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REVIEW OF EXISTING FULLY PROBABILISTIC ASSESSMENTS: THE REGULATOR'S PERSPECTIVE ON THE PSA APPROACH
MILESTONE (N°: M2.2.E.5)

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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 2.

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

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1. Introduction

Addressing uncertainties in safety cases and in particular in safety and performance assessments for radioactive waste disposal facilities is an issue of utmost importance [1]. Uncertainties "… are unavoidable due to the complexity of the phenomena of concern and the scales in time and space under consideration, and their management is central when developing a repository system and assessing its safety." [2]

Uncertainties might either be caused by the stochastic nature of the phenomenon under consideration and its statistical variation (aleatory uncertainty, stochastic uncertainty, type A uncertainty, variation, variability, stochastic variation, statistical inexactness, part of the risk under consideration) or by the lack of knowledge about a phenomenon (epistemic uncertainty, subjective uncertainty, type B uncertainty, imprecise knowledge/ignorance, inexactness due to human judgement, uncertainty in the determination of risk).

It is, however, not always easy and straightforward to decide for a specific uncertainty to which of these categories it belongs. Furthermore, some safety assessors consider such a categorisation not to be relevant and/or helpful and prefer a more pragmatic categorisation which is orientated on the specifics of safety assessment: Uncertainties may

- arise "from an incomplete knowledge or lack of understanding of the behaviour of engineered systems, physical processes, site characteristics and their representation using simplified models and computer codes",

- be "associated with the values of the parameters that are used in the implemented models", or

- be "associated with significant changes that may occur within the engineered systems, physical processes and site over time" [1].

In the first case, uncertainties are often referred to as model uncertainty, in the second as parameter or data uncertainty, and in the third as scenario or system uncertainty. It has to be noted that, to some extent, the decision about the belonging of an uncertainty to one of these classes is dependent on the structure of the assessment and the preferences of the assessor.

In the framework of a safety case, one of the roles of safety assessment is to inform about the existence of uncertainties and their significance with regard to safety. Based on this information, uncertainties might either be ignored (accepted), reduced by research or investigation efforts, or mitigated / avoided by siting or design measures [2] when proceeding to the next step of repository and safety case development. If a safety case is being prepared in order to support or inform a regulatory decision (e.g. as part of a license application), the regulator has to make this decision in the presence of uncertainties and will therefore request information about their existence and significance [3].

Quantitative statements about uncertainties and their effects are considered to be helpful when making such regulatory (or other) decisions in a repository programme. Traditionally and due to the well-developed toolbox of stochastic and statistical methods, probabilistic approaches are most often used when striving for such quantification in safety assessments. There are, however, ongoing discussions about the adequacy and legitimacy of such approaches especially (but not only) when addressing epistemic uncertainties [4][5] as well as on the value of mathematical methods other than probabilistic ones (e.g. interval analysis, fuzzy arithmetic, possibility theory) either on their own or in combination (hybrid methods) [5][6]. Nevertheless, most of the recent (and of the older) rely either on deterministic or on probabilistic approaches[1] or on a combination of the two while the other methods mentioned above are rarely being used. Amongst those assessments using probabilistic approaches there is wide variation with regard to the nature and range of uncertainties being addressed by probabilities or probability density functions. In fact, it is rarely the case that "all" uncertainties are being addressed probabilistically ("all" meaning not all uncertainties which exist but all uncertainties accounted for in the assessment). Strictly spoken, each otherwise probabilistic assessment in which more than one scenario and/or more than one modelling alternative is being used without assigning probabilities to these scenarios or models can be considered an assessment using a "combined" (deterministic-probabilistic) approach.

The subject of this report are, however, assessments in which this is not (or almost not) the case. The idea to of performing such "fully" probabilistic assessments has been promoted as early as in the 80ies and 90ies of the previous century [7][8][9]. An early attempt to carry out such an assessment – interestingly undertaken by a regulatory organisation – was the so-called "Dry Run 3" exercise [10]. Here, the evolution of climate – considered as crucial for the future evolution of the system – had been sampled using Markov chain models and "ordinary" parameter sampling. The climate data were than input for a "classical" PA model which was supported by process modelling and the input parameters of which were also sampled.

An important driver for this exercise was apparently the regulation valid at that time in the UK [11] which asked for the presentation of individual annual risk of serious cancer, and the wish to present this calculation endpoint comprehensively as a function of time. In favour of the

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1 Note that the notions "deterministic" and "probabilistic" are not always being used in an unmistakable way. Here, by "deterministic" we mean the exploration of selected uncertainties by performing calculations according to designs developed in a "targeted" way. The assessor asks specific questions and performs a limited number of calculations in order to address these questions. Thus, he acts "locally". In contrast, there are "global" methods which aim at exploring the whole space of quantifiable uncertainties at the same time, thus specifically asking for the effects of combinations of uncertainties. Interval analysis, fuzzy arithmetic, possibility theory and others might be theoretical bases for such methods but if such a method is based on the assumption that the uncertainties under consideration can be expressed by probabilities or probability density functions, we call it "probabilistic". Thus, we would call assessments according to a fractional factorial design "deterministic" or "local", assessments using a full factorial design "global", but not "probabilistic". Accordingly, latin hypercube designs, if using probabilities or probability density functions, would be called "probabilistic" even if they were based on median (i.e. deterministically chosen) values for the parameter intervals under question.

approach (as opposed to so-called "scenario-based methods" which apparently were seen as its antithesis), it had been argued that

- the existing scientific knowledge was used better and more explicitly and in a way less dependent on subjective judgements about future system evolution,
- the utilisation of well-defined models allowed a better dispute in the case of scientific criticism and a better verification, and
- the approach resulted in a traceable quantified description of potential future evolutions.

Since then, a number of assessments has been carried out in different regulatory environments and by different organisations under the labels "Total System Simulation", "Environmental system simulation", "System Simulation Approach", or "Probabilistic System(s) Assessment (PSA)" in which the above mentioned idea of "fully" accounting for uncertainties by means of probabilistic approaches has been implemented to a varying extent. In the framework of the PAMINA project, an integrated approach to a fully probabilistic safety assessment is being developed and tested. Here, the idea is to account for parameter, model, and scenario uncertainties by probabilities or probability density functions in the case of co-existing phenomena, but to address alternative conceptualisations by weighted branches of a logic tree.

The report presented here compiles the outcome of an exercise undertaken in PAMINA in parallel to the above mentioned development: Existing "fully" probabilistic safety assessments were compiled and evaluated from a regulatory perspective, asking questions such as

- What was the aim and purpose of the assessment? Was it part of a safety case? If so, which programme decisions were supported by this case?
- In which regulatory environment has the assessment been undertaken? What were the required calculation endpoints? Were they defined as limits, targets, or constraints? Were there prescriptions concerning assessment timeframes, the scenarios to be studied, and / or the methodologies to be applied?
- Which scenarios were covered by the assessments, which were (implicitly or explicitly) excluded? How were scenarios developed? How were likelihoods of occurrence derived? Was a completeness or comprehensiveness of the scenario set claimed and, if so, how was that substantiated?
- How were model uncertainties addressed? More generally, how were uncertainties coming from lack of knowledge treated? Which model simplifications had to be made and how ere they justified?
- How were probabilities or probability density functions derived and justified?
- Was risk dilution explicitly addressed? If so, how?
- How and to which audience were the results presented?
- How did the regulator and / or decision-maker reply to the assessment?

The report summarises rules and regulations with a view to their compatibility with "fully" probabilistic approaches and their potential to encourage or discourage such approaches, reports on selected cases and discusses them with regard to their ambitions and to the fulfilment of regulatory requirements or expectations. The selection of assessments to be accounted for in this report remains, given the above mentioned varying extent to which probabilistic methods had been used, by nature to some degree subjective. The following assessments have been selected:

- The above mentioned "Dry Run 3" exercise [10] carried out by the UK HMIP in the early 90ies because it represents the first attempt to thoroughly perform a fully probabilistic assessment and probably even today can be seen as the most consequent implementation of a fully probabilistic assessment,
- the assessments carried out by the U.S. DoE in support of the applications for certification [12] and re-certification [13] of the Waste Isolation Pilot Plant (WIPP) and of the license application for the Yucca Mountain Repository [14] due to their particular approaches to deal with aleatory and epistemic uncertainty in probabilistic assessments,
- the Swedish SR-Can assessment published by SKB in 2006 [15], which dealt with a risk criterion using an assessment approach in which deterministic and probabilistic methods were combined and which is, compared to other recent assessments, one rather heavily relying on probabilistic techniques.

2. Regulations and fully probabilistic assessments

2.1 General issues

The current national regulations are less focussed and less prescriptive on assessment issues than older ones. These days, more emphasis is being put on other, more general issues such as the safety case in general, technical requirements, and issues of optimisation and best available technique (BAT). Nevertheless, requests for compliance of numerical assessment results still form a central part of regulations. So do requests to appropriately address uncertainties.

The way in which this is being requested varies but of course all rule-makers are interested in comprehensiveness of the assessment cases. The attitude towards probabilistic assessment methods in regulations varies.

2.2 International guidance

The final disposal of radioactive waste and spent nuclear fuel is in most countries currently considered a national duty. As there are many national particularities to consider (legislative and regulatory framework, assignment of responsibilities, funding issues, status of the development of the disposal programme, disposal strategy, choice of host rock, involvement of the public,...) an international regulatory framework has not been established. Especially the IAEA offers internationally accepted safety standards and regulatory guidance in this topic, so that most national regulations draw from these international guidances or explicitly refer to them, however there is no all-embracing standard to be followed.

The Safety Requirement WS-R-4 “Geological Disposal of Radioactive Waste” [16] is of special interest. This report was jointly sponsored by the Nuclear Energy Agency (OECD/NEA). IAEA guidance itself evolves – e.g. the IAEA Safety Requirements WS-R-4 “Geological Disposal of Radioactive Waste” are presently being replaced by a more general document addressing all kinds of radioactive waste disposal, and the supporting guidelines are being developed in parallel[2]. The OECD/NEA radioactive waste management committee also reports frequently on the progress made in the regulation and implementation of geological disposal.

The International Commission on Radiological Protection (ICRP) publishes recommendations and advice on radiological protection. The legislation in most countries adheres closely to these ICRP recommendations on radiation effects, doses from radiation exposure, and on protection of the environment. As these recommendations are updated frequently in order to account for the state of science, the national regulations are not always implementing the latest set of recommendations.

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[2] http://www-ns.iaea.org/standards/documents/default.asp?sub=170

The Western European Nuclear Regulators Association's (WENRA) Working Group on Waste and Decommissioning (WGWD) presently attempts to develop so-called "reference levels" for radioactive waste disposal (http://www.wenra.org) but this work is still at its very beginning.

Especially IAEA's WS-R-4 as well as its to-be successor DS354 "Disposal of Radioactive Waste" and the planned supporting Safety Guide DS355 "The Safety Case and Safety Assessment for Radioactive Waste Disposal" refer to the issue of handling uncertainties in assessments. WS-R-4 remains rather general by saying:

"Safety assessment includes quantification of the overall level of performance, analysis of the associated uncertainties and comparison with the relevant design requirements and safety standards."

"Sensitivity analyses and uncertainty analyses will be undertaken to obtain an understanding of the performance of the geological disposal system and its components under a range of evolutions and events."

The issue of applying probabilistic techniques is not mentioned in WS-R-4. The supporting guide DS355 (under development) will most likely advocate a combination of deterministic and probabilistic techniques.

2.3 National regulation

As already mentioned the different national regulations are in different stages of development, mirroring the status of the disposal projects. Hence they offer a wide variation in the level of detail of requirements concerning the handling of uncertainties and the use of deterministic and/or probabilistic techniques when performing assessments in the frame of an application. A short introduction to the regulatory context is found in PAMINA Milestone 1.2.1 [1], chapter 3.2. Here three kinds of different regulatory approaches to the treatment of uncertainty are identified:

1. Prescribed methods for the treatment of uncertainty,
2. Detailed regulatory guidance with only objectives defined,
3. No particular national guidance.

Some of the national regulations for the disposal in deep geological formations are or were in the process of review, so we address in the ensuing sections aspects related to new developments which are not included in PAMINA Milestone 1.2.1 [1]. Other important regulatory issues will be reported in the second sub-chapters of each -chapter of section 3 of this report (i.e. sub-chapters 3.x.2).

2.4 Treatment of uncertainty

With respect to the treatment of uncertainty, let us quote from the following regulations and guidances which have been or are being updated since the publication of Milestone 1.2.1.:

The Section 7 of the Swiss ENSI G03-2009 [17] states with respect to treatment of uncertainty:

“Uncertainties in the data, processes and model conceptions as well as in the future development of a deep repository are inevitable. As far as necessary, uncertainties are to be reduced by research efforts or by data acquisition. Where uncertainties persist the maximal radiological consequences have to be estimated in the safety analysis by computation of enveloping variants by or conservative assumptions.

The influence of uncertainties on the computed results is to be demonstrated systematically, and the conclusions drawn for long-term safety are to be presented.” (unauthorised translation)

In Section 7.2 of the German Safety Requirements/Sicherheitsanforderungen [18] we find

“Prior to any major decision [pursuant to chapter 5.1], a comprehensive, site-specific safety analysis and safety assessment covering a period of one million years must be carried out to provide evidence of long-term safety. This shall comprise all information, analyses and arguments verifying the long-term safety of the final repository, and shall justify the reasons why this assessment is to be trusted. In particular, this assessment and the documentation thereof should include [...] the representation and implementation of a systematic strategy for the identification, evaluation and handling of uncertainties.”

The UK “Guidance on Requirements for Authorisation” for “Geological Disposal Facilities on Land for Solid Radioactive Wastes” 2009 [19], section 7, states closely following the European Pilot Study [2] that

“The developer/operator will need to demonstrate that the environmental safety case, for both the period of authorisation and afterwards, takes adequate account of all significant uncertainties. This will mean establishing and maintaining:

- a register of significant uncertainties;
- a clear forward strategy for managing each significant uncertainty, based on considering, for example, whether the uncertainty can be avoided, mitigated or reduced, and whether it can reliably be quantified.”

All of these approaches are of the above-mentioned type 2, there is no prescribed way to handle the uncertainty.

For comments on the regulatory environment in countries including USA, Canada, France, Belgium, and Japan, see PAMINA Milestone 1.2.1 [1]. Except for the US regulation they can also be categorised as belonging to the above-mentioned type 2.

A regulatory approach of type 1 is found in the US regulation, as laid down by the guidance of the Environmental Protection Agency (EPA) and of the Nuclear Regulatory Commission (NRC). An overview of the US nuclear regulation can be found in [20], for further discussion cf. section 3.2.2. The details of how these regulations were implemented into a probabilistic model of calculating the expected dose can be found in [21] and [22], cf. also section 3.2.

2.5 Primary performance measure

In most national regulations, a dose based approach is used to specify the primary performance criterion (calculation endpoint, safety indicator). A second group of regulations uses a risk-based approach to quantify the long-term performance of the repository. In Table 1, which is reproduced from an evaluation carried out by OECD/NEA, an overview is given. More recent developments include the ones in Canada ([23], reported as “under development”) France ([24], numerical criteria not changed), Germany ([18], lifetime risk of 10^{-4} for likely and of 10^{-3} for less likely scenarios, under development), Japan (no reference available), and the U.K. ([19], risk guidance level after the period of authorisation, i.e. the period of passive safety of 10^{-4} per year).

