

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

Proc. TOP-001-06

Revision 0

**TECHNICAL OPERATING PROCEDURE**

Page 1 of 39

Title

**TOP-001-06 Procedure for Regulatory Requirement Categorization and Compliance Determination Strategy Development**

**EFFECTIVITY AND APPROVAL**

Revision 0 of this procedure became effective on 12/21/90. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
ALL	0	12/21/90

Supersedes Procedure No. N/A

**Approvals**

Written By <i>John P. Hageman</i> John P. Hageman	Date <i>12/21/90</i> 12/21/90	Technical Review <i>Pat Mackin</i> Pat Mackin	Date <i>12/21/90</i> 12/21/90
Quality Assurance <i>Bruce Mabrito</i> for Bruce Mabrito	Date <i>12/21/90</i> 12/21/90	Cognizant Director <i>Allen R. Whiteing</i> Allen R. Whiteing	Date <i>12/21/90</i> 12/21/90

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 2 of 39

**TOP-001-06 PROCEDURE FOR REGULATORY REQUIREMENT CATEGORIZATION  
AND COMPLIANCE DETERMINATION STRATEGY DEVELOPMENT**

1. PURPOSE

The purpose of this procedure is to describe the method and the criteria used to categorize the Regulatory Requirements (RR) for the selection of the appropriate type of Compliance Determination Strategy (CDS) for each RR. This procedure implements the requirements of CQAM Section 3.

2. RESPONSIBILITY

2.1 The CNWRA Waste Systems Engineering & Integration (WSE&I) Element Manager, in coordination with the NRC WSE&I Program Element Manager, shall establish one or more "Analysis Working Groups" to categorize various RRs. The CNWRA WSE&I Element Manager shall select CNWRA individuals to review and comment on the results of Analysis Working Group. The CNWRA WSE&I Element Manager shall ensure the qualifications of each CNWRA member of an Analysis Working Group of to analyze the RR(s) under consideration.

2.2 Each Analysis Working Group shall implement this procedure, document the technical support and rationale for its conclusions regarding RR categorization, and thus determining the appropriate type of CDS (set of General Review Methods). Each member of the Analysis Working Group use and reference applicable technical material necessary to conduct the categorization analyses.

2.3 Individual reviewers shall (1) identify specific instances where the Analysis Working Group failed to fully apply or document use of the criteria in this procedure, (2) provide the rationale for identifying these instances where it is not self-evident, and (3) recommend specific corrective actions for the Analysis Working Group.

3. REGULATORY REQUIREMENT CATEGORIZATION AND CDS DEVELOPMENT PROCEDURE

3.1 Categorization will determine the appropriate type of CDS for a RR. For this procedure, only two categories of "Technical Uncertainties" will be used as discriminating criteria to select the appropriate type of CDS. These are the "High-Order Technical Uncertainties" and

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 3 of 39

"Key Technical Uncertainties." "Low-Order Technical Uncertainties", are not to be considered in this analysis. These terms and additional terms that are more generally applicable to this procedure are presented in Appendix A. The purpose and rationale for categorizing the RRs are discussed in Appendix B.

The CNWRA WSE&I Element Manager, in coordination with the NRC WSE&I Program Element Manager, shall select the Analysis Working Groups and assign sets of RRs for analysis. The CNWRA WSE&I Element Manager shall document the technical qualifications of each CNWRA member of the Analysis Working Group. The CNWRA WSE&I Element Manager shall also select CNWRA individuals to review the results of the Analysis Working Groups in accordance with QAP-002.

3.2 The Analysis Working Group shall categorize assigned RRs using the criteria contained in Table 1 and described in Appendix C. The Analysis Working Group will determine the appropriate type of CDS (set of General Review Methods) associated with a RR using Table 1 and Table 2 and Appendix D. Examples of categorizing the RRs to determine the appropriate type of CDS are given in Appendix E. Results and rationale shall be documented in accordance with TOP-001-02, Attachment A, Section 11 (TOP-001-02).

3.3 The individual reviewers shall review the records generated by the Analysis Working Group to assure compliance with this procedure and document their observations and comments in accordance with QAP-002.

4. RECORDS

Records generated as a result of this procedure shall be maintained in accordance with CQAM Section 17.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 4 of 39

**TABLE 1**

	<b>CRITERION FOR CATEGORIZING PART 60 REGULATORY REQUIREMENTS FOR A SITE UNDER CONSIDERATION</b>	<b>ALT CDS TYPE</b>
1	Regulatory Requirements related to DOE'S License Application	Type I
2	Regulatory Requirements that are Procedural to the License Application	Type I
3	Regulatory Requirements related to either radiological safety or to waste isolation	Type II
4	Regulatory Requirements with a Regulatory or an Institutional Uncertainty	Type III
5	Regulatory Requirements with an aspect which could have an AECC <sup>a</sup>	Type IV
6	Regulatory Requirements with an aspect which could have a Key AECC	Type V
7	Regulatory Requirements with High-Order Technical Uncertainty	Type IV
8	Regulatory Requirements with Key Technical Uncertainty	Type V
9	Regulatory Requirements with a Key AECC where the Key AECC has a Key Technical Uncertainty	Type VI

<sup>a</sup> AECC = Adverse effect on compliance taking compensating factors into account.

