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Quality Assurance in Safety Case of Geological Disposal System

Perspective in Regulation

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Why are we here today?

- It is an important time for Japanese High-level radioactive waste repository project
- Quality of a safety case is a very important issue at every stage of repository planning & implementation
  - Implementers are required to present and explain to a wide range of stakeholders why they are confident in the safety of their programme
  - Regulators will be required to provide information to a wide range of stakeholders on how their regulations will ensure safety
- Key objective is assuring the quality of safety case inevitable to support decision making and to build confidence

A Safety Case

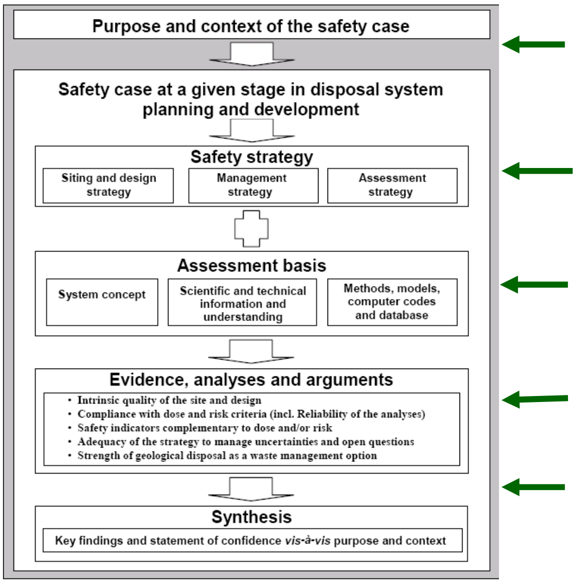
- It is the main vehicle for ensuring that these challenges are met

The safety case is an integration of arguments and evidence that describe, quantify and substantiate the safety, and the level of confidence in the safety, of a geological disposal facility

IAEA Safety Standard for Geological Disposal

- There was, is and will be substantial discussions and developments behind this apparently simple statement

An overview of a safety case and regulators role



- The regulator will define the safety standards that defines the levels of risk that are acceptable for given circumstances and given types of facilities
- The regulator will review the work of the implementor as it proceeds and may develop or define requirements and guidance to arrive at an appropriate set of regulations for the facility during its construction, operation and closure

Developing a safety case

- Developing a safety case for the post-closure period is a challenging task that differs in some key respects from demonstrating pre-closure safety as well as the safety of other types of nuclear facilities
- These differences relate in particular to the limited possibilities for monitoring and corrective actions after closure, and to the uncertainties, arising from the long time over which post-closure safety is assessed

Required quality for safety functions(1/2)

- Engineering function
  - Designed, allocated and manufactured function for each component of EBS e.g.
    - Overpack to prevent the groundwater to come in contact with the waste form
    - Bentonite buffer to absorb the radionuclide that may be dissolved in the groundwater
  - Quality of technology is crucial that may be assured by the similar quality management measures applied for conventional facilities including nuclear reactors

Required quality for safety functions(2/2)

- **Passive function**
  - **Intrinsic (natural=spontaneous) function of the suitable geological environment e.g.**
    - Rock mass to assure the physical isolation of the wasteform
    - Groundwater system to retard and dilute the migration of dissolved radionuclides
  - **Quality of scientific knowledge is crucial for building confidence that is unique to the geological disposal system**

Case studies of QA

- **USA**
  - **NRC･Yucca Mountain Review Plan**
  - **DOE･Yucca Mountain Repository (YMR) License Application**
  - **DOE･WIPP/Quality Assurance Program Document (QAPD)**
- **Sweden**
  - **SKI･Regulatory Code**
  - **SKB･SR-Can**
- **Finland**
  - **POSIVA･Safety Case 2008**

Yucca Mountain Review Plan（excerpt from NUREG-1804）

- **Review Method 1 Model Integration**
  - **Examine assumptions, technical bases, data, and models used by the U.S. Department of Energy in the abstraction of flow paths in the saturated zone for consistency with other related U.S. Department of Energy abstractions. Evaluate whether the descriptions and technical bases provide transparent and traceable support for the abstraction of flow paths in the saturated zone.**
- **Review Method 2 Data and Model Justification**
  - **Evaluate whether sufficient justification has been provided for climatological and hydrological values used in the license application, and whether the description of how the data are used, interpreted, and appropriately synthesized into the parameters is sufficiently transparent and traceable.**
- **Review Method 3 Risk Significance Categorization of Structures, Systems, and Components Important to Safety**
  - **Verify the documentation, analysis, and criteria used for risk significance categorization of structures, systems, and components important to safety is transparent and traceable with a well defined technical basis.**