Table 1 National Dose and Risk Criteria for Disposal of Long-lived Waste in Different Countries (from [25])

Belgium	Dose constraint: 0.1 to 0.3 mSv/yr. Risk constraint: 10^{-5}/yr. (Note: Working values in absence of regulatory values.)	Dose constraint relevant to high probability scenarios and risk constraint to lower probability scenarios.		SAFIR 2.	**Belgium**
Canada	Under development: Interim dose constraint of up to 0.3 mSv/yr for design optimisation as recommended by ICRP & IAEA.	Guidance on timescales, institutional control and other indicators is also under development. A public dose criterion of 1 mSv/yr is used for evaluation of human intrusion scenarios.	Under development		**Canada**
Czech Republic	Dose constraint: 0.25 mSv/yr	Disposal site should provide a natural barrier that assists in keeping the radiological impact to human and the environment within acceptable levels. Safety analysis are required for release scenarios that cannot be excluded.	10^{-5}/yr – scenarios with lower probability need not to be considered in the safety analysis	Decree: No. 307/2002 on radiation protection No. 215/1997 on sitting of nuclear facilities	**Czech Republic**
Finland	Dose Limit: 0.1 mSv/yr for normal evolution. For unlikely events, impact assessed against risk equivalent to dose limit.	Release of radionuclides into human environment to be less than nuclide-specific constraints. Dose/risk constraint applies for several thousand years. RN release limitation applies for longer.	Unlikely events assessed quantitatively where practicable, otherwise by qualitative discussion. Deterministic, conservative analyses with assessment of implications of uncertainties.	Govt. Decision: 478/1999. Guide: YVL 8.4.	**Finland**
France	Dose Limit: 0.25 mSv/yr for normal evolution.	Dose limit applies for 10^{4} yrs, and is a reference for later periods. Institutional monitoring assumed to prevent human intrusion before 500 yrs.	Random, unanticipated events subjected to case-by-case judgement, including glaciations after 50 000 years.	RFS III 2f	**France**
Germany	In order to provide adequate protection of man and the environment, the criteria define the individual dose as the main safety indicator for the post-closure phase. The analysis has to show that an individual dose limit of 0.3 mSv/a will not be exceeded. Currently, the Safety Criteria for the disposal of radioactive waste are being revised. The revised criteria will take into account recent international developments in waste disposal as well as concerning the structure, content and presentation of the post-closure Safety Case.	The Safety Criteria for underground disposal require proof that the site under consideration has favourable mechanical, technical and hydro-geological properties. Safety analysis required for all radionuclide release scenarios that cannot be completely excluded. Demonstration of safety required for period of one million years. Use of further indicators has been required in licensing procedures.	Safety case with uncertainty analyses (requirements during licensing procedures). Presumes knowledge of repository for 500 years, and no human intrusion before then. Targets for individual dose are defined for different classes of likelihood of occurrence. (Derived from natural background radiation variation.) This approach has been chosen, amongst other reasons, in order to avoid conceptual problems linked with the risk concept for long time frames.	Atomic Energy Act of December 23, 1959 (last Amendment April 22, 2002) Safety Criteria for the Final Disposal of Radioactive Wastes in a Mine; 1983,	**Germany**
Hungary	Dose Limit: 0.1 mSv/yr. Risk Limit: 10^{-5}/yr, for impact of individual disruptive events.	The consequences of individual disruptive events shall be evaluated using probabilistic analysis.	In probabilistic analysis, events with likelihood of occurrence of less than 10^{-7} event/year may be neglected.	Decree: 47/2003 (VIII.8) ESZCSM	**Hungary**
Japan	(Under development)				**Japan**
Korea Rep. of	Dose limit : 0.1 mSv/yr for normal evolution Risk limit : 10-6/yr for probabilistic disruptive events	A public dose criterion of 1 mSv/yr is applied for human intrusion scenarios.	Under development	MOST Notice 2005-17	**Korea Rep. of**
Netherlands	Dose Limit: 0.1 mSv/yr, (Optimisation goal: 0.04 mSv/yr), for normal evolution.			1st Report, 2003, under Joint Convention on Waste/Spent Fuel.	**Netherlands**
Norway	(Not available)				Norway

Country	Target Limit of Impact (Most exposed individuals)	Other Limitations or Conditions
Slovakia	Under development – for radioactive waste that contains significant levels of radionuclides with half-lives greater than 30 years	Dose limit 0.1 mSv/yr. (normal evolution scenarios) and 1 mSv/yr. (intruder scenarios) – for low level and intermediate level radioactive waste with limited content of radionuclides with half-lives greater than 30 years.
Spain	Dose Limit: 0.1 mSv/yr. Risk Limit: 10^{-6}/yr. Under revision, according to the ICRP 81	Dose limit relevant to high probability scenarios and risk limit to lower probability scenarios. General criteria for site selection.
Sweden	Risk Limit: 10^{-6}/yr. (Dose/risk conversion factor of 0.073 Sv^{-1} to be used.)	Biodiversity and biological resources also to be protected against the effects of ionising radiation. Quantitative assessment, including collective dose, to be made for the first 1 000 yrs. For period beyond 1 000yrs, general consideration of various possible scenarios for evolution of the repository's properties, its environment and the biosphere (SSI). A safety assessment shall comprise as long time as barrier functions are required, but at least 10 000 years.
Switzerland	Dose Constraint: 0.1 mSv/yr. Risk Target: 10^{-6}/yr.	Dose constraint relevant to high probability scenarios and risk target to lower probability scenarios. (Valid for all time.) Complete containment for 1 000 years.
United Kingdom	Dose constraint: 0.3 mSv/yr. Risk target: $<10^{-6}$/yr. (Dose/risk conversion factor of 0.06 per Sv to be used for dose-rates less than 0.5 Sv/a)	Dose constraint applies to period before control is withdrawn. Risk target to longer periods. Required to show that radionuclide releases are unlikely to lead to significant increase in levels of radioactivity in the accessible environment.
USA (Yucca Mountain)[1]	Dose Limit (no human intrusion): 0.15 mSv/yr. (Equivalent to fatal cancer risk of $8.5*10^{-6}$/yr using conversion factor of 0.0575 cancers per Sv). Dose Limit (after human intrusion): 0.15 mSv/yr as result of a human intrusion at or before 10^4 yrs after	Detailed restrictions apply for 10^4 yrs to radionuclide concentrations in groundwater. Compliance with quantitative dose limit required for 10^4 yrs. Requirement to calculate peak dose if it occurs later, (up to 10^6 yrs, i.e. the assumed limit of geologic stability), but the quantitative standard does not apply beyond 10^4 yrs.
IAEA	Dose constraint: 0.3 mSv/yr. Risk constraint: 10^{-5}/yr.	

Approach to Handling of Probability or Uncertainty	References	Country
	Decision of Chief Hygienist (1988)	**Slovakia**
	CSN Decision on the Proposal of the 1st General Radioactive Waste Plan, approved in 1997. CSN Report to Parliament, 2nd semester 1985. 1st Report, 2003, under Joint Convention on Waste/Spent Fuel.	**Spain**
Uncertainties in the description of the functions, scenarios, calculation models and calculation parameters used in the description as well as how variations in barrier properties have been handled in the safety assessment must be reported, including the reporting of a sensitivity analysis which shows how the uncertainties affect the description of barrier performance and the analysis of consequences to human health and the environment	SSI FS 1998:1 SSI FS 2005:5 SKI FS 2002:1	**Sweden**
For long-term dose calculations: – Reference biospheres. – Population with realistic habits. – Conservative assumptions.	HSK R-21	**Switzerland**
Presentation of information on risks to include desegregation of probability and consequences, where practicable.	Environment Agency "GRA" Document, 1997 (EA, SEPA, DoE(NI)).	**United Kingdom**
10^{-8}/yr cut off for consideration of events/scenarios. (Corresponds to ≈ 10^{-4}/10 000 yrs for post-closure period.)	40 CFR Part 197, as implemented in 10 CFR Part 63	**USA**
Multiple lines of reasoning, e.g., based on natural analogues and paleo-hydrological studies of site and host rock	Safety Requirements currently in draft.	**IAEA**

1. In 2005, certain changes were proposed to the Yucca Mountain standards at 40 CFR Part 197. These changes would extend the period over which a quantitative dose limit applies, out to the estimated time of geologic stability at Yucca Mountain, approximately 1 million years. The dose limits for the first 10 000 years after disposal would remain as shown in the table. The proposed rule would establish a new dose limit of 3.5 mSv/year for the period from 10 000 years to 1 million years for undisturbed performance and, separately, in the event of human intrusion. These limits would assure that any people living near Yucca Mountain up to 1 million years in the future would not receive total radiation doses that exceed natural background radiation levels in comparable geographic and geologic regions. The groundwater standard would not extend beyond 10 000 years. For more details on the proposed rule, visit: www.epa.gov/radiation/yucca. The changes have not yet been made final

The perception is that dose-based regulations are asking for deterministics and risk-based regulations ask for probabilistics is not necessarily true:

On one hand, an implementer can calculate dose values in probabilistic assessments. He runs, however, into problems if (as to be expected) some realisations lead to results violating the numerical criteria and if the regulation does not account for such a possibility. In a risk-based regulatory environment, such a situation in itself is not a problem even if the regulation does not mention this possibility: Risk, interpreted as the mean of the "risk distribution", might remain below criteria even if a considerable number of single calculations lead to values higher than the criterion. The assessment, however, remains unsatisfactory if the uncertainty of the results is not properly addressed: The informed regulator will ask for variation, uncertainty in results, risk dilution and related issues even if these are not addressed in written regulations.

On the other hand, even a risk criterion does not necessarily mean a request for a probabilistic assessment: The assessor can present a risk estimate solely based on deterministic calculations using the scenarios, their likelihoods, the resulting doses and conditional risks, and the dose-risk relationship (or upper bounds for these entities, e.g. unity for scenario likelihoods).

In both cases, the regulator probably only will be satisfied if

- the assessment and its documentation enables him to understand where the uncertainties comes from and what their implications are, and
- he can be reasonably assured that the "uncertainty space" (including correlations, dependencies, and interactions) has been reasonably well explored.

The former is best addressed by a well-structured documentation and a disaggregated presentation of results even in the case of a "fully" probabilistic assessment. "Black boxes" are to be avoided.

For the latter, a probabilistic assessment certainly helps as long as it remains manageable and understandable ("the fuller the better" – but there are limits which were explored in another part of PAMINA WP 2.2.E). Care must, however, be taken when probability density functions (pdf's) or likelihoods of occurrence for scenarios are not sufficiently well justified. The probabilistic assessment might still be valuable because it informs about the uncertainty space in the sense that possibilities and their consequences are well explored. The assessment will, however, not be informative about probabilities to be assigned to subsets of this space (and thus to consequences associated with these subsets). It remains an open question how that can be addressed in regulations (or whether it should be at all addressed). In regulatory environments in which discussion, qualitative appreciation etc. (i.e. common sense) plays a higher role, this is not necessarily a problem. It might, however, be a problem in environments which are, by tradition, very much focussed on formal compliance. In these latter cases, the only way out are detailed regulations (e.g. on scenarios, likelihoods, statistics to be used etc.) which might be perceived to be too prescriptive in other environments.

In the context of risk-based regulation one has to consider the problem of risk dilution, i.e. the possibility that calculated risk (mean) values decrease when assigning a higher degree of uncertainty to the input parameter distributions. In particular this might become an issue when considering initiating short-term events which might happen at any point of a long time interval (e.g. earthquakes) – the expected (mean) consequence for an individual placed at an arbitrary point of the assessment time interval decreases when increasing the time interval over which the initiating effect might happen (the “victim’s perspective” as opposed to the “culprit’s perspective” of the implementer who has to avoid harm at any time of the assessment timeframe, cf. [26]. Swedish (SSI) guidance is amongst the few in which this issue is explicitly addressed, cf. section 3.3.6.

It is moreover a concern that high probability/low impact and low probability/high impact scenarios are attributed to the same level of risk. Rothstein et al. (2006, [27]) comment on this problem, that in this case ”symmetrical regulatory action may create normative conflicts. That is because whilst the manifestation of high probability/low impact risks may be socially or politically tolerable, the manifestation of low probability/high impact risks may be intolerable, even though from a risk-based perspective the collective consequences are identical. Such asymmetry of social and political consequences may account for differences in the role that risk-based decision-making plays within contaminated land and radioactive waste disposal.” In order to address the intolerance against low probability/high impact risks (“risk aversion”) it is sometimes suggested to replace the usual formula “probability times consequence” by others assigning more relative weight to higher consequences.

3. Fully probabilistic assessments: Selected cases

3.1 HMIP Dry Run 3

3.1.1 Aim, purpose, scope, and general description of the assessment

"HMIP Dry Run 3" can be considered a "regulatory demonstration exercise". The report names the demonstration of "a time-dependent probabilistic risk assessment (PRA) procedure that accounts for uncertainties associated with possible future evolutions" and of "systematic, traceable methods of handling information", to provide "comprehensive structured documentation acting as a template for future assessments of real sites" as well as the provision of "a basis for estimating the timescales and resources requires for a real assessment" as objectives. Thus, it can be interpreted that the exercise was aimed at two targets: The assessment capabilities of the regulatory organisation were tested and demonstrated, but, of course, such an exercise is also an expression of regulatory expectations concerning later applications.

The facility under consideration was a hypothetical deep LILW repository at Harwell. The exercise is clearly restricted to assessment and modelling issues; there were no ambitions to build a comprehensive safety case. Consequently, issues beyond the assessment reported in [10] are restricted to data collation and even this information is, at least in the main report, very brief. It can be guessed that there are two reasons for this: (i) The scope of the exercise was clearly restricted to assessment issues, and (ii) the exercise had been carried out at a time at which the concept of a safety case as it is known today was only in the early stage of its development.

In addition it should be mentioned that the authors not believed the exercise to be a "full" assessment; they mention a number of issues (related e.g. to hydrogeological and chemical modelling, expert elicitation, integrated modelling) which were not comprehensively addressed due to purpose of the assessment as well as due to limited resources and practical reasons.

According to the ideas presented in [7], process analysis and modelling took place at different levels of abstraction (cf. section 3.1.4 of this report), the third (highest) of which is of major interest for the issue addressed in this report: At this level, an integrated climate and PA model had been run in a deterministic, but also (as central part of the exercise) in a fully probabilistic framework. The overall assessment flowchart is given in Figure 1.

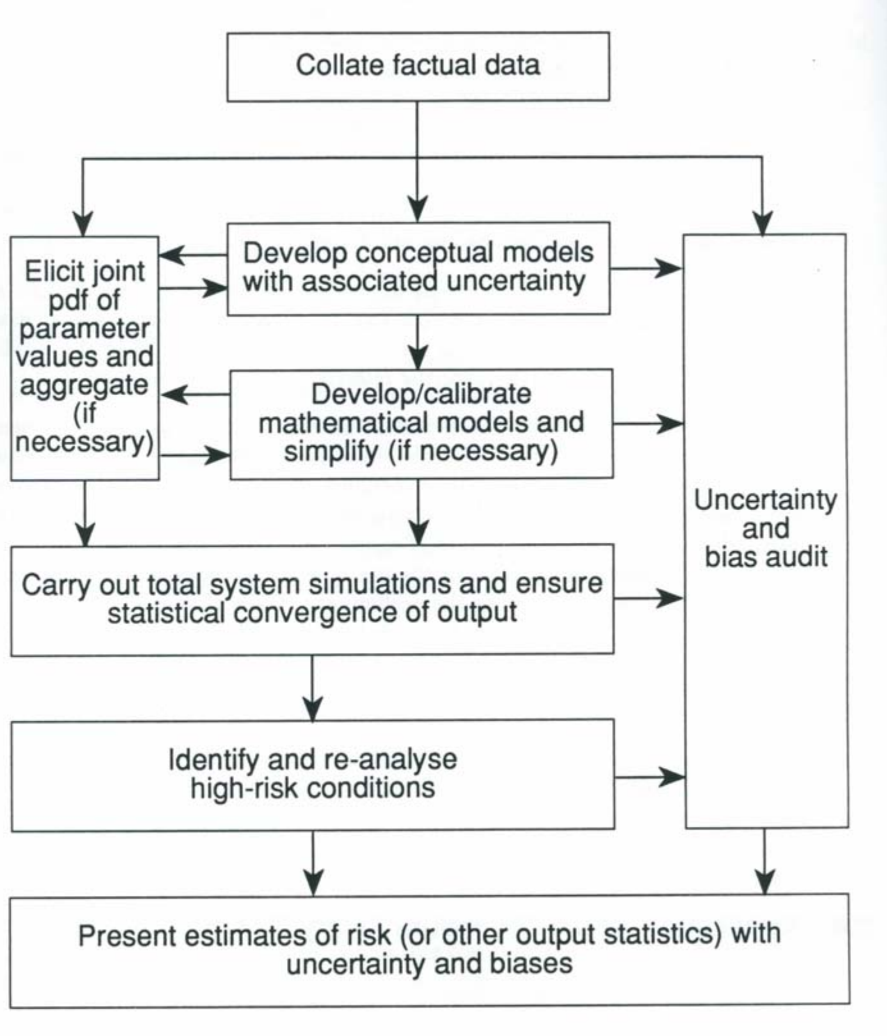

Figure 1 Assessment flowchart in “HMIP Dry Run 3” (from [10])

3.1.2 Regulatory environment

The relevant regulation in force at the time at which “HMIP Dry Run 3” had been produced, the “Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Principles for the Protection of the Human Environment” [11], required the presentation of total risk of “risk or probability of fatal cancer, to any member of the public, from any movement of radioactivity from the facility” and the choice of the site and the facility’s design that this risk “is not greater than 1 in a million in any one year”. In a DoE report [28] which, under the circumstances, can be interpreted as regulatory guidance, it has been concluded that the mean annual risk to an individual for low doses and dose rates to which a linear dose-risk relationship applies can be calculated by

$$\overline{R}(t) = \gamma \int_{\Omega(\vec{x})} p(\vec{x}) \cdot H(\vec{x},t) \cdot dx$$

with

$\overline{R}$ mean annual risk,

t time,

γ ICRP factor (for “HMIP Dry Run 3” 0.0165 Sv^{-1}),

$p(\vec{x})$ joint probability density function,

$\vec{x}$ parameter vector,

$\Omega(\vec{x})$ multi-parameter domain, and

H effective dose equivalent.

3.1.3 Scenarios considered

The “HMIP Dry Run 3” report contains clear statements about the perceived drawbacks of the “scenario approach” which are in line with the ones reported about in section 0 of this report. Furthermore, abstaining from the “scenario approach” was motivated by necessity “to investigate the full range of possible repository and environmental developments, and to assign probabilities coherently so that consequences can be combined” in order to demonstrate compliance with the risk criterion. In other words, the regulatory boundary conditions and namely the risk constraint were a main driver for choosing the assessment methodology.