Note: All criteria must apply to a site under consideration.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 5 of 39

**TABLE 2**

ALTERNATIVE TYPES OF COMPLIANCE DETERMINATION STRATEGIES	GENERAL REVIEW METHODS					
	A	B	C	D	E	F
Type I	X					
Type II	X	X				
Type III	X	X	X			
Type IV	X	X	X <sup>a</sup>	X		
Type V	X	X	X <sup>a</sup>	X	X	
Type VI	X	X	X <sup>a</sup>	X	X	X

<sup>a</sup> To be applied where there is a Regulatory or an Institutional Uncertainty.

**Note: All General Review Methods with an "X" for a given type of Compliance Determination Strategy will be used to guide development of the specific Compliance Determination Method.**

Note: Adjustments to subsystem performance requirements which may be proposed by DOE, as allowed and described in 10 CFR 60.113(b), are a special case and will be reviewed using a Type V CDS.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 6 of 39

**APPENDIX A  
DEFINITIONS**

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TPO-001-06

Revision 0

Page 7 of 39

**APPENDIX A**

**DEFINITIONS**

**1. Adverse Effect on Compliance Taking Compensating Factors into Account (AECC)**

An AECC is (a) an aspect, activity, or condition related to a repository or a site under consideration which could result in a RR not being met or (b) mitigating aspects or condition of a repository or a site under consideration.

Some aspects, activities, or conditions which are an AECC include the following:

- The potentially adverse conditions of 10 CFR 60.122(c) at a site under consideration;
- Site characterization activities which could adversely impact radiological safety or waste isolation at a site under consideration;
- Site characterization activities which result in interference with other site characterization activities (e.g., prevention of data collection);
- Conditions induced by repository construction or operations or by waste emplacement which could adversely impact radiological safety or waste isolation at a site under consideration;
- Any other aspect or condition which could adversely impact radiological safety or waste isolation at the site under consideration.

Compensatory or mitigating conditions for a condition having an AECC will have the same type of CDS for the RR as does the aspect or condition having an AECC.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 8 of 39

2. Key AECC

A Key AECC (Key adverse effect on compliance taking compensating factors into account) is one which could result in a performance objective of the repository not being met. Key compensatory or mitigating conditions will have the same type of CDS for the RR as does an aspect or condition having a Key AECC.

3. Compliance Demonstration Method

How DOE plans to present and support its claim that each REGULATORY ELEMENT OF PROOF has been met. It includes those test results and/or analyses, singly or in combination, that will be presented to the NRC. "Analyses" includes, but is not limited to, methodologies, models, codes, designs, consensus, certification, plans, procedures, and audits of records.

4. Compliance Determination Methods (CDM)

How NRC will determine that each REGULATORY ELEMENT OF PROOF has or has not been met. Includes those investigative or evaluative procedures, techniques, tests, methods, or any other modes of inquiry, or any combination thereof, that may be used within the context of the NRC regulatory program, to address each REGULATORY ELEMENT OF PROOF identified as necessary to determine compliance with a RR. This includes, but is not limited to methodologies, models, codes, consensus, certification, audits of records, etc.

5. Compliance Determination Strategy (CDS)

General approach or overall plan of NRC for determination of compliance with the subject REOP set. Each CDS establishes the scope and depth of the NRC Compliance Determination program for a RR. NRC options in each case range from active Pre-license Application site and design analyses and evaluations to audit-type evaluations of the Safety Analysis Report.

6. Criterion

Any definite rule, principle, or measure established by an authority on which a judgment (i.e., test of quality) or decision may be based.



**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 9 of 39

7. License Application Format and Content Regulatory Guide (FCRG)

An NRC document which explains in more detail the information to be provided to NRC by a license applicant and which establishes the format for presenting the information. The FCRG ensures that the applicant has provided correct and complete information consistent with NRC regulations and contributing to shortening the application review process.

8. License Application Review Plan (LARP)

A document that provides both general and site-specific guidance to NRC staff on review methods and acceptance criteria for review. The structure of the LARP will be based on the Format and Content Regulatory Guide provided to DOE, 10 CFR Part 60 and the License Application Review Strategy (LARS).

9. License Application Review Strategy (LARS)

Provides the staff strategy for conducting reviews. It covers Pre-license Application as well as License Application reviews. It will include scope, objectives and approach to staff review and will serve as a tool to identify important areas for staff review. The LARS will define the general criteria and approach to be used in definition of the Compliance Determination Strategies.

10. Nuclear Waste Management System

System for the disposal of high-level radioactive waste (including spent fuel and defense waste) in a manner that is environmentally acceptable and that protects the public health and safety. The system includes the geologic repository, transportation system, pre-emplacment packaging (e.g., spent fuel rod consolidation), and storage capabilities that may be required.

11. Performance Assessment (PA)

The process of quantitatively evaluating component and system behavior, relative to containment and isolation of radioactive waste, to support

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

Proc. TOP-001-06

Revision 0

**TECHNICAL OPERATING PROCEDURE**

Page 10 of 39

development of a repository of HLW and to determine compliance with the numerical criteria associated with 10 CFR Part 60.