Model Abstraction

- Mechanical Disruption of Engineered Barriers
- Quantity and Chemistry of Water Contacting Engineered Barriers and Waste Forms
- Radionuclide Release Rates and Solubility Limits
- **Climate and Infiltration**
- Flow Paths in the Unsaturated Zone
- Radionuclide Transport in the Unsaturated Zone
- Flow Paths in the Saturated Zone
- Radionuclide Transport in the Saturated Zone
- Volcanic Disruption of Waste Packages
- Airborne Transport of Radionuclides
- Concentration of Radionuclides in Ground Water
- Concentration of Radionuclides in Ground Water
- Redistribution of Radionuclides in Soil
- Biosphere Characteristics

DOE･YMR License Application（excerpt）- (1)

Management systems will ensure that sufficient data exist to confirm TSPA bases are satisfied and that the Performance Confirmation Program provides appropriate confirmatory bases as part of making the determination to permanently close the repository.

5.1QUALITY ASSURANCE

[NUREG-1804, Section 2.5.1.3]

The Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD) describes the requirements of the Quality Assurance Program that apply to quality-related activities at the Yucca Mountain repository. The QARD is prepared in accordance with the requirements of 10 CFR 63.21(c)(20) and 10 CFR 63, Subpart G, addresses the acceptance criteria contained

10 CFR 63.21(c)(20) A description of the quality assurance program to be applied to the structures, systems, and components important to safety and to the engineered and natural barriers important to waste isolation. The description of the quality assurance program must include a discussion of how the applicable requirements of § 63.142 will be satisfied.

63.142 Quality assurance criteria. DOE is required by § 63.21(c)(20) to include in its safety analysis report a description of the quality assurance program to be applied to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to related activities. These activities include: site characterization; acquisition, control, and analyses of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; facility operation; performance confirmation; permanent closure; and decontamination and dismantling of surface facilities.

（DOE,YMR_LA_SAR, 2008） **10**

DOE･YMR License Application（excerpt）- (2)

SAR (Safety Assessment Report):"Data and Model Justification"

2.3.1.3.3 Infiltration Modeling and Uncertainty

[NUREG-1804, Section 2.2.1.3.5.3: AC 1(3), (5) to (7), AC 2(2) to (6), AC 3(1), (3), (4), AC 4)]
Development of the MASSIF model and uncertainties associated with both the MASSIF model and the input parameters for the model are addressed below.

2.3.1.3.3.1 MASSIF Model
The MASSIF model estimates net infiltration at the Yucca Mountain site based on a daily water balance calculation of the near-surface soils. The water balance includes net precipitation as input, water storage and movement within the soil (including evapotranspiration), and water moving either from soil into the underlying bedrock or directly into bedrock where it is exposed at the surface.
The model domain is composed of a number of cells with equal surface area that extend from the surface to the contact with the underlying bedrock. The description of each cell includes the cell depth as defined by the soil layer depth; soil type and associated properties; cell elevation, azimuth, and slope; fraction of the surface covered by the vegetation canopy; and vegetation related characteristics. Each cell is composed of one to three soil layers, depending on the soil depth (Figure 2.3.1-22). However, some grid cells have no soil and therefore have no soil layer in the model (SNL 2008a, Table 6.5.7.6-2[a]).

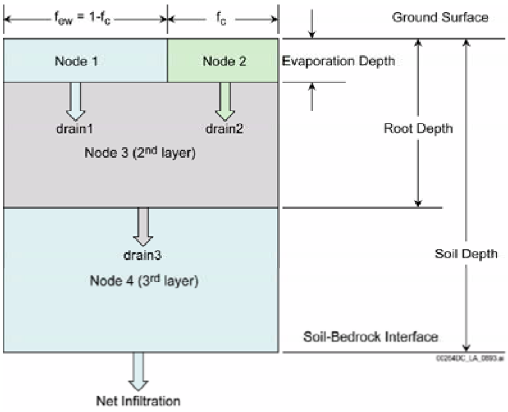


Figure 2.3.1-22.Schematic Showing the Vertical Soil Layers and Computational Nodes Present in a Single Model

（DOE,YMR_LA_SAR, 2008） 11

DOE･YMR License Application（excerpt）- (3)

SAR:"Data and Model Justification"

2.3.1Climate and Infiltration

[NUREG-1804, Section 2.2.1.3.5.3: AC 1, AC 2, AC 3, AC 4, AC 5]

2.3.1.2.1.2.1Relations between Present and Past Climate
The present-day earth climate system is a three-component system (Figure 2.3.1-5) consisting of two active components—the tropical (Hadley) cell and polar cell air masses—and a more passive mixing zone between them (the westerlies or Ferrel cell) (BSC 2004a, Section 6.2).