Insofar, it seems somewhat unreasonable to report about “scenarios” in connection with the “HMIP Dry Run 3” assessment. Nevertheless, the assessment was of course based on a conceptualisation of future evolution(s) of the system: The central hypothesis was that climate evolution would be decisive for the evolution of the disposal system. Consequently, climate changes (in particular glacial cycles) were sampled based on Markov chain models addressing the transition probabilities between climate types (temperate, boreal, tundra, glacial). Within these climate types, precipitation rates were sampled and the impact on erosion, sea level, and the hydrologic cycle, were analysed. This climate modelling was carried out using a code named TIME4[3]. Tectonic, biogenic or anthropogenic effects were not accounted for. The data produced by TIME4 then served as input for the “classical” PA code VANDAL the uncertain input parameters of which were also sampled (Figure 2).

[3] Interestingly, its predecessor TIME2 had been developed in order to aid scenario derivation in the classical sense.)

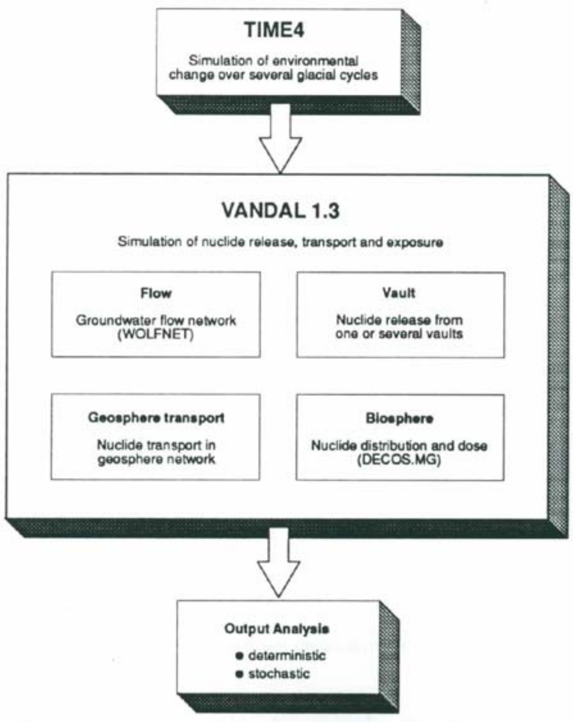

Figure 2 Climate and PA modelling in "HMIP Dry Run 3" (from [10])

The "HMIP Dry Run 3" report also contains discussion about a number of processes (meteorite impact, gross incision by glaciation, direct gas impact, human intrusion) which were, based on the discussion of risks derived from scoping calculations, not included in the reference assessment.

3.1.4 Treatment of model uncertainties

Uncertainties concerning the models upon which TIME4 and VANDAL were based had not been treated within the fully probabilistic assessment but within a "classical" framework of so-called level 1 and level 2 modelling (the TIME4/VANDAL model being level 3, cf. Figure 3) of processes and subsystems. In the "HMIP Dry Run 3" terminology, the "levels" of modelling denominate different degrees of model simplification and aggregation for which different means of confidence building (validation, calibration, probabilistic sensitivity analyses, …) were applied.

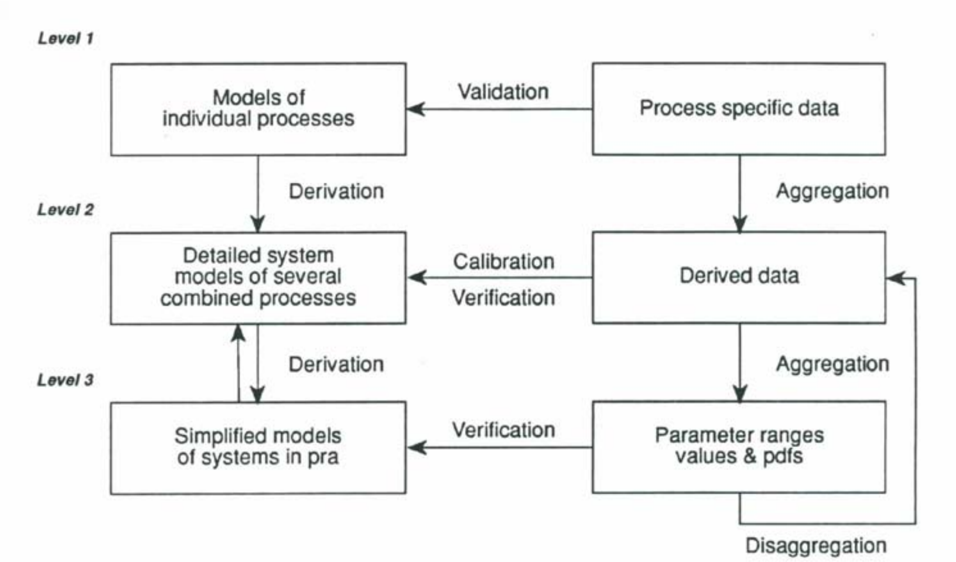

Figure 3 Modelling levels in “HMIP Dry Run 3” (from [10], there quoted as coming from [7])

3.1.5 Derivation and justification of pdf’s

Probabilistic density functions for uncertain parameters were derived from statistics where possible – in particular, this had been done with climate parameters. For other parameters, formal expert elicitation had been carried out. The elicitation was based on a consensus approach which probably in the categorisation of such methods given in [29] would fall under the heading “total interaction group method”. Table 2 provides an overview of the parameter uncertainties addressed by pdf’s.

Table 2 Summary of derivation of pdf's in Dry Run 3 (from [10])

Parameter group	Pdfs or ranges derived by	Comment
Climate state transition and duration	Estimation from the palaeo-climate record	Assumes a unique discretisation of the palaeo-climate record
Temperature and precipitation	From regional meteorological data for present-day and future temperate climate states and from analogue sites for future climate states	Assumes present day spatial variability can represent future temporal variability
Geosphere hydraulic conductivity and dispersion	Not sampled in Dry Run 3	Methodology for consistent sampling was under development in parallel study
Geosphere kinetic and total porosity	Formal elicitation by expert group	—
Geosphere sorption coefficients, K_d	Formal elicitation for I-129[1]. Expert judgement guided by literature and chemical modelling for other nuclides	Assumes the overall effect of all geochemical retardation processes can be represented as a single reversible process
Hydraulic conductivity and porosity of vault liner and buffer	Engineering judgement taking account of post-closure degradation	—
Biosphere parameters	Selected soil K_d and plant concentration factors elicited by expert group	Values used in deterministic biosphere sensitivity studies only. Sampling not allowed in VANDAL version 1.3, used for Dry Run 3

3.1.6 Risk dilution

The issue had not been explicitly addressed. In particular, no discussion of calculated peak doses is reported in [10]. The issue has, however, been addressed indirectly in the so-called "high-risk re-analysis" (cf. section 3.1.8).

3.1.7 Presentation

The exercise had been documented in an overview report [10] and nine supporting technical reports. The overview report provides a motivation and an overview of the assessment strategy, of modelling issues and activities, of the results obtained, and of managerial issues connected with the exercise together with conclusions. Due to the objectives of the study and to the limitations of the assessment scope it abstains from presenting risk estimates in an integrated way but expresses the expectation that such a presentation would form a central part of a more realistic assessment. Instead, results were presented in a disaggregated way (for different assessment and sampling approaches, for different parameters etc.).

3.1.8 Other issues

Apart from the features already mentioned, two components of the exercise are of special interest for this report (cf. Figure 1):

1. In a "high-risk re-analysis" those realisations which lead to high calculated consequences were examined one-by-one in order to verify that they represent physically realistic conceptualisations (i.e. that the sampling did not lead to unrealistic parameter combinations, e.g. due to correlations existent in reality but not properly accounted for in the assessment). For these runs, sub-models of the level 3 conceptualisation were also compared to lower level models in order to check the realism of the simplified level 3 models. In the exercise, this re-analysis was not carried out in full but focused on geochemistry and hydrogeologic modelling. It led to conclusions about the necessity of model modifications.

2. An "uncertainty and bias audit" was carried out based on the work of an independent expert group. The audit dealt with methodological questions, process understanding, and modelling issues. One of the outcomes was the list of processes (meteorite impact, gross incision by glaciation, direct gas impact, human intrusion) mentioned in section 3.1.2 of this report which were then screened out on the basis of scoping calculations.

3.1.9 Results of the study and conclusions of the authors

Despite of the self-imposed and acknowledged limitations of scope and resulting gaps of the assessment (e.g. w.r.t. hydrogeological modelling, expert elicitation and parameter derivation in general) the authors concluded that the exercise was a successful demonstration of methodology. In particular, the significance of the evolution of environmental conditions had been demonstrated. It had been shown that this evolution can, in analogy to parameter uncertainties, could be addressed by means of probabilistics. This was considered important due to the impossibility to define conservative data sets *a priori*.

3.1.10 View of the regulator

The exercise itself can be considered as an outcome of regulatory research and therefore represents the view of the regulator at that time. It underwent, however, a peer review carried out by Sandia National Laboratories [30] the main findings of which can be summarised as follows:

The analysis method was in general considered appropriate. Criticisms were related to documentation issues as well as to modelling issues. The latter focussed on hydrogeological modelling; in particular, the use of the groundwater network model as implemented in VANDAL, the treatment of transient behaviour and of spatial variability was considered inappropriate. Moreover, certain model assumptions were questioned. The consistency of the different model levels and model verification and validation efforts as undertaken in connection with the exercise were criticised as inappropriate.

With regard to the quantification of uncertainties, the methods for the derivation of pdf's including the formal approach to expert elicitation as well as the sampling methods used were criticised.

The review team shared HMIP's view that only probabilistic methods are the adequate way for carrying out safety analyses. It was, however, doubtful about HMIP's attitude towards the "scenario approach" (cf. sections 0 and 3.1.2):

"While the modelling capability to simulate time-dependent environmental changes was demonstrated in *Dry Run 3*, the conclusions regarding the relative adequacy of this approach to risk assessment versus the scenario approach are not definitive. This issue cannot be resolved until the two approaches are compared on an equal basis. Furthermore, the review finds that results from *Dry Run 3* leading to the stated conclusions could have been considerably influenced by the modelling approach."

It has to be noted that the final Dry Run 3 report [10] had been prepared and published *after* the peer review – it contains HMIP's responses to the review and it appears that also some modifications of the "HMIP Dry Run 3" report took place afterwards. To some extent, this is explicitly stated by the "HMIP Dry Run 3" authors but especially the discussion about the pros and cons of the scenario approach is a bit hard to understand for today's readers: It seems that in the initial version of the Dry Run 3 report the preference for the fully probabilistic approach was justified by equalising or at least associating the scenario approach with stationary (as opposed to transient) modelling and that this lead to the reaction of the review team as quoted above.

3.2 DoE's assessments in support of applications for certification and re-certification of the Waste Isolation Pilot Plant (WIPP) and of the license application for the Yucca Mountain Repository

3.2.1 Aim, purpose, scope, and general description of the assessments

Although different in scope and objectives, the three assessments show similarities w.r.t. the subject of this report. Therefore, they are addressed in a single section.

The Waste Isolation Pilot Plant (WIPP) close to Carlsbad (NM, USA) is a disposal facility for transuranic (TRU) radioactive waste created during the research and production of nuclear weapons. The TRU waste is disposed of in a bedded salt layer appr. 650 m below the surface. The WIPP capacity is 175,570 cubic meters of TRU waste. In 1996, the U.S. Department of Energy (DoE) applied for a compliance certification decision ("CCA", [12]) based on which the Environmental protection Agency (EPA) certified the facility in 1998. In 2004, DoE officially submitted the Compliance Recertification Application (CRA) [13] to EPA, initiating the recertification process required by law. Recertification is not a reconsideration of the decision to open WIPP, but rather a process to verify that changes at the facility in the preceding five-year period comply with EPA's disposal standards for radioactive waste. EPA recertified the WIPP's continuing compliance with the disposal regulations in 2006.

In June 2008, DOE submitted a License Application [14] for construction authorisation of a Geologic Repository for spent nuclear fuel and high-level nuclear waste in a tuff formation at Yucca Mountain (NV, USA). Amongst many other components, the application contains a Total System Performance Assessment TSPA-LA (LA = License Application).

It is not the aim of this report to comprehensively report on the content of these three applications. Even the documentation directly linked to the assessments of long-term safety (performance assessments) of the two facilities is far too voluminous to be appropriately reflected here. Rather, the report would like to draw the attention to a feature the three assessments have in common:

For the scenarios considered, aleatory and epistemic uncertainties are distinguished and both are handled probabilistically but separately. Uncertainties are mostly categorised "aleatory" if they concern a single disruptive event (e.g. drilling or volcanic eruption) while epistemic uncertainties mostly concern modelling parameters such as hydraulic conductivity.

For the latter, the WIPP CCA [12] states:

"Uncertainty is incorporated in the analysis through a Monte Carlo approach in which multiple simulations (or realizations) are completed using sampled values for 57 imprecisely known or naturally variable input parameters. Distribution functions are constructed that characterize the state of knowledge for these parameters, and each realization of the modeling system uses a different set of sampled input values. A sample size of 100 results in 100 different values of each parameter. Therefore, there are 100 different sets (vectors) of input parameter values."

Aleatory uncertainties were accounted for as follows:

"Probabilities of scenarios composed of specific combinations of features, events, and processes are estimated based on regulatory criteria (applying to the probability of future human action) and the understanding of the natural and engineered systems. Cumulative radionuclide releases from the disposal system are calculated for each scenario considered and probabilities of the scenarios are summed for each realization of the modeling system to construct distributions of CCDFs. Sampling of the input parameters was performed in three separate replicates resulting in three independent distributions of CCDFs and allowing the construction of three independent mean CCDFs, each based on 100 individual CCDFs."

The 100 parameter vectors were generated by Latin Hypercube Sampling (LHS). The scenario probabilities were related to prognoses on future drilling rates (the scenario under consideration being a drilling scenario) and accounted for by a Poisson process based on data from past drilling rates. For each of the 100 LHS parameter samples a CCDF was constructed accounting for the scenario probabilities. Of this analysis, three replicates with different seeds were produced in order to demonstrate statistical confidence.

Figure 4 shows one of these replicates for the calculation endpoint summed normalised release as specified in the regulations (cf. section 3.2.2). The other two show "very similar results” [12]. This statement of statistical confidence is further substantiated in Figure 5, in which the means of these replicates and the overall mean is presented, and a presentation of the overall mean together with the 0.95 confidence interval of the Student’s t-distribution estimated from the individual means of the three independent replicates. Although for regulatory compliance the mean is of central interest (cf. section 3.2.2), uncertainty was further addressed by presenting additional summary information (quantiles) about the distributions of CCDFs, all of which lie below the regulatory limit.

