



# Regulatory Review and Authorization for Disposal of DSRS

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# Topics

- Independent Review and Assessment
- Objectives and Attributes of the Regulatory Review Process
- Managing the Review Process
- The Use of a Graded Approach by the Regulatory Body
- Conduct of the Review and Reporting of Review Findings

# Independent Review and Assessment

- Primary objective of the safety case is to support decision making relevant to the stage of the development, operation and closure of a disposal facility
- Operator of a disposal facility should submit the safety case and its associated safety assessment to the regulatory body for independent review and assessment
- Principal aim of review is to judge the quality of the safety case in the context of the regulatory requirements and the stage that the project has reached
- Requires an examination of the arguments, data and level of understanding (e.g. uncertainties) presented by safety case

# Independent Review and Assessment

- Independent review and assessment evaluate whether:
  - Compliance with safety requirements is demonstrated
  - Safety case contains and presented in sufficient detail
  - Data and information presented are sufficiently accurate
  - Safety case demonstrates the design has been optimized and (with reasonable assurance) that the safety objectives & criteria will be met
  - Management system(s) is adequate and arrangements for the preservation of records are adequate

# Objectives and Attributes of the Regulatory Review Process

- Overall goal of regulatory review is to verify that the disposal facility will not cause an unacceptable adverse impact on human health or safety, or on the environment, both now and in the future

# Objectives and Attributes of the Regulatory Review Process

- To achieve this goal, the regulatory review process will typically have the following objectives:
  - Determine if safety case has been developed to an acceptable level (fit for purpose)
  - Verify that safety case and assumptions on which it is based comply with, or are in accordance with, accepted principles for radioactive waste management and regulatory requirements and expectations
  - Determine whether safety case provides an adequate and appropriate basis to demonstrate that the proposed facility will be operated safely and provides reasonable assurance of compliance
  - Verify that measures for mitigating unlikely potential effects have been identified and addressed, & that adequate follow-up plans for their implementation have been developed
  - Identify unresolved issues & verify that plans to address these issues have been developed

# Objectives and Attributes of the Regulatory Review Process

- To facilitate the evaluation of the safety case against the primary objectives of the regulatory review, secondary objectives may be specified
  - Has been developed within an appropriate context
  - Is sufficiently complete, given the stage of development of the disposal facility
  - Is sufficiently transparent in its presentation of data and information
  - Has been prepared by competent personnel applying an established management system
  - Is based on appropriate assumptions and makes use of adequate assessment techniques and models, and contains satisfactory supporting arguments

# Objectives and Attributes of the Regulatory Review Process

- To facilitate the evaluation of the safety case against the primary objectives of the regulatory review, secondary objectives may be specified
  - Demonstrates an adequate understanding of the disposal system that includes identification and screening of hazards and related scenarios such that all relevant safety functions and safety concerns are addressed
  - Identifies the uncertainties associated with the understanding of the disposal system (input data/models used) and the performance of the disposal facility
  - Provides an adequate assessment and supporting justification that any radiation exposure and risks associated with the facility will be as low as reasonably achievable (ALARA)
  - Demonstrates that good engineering practices with adequate defence in depth have been used in developing the design of the facility

# Managing the Review Process

- The management of the review of a safety case or safety assessment should be treated as a project in itself, to which the principles of good project management apply
- Depending on the scale of the review, it may be necessary to establish a dedicated team of personnel to conduct the review
- Composition and characteristics of the review team
  - Responsibility of the review team
  - Technical capabilities
- Regulatory review may be conducted by the regulatory body with or without support from external organizations

# Managing the Review Process

- Results of the review are the responsibility of the regulatory body and should be fully 'owned' by it
- The regulatory body should have in place well established and documented procedures for the review process as part of the overall management system for the organization
- Review procedures should allow the regulatory body to verify that the review of the safety case has been performed by competent people, and has been recorded in a traceable and auditable manner
- A review plan will be necessary to provide guidance on procedural and technical aspects of the review

# The Use of a Graded Approach by the Regulatory Body

- Level of scrutiny and the scope of the regulatory review of a safety case should follow a graded approach
  - Stage of development and operation of the disposal facility or component of the disposal system
  - Magnitude of the hazards and risks in the period after closure, with consideration given to relevant site factors, facility design aspects, the waste to be disposed of, the likelihood of human intrusions, etc.
  - Complexity, safety significance and maturity of the proposed disposal facility or component of the disposal system

# The Use of a Graded Approach by the Regulatory Body

- Level of scrutiny and the scope of the regulatory review of a safety case should follow a graded approach
  - Complexity, safety significance and maturity of the proposed disposal facility or component of the disposal system
  - Use of well established practices, procedures and designs
  - Available knowledge of the operational performance of similar facilities
  - Relevant experience from similar disposal facilities
  - Technical or safety concerns of other competent authorities

# Conduct of the Review and Reporting of Review Findings

- A regulatory review will normally have four phases:
  - A pre review phase, prior to the receipt of any documents from the operator, in which initial planning for the review should be carried out. This should normally involve meetings with the operator to seek to understand the extent of the information that will be provided.
  - An initial review phase, during which the regulatory body should make an initial evaluation of the submitted documents to assess the completeness of the safety case and the availability of supporting documents, and to make a preliminary identification of those issues that are most important to safety

# Conduct of the Review and Reporting of Review Findings

- A regulatory review will normally have four phases:
  - A **main technical review phase** in which the bulk of the effort will be expended. This should include the development of detailed review comments, and may include evaluation of additional information provided by the operator in response to comments
  - A **completion phase**, in which the main conclusions of the review should be identified and used to inform the decision making process



Thank You for Your Attention!