2.3.1.2.1.2.3Earth-Orbital Parameters and the Timing of Past and Future Climate Change

The precession methodology was used to forecast the timing of climate change over the next 100,000 years (Figure 2.3.1-12). The timing of possible climate change toward and away from the next glacial period is the same as for the cycle beginning about 400,000 years ago because of a repeat of the earth's long eccentricity cycle (Figures 2.3.1-10 and 2.3.1-11). The duration of the period between the initiation (I) of climate change toward the glacial climate at 399,000 years ago and the climate change away (T) from the glacial climate is 44,000 years. In Figure 2.3.1-12, the time between a change toward the glacial climate (I) at 1,000 years ago to the change away (T) at 44,000 years in the future is 45,000 years. As shown in Figure 2.3.1-11, the timing for the change toward and away is much longer for the remaining three glacial periods in the 400,000-year cycle, with durations of 58,000, 80,500, and 83,000 years, respectively.

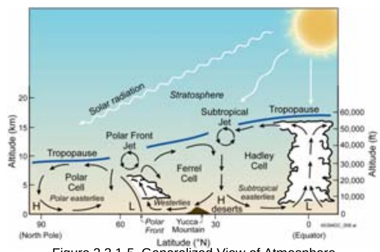


Figure 2.3.1-5. Generalized View of Atmosphere Circulation under Present-Day Climatic Conditio

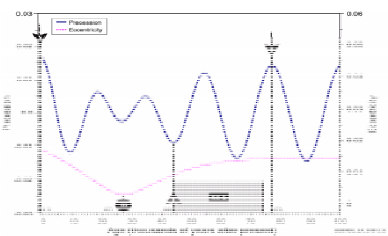


Figure 2.3.1-12. Forecast of Timing of Future Climate Change during the Next 100,000 Years

（DOE,YMR_LA_SAR, 2008） 12

DOE･WIPP/QAPD（excerpt）

- Basis：NQA-1,2a,3（ASME, 1989, 40CFR194, 1996）
- Processes applied
  - Performance assessment
  - Inspection and testing
  - Scientific investigation
- Object of QC
  - **Tools**
  - **Sample**
  - **Software**
  - **Documents**
  - **Records**
  - ・・・・・・・・
- QA Principle：T2R3*

① Traceable
② Transparent
③ Reviews
④ Reproducible
⑤ Retrievable

(＊Pikering, 2000)

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SKI･Regulations concerning Safety in Nuclear Facilities (excerpt)

- **Chapter 4. 1 § Safety analyses**

A safety analysis should generally be of high quality with respect to documentation, references, review procedures etc. The objective of the analysis should be clearly specified as well as the uncertainties and limitations of the analysis. Furthermore, the analysis should have a good traceability and well-justified assumptions and data which are relevant for the facility. The report of results should contain an explicit conclusion regarding the safety of the facility within the conditions and limitations of the analysis.

(SKIFS 2004:1, November 18, 2004)

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SKB･SR-Can (excerpt)

- ***Quality assurance of SR-Can***
  - **Now that SKB is approaching the stage of license applications for new installations, the importance of quality assurance and traceable documentation increases. Future safety reports need to be traceable and transparent, and it should be possible to reproduce analyses that are important for long-term safety and radiation protection.**

(SKB Technical Report TR-06-09)

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POSIVA･Safety Case 2008（excerpt）

5 MANAGEMENT OF QUALITY

- 5.1 Goals and principles

The purpose of Posiva's management system is to ensure, in a documented and traceable way, that Posiva's products - whether in the form of abstract knowledge and information published reports or physical objects - fulfil the requirements set for them. The general quality objectives, requirements and instructions defined in Posiva's management system will also form the foundation for the quality management of safety case activities carried out in the future. However, special attention will be paid to the management of the processes that are applied to produce the safety case and its basis. The purpose of this enhanced process control is to offer full traceability and transparency of the data, assumptions, modelling and calculations.

(POSIVA 2008-05, July 2008)

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Important Keyword of QA in PA

"Transparency and Traceability"

Transparency- a safety case should be presented in ways that are both clear and understandable to the intended audience; the objective is to inform the audience's organisational or personal decisions regarding safety;

Traceability- with respect to the step by step decision making process and for more technical audiences, it must be possible to trace all key assumptions, data and their basis, either through the main documents or supporting records;

OECE/NEA 2004

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Traceability

"An unambiguous and complete record of the decisions and assumptions made, and of the models and data used in arriving at a given set of results "

To be complete, at a minimum, this record should include,

a. information on when and by whom various decisions and assumptions were made,
b. the basis for the assumptions,
c. how these decisions and assumptions were implemented, and
d. what versions of codes and data sets were used

(NEA, 1998)

"Traceability exists when there is an unbroken chain linking the result of an assessment (e.g., final dose calculation) with models, assumptions, expert opinions, and data used in the formulation of the result."