12. Program Architecture

A systematic computer-assisted approach to analysis of program requirements, program planning and evaluation, and management. Taken in total, it is a description of the NRC high-level nuclear waste regulatory program. It is mission-oriented, requirements-based and proactive, and it provides the basis for integration of all aspects of the NRC regulatory program under the NWPAA. Program Architecture comprises: (a) assessment of statutory and regulatory responsibilities by means of Systematic Regulatory Analysis, (b) program planning, including evaluation of program alternatives and risks, and (c) program management, including implementation of plans (for providing timely regulatory guidance and reviews, developing analysis methods, and conducting research), cost and schedule control, integration, and tracking work progress.

Or, the overall system description for the Nuclear Regulatory Commission High-Level Waste (NRC-HLW) repository licensing system.

13. Quality Assurance (QA)

Comprises all those planned and systematic actions necessary to provide adequate confidence that a product or service will perform satisfactorily. The purpose of a graded QA program is to select the QA requirements and measures to be applied to activities related to NRC licensing of the HLW repository consistent with their applications toward achievement of NRC objectives.

14. Regulatory Element of Proof (REOP)

What must be demonstrated to support a conclusion that the RR has been met. REOP must be directly stated in the requirement itself. When a potential REGULATORY or INSTITUTIONAL UNCERTAINTY exists and rulemaking is a potential uncertainty reduction method, the revised language of the affected rule must be postulated. When this occurs, the resulting POSTULATED UNCERTAINTY REDUCTION LANGUAGE (PURL) is developed as a part of the NRC UNCERTAINTY REDUCTION METHOD.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 11 of 39

15. Regulatory Requirement

A statement of a requirement pertaining to the NWSA Nuclear Waste Management System, as quoted from one or more statutes, regulations, or other sources which have the force of law. Each such quotation is a complete REGULATORY TEXT. Thus, a RR is composed of one or more closely related REGULATORY TEXTS.

16. Review

An analysis, inspection, examination, audit, or study of DOE's plans and information for compliance determination, and the subsequent documentation and interface activities associated with the review.

17. Screening Review

A screening review consists of reading the document under review for identification of potential items of concern in it, without investigating sources (data, analyses, references, etc.) Further review of identified items of concern is not part of the screening review, but is an additional review.

18. Systematic Regulatory Analysis (SRA)

That portion of the PROGRAM ARCHITECTURE which assesses the statutory and regulatory responsibilities of NRC in a comprehensive, structured manner. This assessment is controlled by appropriate technical operating procedures. SRA identifies statutory and regulatory requirements related to the High-Level Waste Management System; identifies and evaluates associated UNCERTAINTIES; and develops methods for uncertainty reduction. In addition, strategies and methods for compliance determination are generated with associated information requirements.

19. Technical Review Components (TRC)

The analytical results necessary to review a DOE demonstration of compliance and/or to support an NRC determination of compliance with an individual REGULATORY ELEMENT OF PROOF, as well as the supporting material necessary to verify the technical adequacy of those analytical results. The

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 12 of 39

"technical adequacy" of results used for compliance demonstration and/or determination includes the validity and applicability of the method (e.g., the theory; investigative or analytical method; analytical uncertainties; model), and the adequacy of the data used (e.g., measurement techniques and instrumentation, measurement uncertainties, data collection procedures [including quality assurance provisions], realism of environment simulation, sample size, spatial and temporal distribution of measurements).

20. Uncertainty

Generally, a perceived insufficiency in a specific item or lack of specificity in the statement of NRC's purpose in promulgating the regulation. Three types of Uncertainties include:

**Institutional Uncertainty:** Lack of certitude regarding: (1) roles, missions, actions, and schedules of agencies with RRS that affect the high-level waste regulatory program; (2) impacts of those RRS; or (3) integration of those RRS with the NRC regulatory program.

**Regulatory Uncertainty:** Lack of certitude as to what is meant by the RR, or the clarity, adequacy, completeness, and/or necessity of the requirement. Regulatory Uncertainty also may be related to the logical relationship of two or more REOPs

**Technical Uncertainty:** In general, Technical Uncertainty is present when there is lack of certitude as to (1) how to demonstrate (DOE action) or determine (NRC action) compliance, (2) how to acceptably reduce a previously identified technical uncertainty, or (3) how to obtain the requisite information for either purpose. "How to..." refers to the method to be used to demonstrate or determine compliance, reduce the uncertainty, or obtain information. Such "lack of certitude" may result from circumstances such as the lack of an applicable theory, the absence of an accepted test or evaluation method, the unavailability of satisfactory instrumentation, the inability to quantify the margin-of-error in a measurement, analysis or model, too large a margin-of-error in a measurement, or other similar conditions.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 13 of 39

A Technical Uncertainty is created by the absence of a defined and accepted means to resolve a technical program need. Technical Uncertainties are derivable from DOE Compliance Demonstration Methods, NRC CDMs, Uncertainty Reduction Methods and Information Requirements.

**High-Order Technical Uncertainty:** A High-Order Technical Uncertainty is a unique case of a Technical Uncertainty that is only associated with demonstrating or determining how a RR and its REOP can be met. A High-Order Technical Uncertainty is present when the current technical state of the art is such that NRC (or DOE) does not know how to determine (NRC action) or demonstrate (DOE action) compliance with a RR. Also, a High-Order Technical Uncertainty exist if there is a current lack of certitude as to (1) how to acceptably reduce a previously identified technical uncertainty, or (2) how to obtain the requisite information for technical uncertainty reduction. High-Order Technical Uncertainties are derivable directly from the RR.

