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Title

Development of Compliance Determination Strategies

EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on 04/30/92. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1-35	0	04/30/92

SUPERSEDED *by Revision 1, Change 0
1/18/93*

Supersedes Procedure No. None.

Approvals

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Quality Assurance <i>Bruce E. Mabrito</i> Bruce E. Mabrito	Date <u>4/30/92</u>	Cognizant Director <i>Wesley Patrick</i> W. C. Patrick	Date <u>4/30/92</u>

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**TOP-001-11
DEVELOPMENT OF COMPLIANCE DETERMINATION STRATEGIES**

1. PURPOSE

To provide guidance for the development of Compliance Determination Strategies (CDS) for the Yucca Mountain site. This procedure implements the requirements of Center Quality Assurance Manual, Section 3.

2. REFERENCES

CNWRA TOP-001: Program Architecture Development and Maintenance

3. DEFINITIONS

3.1 Compliance Determination Strategy (CDS). The general approach or overall plan of the NRC for determination of compliance with the Regulatory Element of Proof (REOP) set. Each CDS establishes the scope and depth of the NRC compliance determination review for a Regulatory Requirement (RR). NRC options in each case range from Acceptance Review to a Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations.

3.2 License Application Review Plan (LARP). That document which provides detailed guidance to the NRC staff on how to conduct the License Application review.

3.3 Technical Uncertainty. Lack of certitude as to how to demonstrate (DOE action) or determine (NRC action) compliance. This includes lack of certitude (even controversy) about: (1) methods for obtaining information, (2) methods for analyzing information, or (3) the understanding of conditions or processes. It also includes staff concerns with DOE's program documented as objections, comments, or questions.

3.4 Key Technical Uncertainty. A Technical Uncertainty which poses a high risk of non-compliance with a performance objective of 10 CFR Part 60. It may also be associated with reducing a high risk of non-compliance with a performance objective.

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For example, a Key Technical Uncertainty exists where there is a lack of certitude about a methodology that is needed to either demonstrate or determine compliance with a performance objective (e.g., scenario analysis methods are necessary to demonstrate compliance with the containment requirement of 40 CFR 191). A Key Technical Uncertainty also exists where (1) there is a lack of understanding about a condition or process, and (2) it is credible that the condition or process exists (or will exist) and could have either a significant adverse or favorable affect on repository performance.

Additional definitions may be found in TOP-001.

4. BACKGROUND

In the development of the program architecture through Systematic Regulatory Analysis (SRA), the first step is the definition of the Regulatory Requirements (RR) and their associated Regulatory Elements of Proof (REOP). The resulting number of RRs, and the limited quantity of staff time and resources necessitate an evaluation of the level of resources to be applied to examining compliance with each of the RRs based on technical urgency and difficulty, risk of non-compliance with repository performance objectives, and other factors.

The CDS establishes the scope and depth of the NRC compliance determination review for a given RR for the Yucca Mountain site. The CDS is developed after the RR/REOP structure has been approved for the associated RR. Once developed, it controls the preparation of Compliance Determination Methods (CDM) for that RR by defining any limits on the type and extent of those methods. Portions of the CDSs and the CDMs will be included in the License Application Review Plan for the Yucca Mountain site.

CDS development occurs in two steps. First, the types of review are chosen, then the review strategy is prepared. It is recognized that these steps may overlap.

The review strategy describes the type(s) of License Application review for the subject RR. It should not include descriptions of pre-licensing review activities; however, it should recognize that analysis capability and research needed to support some of the License Application reviews will be done before DOE's submittal of the License Application. It should define the scope and approach of the reviews and tests or analyses (if appropriate) to be used by the NRC and Center staffs to review the License Application and determine compliance with the associated RR. Where possible, reviews, tests, and analyses should be identified that are appropriate for: (1) the specific nature of the RR, (2) the type of review selected, (3) any key Technical Uncertainties that are associated with the RR, and (4) the methods to reduce, remedy, or compensate for the key Technical Uncertainties. This portion of the CDS is not intended to describe specifically HOW (i.e.,

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step-by-step procedure) the reviews, tests, or analyses are to be performed, but rather to bound and guide the subsequent development of the CDM. The CDMs should prescribe how the review for compliance determination will be performed, including the details of the method (as in an NRC Standard Review Plan review procedure) and associated acceptance or compliance determination criteria.

It is anticipated that CDS Groups will discuss a wide range of information, including potential Technical Review Components and CDMs, as they formulate the CDS; however, this information should not be documented as part of the CDS, since it will be developed and documented separately. The CDS will be reviewed annually and updated as needed based on new information and understanding.

