-system performance indicators (in US NRC 10 CFR Part 60; NRC, 1988), although a wide range of indicators have been considered within the project. One "gap" may be an indicator relating directly to container lifetime.

Sub-system performance indicators can be programme-specific or disposal concept-specific. As such, they should be established by the developer/operator in dialogue/conjunction with the national regulator(s). In particular, regulators should avoid imposing generic criteria for sub-system performance indicators, which may result in a sub-optimal final design. The most appropriate sub-system performance indicators for a specific site and design should be selected by the developer/operator to support/illustrate specific arguments in the safety case; some indicators are more suitable for particular host rock types and designs.

The use of site-specific sub-system performance measures can demonstrate an understanding of sub-system behaviour by showing how different barriers work together and where the radionuclides are retarded or retained. The developer/operator can use them to demonstrate a detailed understanding of the disposal system and, hence, improve confidence in the performance assessment. Furthermore, the identification of sub-system performance criteria by the developer/operator can assist in making choices about site selection and in optimising the design of engineered barriers.

**Table 3.2**: Sub-system performance indicators studied by PAMINA participants in WP3.4.

| Performance Indicator | Participant | Method of calculation | | Comment | Reference |
|---|---|---|---|---|---|
| **Activity in Compartments (Bq)** | SCK•CEN | Activity of radionuclides in each compartment (single radionuclide or sum of all radionuclides). This is time-dependent. | | Useful for investigating the separate behaviours of the different types of radionuclides within a disposal system. | SCK•CEN, 2009 |
| | NRG | As above. | | | NRG, 2008 |
| **Radiotoxicity Inventory in Different Compartments (Sv)** | SCK•CEN | Activity of radionuclide/s multiplied by ingestion dose coefficient for that radionuclide (single radionuclide or sum of all radionuclides). Dose coefficients are used as a weighting factor that is related to the potential radiological risk and allows radionuclides to be summed. | | Useful for all fission and activation products; could use number of moles in compartments for actinides to simplify calculations. | SCK•CEN, 2009 |
| | GRS | The total mobilised radiotoxicity in the compartment. | | | GRS, 2009a |
| | NRI | Radiotoxicity in compartments = sum of (activities in compartment × dose ingestion factors). | | | NRI, 2008 |
| **Radiotoxicity Flux from the Disposal Facility to the Geosphere*** | GRS | Reference value should refer to the activity concentration in the deeper aquifer system above the salt dome. | Flux from geosphere to biosphere used to estimate flux in deeper system. | Limited data available for deeper system. | GRS, 2009a |
| | NRG | Calculated by the SPIN project. | 60 Sv/y radiotoxicity flux to geosphere. | Independent of biosphere pathways and dilution factors. | NRG, 2008; Storck and Becker, 2004 |

| Performance Indicator | Participant | Method of calculation | Comment | Reference |
|---|---|---|---|---|
| **Radiotoxicity Fluxes from Compartments (Sv/y)** | SCK•CEN | Represents the radiotoxicity flux from a compartment (single radionuclide or sum of all radionuclides). | Key radionuclides can be shown individually and values tabulated after 1 million years, or 10 million years for actinides. | SCK•CEN, 2009 |
| | GRS | As above. | | GRS, 2009a |
| | NRI | Sum of (activity flux from one compartment to the next × dose ingestion factors). | Activity flux from compartments can also be calculated. | NRI, 2008 |
| **Integrated Radiotoxicity Fluxes from Compartments (Sv)** | SCK•CEN | The cumulated radiotoxicity flux from a compartment for single radionuclides, as well as summed over all radionuclides. | | SCK•CEN, 2009 |
| | GRS | The radiotoxicity flux from a waste compartment represents the overall flux from the corresponding boreholes in this compartment. | Enables comparison of integrated radiotoxicity fluxes with the initially emplaced radiotoxicity in the waste compartments. | GRS, 2009a |
| | NRG | Amount of radiotoxicity that has been released from a compartment up to a given time, regardless of radioactive decay of these radionuclides after they left the compartment. | Integrated flux compared to the initial radiotoxicity in the waste provides an indication of the level of isolation provided by a part of the barrier system. | NRG, 2008 |
| | NRI | Time integral of each of the previous fluxes. | | NRI, 2008 |