**Key Technical Uncertainty:** In SECY-90-207 (NRC 1990a) the NRC staff identified category called Key Technical Uncertainties. Key Technical Uncertainties are considered to be a subset of the High-Order Technical Uncertainties, and are defined as the "... highest uncertainties that are also significant to repository performance at the ...site [under consideration]". Key Technical Uncertainties are those which, if not reduced, could result in non-compliance with a performance objective or inability to adequately demonstrate or determine compliance with a performance objective.

**Low-Order Technical Uncertainty:** Low-Order Technical Uncertainty exists when the required information is not known well enough, versus not knowing how to obtain the required information. Most Low-Order Technical Uncertainties are expected to be identified by development of specific CDMs and be reduced during the data development and review process. Low-Order Technical Uncertainties include, for example, such things as lack of technical adequacy or lack of required information, and can be referred to as "how well" something is done. They could be categorized as noted below:

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 14 of 39

1. Data Uncertainties: Imprecision in the raw data or factual input to the analysis due to, e.g., possible measurement error, statistical limitations of the data, ambiguities concerning the applicability of the available data to the case at hand or problems of interpolation or extrapolation.

2. Modeling Uncertainties: Imprecision or imperfections in the ability to manipulate data to generate estimates of the output parameters of interest, inaccuracies in the understanding of relevant processes, the mathematical modeling of processes, or inaccuracies in the computation of results. Processes, as used here, include physical processes and the behavior of personnel whose actions can affect the potential risks under consideration.

3. Completeness Uncertainties: Possible failures to recognize and model scenarios, physical phenomena, or personnel behavior, including common cause failure mechanisms. Possible omission or misrepresentations of considerations or phenomena.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES  
TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 15 of 39

**APPENDIX B  
CATEGORIZATION PURPOSE & RATIONALE**

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 16 of 39

**APPENDIX B**

**CATEGORIZATION PURPOSE & RATIONALE**

The approach for NRC to review DOE's license application plans and information for the repository will be flexible and evolving. This is necessary because a repository will be a complex and a first-of-a-kind facility. This approach does not use prescriptive criteria to review a licensee's compliance with the regulations. "Prescriptive" means instructing the applicant exactly what to do or in the case of directions to a reviewer, instructing the reviewer exactly what and how to review. The "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," NUREG-0800, is an example of a prescriptive review approach. This approach is appropriate for a mature industry with established engineering solutions.

The licensing review process was also designed to account for an evolving program. The regulation and the Regulatory Strategy (NRC 1988a) describe the phases of repository licensing. Each phase represents a step in an evolving decision-making process that incorporates new information and repository design changes. NRC staff will not prescribe sufficiency. The applicant will develop what sufficiency is in interactions with NRC Staff. "Sufficiency" is, in a sense, a preliminary compliance determination. Reviews are not just for commenting on DOE's material; NRC must interact with DOE and review how DOE addresses or resolves NRC concerns.

More specifically, the Pre-license Application review phase of the licensing process allows program flexibility to accommodate the evolving and exploratory nature of the program. The site characterization process recognized by the Nuclear Waste Policy Act (NWPA) and implemented by both NRC and DOE is the intended mechanism for developing the detailed site, design, and performance information necessary for DOE to demonstrate compliance with the regulations. It is through review and consultation between NRC and DOE that the application of the regulations can be clarified for a specific site. The State of Nevada and units of local government have the opportunity to participate in all such consultations between the staff and DOE, and the public is invited to observe. This ongoing, iterative review process also includes DOE's preparation of semi-annual progress reports which document

B-1



**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 17 of 39

progress and changes as the program evolves and adjusts to new information obtained about the site. This process, therefore, anticipates and allows for changes to be made as site characterization and design activities proceed.

NRC has also agreed to DOE's planned issue resolution strategy and performance allocation process. This process, described in DOE's Site Characterization Plan, is intended to be a decision-aiding process for eventually determining if enough information has been collected and assessed to demonstrate compliance with the RRs. This process gives direct consideration to how uncertainties should be treated. It also permits DOE to propose adjustments to the performance allocation of the subsystem barriers and their components to fit the needs for a specific site and specific designs. These adjustments can then be reflected in adjustments to the subsystem requirements, as allowed for in 10 CFR 60.113(b). The NRC staff would expect that initial performance allocation goals would change as new information about the site is obtained and as DOE refines its conceptual designs. Finally, the NRC staff would review DOE's proposed adjustments in light of the information at hand.

There are several RRs that are applicable to DOE's License Application for a geologic repository. DOE will submit extensive plans and information to demonstrate compliance with these regulations. NRC's task is to review DOE's submitted material to determine adequate compliance with the RRs. In order to effectively review DOE's extensive plans and information, it is essential for NRC to determine an appropriate type of CDS for each RR. Determining the appropriate type of CDS will guide the effective development of the specific CDMs for each RR's REOP and associated Technical Review Components.

The type of CDS that is appropriate for a given RR should be based on criteria that discriminate among the RRs. This discrimination is necessary so that different types of CDSs can be applied to the different RRs, since the review approach needed to determine adequate compliance will be different for various RRs.