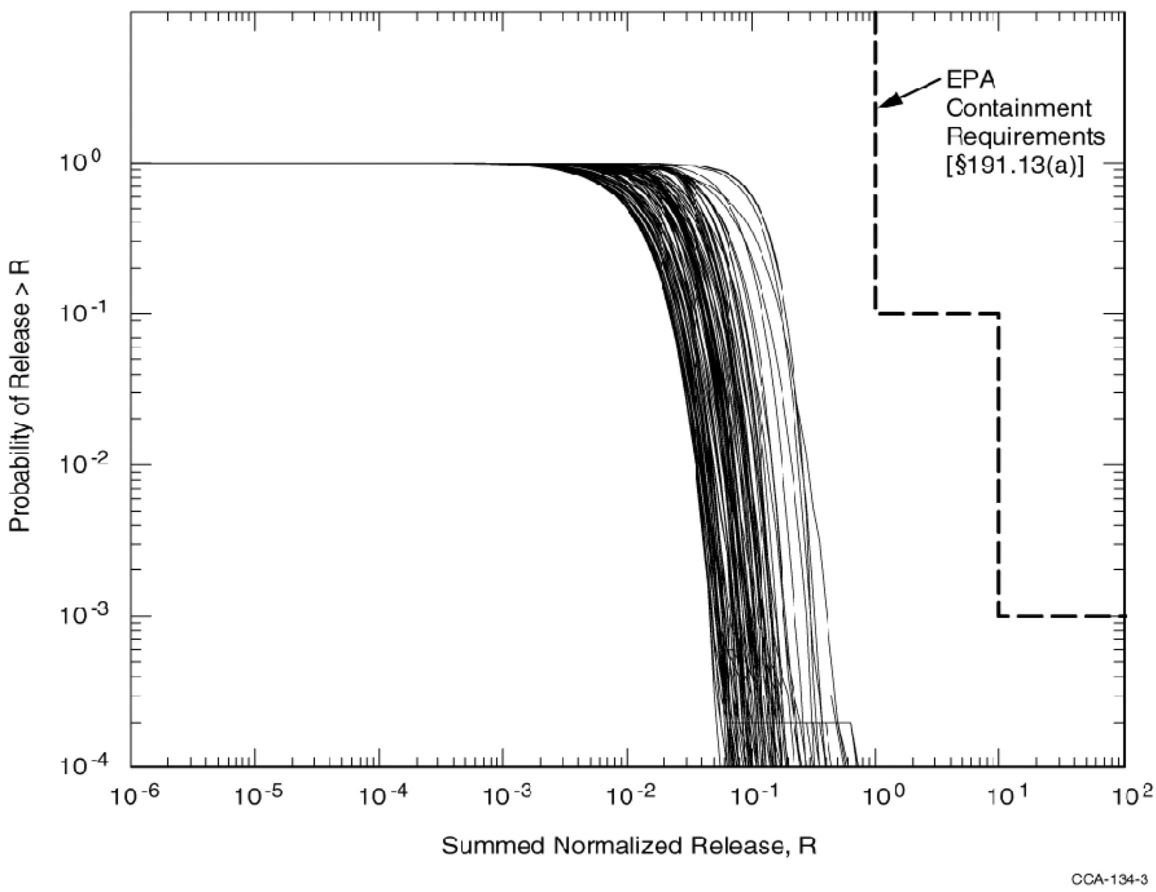

Figure 4 WIPP CCA: 100 CCDFs (one replicate) of summed normalized release (from [12])

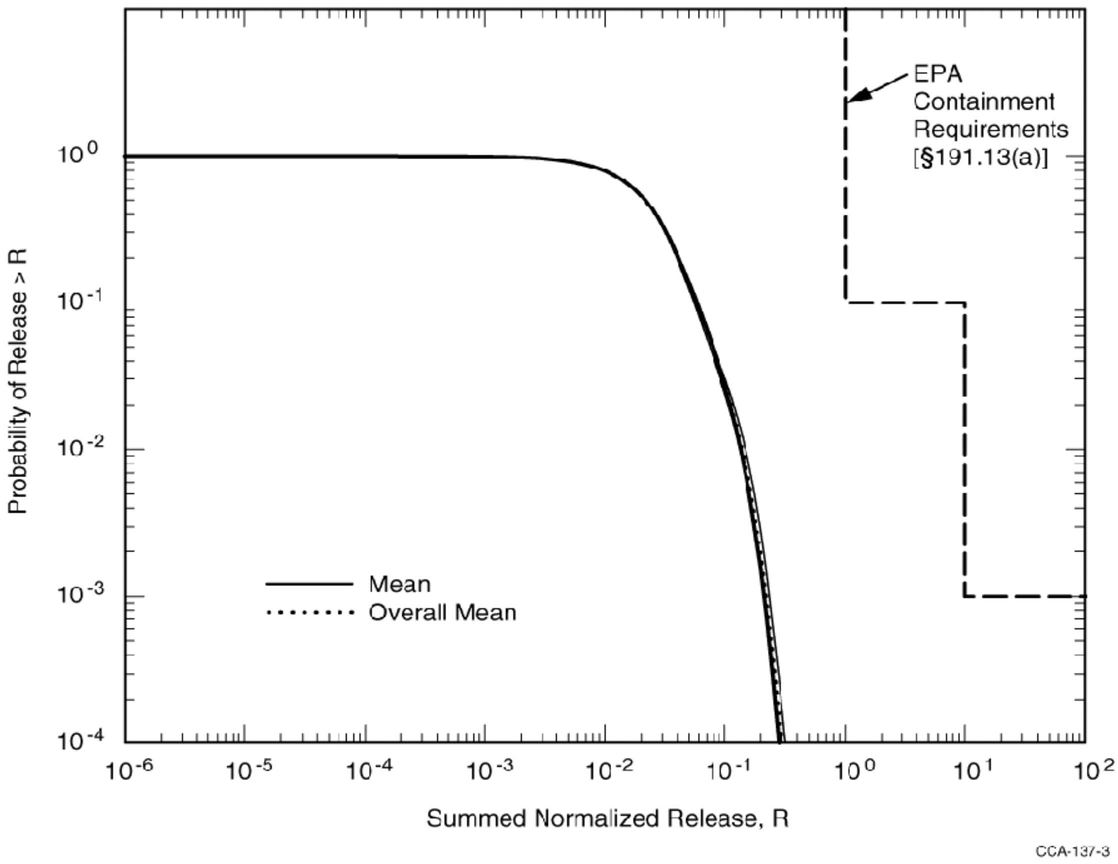

Figure 5 WIPP CCA: Mean CCDFs per replicate and overall mean of summed normalized release (from [12])

This approach, which in a similar way is also used in the CRA [13], is based on the methodological work by Kaplan and Garrick [31] and by the regulatory framework (cf. section 3.2.2) which, in turn, also is orientated on the ideas developed Kaplan and Garrick.

Although developed under a different regulatory framework, and as a consequence presenting the final results in a different way, the Yucca Mountain TSPA-LA is based on a similar philosophy. The general approach is shown in Figure 6.

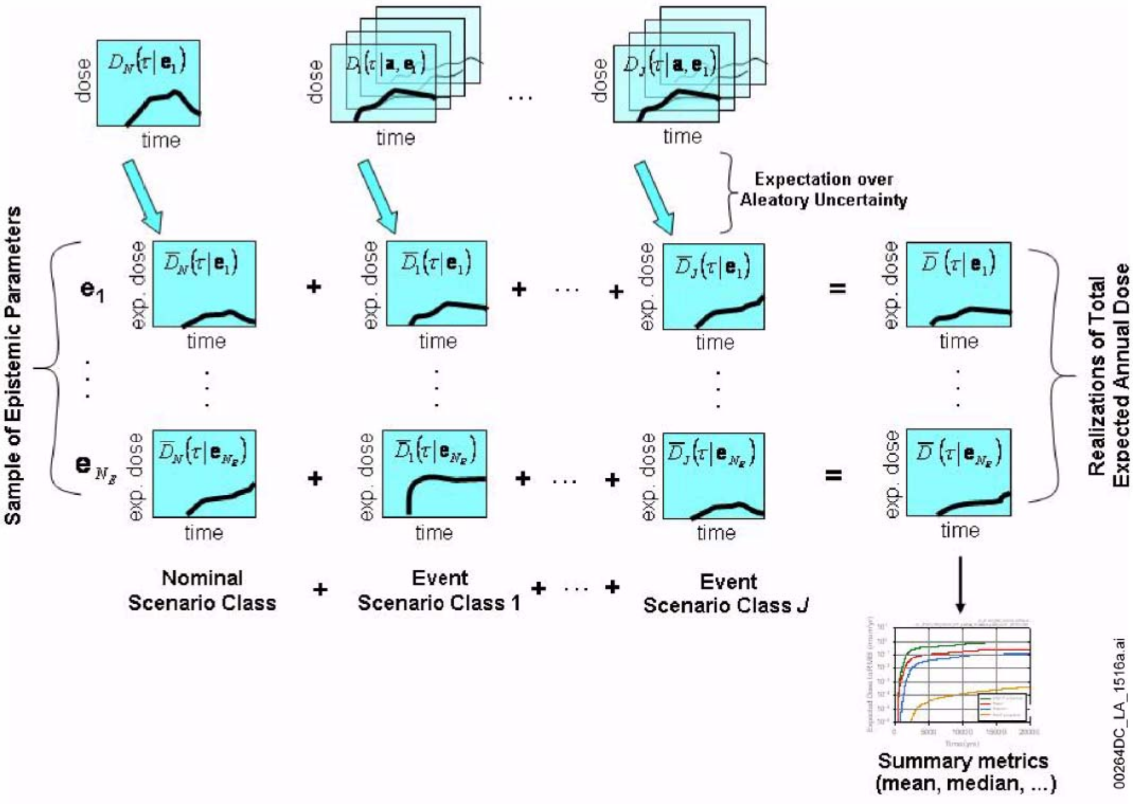

Figure 6 Yucca Mountain TSPA-LA: Computational Strategy for Computing The Total Expected Annual Dose (Expectation Over Aleatory Uncertainty) as a Sum of Expected Annual Doses for Each Event Scenario Class (or Each Modeling Case) (from [14])

To better explain this rather complicated procedure which was implemented in a GoldSim model (cf. http://www.goldsim.com/), the example of the eruptive event case will be used: Figure 7 shows consequences for 40 parameter samples assuming an eruptive event at time zero. If these consequences are averaged, this results in the curve most to the left in Figure 8, the others being averages assuming other times of the eruption. The other way round, Figure 9 provides an averaging over the uncertainty concerning the time of eruption, leaving the parameters constant for each curve. Finally, the overall averaging, addressing numerical compliance, is being presented in Figure 10.

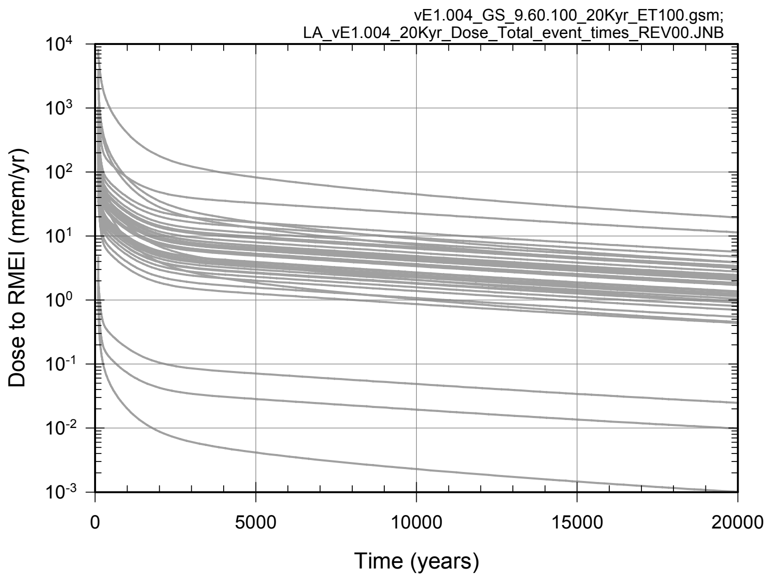

Figure 7 Yucca Mountain TSPA-LA: Doses for 40 realizations of parameter uncertainty conditional on a single eruption at time zero (“RMEI” = reasonably maximally exposed individual) (from [14])

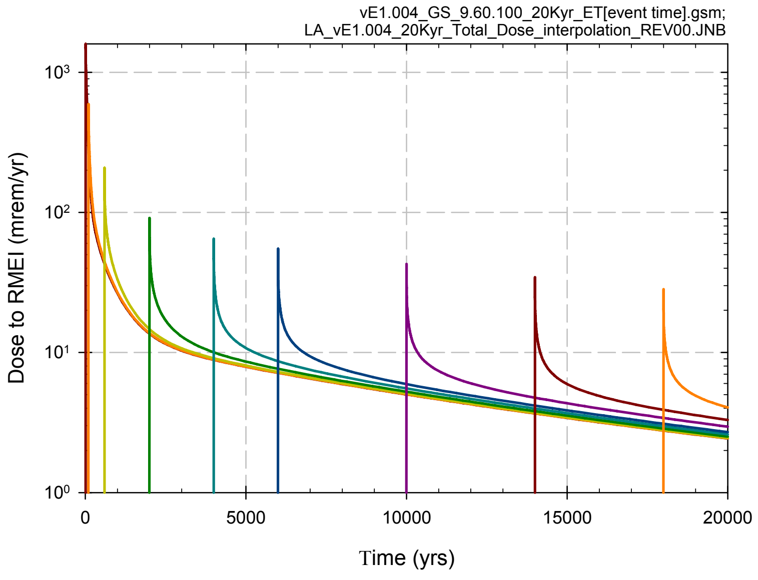

Figure 8 Yucca Mountain TSPA-LA: Doses averaged over parameter uncertainty associated with a single eruption, eruptions at multiple times (from [14])

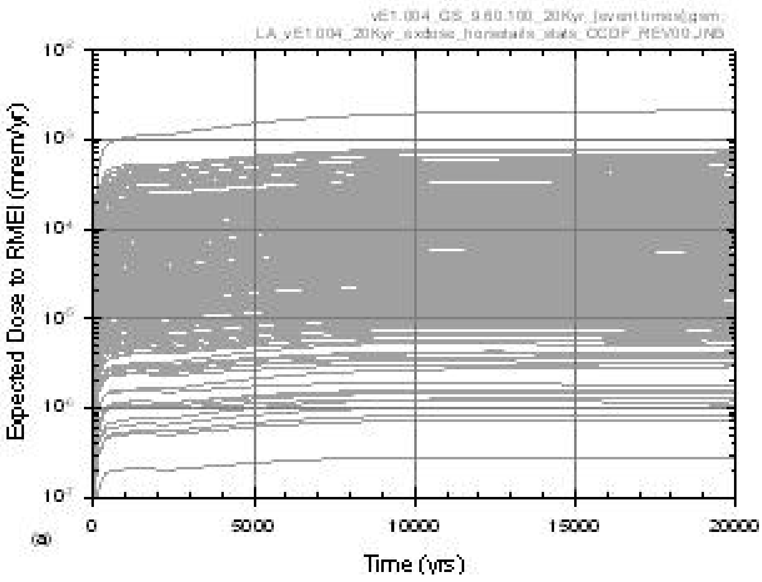

Figure 9 Yucca Mountain TSPA-LA: 300 realizations, each showing contribution to expected dose from a single sampling of parameter uncertainty with events at all times (from [14])

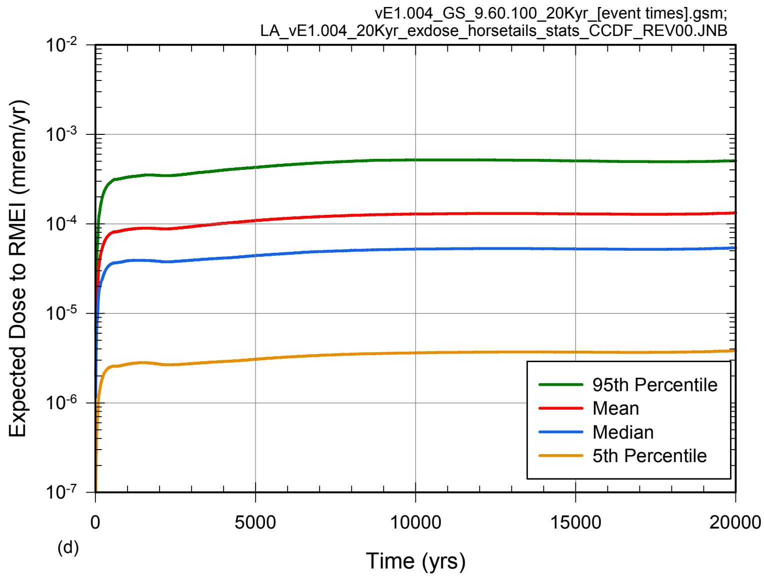

Figure 10 Yucca Mountain TSPA-LA: Summary curves showing overall contribution to mean dose from eruption (from [14])

3.2.2 Regulatory environment

Different regulations are in place for the two facilities.

Amongst other things, the EPA regulations 40 CFR Part 191 [32] § 191.13 for the WIPP CCA stated so-called “Containment Requirements”:

“(a) Disposal systems for spent nuclear fuel or high-level or transuranic radioactive wastes shall be designed to provide a reasonable expectation, based on 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 1 (Appendix A); and

(2) Have a likelihood of less than one chance in 1,000 of exceeding ten times the quantities calculated according to Table 1 (Appendix A).

(b) Performance assessments need not provide complete assurance that the requirements of § 191.13(a) will be met. Because of the long time period involved and the nature of the events and processes of interest, there will inevitably be substantial uncertainties in projecting disposal system performance. Proof of the future performance of a disposal system is not to be had in the ordinary sense of the word in situations that deal with much shorter time frames. Instead, what is required is a reasonable expectation, on the basis of the record before the implementing agency, that compliance with 28 § 191.13(a) will be achieved.”

The regulation also specify how to calculate the assessment endpoint “summed normalised release” which is essentially a weighted sum of cumulative radionuclide releases, put in relation to the total amount of this radionuclide present in the facility. Furthermore, Appendix A of the regulation provides guidance on the assessment timeframe (10,000 years), the use of CCDFs when addressing compliance with the containment requirement, and the frequence and severity of drilling to be accounted for in the assessment. Furthermore, advice is given about how to derive a drilling scenario:

“The implementing agencies should consider the effects of each particular disposal system's site, design, and passive institutional controls in judging the likelihood and consequences of such inadvertent exploratory drilling. However, the Agency assumes that the likelihood of such inadvertent and intermittent drilling need not be taken to be greater than 30 boreholes per square kilometer of repository area per 10,000 years for geologic repositories in proximity to sedimentary rock formations, or more than 3 boreholes per square kilometer per 10,000 years for repositories in other geologic formations. Furthermore, the Agency assumes that the consequences of such inadvertent drilling need not be assumed to be more severe than: (1) Direct release to the land surface of all the ground water in the repository horizon that would promptly flow through the newly created borehole to the surface due to natural lithostatic pressure-or (if pumping would be required to raise water to the surface) release of 200 cubic meters of ground water pumped to the surface if that much water is readily available to be pumped; and (2) creation of a ground water flow path with a permeability typical of a borehole filled by the soil or gravel that would normally settle into an open hole over time-not the permeability of a carefully sealed borehole.”