（Standards Laboratories,1994）

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Transparency

"… written in such a way that its readers can gain a clear picture, to their satisfaction, of what has been done, what the results are, and why the results are as they are …"

(NEA, 1998)

"Transparency exists when there are systems (e.g. procedures, protocols, and conventions) in place that ensure the reliability of data, processes, and methods and provide the reviewer or user with clear evidence of reliability." **(King,1992)**

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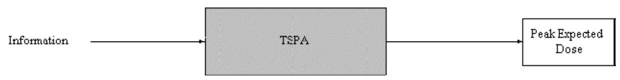
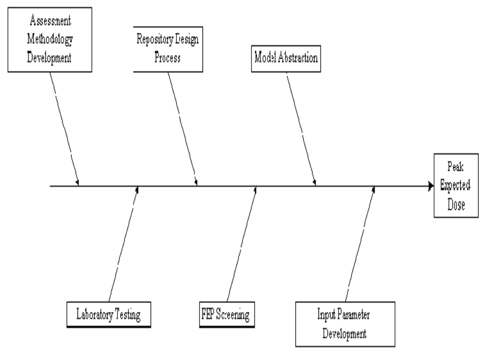
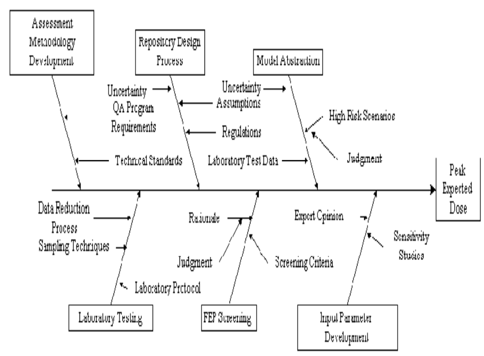
Examples of degree of transparency



(a) black box



(b) partially transparent



(c) fully transparent

(Mohanty, et al., 2001)

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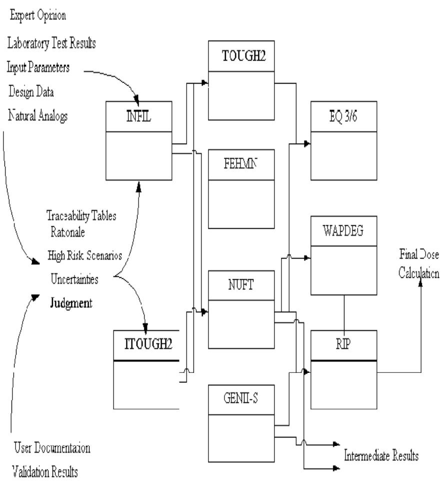
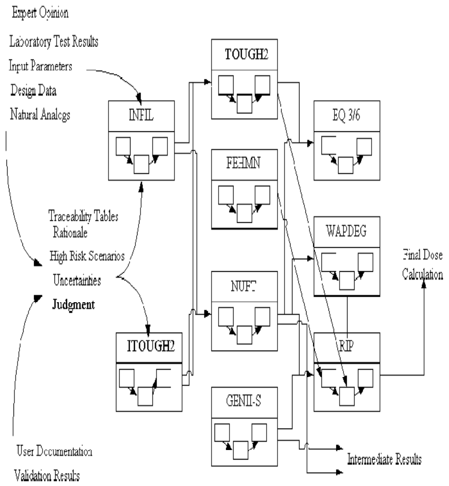
Examples of modularity in the PA model



(a) with partial transparency



(b) with additional transparency

(Mohanty, et al., 2001)

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QC Items for Performance Assessment (1/3)

1. Validation of scenario and model

- ✓ Validation of data for scenarios and models
- ✓ Validation and verification of models and assessment codes
- ✓ Introduction of expert elicitation process for the input data and models based on expert judgement to make them transparent and unbiased (POSIVA Safety Case 2008-5)

QC Item	Process	Required Quality
Scenario	•Identification and screening of FEP's •Development of scenarios	•Validity of FEP list •Distinct knowledge of supporting evidence for selection •Objective validity of scenario classification
Model	Abstraction of important phenomena and formulation of conceptual and mathematical model	Objective knowledge to support model justification and to define uncertainties in

QC Items for Performance Assessment (2/3)