NRC cannot anticipate having either the time or the resources to review all Pre-license Application or License Application submittals equally, nor is this necessary. Reviews of DOE materials should focus more on some RRs. NRC experience in other licensing reviews has indicated that complete

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 18 of 39

and equal review of every submission made by the applicant is not necessary for a thorough, high-quality review. Reviews of the various levels of detail of plans and information can differ depending on the RR which the submittal addresses.

There are two general types of DOE submittals: (1) plans and procedures for compliance and (2) the information resulting from application of the plans and procedures. As the plans and information become more detailed, the volume of the documentation will increase.

The general levels of detail for plan and procedures are:

- Compliance demonstration strategies
- Program plans
- Study plans or activity plans
- Technical procedures

The general levels of detail for information are:

- Overall compliance demonstration
- Performance assessments using the data interpretations
- Repository designs or site descriptions
- Data analyses or interpretations
- Data
- Data collection activities

Since the more detailed levels of plans and information cannot be reviewed equally the more detailed levels will be reviewed by a focused (or selected) approach. An appropriate review method to determine compliance (CDM) will be applied to each level of the plans or information. Development

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 19 of 39

of the appropriate CDM should be systematic and consistent. Determination of the type of CDS which will guide the CDM is discussed in the next Section.

The type of CDS appropriate to a RR will provide the basis for development of the specific CDMs for that RR's Elements of Proof and their Technical Review Components. The type of CDS most appropriate to each RR will depend on the characteristics of the RR. Example characteristics include uncertainties or AECCs.

Determination of the appropriate types of Compliance Determination Strategies is done by a two-step screening process:

- Assessment of the characteristics of a RR concerning to its significance in regulatory compliance and the specific uncertainties associated with it;
- Selection of the appropriate combination of General Review Methods for each RR. These sets of General Review Methods constitute a type of CDS.

The characteristics of a RR in relation to meeting the repository performance objectives may be assessed by comparing it to a set of discriminating categorization criteria. These criteria may be applied to the RRs of 10 CFR Part 60 to determine the most appropriate type of CDS, and thus, the applicable set of General Review Methods for each RR.

The categorization criteria are discussed in detail in Appendix C and are summarized in Table 1, of this procedure. All of the criteria must apply to a specific site. Also, after a RR is categorized the type of CDS that is appropriate for the RR is given in the right hand column of Table 1, of this procedure.

The set of General Review Methods is the combination of the methods which compose the type of CDS. Table 2, of this procedure, presents the relationship of the alternative types of Compliance Determination Strategies to the General Review Methods. All criteria should be applied to all RRs. When the categorization criteria are applied to a RR, the REOPs that compose the RR should be considered.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 20 of 39

Adjustments to subsystem performance requirements which may be proposed by DOE, as allowed and described in 10 CFR 60.113(b), are a special case and will be reviewed using a Type V CDS.

NRC will review DOE's compliance demonstrations for the RRs applicable to a site under consideration. The review of these RRs will be focused for review by categorization, and additional prioritization. After categorizing the RRs by using this procedure, prioritization of the RR reviews will be based on scheduling, resource availability and other factors. Prioritization is beyond the scope of this procedure, but is discussed below so the Analysis Working Group members are aware of the additional considerations that will be addressed in a process separate from this procedure.

This prioritized approach to conducting reviews is designed to ensure that NRC will assess DOE's compliance with applicable RRs and will emphasize those RRs that present greater challenge for, or importance to, compliance determination. After the need for and the type of technical review is determined, the timing and use of resources will need to be incorporated into the HLWM Regulatory Strategy, the NRC Five-Year Plan, and any other appropriate work planning documents.

Review of DOE plans, processes, and information will focus on their adequacy to support demonstrating compliance with the RRs and on the quality assurance programs needed to substantiate that the RRs are being implemented properly. Reviews will also be focused on those aspects of compliance that are most directly linked to assuring that the performance objectives are met.

Other parties' technical comments on DOE's plans and information must be considered. NRC staff will screen these comments to determine their applicability to NRC's reviews and resource prioritization. The technical staff is free to use any source of technical information in its review planning. Even though NRC may choose to use or reference these other parties' comments, NRC is not bound to address, acknowledge, respond to, or incorporate them.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES  
TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 21 of 39

**APPENDIX C**

**CATEGORIZATION CRITERIA**

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES  
TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 22 of 39

**APPENDIX C**

**CATEGORIZATION CRITERIA**

The type of CDS appropriate to a RR will be determined by its inherent characteristics. The CDS will provide the basis for development of the specific CDMs for that Regulatory Requirement's Elements of Proof and their Technical Review Components.

The characteristics of a RR in relation to meeting the repository performance objectives are assessed by evaluating each RR to a set of discriminating categorization criteria. These criteria may be applied to all of the RRs to determine the most appropriate type of CDS, and thus, the applicable set of General Review Methods.

The categorization criteria are discussed below, and are summarized in Table 1 of this procedure. All of the criteria must apply to a specific site. After a RR is categorized, its appropriate type of CDS is indicated in the right hand column of Table 1, of this procedure.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES  
TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 23 of 39

Categorization Criterion 1:

RRs Related to DOE's License Application

The first criterion requires that the RR is one that DOE must demonstrate compliance with in its Pre-license and License Application plans and information and that the RR applies to the site under consideration. This criterion was needed because some RRs do not require DOE to demonstrate compliance.