The effect of possible future mining had also to be taken into account:

"Assessments of mining effects may be limited to changes in the hydraulic conductivity of the hydrogeologic units of the disposal system from excavation mining for natural resources. Mining shall be assumed to occur with a one in 100 probability in each century of the regulatory time frame. Performance assessments shall assume that mineral deposits of those resources, similar in quality and type to those resources currently extracted from the Delaware Basin, will be completely removed from the controlled area during the century in which such mining is randomly calculated to occur. Complete removal of such mineral resources shall be assumed to occur only once during the regulatory time frame."

For Yucca Mountain, the regulation [33] requires:

"(a) DOE must demonstrate, using performance assessment, that there is a reasonable expectation that the reasonably maximally exposed individual receives no more than the following annual dose from releases from the undisturbed Yucca Mountain disposal system:

(1) 0.15 mSv (15 mrem) for 10,000 years following disposal; and

(2) 1.0 mSv (100 mrem) after 10,000 years, but within the period of geologic stability.

(b) DOE's performance assessment must include all potential pathways of radionuclide transport and exposure."

Concerning the meaning of "reasonable expectation" it is said:

"Reasonable expectation means that the Commission is satisfied that compliance will be achieved based upon the full record before it. Characteristics of reasonable expectation include that it:

(1) Requires less than absolute proof because absolute proof is impossible to attain for disposal due to the uncertainty of projecting long-term performance;

(2) Accounts for the inherently greater uncertainties in making long-term projections of the performance of the Yucca Mountain disposal system;

(3) Does not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence; and

(4) Focuses performance assessments and analyses on the full range of defensible and reasonable parameter distributions rather than only upon extreme physical situations and parameter values."

Furthermore, general requirements concerning the use of data in the assessment, uncertainty handling, the use of alternative conceptual models, FEP processing are being made.

Thus, the Yucca Mountain regulation becomes much less prescriptive w.r.t. assessment methodology than the WIPP regulation. In particular, much more freedom is left to the implementer w.r.t. scenario definition and w.r.t. the derivation of probability distributions. The formulation on "reasonable expectation" lead to the use of mean dose as calculation endpoint.

3.2.3 Scenarios considered

For the WIPP CCA, it is concluded in [12] that the "undisturbed performance" would not lead to any radionuclide release during the assessment timeframe of 10,000 years. The same conclusion is achieved in the CRA [13].

According to the regulation described above, for the disturbed evolution in the CCA [12] (and similarly in the CRA [13]) human intrusion by drilling is assumed as "…the only mechanism for significant releases of radionuclides from the disposal system. These releases may occur by five mechanisms:

(1) cuttings, which include material intersected by the rotary drilling bit,

(2) cavings, which include material eroded from the borehole wall during drilling,

(3) spallings, which include solid material carried into the borehole during rapid depressurization of the waste-disposal region,

(4) direct brine releases, which include contaminated brine that may flow to the surface during drilling, and

(5) long-term brine releases, which include the contaminated brine that may flow through a borehole after it is abandoned."

"Human intrusion scenarios evaluated in the performance assessment include both single intrusion events and combinations of multiple boreholes. Two different types of boreholes are considered:

(1) those that penetrate a pressurized brine reservoir in the underlying Castile Formation, and

(2) those that do not."

According to the regulation, both assessments account for possibly future mining by conductivity changes in the models, which was combined with the drilling event according to Figure 11.

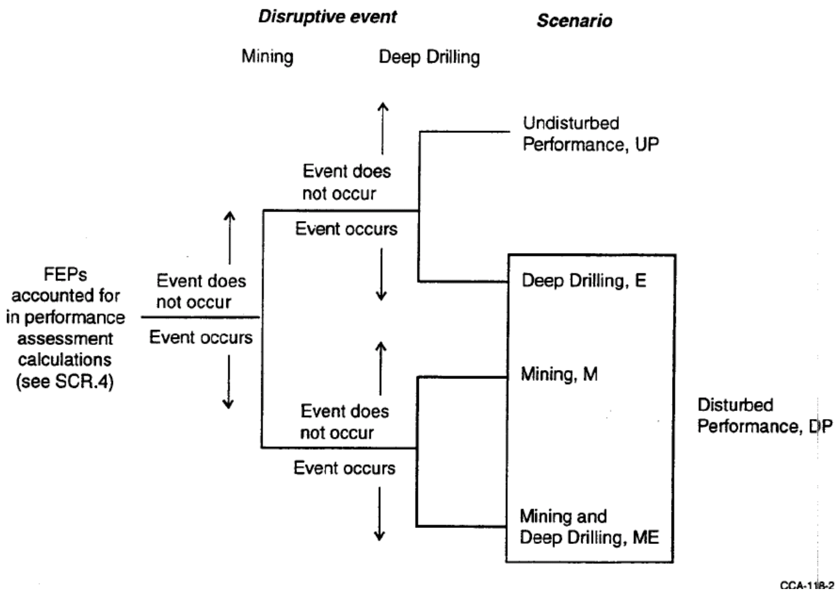

Figure 11 WIPP CCA: Logic tree for scenario selection (from [12])

For Yucca Mountain, scenarios were derived by a "classical" FEP method. Four scenario classes divided into seven modelling cases were identified:

- Nominal Scenario Class
  - Nominal Modeling Case (included with Seismic Ground Motion for 1,000,000-yr analyses)
- Early Failure Scenario Class
  - Waste Package Modeling Case
  - Drip Shield Modeling Case
- Igneous Scenario Class
  - Intrusion Modeling Case
  - Eruption Modeling Case
- Seismic Scenario Class
  - Ground Motion Modeling Case
  - Fault Displacement Modeling Case

3.2.4 Treatment of model uncertainties

In all three assessments, model uncertainties are addressed by "conventional" means, i.e. by confidence building, verification, validation, use of alternative conceptualisations etc. No attempt to address model uncertainty probabilistically or to otherwise quantify it is undertaken.

3.2.5 Derivation and justification of pdf's

The WIPP CRA [13] states:

"Information used in the CCA about the ranges and distributions of possible values were drawn from a variety of sources, including field data, laboratory data, and literature. Where sufficient data were not available, the documented solicitation of experts was used. A review process led from the available data to the construction of the distribution functions that characterize uncertainty in input parameters in PA … . This addressed the scaling of data collected at experimental scales of observation to the parameter ranges applied to scales of interest in the disposal system. The nature of the available data and the type of analysis unavoidably involved some judgment from investigators and analysts involved. …

The outcome of the review process is a cumulative distribution function (CDF) … ."

Similar but weaker formulations ("can be drawn" instead of "were drawn" etc.) can be found in the WIPP CCA. It should be noted that the WIPP regulation is much less restrictive w.r.t. the quantification of epistemic (compared to aleatory) uncertainties.

For Yucca Mountain, various means for deriving probabilities were employed. As an example, the text about the derivation and use of occurrence probabilities for the igneous scenario class is quoted here:

"A probabilistic volcanic hazard analysis (PVHA) was performed to assess the volcanic hazard at Yucca Mountain. For the PVHA, an expert panel was convened in 1995 to review pertinent data relating to volcanism at Yucca Mountain and, based on these data, to quantify both the annual probability and associated uncertainty of a volcanic event intersecting a proposed repository sited at Yucca Mountain … ."

Similar methods were applied for the seismic scenario class, while the procedure for the early failure scenario class was more complicated since both aleatory and epistemic uncertainties played a role here.

3.2.6 Risk dilution

Risk dilution is not explicitly addressed in the assessments. However, the presentation of disaggregated results allows judging its effects.

3.2.7 Presentation

The documentation of the three assessments is voluminous. Examples of the presentation of calculation results leading to compliance statements are given in the preceding sections. The degree of disaggregation when presenting results is high (as indicated by these examples).

3.2.8 Other issues

As said before, the assessment reports provide by far more information than given in the preceding sections of this report. It would, however, go beyond the possibilities of this report to fully account for this material. Nevertheless, it is hoped that the exemplified information given above provides insight in the assessment methodologies used.

3.2.9 Results of the study and conclusions of the authors

In all three cases, the implementer concluded compliance with the regulations as a basis for application.

3.2.10 View of the regulator

The WIPP facility was certified in 1998 and re-certified in 2006. Numerous comments were made by the authorities in both cases. They are compiled in so-called Compliance Application Review Documents (CARDs) and Technical Support Documents (TSDs)[4]. For the CCA, important findings concerning assessment methodology were:

"EPA found that information documenting DOE's process of developing and identifying FEPs that are potentially relevant to the site and the scenarios that DOE developed from the selected FEPs to be generally thorough and complete … . EPA challenged various initial DOE assumptions used to screen out oil production related fluid injection (for brine disposal and secondary oil recovery) on the basis of low consequence. … EPA also questioned a number of important input parameter values and distributions used in the PA." (CARD No. 23)

"EPA reviewed DOE's implementation of drilling rate and location assumptions and concluded that DOE used appropriate methodologies to derive drilling rates and locations." (CARD No. 33)

"EPA concluded that DOE appropriately considered natural processes and events, as well as human-initiated events, in its PA-related evaluations. EPA believes that all models but the spallings model are adequate for use in the CCA PA calculations, that the results from the spallings model are reasonable, and that the spallings model results may even overestimate releases … . EPA found that all significant FEPs and scenarios were included in the generation of CCDFs. The CCDFGF program also reports results of several internal diagnostic tests designed to ensure that the probabilities of events generated by the model match closely with calculated probabilities from the assigned probability distributions … ." (CARD No. 34)

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[4] http://www.wipp.energy.gov/library/CRA/BaselineTool/Index/CCA%20CARD%27s%20&%20TSD%27s.htm for the CCA and http://www.wipp.energy.gov/library/CRA/BaselineTool/Index/CRA%20CARD%27s%20&%20TSDs.htm for the CRA

“Upon reviewing models and computer codes, the Agency questioned a number of important input parameter values and distributions used in the PA.” (CARD No. 34)

“EPA examined DOE’s presentations in Chapter 6 of the CCA, and concluded that DOE appropriately presented the PA results in CCDFs showing the probability of exceeding regulatory levels of cumulative releases.” (CARD No. 34)

Concerning the assignment of pdf’s it is stated:

“EPA conducted a thorough review of the parameters and the parameter development process … . It reviewed parameter packages for approximately 1600 parameters used in the CCA PA calculations, including the 57 subjective parameters. The Agency found that DOE adequately documented the probability distributions in Appendix PAR, and discussed the data from which, and the method by which, the probability distribution of each of the 57 sampled variables was created.

…

Upon reviewing models and computer codes, the Agency questioned the basis for and importance of 58 parameter values and distributions used in PA … . In response to EPA’s letter, DOE provided additional documentation to support some of its parameter values … . After reviewing this information and conducting further technical review, including parameter sensitivity analyses, EPA still had concerns about 24 parameters. The Agency believed that these 24 parameters – either individually or in combination with other parameters – might have a significant impact on the results of PAs. In addition, both EPA and DOE had identified some problems with the PA computer codes that required changes.

…

EPA directed DOE to demonstrate the combined effect of the parameter and code changes by conducting additional calculations in a Performance Assessment Verification Test (PAVT). The PAVT was an independent computer simulation of the WIPP’s performance conducted under EPA’s authority to require independent verification computer simulations … . It implemented DOE’s PA modeling, using the same sampling methods as the CCA PA, but incorporating parameter values mandated by EPA … . The methods used to execute the PAVT were identical, from a technical standpoint, to those used for the CCA PA. That is, DOE used the same computer codes, same sampling methodologies, etc., but changed the parameters identified by EPA and modified some of the computer codes in response to EPA’s questions about the codes.

…

The PAVT resulted in 300 CCDF curves that verified that the combined effect of computer code changes and altered parameter values did not significantly alter the results of the PA and did not cause the predicted releases from the WIPP to violate the containment requirements.“ (CARD No. 34)

Further comments, in part based in independent calculations, were made on statistical confidence issues.

It can be summarised that none of the review comments substantially questioned the assessment methodology as applied by DoE. However, numerous questions and criticisms arose w.r.t. other issues. In the CRA, the implementer attempted to account for the comments made by the authorities about the CCA. Again, no significant criticisms of the assessment methodology of the CRA were made by EPA.

The regulatory review of the Yucca Mountain application is still going on.

3.3 The SR-Can assessment

3.3.1 Aim, purpose, scope, and general description of the assessment

SR-Can [15] can be considered as a demonstration or test of an approach to long-term safety assessment for regulatory compliance purposes and as a preparation for an assessment to be carried out in connection with a license application for constricting a deep SNF repository based on the KBS-3 concept which is planned for 2009. For the authorities SSI and SKI[5] it was an opportunity to review and comment and thus for testing their approaches and methods but also for providing feedback to the Swedish Nuclear Fuel and Waste Management Company (SKB) which had produced SR-Can. Furthermore, SR-Can was meant to assess the safety of KBS-3 repositories at the two sites which were under consideration and to provide feedback to research, development, and design activities.

The KBS-3 concept foresees the emplacement of copper canisters with cast iron inserts encapsulating the spent nuclear fuel to be disposed of at a depth of appr. 500 m in crystalline bedrock. In the reference concept, the canisters will be emplaced in vertical boreholes and surrounded by a bentonite backfill.

For the assessment, SKB applied a 10-step methodology visualised in Figure 12. For this report, boxes 5 and 7-10 in Figure 12 are of special interest because they represent the parts crucial for the methodology of the numerical assessment: The definition of safety function and function indicators (box 4) and of the reference evolution (box 7) were bases for the selection and analysis of scenarios (boxes 8 and 9) and for deriving conclusions (box 10).

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[5] In 2008, the new organisation SSM (Swedish Radiation Safety Authority) took over the responsibility from SSI (Swedish Radiation Protection Institute) and SKI (Swedish Nuclear Power Inspectorate).

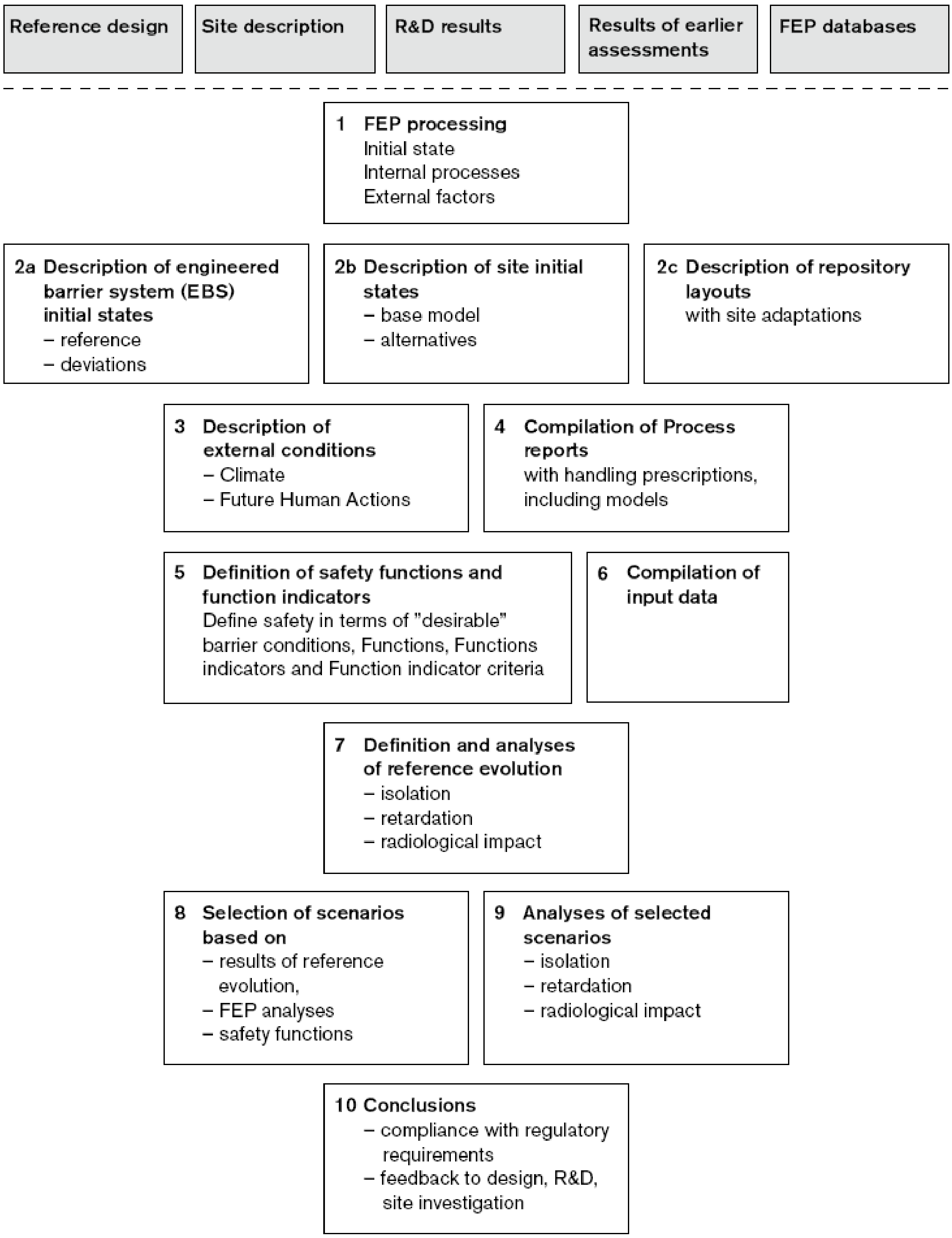

Figure 12 Assessment steps in SR-Can (from [10]). The boxes at the top above the dashed line are inputs to the assessment.