5. RESPONSIBILITIES

5.1 The Deputy Technical Director for Systems Engineering and Integration is responsible for implementation of this procedure.

5.2 Members of CDS Groups are responsible for developing CDSs in accordance with this procedure.

6. CDS GROUP MEMBERSHIP, TECHNICAL BACKGROUND, AND TRAINING

CDS Group members shall be assigned by HLWM Division directors, Branch Chiefs, and CNWRA Element Managers, as appropriate. Members shall be familiar with background information pertinent to the RR (see Attachment A) and the technical aspects of the CDS to be developed for the Yucca Mountain site, and shall be provided with general SRA specific training and with training for this procedure.

7. PROCEDURE

7.1 Using the CDS format (Attachment C) and the example CDS (Attachment D) develop the CDS as follows:

7.1.1 Complete the identifying information for the CDS, including the PASS ID and Topic of the RR, the primary regulatory citation (if appropriate), and the PASS ID of the CDS. This information may be obtained from the RR report and from the Center Waste Systems Engineering and Integration Element.

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- 7.1.2 Determine the review type(s) to be applied to the RR as a whole and to each REOP by referring to the detailed discussion of review type selection criteria in Attachment B. Prepare a list of the REOP PASS IDs by review type. This list shall be placed in the "APPLICABLE REGULATORY ELEMENTS OF PROOF" section of the CDS.
- 7.1.3 Complete the "TYPES OF REVIEW" section of the CDS by listing all the review types applicable to the RR (this information was developed through step 7.1.2 above). When listing the review types, consider that all RRs related to the License Application will receive a Type 1 Acceptance Review, only procedural RRs will receive a Type 2 Procedural Review, and an RR related to radiological health and safety or waste isolation will receive a Type 3 review. It can, in addition, receive Types 4 and/or 5 reviews.
- 7.1.4 Complete the "RATIONALE FOR TYPES OF REVIEW" section by justifying the choice of review types. It is recognized that technical judgement will be needed where specific evidence is lacking. However, where judgement is used, the basis must be explained. The information to be included in this section is as follows:
- For each review type applicable to the RR or its REOPs, provide the rationale for selection of that review type. The Standard Rationales for Types of Compliance Determination Strategies (Appendix 1 to Attachment C) should be used as a basis. These standard rationales shall be modified as appropriate such that specific characteristics, aspects, system operating concepts, or scenarios associated with the RR, which influenced the selection of the individual review type, are addressed. Also, provide the assumptions for determining the type. If these assumptions differ significantly from those made by DOE regarding the site, the difference should be discussed.
 - For RRs with review Types 4 or 5, provide the topic and description of any associated key Technical Uncertainty, the specific performance objective which is at risk, and an explanation of the nature of the risk. Identify the REOP with which the key Technical Uncertainty is associated. In deciding to assign review Types 4 and 5, it is important to note the criteria for a Type 4 and 5 in Attachment B, the definition of key Technical Uncertainty in Section 3, and that professional judgement might be needed where evidence does not exist.
 - For RRs with review Type 5, also explain why the key Technical Uncertainty is most difficult to resolve and what uncertainty remains.

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7.1.5 Prepare the "REVIEW STRATEGY" text. The text shall be developed as follows:

- Include a general description of the evaluation method(s) to be applied to the group of REOPs assigned to each review type. The scope and approach of reviews, tests, or analyses that are appropriate to the nature of the REOPs and their associated key Technical Uncertainties shall be included, as appropriate. Specific uncertainty reduction methods, remedies, compensatory measures, models, tests, or reviews may be identified for specific REOPs if (a) they are standard practice, (b) they now exist, or (c) they are described in current NRC or CNWRA plans.
- There shall be no discussion of pre-licensing activities.
- End the text with the name(s) of the contributing analyst(s) and the date of the analysis.

7.1.6 As an option, provide a "RATIONALE FOR REVIEW STRATEGY (OPTIONAL)". This rationale shall consist of the following:

- If specific reviews, tests, or analyses are identified in the Type 4 and 5 reviews, there may be value in discussing why these were selected. Generally, Type 4 and 5 reviews are where selections are made on what and how to review and, therefore, where some additional rationale might be useful.
- If independent analyses or research are considered to be needed for a Type 4 review, include the rationale for such efforts here.
- End the Rationale with the name(s) of the contributing analyst(s) and the date of the analysis.