Categorization Criterion 2:

RRs that are Procedural to DOE's License Application

The second criterion is that the RR deals only with procedural or administrative matters and is not directly related to radiological safety or waste isolation. Compliance with an administrative or procedural requirement will be determined by verifying that the material submitted for review complies with the relevant sections of the License Application Format and Content Regulatory Guide (NRC 1990c) or with the RR itself. This criterion identifies RRs for which the compliance need not be technically detailed or complex.

Categorization Criterion 3:

RRs Related to either Radiological Safety or to Waste Isolation

The third criterion identifies RRs that go beyond procedural or administrative matters. It is the first category which requires more complex and detailed technical reviews. It encompasses RRs which were not identified by the first two criteria. Some RRs, like those concerned with standard radiological safety practices or those dealing with standard and accepted designs, will meet only this criterion. RRs which meet only this criterion are associated with requirements that could be met by the use of standard and accepted engineering methods. These RRs have no associated Regulatory Uncertainty, High-Order Technical Uncertainties, or AECC.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 24 of 39

Categorization Criterion 4:

RRs With Regulatory or Institutional Uncertainty

The fourth identifies a RR which is related to radiological safety or to waste isolation with a Regulatory or Institutional Uncertainty will require review sufficient to determine if DOE's program is consistent with NRC's reduction of the Regulatory or Institutional Uncertainty. This criterion is provided to ensure that DOE understands and appropriately responds to the reduction method of the uncertainty associated with the RR.

Categorization Criterion 5:

RRs with an Aspect Which Could Have an AECC -

The fifth criterion identifies a RR with an aspect which could have an AECC. The fifth and the following criteria were defined to differentiate among degrees of significance to radiological safety or to the ability of the repository to isolate high-level radioactive waste from the accessible environment.

Categorization Criterion 6:

RRs With An Aspect Which Could Have a Key AECC -

The sixth identifies a RR with an aspect which could have a Key AECC. This criterion is necessary because it associates an AECC with meeting a performance objective.

Categorization Criterion 7:

RRs With High-Order Technical Uncertainties

This criterion was defined to address if a RR has the greater degree of significance to waste isolation from the point of view of Technical Uncertainties. Review is different for a RR for which there is certitude as to how to demonstrate or determine compliance with a RR for which there is not such certitude.



**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 25 of 39

Categorization Criterion 8:

RRs with Key Technical Uncertainties

This criterion is defined to associate a RR with a Key Technical Uncertainties and thus not meeting a performance objective. As information is attained and as iterative performance assessments are completed, some additional Key Technical Uncertainties may be identified requiring an update of the specific CDS developed for some RRs.

Categorization Criterion 9:

RRs With an Aspect Which Could Have a Key AECC, Where That Key AECC Has A Key Technical Uncertainty

This criterion identifies a RR with a Key AECC where that Key AECC has a Key Technical Uncertainty. The ninth criterion combines aspects of the sixth and eighth criteria and will require the most complex methods of review.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 26 of 39

**APPENDIX D  
GENERAL REVIEW METHODS**

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 27 of 39

**APPENDIX D**

**GENERAL REVIEW METHODS**

The General Review Methods are identified here as General Review Methods A through F, and are described below. The type of CDS determined to be appropriate for a RR will define the General Review Methods to be applied to the REOP and their Technical Review Components. For example, for a CDS Type V, General Review Methods A, B, C, D, and E would be used for developing the specific review method, and is depicted in Table 2, of this procedure.

General Review Method A - General Review Method A includes general reviews of the DOE Pre-license Application and License Application information to ensure license completeness and sufficiency. For example: review of DOE's annotated outline of the License Application for a site under consideration, review of DOE information in Pre-license Application submittals for completeness according to the License Application Format and Content Regulatory Guide, and the License Application acceptance review. General Review Method A is essentially a checkoff review in which the information submitted is compared to the appropriate list or summary of information required. Determination of compliance is assured by the completeness of the submitted information. Sources and development of the information submitted would not be reviewed. Acceptance review of the License Application would utilize this method since Pre-license Application reviews, using all of the review methods as appropriate, will ensure that the License Application is complete and of high quality before it is submitted.

General Review Method B - General Review Method B includes reviews of progress reports, e.g., program plans, upper-level plans and documents, DOE "requirements documents" and DOE processes. For example General Review Method B includes review of Quality Assurance plans, the Site Characterization Plan, or Site Characterization progress reports. This method applies the principles of a Quality Assurance-type review. It is thus a review of any plans to ensure that, if the planned activities are done in accordance with the procedure presented, they would yield the appropriate results and demonstrate compliance. This review method also applies to protection of radiological health and radiological safety in cases where standard engineering and design methods exist, and to analysis of site

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 28 of 39

characterization data and other relevant data where standard analytical methods exist. In this general review method, evaluation of the application of standard methods is made to, but the review would not repeat the standard demonstration method applied.