3.3.2 Regulatory environment

Both SSI and SKI had issued regulations directly relevant for the assessment methodology as applied in SR-Can. These regulations address a number of issues relevant to the repository layout and to the safety case such as the request for passive safety and for the application of optimisation and best available technique and requirements concerning the function of barriers. Hereinafter, we focus on the issues directly affecting assessment methodology.

The SSI regulation [34] requests that “the annual risk of harmful effects after closure does not exceed 10^{-6} for a representative individual in the group exposed to the greatest risk”. The risk should be calculated based on ICRP coefficient of 7.3% per Sievert. For the first 1000 years after closure an assessment more detailed than for later times was required. Other requirements concerned the demonstration of protection of the environment, biosphere modelling and human intrusion. In a supporting guidance, an assessment timeframe of 1 million years after closure was defined but a strict demonstration of numerical compliance beyond 100,000 years was considered not meaningful. Advice is given on the definition of the exposed group, the averaging of risk over lifetime and between generations (with reference to the issue of risk dilution), the selection of scenarios, biosphere modelling, and reporting issues.

The SKI regulation [35] requires a safety assessment based on FEPs which might lead to the dispersion of radionuclides for as long as the barrier functions were needed, but at least for 10,000 years. It contains requirements concerning the reporting of details of the assessment and its methodology (in particular naming the system description and evolution, the selection of scenarios, the justification of models and parameters, and the handling of uncertainty and sensitivity analyses). It also asks for the assessment of a main scenario and of scenarios evaluating defects of engineered barriers and other uncertainties. In a supporting document, more detailed guidance on the classification of scenarios (main, less probable, residual) and uncertainties (scenario, system, model, and parameter uncertainty as well as spatial variation) is given and advice is provided about their handling in the assessment. It asks for an approach combining deterministic and probabilistic methods and discusses the necessity to estimate scenario probabilities with regard to the above mentioned risk criterion but also acknowledges the limitations of such estimates. There is an explicit request for addressing climate variants including glacial cycles in the scenarios.

3.3.3 Scenarios considered

The annual risk R can be described as

$$R = \int_X \gamma \; c(x) \; p(x) \; dx \, ,$$

X being the space of all conceivable states and evolutions of the system, c the annual dose in any year arising for a certain element x of this space with probability p (without further distinctions concerning the uncertainties or variability p might describe but satisfying the rule that integral of p(x) is equal to unity) and γ the conversion factor as described in SSI regulations (for simplicity reasons no time-dependence accounted for).

In principle, a thorough risk summation has to be based on the prerequisites that a set of mutually exclusive scenarios with known probabilities can be found which together cover the whole space of all conceivable states and evolutions of the system. The overall annual risk in any year can then be approximated by

$$R = \sum_i p_i R_i \approx \sum_i p_i \frac{1}{n_i} \sum_{j=1}^{n_i} \gamma \, c_{i,j} \quad ,$$

$R_i \approx \frac{1}{n_i} \sum_{j=1}^{n_i} \gamma \, c_{i,j}$ being the conditional risk R_i arising from scenario A_i, approximated by a finite number n_i of equally probable calculations (realisations) and p_i being the scenario's likelihood.

The SR-Can main report [15] states in section 2.9.2 “Scenario disaggregation”:

“In principle, the product of dose consequences and likelihoods of all possible future evolutions of the repository should be weighed together and presented as a time-dependent risk. The spectrum of possible evolutions is, however, very wide and cannot be captured in a detailed sense. … The usual approach taken in safety assessments, and also in SR-Can, is to work with scenarios and variants that are designed to capture the broad features of a number of representative possible future evolutions. Together, these are intended to give a reasonable coverage of possible future exposure situations. Conditional risks are calculated for each scenario and variant and these are then weighed together using the probability for each scenario/variant. Furthermore, each variant, represented by a specific calculation case, may be evaluated probabilistically in order to determine the mean exposure given the data uncertainties for the particular variant.”

The risk summation in SR-Can summation is based on the assumption that scenarios of natural origin (human intrusion is addressed separately) for which no safety function is failed lead to zero dose rates and can therefore be excluded from the risk summation. In order to address SKI guidance, a main scenario with the two climate variants was defined by SKB (investigating climate variants is a regulatory requirement from SSI). The scenario comprises the failure mode canister corrosion & buffer advection (to the extent derived for the reference evolution), while all others were put aside based on low likelihood considerations. For the main scenario, the likelihood of occurrence was conservatively overestimated to be 1. The climate variants are obviously mutually exclusive. The difference between the two in terms of calculated risk is, however, negligible. Consequently, the conditional risks (two values for the two sites considered) calculated for base climate variant were considered the ones for the whole main scenario.

As stated above, only a violation of safety functions might lead to contributions to risk. As potential causes 3 failure modes for the canister (corrosion, isostatic pressure, shear movement) and 3 modes for the buffer (advection exceeding the one assumed for main scenario, transformed buffer, frozen buffer) were identified. Many of these failure modes and their combinations were then screened out based on phenomenological / logical and likelihood-related arguments. The only remaining combinations which were propagated to risk summation were buffer advection combined with copper corrosion (the “copper corrosion scenario”) and canister failure due to shear movement along a fracture.

This “copper corrosion scenario” is different from the main scenario in that the extent of buffer advection is higher than the one assumed for the main scenario. The scenario (more precisely: its most pessimistic case) leads to a higher conditional risk than the main scenario. The main scenario and the copper corrosion scenario are mutually exclusive (since the conditions for the buffer are different), therefore, the conditional risk for the copper corrosion scenario has been propagated to the risk summation as an upper estimate for the contributions from the main and copper corrosion scenarios.

The estimate for the total risk thus became

$$\frac{1}{n_{copp\_corr}} \sum_{j=1}^{n_{copp\_corr}} \gamma \, c_{copp\_corr,j} + p_{shear} \frac{1}{n_{shear}} \sum_{j=1}^{n_{shear}} \gamma \, c_{shear,j} \, ,$$

where the indices “copp_corr” and “shear” describe the scenarios, the n values the number of realisations considered for each scenario, the c values the calculated doses, and p_{shear} the probabilities for shear failure (different values for the two sites derived on the basis of earthquake probabilities, fracture detection probabilities and probabilities for fractures intersecting canisters). A probability for the copper corrosion scenario has not been derived – as explained above the consequences from this scenario had been used as an upper estimate for the contributions from the main and copper corrosion scenarios, the probability of the former having been overestimated with 1.

3.3.4 Treatment of model uncertainties

A number of conceptual and model uncertainties (in particular concerning release, flow, migration, and exposure modelling, hydrogeological interpretation, but also w.r.t. the presence / absence and significance of features such as spalling, EDZ properties, increased conductivity in tunnels, lost swelling pressures in tunnel backfill, gas effects, radium co-precipitation, climate effects) had been identified and handled in SR-Can. Means for doing so were conceptualisations at different levels of simplification and the use of alternative models and comparison of the results (both deterministically and probabilistically). E.g., epistemic and aleatory uncertainty concerning the hydrogeology were addressed by

- one-by-one usage of alternative models concerning hydraulic rock properties,

- probabilistic runs addressing spatial variability based on pessimistic, average, and favourable values, respectively, for the epistemic uncertainties.

This rather sophisticated procedure is (for this particular case) illustrated in Table 3 as well as in Figure 13 and in Figure 14.

Most of the conceptual and model uncertainties were, however, handled deterministically in so-called sensitivity cases for which the impact on the consequences were studied and discussed. Moreover, alternatives for correlation models, distribution shapes were tested. A number of stylised additional cases were calculated to illustrate barrier functions.

Table 3 Data used in the illustration of uncertainty due to lack-of-knowledge and spatial variability (from [15])

	Nuclide/ Element specific	The growing pinhole failure	Separation of uncertainty related to lack-of-knowledge (green) and spatial variability (yellow)
Number of failed canisters	–	One. (Postulated number; no pinhole failures are expected.)	=
Radionuclide inventory	N	Data for 38 MWd/kgU BWR fuel.	=
Instant release fraction (IRF) of inventory	N	Triangular distributions for all simulated nuclides except actinides, Sm-151 and Zr-93 (zero IRF) and Ca-41, Nb-94, Ni-59 and Ni-63 (100% IRF).	Min, mode and max values used in three illustrative cases.
Time for onset of radionuclide transport	–	1,000 years.	=
Time between onset and complete loss of transport resistance in canister	–	Single canister: 10,000 yrs. Triangular (0, 10^5 , 10^5) yrs to illustrate uncertainties and risk dilution.	Single canister: 10,000 yrs.
Canister defect sizes		Between onset and complete loss: 2 mm radius penetrating pinhole. After complete loss: Full contact between canister interior and bentonite compartment next to initial defect.	=
Fuel dissolution rate	–	Log-triangular (10^{-8}/yr, 10^{-7}/yr, 10^{-6}/yr).	Min, mode and max values used in three illustrative cases.
Concentration limits	E	Calculated distribution based on site-specific groundwater composition.	=
Buffer porosities		Anions: Triangular (0.12, 0.17, 0.24). Cations: Constant = 0.43. (The difference derives from the inclusion of anionic exclusion from part of the pore space.)	Anions: Min, mode and max values used in three illustrative cases. Cations: Constant = 0.43.
Buffer diffusivities	E	Triangular distributions.	Min, mode and max values used in three illustrative cases.
Buffer sorption coefficients	E	Log triangular distributions.	See above.
Backfill diffusivity coefficients	E	Triangular distributions.	See above.
Backfill sorption coefficients	E	Log triangular distributions.	See above.
Rock porosities		Lognormal, site-specific distribution.	=
Rock diffusivities	E	(Log-normal, site-specific formation factor) × (element specific diffusivity considering also anion exclusion).	=
Rock sorption coefficients	E	Log triangular distributions, same for both sites.	Min, mode and max values used in three illustrative cases.
Hydrogeological data related to flow and transport Water flow in the deposition tunnel* Equivalent flow from deposition hole to fracture(s) intersecting deposition hole (Q1), to EDZ (Q2), and to fractures intersecting deposition tunnel (Q3); data for Q1 available with and without effect of spalling* Darcy flow at deposition hole (U1)* Rock transport resistance, F for paths beginning at Q1, Q2 and Q3* Rock advective travel time, t_w for paths beginning at Q1, Q2 and Q3* *Correlated distributions covering ensemble of deposition holes	–	Data distributions from several model calculations propagated from hydro analyses: *Forsmark* CPM DFN fully correlated case DFN semi-correlated case *Laxemar* DFN semi-correlated case	Fully correlated DFN Forsmark with spalling used in most cases.
Rock Peclet number, Pe	–	Constant = 10	=
Max. penetration depth in rock matrix, D_{Pen}	–	Triangular distribution (0.01, 10, 10) m, same for both sites	=
Biosphere LDF factors	N	Calculated, constant LDF values, see section 10.2	=

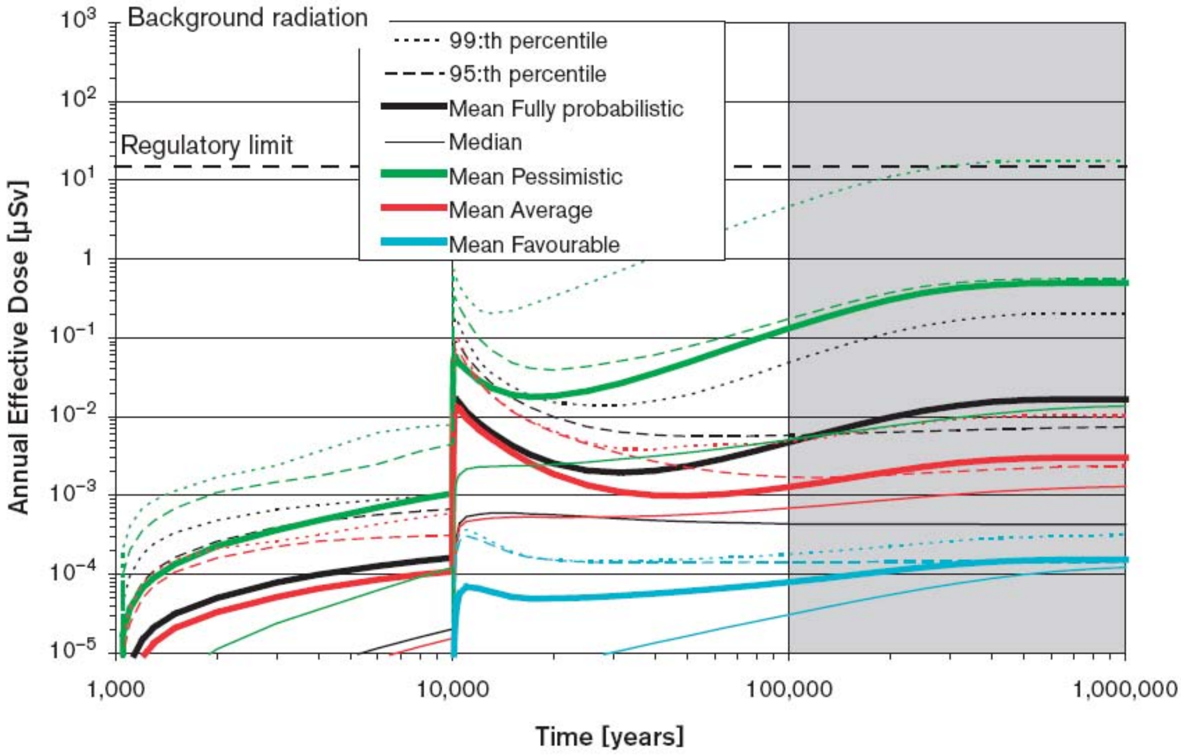

Figure 13 SR-Can: Illustration of relation between uncertainty due to lack-of-knowledge and spatial variability. Thick lines: Mean values taken over spatial variability for a number of assumptions regarding all data affected by lack-of-knowledge (all pessimistic, all average, all favourable). Thin lines: Other statistics of the calculation cases, to illustrate spatial variability within each case. (from [15])

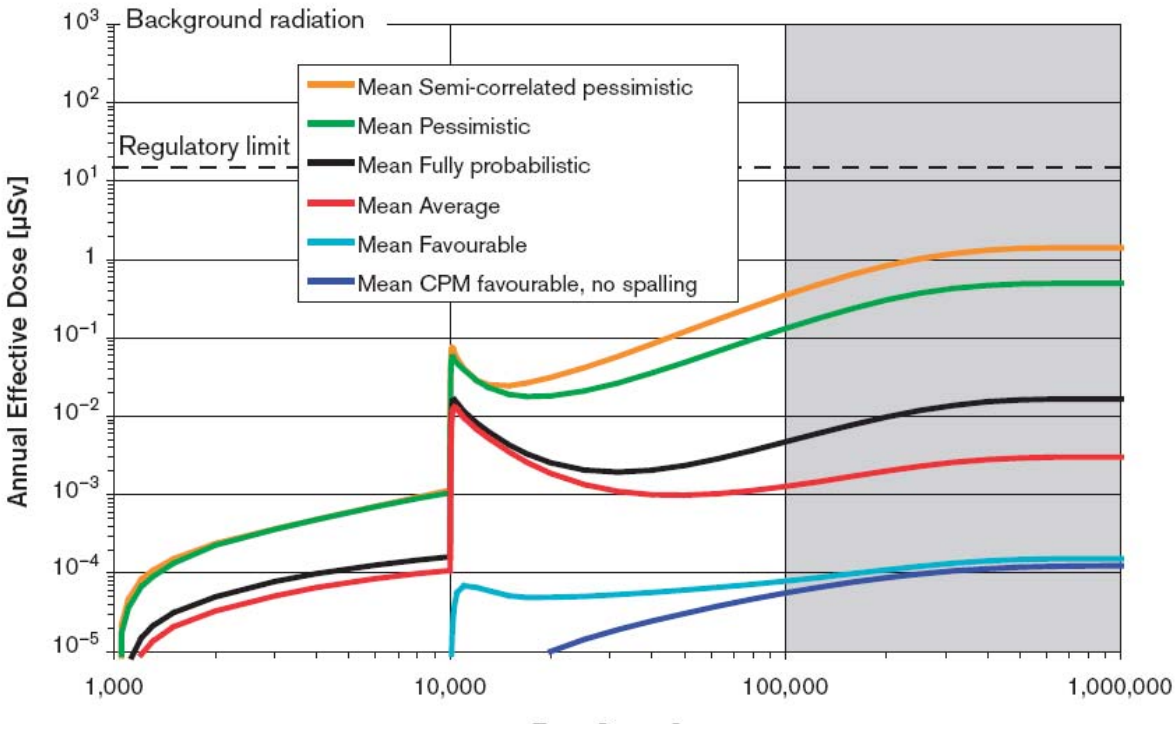

Figure 14 SR-Can: Extension of the analysis, including also the semi-correlated hydrogeological DFN model for Forsmark with pessimistic data and the CPM model with favourable data and neglecting spalling (all other results with the base-case fully correlated hydrogeological DFN model). (from [15])

3.3.5 Derivation and justification of pdf's

Input data for the assessment were, together with statements about associated uncertainties, compiled in the so-called SR-Can Data Report [36]. There it is reported how, "… data are assessed through standardized procedures, adapted to the importance of the data, aiming at identifying the origins of uncertainties and in which the input provided by experts is distinguished from judgements made by the SR-Can team. … The data report is based on the judgements made in those [supporting technical] reports [on processes, initial system state, site description, and scenario selection] … . However, additional judgements are sometimes needed, in order to define input data in a form appropriate for use in the assessment." The elicitation of data and uncertainty information from experts followed a standardised procedure and questionnaire.