7.1.7 Complete the "APPLICABLE REGULATORY ELEMENTS OF PROOF" section by listing each REOP PASS ID by its associated review type. (Note that all REOPs for all RRs will receive a Type 1 Acceptance Review, so it is not necessary to list the REOPs for a Type 1 review.)

7.1.8 List and number the REFERENCES CITED in the CDS in the order cited, using standard formats. Indicate the beginning and ending page numbers of the relevant material.

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7.2 NRC and Center staffs shall review the CDS. The Center reviews shall be conducted as specified by QAP-002. After approval by the NRC and the Center, the CDS shall be entered into the PADB by Center staff.

8. RECORDS

8.1 CDSs shall be maintained as QA Records in accordance with CQAM Section 17.

8.2 Review documentation developed by the Center as a result of conducting CDS related activities shall be maintained as QA Records as specified in QAP-002.

8.3 Review documentation developed by the Division of HLWM shall be provided to the Center for maintenance as QA Records in accordance with CQAM Section 17.

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**ATTACHMENT A TO TOP-001-11
EXAMPLE LIST OF PERTINENT BACKGROUND MATERIAL
FOR REVIEW TYPE SELECTION AND REVIEW STRATEGY DEVELOPMENT**

CDS Development Group members should be generally familiar with the relevant sections of the following documents.

1. CNWRA RR/REOP report.
2. Statement of considerations for 10 CFR Part 60.
3. Rationale and staff analysis of comments on proposed rule 10 CFR Part 60, NUREG-0804.
4. DOE's Site Characterization Plan for the Yucca Mountain Site (e.g., licensing strategies to resolve issues in Chapter 8, including DOE's performance allocations: this information provides insight on what DOE considers to be the important areas of repository performance), and periodic revisions and status reports.
5. DOE's Final Environmental Assessment for the Yucca Mountain site.
6. NRC staff's Site Characterization Analysis (SCA).
7. NRC staff's response to DOE's response to NRC's SCA.
8. Key site-specific topics listed under each review guide in the NRC staff's SCP Review Plan.
9. Identified Regulatory and Institutional Uncertainties in CNWRA 90-003; SECY-90-207, Enclosure 5; and SECY-91-225, Enclosure 3, which have not, to date, been excluded or otherwise resolved.
10. Technical Position topics listed in Enclosure 8 of SECY-88-285 and any revisions thereto.
11. Issued Staff Technical Positions and Staff Positions.
12. Major issues at the Yucca Mountain site listed in SECY-87-137 and any revisions thereto.
13. Other documents identified by NRC/Center Management or CDS Development Group.

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14. DOE's Report of Early Site Suitability Evaluation of the Potential Repository Site at Yucca Mountain, Nevada.
15. Nuclear Waste Policy Act of 1982, as Amended.
16. 48 FR 28222 of June 21, 1983 (the source document for 10 CFR Part 60, Subpart E).
17. DOE's Test Prioritization Plan.
18. NRC and DOE performance assessment reports.

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**ATTACHMENT B TO TOP-001-11
DEFINITION OF REVIEW TYPES AND CRITERIA
FOR REVIEW TYPE SELECTION**

There are five types of reviews. Each Regulatory Requirement (RR) must be assigned one or more of these review types. Each of the five review types is defined below. Selection criteria for assigning the review type to a particular RR are also defined. The individual Regulatory Elements of Proof (REOP) for a given RR shall also be assigned review types.

REVIEW TYPE DESCRIPTION:

Type 1 - Acceptance Review

This type of review is to determine if the LA is complete and acceptable for docketing and for conducting the compliance review in an effective and timely manner. This is not a review to determine adequacy.

Type 2 - Procedural Review

This type of review is to determine the adequacy of the compliance demonstrations for procedural requirements of 10 CFR Part 60.

Type 3 - Safety Review

This type of review is to determine the adequacy of the compliance demonstrations and associated system descriptions which are related to radiological health and safety or waste isolation. The focus of this review is primarily on the LA itself, although some references might also be reviewed if they contain essential compliance demonstration information. Generally, however, the detailed information supporting the compliance demonstration in the LA references will not be the focus of this type of review. The safety review might also be supported by simple verifications using handbooks, standard formula, or "back-of-the-envelope" calculations. However, detailed verifications using complex numeric modeling should not be used. A Type 3 review might eventually be changed if new information leads to a key Technical Uncertainty.

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Type 4 - Detailed Safety Review Supported by Analyses

This review is an expansion or extension of the Type 3 Safety Review in that it is a detailed review of the adequacy of selected detailed information supporting the compliance demonstration in the LA (i.e., "vertical slice" reviews of data, analyses, methods, and technical procedures). Specifically, Detailed Safety Reviews would focus on the level(s) of detail appropriate for the assessment of the key Technical Uncertainty(ies) associated with the RR and how the key Technical Uncertainty is reduced, compensated for, or remedied.