2. Collection and Validation of data
   - ✓ Field and lab test
   - ✓ Natural analogue
   - ✓ Implication of academic data
   - ✓ Expert opinion（including tacit knowledge）

   - ✓ System components relevant to post closure safety

Component	Process	Required Quality
Waste Form	Characterization	Description of leaching/dissolution performance and uncertainties associated
EBS	Design, fabrication and construction	Description of performance of each EBS components and uncertainties associated
Geological Environment	Site characterization	Synthesis of data into a set of knowledge to illustrate geological environment
	Collection of broader geological knowledge	Appropriate implication from viewpoint of repository safety

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QC Items for Performance Assessment (3/3)

3. Interpretation of assessment result
   - Knowledge to examine :
     - ✓ Traceability of assumption, abstraction and modeling
     - ✓ Sensitivity
     - ✓ Reproducibility

4. Attributes for ensuring transparency of assessment tools
   - ✓ Design of codes
   - ✓ Data flow
   - ✓ Verification of calculation codes
   - ✓ Supporting documents

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QC Requirement (1/2)（excerpt from WIPP/QAPD）

PERFORMING SCIENTIFIC INVESTIGATIONS

- **Performed in accordance with documented test plans, procedures, and scientific notebooks.**
- **Scientific notebooks;**
  1. **Statement of the objectives and description of work**
  2. **Methods**
  3. **Samples**
  4. **Measuring and Test Equipment**
  5. **Work and results, the names of individuals, date, initials or signature of individuals**
  6. **A description of changes in methods**
  7. **Controls of potential sources of uncertainty and error**
- **Scientific results periodically reviewed to verify sufficient detail to confirm the results**
- **Practices, techniques, equipment, and manual or computerized methods be verified technical soundness**
- **Controls to ensure proper implementation, including controls to prevent tampering.**
- **Controls in Data collection and analysis to allow processes to be repeated.**
- **Quality control checks using methods such as replicate, spike, and split samples; control charts; blanks; reagent checks; replication of the methods; alternate analysis methods.**
- **Test media (e.g., fluids), be characterized and controlled**
- **Scientific notebooks and technical documents be maintained as QA records.**

QC Requirement (2/2)（excerpt from WIPP/QAPD）

Data Validation

Data validation is a systematic process used to review data to ensure that the required data quality characteristics have been obtained. Results of the review may require that qualifiers be placed on the use of the data.

A. Validation methods shall be planned and documented. The documentation shall include the acceptance criteria used to determine if the data are valid.

B. All applicable data collected shall be validated. Validation shall include the following:

1. The relevant documentation is reviewed to evaluate the technical adequacy, the suitability for the intended use, and the adequacy of the QA record.
2. The results of the data review shall be documented.
3. The reviewer shall be independent of the collection activities.

C. Data validation shall be controlled to permit independent reproducibility by another qualified individual.

D. Data considered as established fact by the scientific and engineering community, such as engineering handbook data or critical tables, do not require validation.

KMS developed by JAEA

- **Current status**
  - **Concept (JAEA H-17 Progress Report)**
    - Structuring a knowledge basis from the viewpoint of building a safety case
    - Produce, maintain, refine and transfer relevant knowledge by introducing knowledge management
  - **Developing the system using state-of-the-art technology in the fields of knowledge engineering and IT**
  - **Partial demonstration by a prototype system**
    - ISIS (Information synthesis and interpretation system)
    - Performance assessment “All-in-one” report
    - “Coolrep” protocol for KMS users
  - **International peer review**
    - JAEA/KMS workshop (11-14 November 2008)

KMS potential application

- **“ISIS”**
  - ✓ **Assuring the sufficiency of data required for building a safety case**
  - ✓ **Quality management of data and information**
  - ✓ **Ensuring T&T in repository siting**
- **“All-in-one” report**
  - ✓ **Quality management of analytical tools and processes**
  - ✓ **Ensuring T&T in performance assessment**
- **Knowledge base**
  - ✓ **Analytical tools, database, know-how and case studies**
  - ✓ **Reference access**
- **“Coolrep”**
  - ✓ **Representing the entire picture of technology relevant to building a safety case for a geological disposal system**
  - ✓ **Easy and free access to the relevant technical documents by digital forms**

Future directions

- Assessing the applicability of foreign QA elements to the Japanese case
  - ✓ Volunteer approach
  - ✓ Difference in allocation between engineering/passive performances
  - ✓ Considering ethical and cultural aspects
- Case studies in the other fields of industry
  - ✓ Software development
  - ✓ Land and ocean resources development
  - ✓ Climate and space
- Establishing and applying the QC manual as a key to assure the overall quality of JAEA/KMS

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