The reporting for the separate data follows a standardised outline "covering

- modelling in SR-Can,
- sensitivity of assessment results to the parameter or parameters,
- source of information,
- conditions for which data are supplied,
- conceptual uncertainties,
- data uncertainties,
- spatial and temporal variation,
- correlations,
- quantification of the data with uncertainty."

For the latter, the following is stated:

"The preferred option was to describe the uncertainty as a *distribution function*, but the distribution had to be justified. For example, for a spatially varying function well described by a given stochastic process, e.g. through a variogram or as realised in a DFN, a potential distribution function would be to state that all realisations of this spatially varying function are equally probable.

Another option is to only provide *subjective percentiles* a_i in the distribution function: $P(x < a_i) = p_i$, i.e. a_i is the parameter value where the subjective probability that the parameter will take a value less than a_i is p_i. If sensitivity analyses show that only part of the range has an impact on the function, less effort may be given to quantification of the distribution of parameter values outside this range. The experts were requested to justify these subjective percentiles.

If distribution functions or subjective percentiles could not be supplied, the uncertainty could instead be described as a *range*. However, the meaning of the range had then to be provided, e.g. does it represent all possible values, all "realistically possible" values or just the more likely values? Preferably, the expert should have provided two ranges *i*) the range for which it is extremely unlikely that the parameter would lie outside this range and ii) a range for which it is likely that the parameter would lie within it.

Finally, it may also be impossible to express the uncertainty by other means than a selection of alternative data sets.

Furthermore, there are a number of uncertainties that cannot be managed quantitatively in any other rigorous manner from the point of view of demonstrating compliance than by pessimistic assumptions. This was thus allowed, as long as the expert clearly documented this together with the motivation for adopting this approach.

The uncertainty estimates were also required to provide information on correlations. The expert was asked to list other parameters to which the parameter in question may be correlated, and where this correlation is not already taken care of by functional relations in the safety assessment models. An important example was the correlation between different elements (e.g. K_d-values and solubilities) or between different radionuclides (e.g. inventory and LDF:s)."

"… the SR-Can team judges whether the expert input can be supported. In particular, the expert input on uncertainties and correlations may have had to be interpreted into more closed-form mathematical expressions (such as distribution functions), such that it can be used for the assessment calculations. For instance, if a most likely value and an upper and a lower bound were given, a triangular distribution may have been selected by the assessment team. The procedure of assigning distributions (needed by the assessment calculations) to input data based on small data sets includes a degree of subjectivity by the assessment team …. It was however shown in the SR-Can Interim main report /SKB 2004f/ that the impact of the use of different distributions had a limited impact on the assessment results. Corresponding work for the SR-Can assessment are shown in the Main report."

3.3.6 Risk dilution

In SR-Can, risk dilution was explicitly addressed: "This effect is inherent in the concept of risk as defined in SSI's regulation and is thus an inevitable consequence of a risk criterion which is to be applied as a function of time and where the quantity to be determined is the mean value considering all relevant uncertainties. Therefore, SSI's general guidance also requires that the issue of risk dilution is addressed when the consequences of releases from the repository are assessed." [15]

While in earlier SKB work often the presentation of risk ("peak of the mean") was complemented by a presentation of the "mean of the peaks" (the difference indicating the impact of risk dilution), in SR-Can a "Disaggregated calculations and disaggregated discussions of the results of more integrated calculations" was the "main approach taken in SR-Can" [15]. "A simple but effective means of avoiding risk dilution when its cause has been identified is to illustrate the effect by replacing probabilistic input data of e.g. canister rupture times with a fixed time." This is illustrated in Figure 15. Here, the "base case" used for the risk estimation conservatively assumes a fixed time for canister failure.

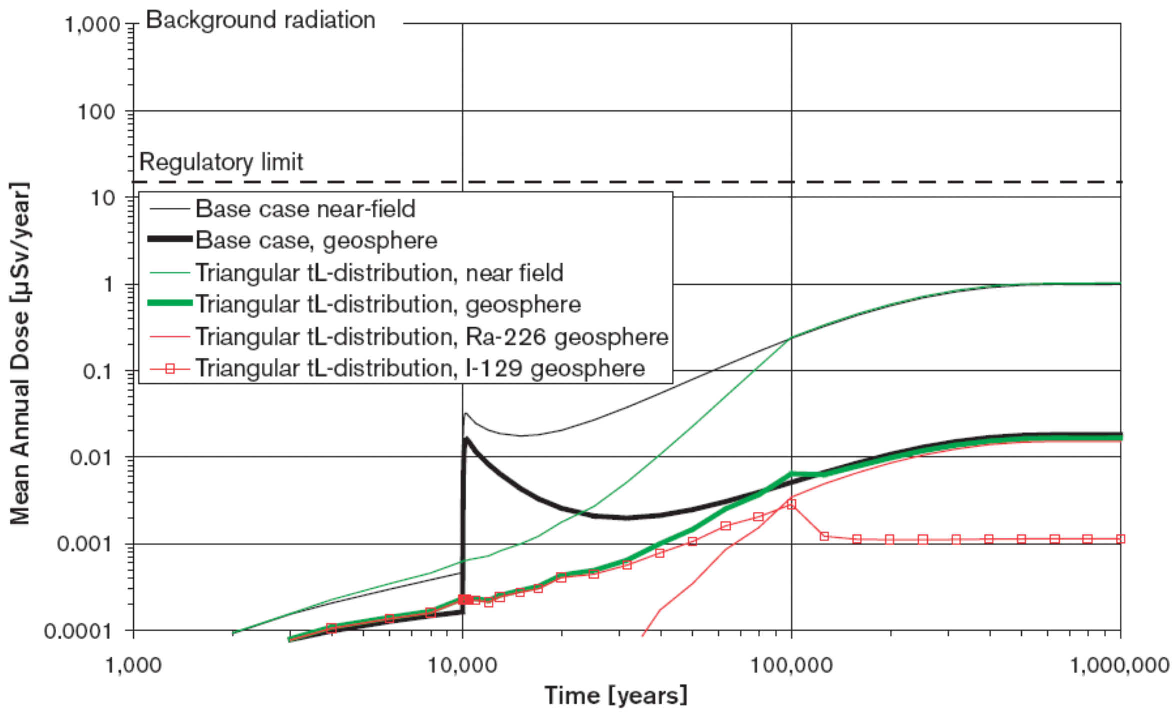

Figure 15 SR-Can: Demonstrating the effects of risk dilution by comparing results obtained for a fixed time of canister failure ("base case") with results assuming a triangular distribution. For the latter, also contributions from dominating radionuclide are shown in order to explain effects leading to risk dilution (I-129) or otherwise (Ra-226) (from [15])

3.3.7 Presentation

SR-Can was presented in a main report [15] which refers to numerous supporting reports (including the above mentioned data report [36]), the most important of which are shown in Figure 16. For the scope of the report presented here, the main and data reports are of special interest. The main report follows starts with introductory and methodological parts and follows then the assessment steps as depicted in Figure 12. Disaggregation of presentation is achieved by presenting interim and "side" results and related discussions throughout the report. All these disaggregated information finally leads to the presentation of the risk summation results (cf. section 3.3.3 above) in order to demonstrate numerical compliance (Figure 17, also showing the contributions from the two scenarios as discussed above in section 3.3.3).

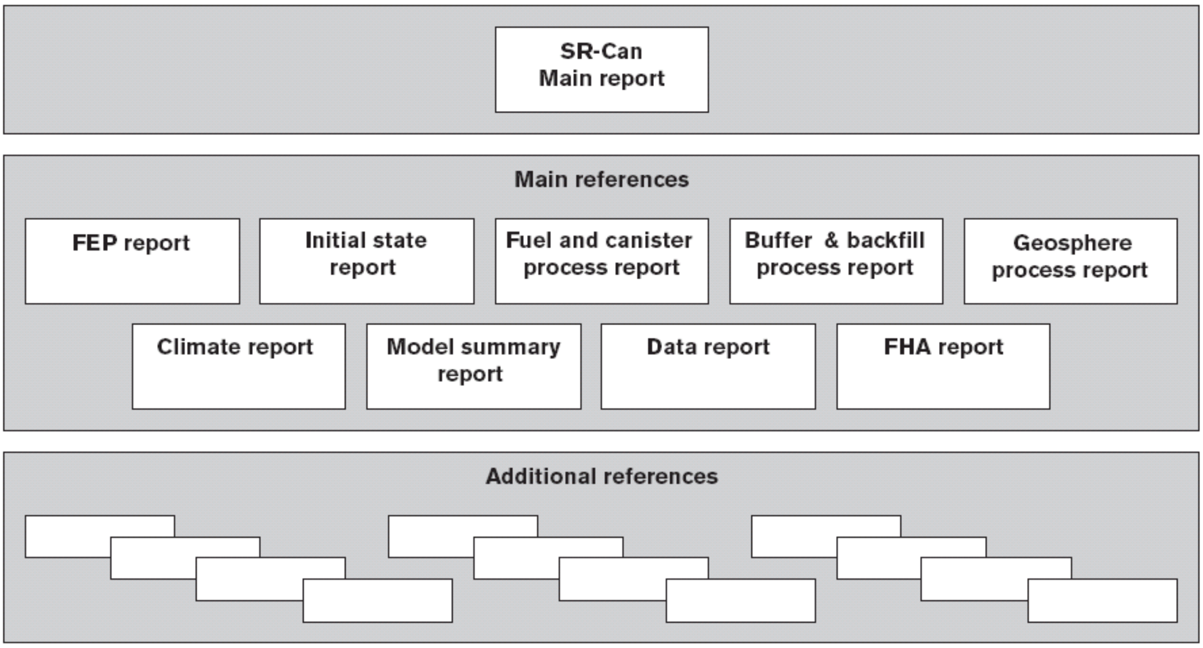

Figure 16 SR-Can: Hierarchy of the reports (from [15])

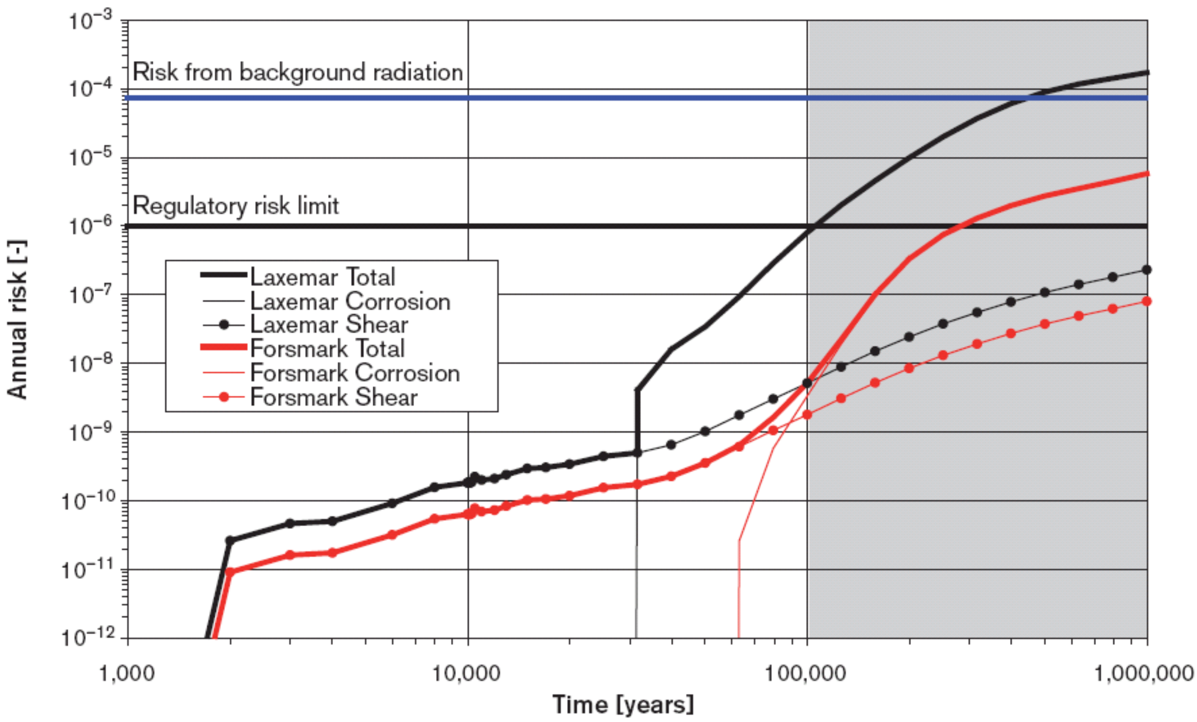

Figure 17 SR-Can: results of risk summation (from [15])

3.3.8 Other issues

Although the SR-Can report provides by far more information than given above in sections 3.3.1 to 3.3.7, these sections are considered sufficient for the discussion of “fully” probabilistic assessment approaches.

3.3.9 Results of the study and conclusions of the authors

First (and of most interest for this report), SKB discusses the compliance with the risk criterion. The assessment result that no canisters will fail in the first couple of thousand years is, with a view to SSI’s requirement to especially address the first 1000 years, especially emphasised. According to Figure 17, compliance with the risk criterion for both potential sites[6] is stated. For the Laxemar site, it is indicated that the hydraulic interpretation was not yet sufficiently representative and that further information was likely to improve the results. However, the fact that the calculated risk exceeds the regulatory limit almost exactly at the end of the assessment timeframe is not addressed.

The discussion of numerical compliance is followed by discussing several climate (especially glacial) conditions and scenarios, thus addressing specific regulatory requirements. A number of issues related to barrier performance which require further studies (positioning of emplacement boreholes, spalling, performance of the backfilled tunnels, EDZ issues) is named.

Some of the above is being repeated in a dedicated section in which regulatory compliance in general is addressed. Amongst the issues discussed there, the questions of compliance with the risk criterion (cf. above), of confidence building and of other issues related to safety assessment methodology (namely the request to present bounding cases) are of special interest for this report.

In the discussion of concerning confidence building, it is stated that a statement of confidenc has to be developed for the planned license application. Technology, site investigation, and research issues are addressed. In particular (and of interest w.r.t. assessment methodology) it is stated that the understanding of safety is strongly related to the tool of safety functions. With regard to completeness issues it is stated that the R&D efforts behind SR-Can and the methodologies applied support “… the claim that the SR-Can assessment is comprehensive, whereas completeness in a strict sense can never be proved. In this context it is, therefore, relevant to discuss possible consequences if completeness would not be achieved, for example if an important detrimental process would remain unidentified despite all efforts to ensure the opposite. In its most extreme form, such a discussion may take the form of the consequences of complete, early loss of safety functions. As evidenced by the section below, even very extreme and completely unrealistic assumptions regarding early barrier losses yield calculated doses that are comparable to those caused by the background radiation.

[6] In June 2009, SKB decided to file an application for a repository at the Forsmark site.

Based on the above reasoning, it is concluded that the SR-Can assessment is sufficiently comprehensive for its purposes."

An important part of the conclusions concerns the feedback to repository design, to canister design and fabrication, to site investigation and modelling, and to the R&D programme in general.

With regard to safety assessment methodology, it was concluded that the 10-step methodology in general was appropriate. For each of the steps, necessities for further development were discussed. In particular, this concerns updates of the FEP catalogue, the initial state description, the site descriptive models, of model flowcharts, and of definitions of safety functions, of data. The approaches to analysing the reference evolution and to derive and analyse scenarios were considered appropriate and to be re-used in the license application. It was acknowledged that scenario probabilities often could not be determined but were conservatively estimated which was "… primarily motivated by lack of knowledge on which to base estimates of probabilities." [15] Nevertheless, "essentially the same" was foreseen for the license application although some conservatisms might decrease.