| Performance Indicator | Participant | Method of calculation | Comment | Reference |
|---|---|---|---|---|
| **Time to Closure (y)** | NRG | Measure of the sealing of the disposal cell from the adjacent structures after which any release of radionuclides from the disposal cell will be terminated, particularly for a salt host rock. | Only applicable to designs that are equipped with compacted salt sealing plugs. Included in activity and radiotoxicity flux from compartment performance indicators. | NRG, 2008 |
| **Containment Factor** | SCK•CEN | Radiotoxicity released from host formation divided by radiotoxicity in disposed waste. | | SCK•CEN, 2009 |
| **Transport Time through Compartments (y)** | SCK•CEN | Transport times can be compared with the radionuclide half-life to estimate whether or not the radionuclide will largely decay within a compartment. | It is not easy to calculate, because a concentration front is normally spread during the transport, and it is difficult to define unique points of time for entering and leaving the compartment, especially if radioactive decay plays a role during the transport time. | SCK•CEN, 2009 |
| | NRG | Transport time through compartments quantifies the capability of the barriers to delay the release of radionuclides. | | NRG, 2008. |
| | NRI | Time of maximum chemical outflux from the compartment – time of maximum chemical influx to the compartment. | Compared with radionuclide half-life. | NRI, 2008 |

* Some participants in WP3.4 considered “Radiotoxicity Flux from the Disposal Facility to the Geosphere” to be a safety indicator, whereas GSL considers it to be a sub-system performance indicator as it does not provide an indication of the safety of the system as a whole.

# 4 Summary

Regulators establish criteria for primary safety indicators, such as dose rate or risk, which the developer/operator uses as reference values in safety assessment. International guidance recommends the use of complementary safety indicators to support dose rate and/or risk indicators to strengthen the safety case. However, there is relatively limited regulatory guidance at the national level and only two cases (the US Waste Isolation Pilot Plant and Finland) of the regulation of geological disposal facilities being based on use of complementary safety indicators as performance measures. Regulations in the UK specify that complementary safety indicators should be presented in the safety case, but do not provide quantitative criteria.

With regard to sub-system performance measures, only the US regulator developed requirements (NRC 10 CFR Part 60); this regulation is no longer in use. Generic sub-system performance measures, such as those in 10 CFR Part 60, can be over-prescriptive and could result in a sub-optimal disposal system design.

PAMINA participants in WP3.4 studied the application of safety and performance indicators to geological disposal facilities in clay and salt host rocks. All participants consider radiological dose rate as the primary safety indicator, in relation to a regulatory dose rate constraint. A number of site-specific and concept-specific reference values have been developed for complementary safety indicators of the types “flux” and “concentration”. Similarly, a range of sub-system performance indicators, based on radionuclide activities and concentrations, fluxes, time to closure, containment factor, and travel times within and across model compartments (or components of the disposal system) has been used in the programmes reviewed.

It is clear that the PAMINA participants in WP3.4 are generally currently exceeding the requirements concerning the use of safety and performance indicators set out by regulators, most of whom currently only specify a primary safety indicator (dose rate or risk).

In terms of developing the regulatory requirements in this area, it is important to note that reference values are difficult to determine for safety indicators other than dose rate, and that site-specific reference values would normally be needed due to differences in environment, host rock type, facility design, and background radiation levels. Similarly, sub-system performance indicators can be programme-specific or disposal concept-specific, such that the specification of generic criteria for sub-system performance indicators, which may result in a sub-optimal final design, should be avoided.

If regulatory criteria are specified for complementary safety indicators, they are likely to be back-calculated from the criteria from dose rate or risk. This calculation requires the regulator to develop generic, stylised biosphere assumptions In this case, the developer/operator does not need to model the biosphere to demonstrate compliance with the regulatory criteria. As an alternative, the regulator may specify that the developer/operator should use site-specific stylised biosphere assumptions or bounding scenarios to back-calculate a particular complementary safety indicator, for comparison with the results of safety assessment calculations. Whether the regulator or the developer/operator calculates the criteria for complementary safety indicators, the assumptions relating to future populations and biosphere environments are inherent, but are presented separately from the safety assessment calculations.

Regulatory decisions on the acceptability of a disposal system are unlikely to be based on safety assessment calculations alone, due to the very long timescales involved. It is likely that complementary lines of reasoning that demonstrate an understanding of the performance of compartments or barriers during the evolution of the disposal system will also be required. Sub-system performance indicators allow developers/operators to demonstrate a detailed understanding of the disposal system, and their inclusion in the safety case will therefore assist the regulatory decision-making process.

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