General Review Method C - General Review Method C includes a screening review to determine if DOE has understood the reduction method for the Regulatory or Institutional Uncertainty, and if DOE's program is consistent with NRC's uncertainty reduction method. This screening review will be used together with detailed technical reviews for identified items of concern or inconsistencies with NRC's uncertainty reduction method. The screening review should identify any discontinuities between DOE's submittals for compliance demonstration and the NRC Regulatory Strategy with respect to identified uncertainty reduction. Identified items of concern and inconsistencies determined by the screening review may require the submitted plans or information to be reviewed in more detail in order to determine compliance. That is, there may be specific instances where the review would extend to data analysis, data collection activities, or technical procedures.

General Review Method D - General Review Method D consists of a screening review to identify potential items of concern, and follow-up detailed technical reviews of plans or information for those identified items of concern. The screening review is to identify any potential concerns related to an AECC, or to High-Order Technical Uncertainties. Identification of these could require the review to extend to data analysis, data collection activities, or technical procedures. Review using General Review Method D may require the use of iterative performance assessment, using available models.

General Review Method E - General Review Method E requires detailed technical reviews at all levels of plans and information supported by independent analyses, Quality Assurance audits, and data collection observation audits. The analysis is independent in this case, but should apply available review methods and performance assessment models. This method may require iterative performance assessment, using established models, and analysis of data using established analytical methods.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 29 of 39

General Review Method F - General Review Method F requires detailed technical reviews supported by appropriate independent analysis using models developed independently by NRC or CNWRA or independent NRC research, as appropriate. These independently developed analyses or models would be made publicly available. General Review Method F is called into play where a Key AECC has a Key Technical Uncertainty and may utilize independently developed models or research whose results can then be compared to those obtained by DOE to demonstrate compliance. This review method is necessary when the issues associated with a RR are very complex and require considerable independent analyses or research by NRC or CNWRA staff to ensure compliance determination.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 30 of 39

**APPENDIX E**

**EXAMPLES OF REGULATORY REQUIREMENT CATEGORIZATION  
FOR COMPLIANCE DETERMINATION STRATEGY DEVELOPMENT**

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 31 of 39

**APPENDIX E**

**EXAMPLES OF REGULATORY REQUIREMENT CATEGORIZATION  
FOR COMPLIANCE DETERMINATION STRATEGY DEVELOPMENT**

In the examples below, all criteria are applied, one at a time, to each RR. The criteria have been rephrased as questions.

Example 1: RR-3017 - 10 CFR 60.152(a)(2) - Quality Assurance Implementation

1. Is the RR related to the DOE's License Application for a site under consideration?

Yes. The licensing hearing will consider implementation of quality assurance procedures.

2. Is the RR procedural to the License Application?

No. The related regulation 10 CFR 60.150 defines quality assurance as including all planned and systematic actions necessary to provide confidence that the repository and its systems and subsystems will perform satisfactorily. Moreover, quality assurance is defined in 10 CFR 60.150 as including quality control. There are thus aspects of quality assurance which go well beyond the purely procedural.

3. Is the RR related to radiological safety or to waste isolation, at a site under consideration?

Yes. The RR is related to waste isolation, since it deals with assurance that the repository and its systems and subsystems will perform satisfactorily.

4. Does the RR have a Regulatory or Institutional Uncertainty?

Yes. Table B1g of CNWRA 90-003 (CNWRA, 1990c, p.B-vii) indicates a Regulatory Uncertainty for this RR.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 32 of 39

5. Does the RR include an aspect which could have an AECC?

No. The RR deals only with implementation of a quality assurance program.

6. Does the RR include an aspect with a Key AECC?

No.

7. Does the RR include a High-Order Technical Uncertainty?

No. There is no High-Order Technical Uncertainty in implementing a quality assurance program.

8. Does the RR include a Key Technical Uncertainty?

No. Since Criterion 7 is not met, the RR does not meet Criterion 8 either.

9. Does the RR include a Key AECC where that Key AECC has a Key Technical Uncertainty?

No. Since the RR does not include a Key AECC there is no Key AECC to have a Key Technical Uncertainty.

Determination of the Type of CDS and Applicable General Review Methods:

The RR meets Criteria 1, 3 and 4. Thus, from Table 1, a Type III CDS would be appropriate. From Table 2, Review Methods A, B and C are appropriate.



**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

Proc. TOP-001-06

Revision 0

**TECHNICAL OPERATING PROCEDURE**

Page 33 of 39

Example 2: RR-0055 - 10 CFR 60.121(a) - LAND OWNERSHIP AND CONTROL

1. Is the RR related to the DOE's License Application for a site under consideration?

Yes. The RR refers to ownership of, and control over, the land on which the geologic repository operations area (GROA) and the controlled area are located. Both the GROA and the controlled area are part of the licensing process.

2. Is the RR procedural to the License Application?

No. Although the RR deals with encumbrances on the land, potentially competing leasing rights, rights-of-way, water rights, and DOE jurisdiction and control, the purpose of DOE control is stated in the regulation to be necessary to prevent human actions that could significantly effect the repository's ability to achieve waste isolation. Assurance of DOE jurisdiction thus goes beyond the purely procedural.

3. Is the RR related to radiological safety or to waste isolation?

Yes. Waste isolation is stated as one of the purposes of the RR.

4. Does the RR have a Regulatory or Institutional Uncertainty?

Yes. Table Bla of CNWRA 90-003 (CNWRA, 1990c, p.B-i) indicates a Regulatory Uncertainty for this RR.