3.3.10 View of the regulator

The views of SKI and SSI about SR-Can are summarised in a review report [37], the main findings of which "… are:

- SKB's safety assessment methodology is overall in accordance with applicable regulations, but part of the methodology needs to be further developed for the licence application.
- SKB's quality assurance of SR-Can is not sufficient for a licence application.
- The knowledge base needs to be strengthened for a few critical processes, such as buffer erosion, with potentially large impact on the calculated risk
- The link between assumed initial properties of repository components and quality routines of manufacturing, testing and operation need to be strengthened before the licence application.
- There is a need for a more elaborate reporting on the potential for early releases from the repository.

The first of these conclusions is of particular interest for this report. It is further substantiated by the following statements which are quoted without further comment because they appear to be condensed and comprehensive on their own:

"SKB's ambition is to structure the main report according to the ten steps in the safety assessment method. However, the SR-Can report is repetitive and, in some respects, complex. The authorities therefore consider that SKB may need to review the pedagogical aspects of the presentation prior to SR-Site. One example concerns the description of the method for safety assessment which is spread over several chapters, e.g. the strategy for uncertainty and sensitivity analysis, choice of scenarios, formulation of probabilistic and deterministic calculation cases, and risk summation. A description and justification of a compilation of the methods chosen for the safety assessment are needed (see also SAM)."[7]

"The authorities consider that SKB's system for documentation of different types of expert judgments has prerequisites to contribute to traceability of the data and assumptions on which the calculations in the safety assessment are based. However, SKB should clarify the roles of the different experts and the different levels of expert judgments."

"The authorities consider that SR-Can contains a set of calculation cases that together provide a good illustration of how uncertainties in the reference evolution affect the calculation results. However, the report is unstructured and an integrated description and justification of the strategy for uncertainty and sensitivity analyses is lacking, which has also been pointed out by SAM. A better explanation is needed prior to SR-Site of the purpose of different analyses and how SKB has selected calculation cases to shed light on critical uncertainties.

The report and discussion of the results from the uncertainty and sensitivity analyses are in some respects too brief to be able to understand the importance of different uncertainties (which could probably be explained by the lack of a dedicated report for the radionuclide transport calculations). A measure put forward by Maul et al (2008) is that all probabilistic calculations of risk should be based on a deterministic calculation case to illustrate critical factors. Another is to produce more complete texts for important figures."

"The authorities consider that SKB has described the problems with risk dilution in a correct way in SR-Can. The authorities also consider that SKB has illustrated the effects of risk dilution for the analysed canister failure cases in a credible way and that this approach is also a good starting point for the analyses in SR-Site. One exception applies to the calculation of dose factors for the biosphere (LDF) where it is not clear whether the dilution of radionuclides between different landscape objects can be justified taking into consideration the major uncertainties in the hydrogeological models … ."

"The authorities consider that the principles for choice of scenarios reported in Chapter 11 in the SR-Can main report comply with SKI's and SSI's regulations. The authorities consider like SAM that SKB's new approach of using safety functions to identify scenarios provides a good focus on the critical safety issues. However, the authorities have identified a number of issues in the application of the method, which should be taken into account prior to SR-Site. It is, for example, difficult to assess the completeness of the derivation of factors or combinations of factors that may affect the different safety functions/scenarios in Chapter 12 of the main report. The authorities also consider that a clearer description is needed of the method for choice of scenarios, including the newly-developed terminology, for example, the distinction between failure modes and scenarios."

[7] „SAM“ (Safety Assessment Methodology) refers to an external review reported in [38].

"The function indicators provide a good starting point for choice of scenarios, although since these function indicators do not claim to be complete, other factors may need to be taken into account to convince about the completeness of the choice of scenario, for example,

- alternative sequences and timescales for the climate evolution (see SSI FS 2005:5)
- gradually overlapping failure modes
- deviations in the initial state with respect to manufacture, handling and operation
- the importance of certain processes in the FEP database which have been excluded from further treatment early on"

"SKB's principles, as reported in SR-Can, for summing risk contributions from different scenarios complies with SSI's regulations and general guidelines (SSI FS 1998:1, 2005:5). This also applies to SKB's presentation of risk as a function of time and handling of risk dilution. Application of these principles in the final risk summation in SR-Can (section 12.12 in SR-Can main report) is, however, not clearly explained and entails a departure from SKB's own principles (the effects of buffer erosion have been formed by average values over a complete glaciation cycle despite erosion being assumed to begin first in connection with the first glaciation)."

"As mentioned previously the authorities consider that SKB's principles for risk summation and analysis of risk dilution comply with the authorities' regulations, which also applies to the division into time periods for reporting of risk. The final risk summation, as presented in Chapter 13 of the main report, is, however, insufficiently explained and does not describe the risk as a function of time in a correct way (the risk curve indicates in conflict with the scenario analysis that canisters will fail already before the next glaciation). The authorities further consider that SKB prior to SR-Site should provide a more detailed description of the risk curve presented in order to better show how different factors contribute to the risk during different time periods. The authorities also consider that SKB should complement the analysis of risk with a discussion about the importance of risk dilution. SKB has in the analysis of radionuclide transport carried out creditable analyses of risk dilution, but it is a deficiency that the results are not discussed in the overall risk assessment in Chapter 13 of the main report."

4. Summary and conclusions

The report presented here attempts to shed light on the role of regulations and regulatory expectations in relation to the application, applicability, and acceptability of so-called fully probabilistic assessment approaches as advocated by Thompson already in the 80ies of the last century [7]. It has to be distinguished between

- the degree to which (written) regulation prescribes / requires (or otherwise) the application of such methods on one hand, and

- the regulatory review process during which such an assessment will undergo scrutiny on the other.

Concerning the former, PAMINA Milestone 1.2.1, chapter 3.2 distinguishes, as described in Section 2.3, between three kinds of different regulatory approaches to the treatment of uncertainty:

1. Prescribed methods for the treatment of uncertainty,

2. Detailed regulatory guidance with only objectives defined,

3. No particular national guidance.

Almost all developed national regulations belong to type 2, the only exception being US regulations. Especially in the case of WIPP, assessment methods were prescribed at a very detailed level.

Apart from the prescription of methods, the definition of calculation endpoint(s) for numerical compliance demonstration appears to be a driver for choosing specific assessment methodologies: At a first glance, it seems that dose-based regulations are encouraging the use of deterministic methods while risk-based regulations are encouraging probabilistics. The former is due to the fact that, if one calculates doses in a probabilistic assessment, it is to be expected that some realisations lead to results violating the numerical criteria set by the regulation – and most dose-based regulations (e.g. the Swiss ENSI „maximal radiological dose“ formulation [17]) do not account for such a possibility. Consequently, “fully” probabilistic assessments in a dose-based regulatory environment are rare. The Yucca Mountain example shows, however, that such assessments are possible provided that the regulation appropriately addresses the issues relevant for probabilistic analyses. In the case of the Yucca Mountain regulation, „reasonable expectation“ is the key term around which this is being done.

In contrast, risk, interpreted as the mean of the “risk distribution”, might remain below the primary performance criterion (the “calculation endpoint”, primary safety indicator) even if a considerable number of single calculations lead to values not complying with the criterion. The assessment, however, remains unsatisfactory if the uncertainty of the results including the potential for risk dilution and risk aversion is not properly addressed and reported. But it must also be noted that even a risk criterion does not necessarily mean a request for a probabilistic assessment: The assessor can present a risk estimate solely based on deterministic calculations using the scenarios, their likelihoods, the resulting doses and conditional risks, and the dose-risk relationship (or upper bounds for these entities, e.g. unity for scenario likelihoods).

Experience shows, however, that assessments which combine deterministic and probabilistic calculations are effective when exploring the space of uncertainties even in cases in which not every probability statement resulting from these analyses is fully justified because the choice of input parameter distributions is sometimes hard to substantiate. International guidance such as the evolving IAEA Safety Guide DS355 "The Safety Case and Safety Assessment for Radioactive Waste Disposal"[8] accounts for this experience; and the Swedish SR-Can assessment gives an example in which deterministic and probabilistic methods were combined in a pragmatic way in order to demonstrate compliance with a risk criterion.

This report is not meant to discuss the pros and cons of dose-based versus risk-based criteria (or combinations of the two) in general but from the above it follows that

- dose-based criteria should avoid language which prevents from exploring the uncertainty space due to the fear that some calculations might yield results exceeding the criterion, and
- risk-based criteria should not be limited to requesting the presentation of mean values but encourage to address the whole uncertainty space.

Concerning the regulatory review process, it is evident that the informed regulator will ask for variation, uncertainty in results, risk dilution and related issues even if these are not addressed in written regulations. By default, this leads to the necessity for the applicant to disaggregate the presentation of results even in cases in which written regulations do not require such disaggregation. In the case of probabilistic assessments, it is of high interest to learn about the full result distribution including statistics other than mean values, e.g. percentiles etc.[9]

In the following, some aspects of such disaggregation are discussed based on the review of selected assessments as reported in the previous sections of this report. As discussed in the introduction, the selection of assessments for review had to be subjective, especially because "fully" probabilistic assessments in the strong sense of the word do not really exist (perhaps with Dry Run 3 as the only exception).

The following assessments have been selected for review in this PAMINA WP:

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[8] http://ns-files.iaea.org/fileshare/files/nsrw/647/METCALFDS355SafetyCaseRadWaste09-04-09.doc

[9] Of course, other disaggregated results informing about the contributions of different radionuclides, pathways of release, or scenarios to the overall consequence or the performance of different barriers are of equally high interest but these issues go beyond the scope of this report.

- The “Dry Run 3” exercise [10] carried out by the UK HMIP in the early 90ies because it represents the first attempt to thoroughly perform a fully probabilistic assessment and probably even today can be seen as the most consequent implementation of a fully probabilistic assessment,
- the assessments carried out by the U.S. DoE in support of the applications for certification [12] and re-certification [13] of the Waste Isolation Pilot Plant (WIPP) and of the license application for the Yucca Mountain Repository [14] due to their particular approaches to deal with aleatory and epistemic uncertainty in probabilistic assessments, and
- the Swedish SR-Can assessment published by SKB in 2006 [15], which dealt with a risk criterion using an assessment approach in which deterministic and probabilistic methods were combined and which is, compared to other recent assessments, one rather heavily relying on probabilistic techniques.

It is not always clear what is meant by a “fully” probabilistic assessment: “Conventional” probabilistic assessments are those restricted to parameters for which a pdf can be derived reasonably well (“aleatory uncertainty”). Possible extensions of this concept are:

- assigning pdf’s to unknown parameters without having a sufficient statistical basis (“epistemic uncertainty”), i.e. by means of formal expert elicitation for which a variety of approaches is in use,
- addressing scenario (“temporal”) uncertainty by assigning likelihoods of occurrence to scenarios), and
- addressing alternative conceptualisations and modelling approaches which is an issue further to be explored in another part of this PAMINA WP.

The first of these possibilities is not further discussed here since it was comprehensively addressed elsewhere within PAMINA [29]. It should, however, be noted that the US assessments reviewed here make, based on regulatory requirements, a clear distinction between addressing aleatory and epistemic uncertainties.

There were not many examples for formally addressing conceptual or model uncertainties in a quantitative way. The WIPP PA did consider conceptual model uncertainties by using an indicator variable as an uncertain parameter in the system-level analysis that selected between the alternative models (by assigning weights to the models). The SR-Can assessment is an example in which a deterministic treatment of such uncertainties was systematically incorporated into a probabilistic framework.

Concerning “scenario” or “temporal” uncertainty the question arises whether the “scenario approach” as opposed to a “fully” probabilistic assessment is indeed and still an antagonism as suggested by Thompson [7]. It is clear that some kind of scenario development is needed in any assessment – even Dry Run 3 was based on previously developed scenarios, although without explicitly acknowledging this. In recent assessments it became increasingly clear that the attempt "to investigate the full range of possible repository and environmental developments, and to assign probabilities coherently so that consequences can be combined" [10], i.e. to be complete in the full sense of the word is neither feasible nor necessary. Instead, scenario development based on safety functions provide the possibility of being comprehensive in the sense that conceivable violations of these functions are sufficiently accounted for in the scenarios considered. The Swedish example shows that this does not prevent from performing assessments in a risk-based regulatory environment. Moreover, it can be seen as a demonstration of how to combine deterministic and probabilistic methods in such an environment.

As reported in the introduction, it had further been argued in favour of fully probabilistic approaches that

- the existing scientific knowledge was used better and more explicitly and in a way less dependent on subjective judgements about future system evolution,
- the utilisation of well-defined models allowed a better dispute in the case of scientific criticism and a better verification, and
- the approach resulted in a traceable quantified description of potential future evolutions.

Experience shows, however, that the first two of these requirements are equally well fulfilled in most recent assessments no matter to which degree they are "fully" probabilistic. As far as traceability is concerned, the same holds for the last requirement. The question of quantification or quantifiability, however, remains the central and decisive point for the choice of approaches while the point of aggregating or disaggregating results seems not to be decisive here.

In a predecessor of the above-mentioned Yucca Mountain Assessment, the so-called TSPA-VA (VA = Viability Assessment) [39], this question of aggregation or disaggregation had been discussed as follows:

"In some cases, these alternatives form a continuum, and sampling from the continuum of assumptions fits naturally within the Monte Carlo framework of sampling from probability distributions. In other cases, the assumptions or models are discrete choices. In particular, some processes are so highly uncertain that there is not enough data to justify developing continuous probability distributions over the postulated ranges of behavior. In other words, a high degree of sampling is unwarranted, and it is better just to look at two or three cases that are assumed to encompass (bound) the likely behavior.

There are two possible approaches to incorporating discrete alternative models within the TSPA: weighting all models into one comprehensive Monte Carlo simulation (lumping), or keeping the discrete models separate and performing multiple Monte Carlo simulations for each discrete model (splitting).

There are advantages and disadvantages to both approaches. Lumping has the conceptual advantage that a single CCDF can be said to include all the system uncertainty. Splitting can lead to a profusion of cases that makes it difficult to quantify the relative importance of the various discrete assumptions. The main disadvantage of lumping is the concern that individual cases with poor performance might be diluted within a multitude of more favorable cases. In other words, there could be a combination of the discrete assumptions with poor performance that might not be obvious under the lumped approach but that would stand out if that combination were presented separately. Another potential disadvantage of lumping occurs if there is no good justification for the probabilities used - if the weighting of the alternatives is artificial, then the results will be artificial as well.

For this TSPA, a combination of the two approaches is used. In particular, the TSPA-VA "base case" model … can be considered an implementation of the splitting approach, because it is based on a limited range of uncertainty."

The above-mentioned concern about low-probability cases or scenarios, especially with regard to the statistical confidence in results, was also addressed in the Canadian 1994 assessment [40][41]. We did not review this assessment in section 3 – it is another assessment in a risk-based regulatory environment based on an approach inspired by "HMIP Dry Run 3". Even the calculation code SYVAC-CC3 belongs to the same family as the VANDAL code used in "HMIP Dry Run 3". It is, however, to less a degree a "fully" probabilistic assessment since it separates low-probability scenarios from the ones to be handled within the "fully" probabilistic framework (the so-called "SYVAC" scenarios):

"We have determined that a practical approach to evaluate a low-probability scenario is to treat it separately from high-probability scenarios. Thus we not included the factor for inadvertent intrusion in the SYVAC scenarios, and we do not estimate impacts for human intrusion using the system model in SYVAC3-CC3. (If we were to include in SYVAC3-CC3 an event whose probability of occurrence is 10^{-6}, we would need to perform more than 3 million randomly sampled simulations to be confident (at the 95 % level) that the event would have been selected in at least one simulation ... .)" [41]

It can thus be concluded that, to a certain extent, the decision about when to aggregate and when to do otherwise has to be based on common sense. (There are, however, limitations if regulations are restrictively addressing this issue). Aggregation ("lumping") makes sense when pdf's, dependencies, correlations, interactions are well-known. It helps exploring the full uncertainty space, but probability statements have to be taken with care when their basis (input parameter pdf's) is not sufficiently justified. In contrast, disaggregation ("splitting") is sensible for cases or sub-spaces with low or unknown probabilities and for demonstration purposes. It is also essentially for assessments serving repository development rather than compliance demonstration. It helps understanding and communicating specific issues such as the performance of single repository components.

The questions whether "fully" probabilistic assessments really circumvent the problems of looking for conservative data (as claimed by Thompson) needs further to be investigated.

More generally, the question of conservatisms in probabilistic assessments deserves further attention. If assessments are undertaken to support repository development and thus the major objective is *understanding*, fully probabilistic assessments might to be used to “find” critical subsets of the uncertainty space. This would, however, only work if the full model is “very” realistic, every rough estimate or conservatism might spoil this search. For the purpose of compliance demonstration, conservatisms are not so much a problem as long as they do not result in too much overestimation of potential consequences.

Finally, it should be mentioned that the idea of using the toolbox of stochastic processes to address temporal uncertainties had only been materialised in the “HMIP Dry Run 3” and in the US assessments. It might be worthwhile to explore its potentials further in other assessment contexts.

5. List of Figures

6. List of Tables

7. References

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