5. Does the RR include an aspect which could have an AECC?

Yes. If DOE land jurisdiction and control is not adequate, there would be an adverse effect on compliance with 10 CFR 60.122(a)(1).

6. Does the RR include an aspect with a Key AECC?

No. The RR affects human actions which might potentially interfere with waste isolation, but it has no effect on repository performance as such.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 34 of 39

7. Does the RR include a High-Order Technical Uncertainty?

No. There is no High-Order Technical Uncertainty in ascertaining adequate land jurisdiction or water rights.

8. Does the RR include a Key Technical Uncertainty?

No. Since Criterion 7 is not met, the RR does not meet Criterion 8 either.

9. Does the RR include a Key AECC where that Key AECC has a Key Technical Uncertainty?

No. Since the RR does not include a Key Technical Uncertainty, it does not meet Criterion 9.

Determination of the Type of CDS and Applicable General Review Methods:

The RR meets Criteria 1, 3, 4 and 5. Thus, from Table 1, a Type IV CDS would be appropriate. From Table 2, Review Methods A, B, C and D are appropriate.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 35 of 39

Example 3: RR-0082 - 10 CFR 60.132(d) - DESIGN OF WASTE TREATMENT FACILITY

1. Is the RR related to the DOE's License Application for a site under consideration?

Yes. The RR deals with treatment of radioactive wastes generated at the GROA during operation, which is considered during the licensing process.

2. Is the RR procedural or administrative only?

No. The RR involves application of design criteria and plans for operation.

3. Is the RR related to radiological safety or to waste isolation?

Yes. The RR requires design and operation of the waste treatment facility to ensure radiological safety.

4. Does the RR have a Regulatory or Institutional Uncertainty?

No.

5. Does the RR include an aspect which could have an AECC?

Yes. Improper design of the facility could adversely affect radiological health protection (and safe disposal, if applicable) and, thus, could affect compliance with 10 CFR 60.111(a).

6. Does the RR include an aspect with a Key AECC?

Yes. The RR affects compliance with 10 CFR 60.111(a), a pre-closure performance objective of the repository.

7. Does the RR include a High-Order Technical Uncertainty?

No. There is no High-Order Technical Uncertainty in design of the waste treatment facility.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

Proc. TOP-001-06

Revision 0

**TECHNICAL OPERATING PROCEDURE**

Page 36 of 39

8. Does the RR include a Key Technical Uncertainty?

No. Since Criterion 7 is not met, the RR does not meet Criterion 8 either.

9. Does the RR include both a Key AECC where that Key AECC has a Key Technical Uncertainty?

No. Since the RR does not include a Key Technical Uncertainty, it does not meet Criterion 9.

Determination of the Type of CDS and Applicable General Review Methods:

The RR meets Criteria 1, 3, 5 and 6. Thus, from Table 1, a Type V CDS would be appropriate. From Table 2, Review Methods A, B, D and E are appropriate.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 37 of 39

Example 4: RR-3007 - 10 CFR 60.61 - PROVISION OF INFORMATION

1. Is the RR related to the DOE's License Application for a site under consideration?

No. The RR deals with provision of information by the Director of the NRC's Office of Nuclear Materials Safety and Safeguards to affected States and Indian Tribes, and is not related to DOE's demonstration of compliance in their License Application, and thus will not be reviewed by NRC.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 38 of 39

**APPENDIX F**

**REFERENCES**

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

**TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06

Revision 0

Page 39 of 39

**APPENDIX F**

**REFERENCES**

- CNWRA 1990c Center for Nuclear Waste Regulatory Analyses (CNWRA) FY91-92 Operations Plans for the Division of High-Level Waste Management, November 1, 1990.
- NRC 1988a U.S. Nuclear Regulatory Commission, Regulatory Strategies and Schedules for the High-Level Waste Repository Program, SECY-88-285, October 5, 1988.
- TOP-001-02 Technical Operating Procedure 001-002 "Program Architecture Relational Database Content and Development Instructions", September 28, 1989.

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES  
TECHNICAL OPERATING PROCEDURE**

Proc. TOP-001-06  
Revision 0  
Page 1 of 39

Title  
TOP-001-06 Procedure for Regulatory Requirement Categorization and Compliance Determination Strategy Development

**EFFECTIVITY AND APPROVAL**


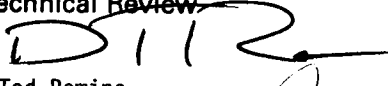
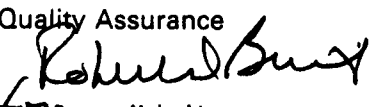
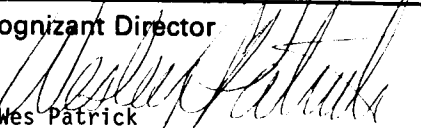
Revision 0 of this procedure became effective on 05/14/92. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1-39	0	12/21/90

THIS PROCEDURE IS SUPERSEDED BY TOP-001-11, REVISION 0, EFFECTIVE 04/30/92.

Supersedes Procedure No. None

**Approvals**

Written By  Patrick Mackin	Date 5/14/92	Technical Review  Ted Romine	Date 5/18/92
Quality Assurance  Bruce Mabrito	Date 5/18/92	Cognizant Director  Wes Patrick	Date 5/15/92