The Detailed Safety Review should be supported, if relevant and needed, by analyses conducted by the staff of specific key Technical Uncertainties. Such analyses could include use of complex numerical models. Unless justified based on the unique nature of the key Technical Uncertainty, the detailed analyses methods would not be developed by the staff. Instead, the staff would use methods developed by DOE or other parties that have been reviewed and found acceptable by the staff. While this type of review requires the staff to obtain and become proficient in using a particular method or making minor modifications to the method, it does not require, for most cases, the extensive resources needed for the staff to develop its own independent method. (For special cases, such as where the staff may have concerns with DOE's data interpretation or method of analysis, the staff could modify DOE's method or use another party's method.) Independent investigations, including research, can also support Type 4 reviews if justified; however, these investigations would be lower priority than those supporting a Type 5 review.

It is important to note that a review type might eventually be changed to a lower or higher type should new information or lack of information either reduce the Key Technical Uncertainty causing the risk of non-compliance, or lead to identifying a new key Technical Uncertainty.

Type 5 - Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations

This type of review further supports the Detailed Safety Review with either analyses, tests (laboratory or field), or other investigations conducted by the staff or using methods (e.g., numerical modeling) independently developed by the staff. Such independent investigations could focus on all or a part of a specific key Technical Uncertainty. This type of review might also further supplement the Detailed Safety Review by verifying some of the LA data or descriptions of conditions or processes with data collected by the staff or the understanding of conditions and processes obtained by the staff's own investigations (e.g., results of the Research Program). Furthermore, the understanding of processes may also support the staff's independent model development. In addition to analyses and tests, this type of review could, if appropriate, be supported by other kinds

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of investigations such as expert panel solicitations. The specific type of supporting investigations selected should be based on what is technically needed to address the key Technical Uncertainty(ies).

It should be emphasized, however, that the independent investigations conducted by the staff are for verification purposes and are not a substitute for data or analyses that DOE should be providing to support its compliance demonstration in the LA.

It is important to note that a review type might eventually be changed to a lower or higher type should new information or lack of information either reduce the key Technical Uncertainty causing the risk of non-compliance, or lead to identifying a new key Technical Uncertainty.

REVIEW TYPE SELECTION CRITERIA:

Type 1 - LA Related

These are RRs/REOPs for which DOE must demonstrate compliance in its LA, or RRs/REOPs which directly affect the content or submittal of the LA. These are also the RRs/REOPs that would be addressed in the staff's compliance review of the LA and for which findings will be made in the staff's Safety Evaluation Report. Table B-1 identifies the LA related RRs consistent with the LA Format and Content Regulatory Guide. This list should be used in evaluating the RRs for this criterion.

Excluded from these RRs/REOPs would be those not related to the LA, whether DOE RRs (e.g., Site Characterization Plan requirements in 10 CFR 60.16 and 10 CFR 60.17), NRC RRs (e.g., review of site characterization activities in 10 CFR 60.18 and construction authorization in 10 CFR 60.31), or other procedural RRs (e.g., participation of State governments and Indian tribes in 10 CFR Part 60, Subpart C).

Type 2 - Procedural Related

These are RRs/REOPs related to the LA but which are only procedural in nature, and are not related to radiological safety or waste isolation [e.g., filing the LA as required by 10 CFR 60.22 or the LA completeness requirement in 10 CFR 60.24(a)].

Type 3 - Radiological Safety and Waste Isolation Related

These are RRs/REOPs for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31. These include those RRs/REOPs which embody Subparts E, G, H, and I as well as 10 CFR 60.21 (which addresses descriptions of the repository required in 10 CFR 60.31).

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Type 4 - High Potential Risk of Non-Compliance with a Performance Objective of 10 CFR Part 60

These RRs/REOPs are the subset of all the radiological health and safety or waste isolation related RRs/REOPs for which there is a high potential risk of non-compliance with one or more of the performance objectives in 10 CFR 60.111, 112, or 113.

The high potential risk of non-compliance comes from the existence of key Technical Uncertainties.

A key Technical Uncertainty is a Technical Uncertainty which poses a high risk of non-compliance with a performance objective of 10 CFR Part 60. It may also be associated with reducing a high risk of non-compliance with a performance objective.

For example, a Key Technical Uncertainty exists where there is a lack of certitude about a methodology that is needed to either demonstrate or determine compliance with a performance objective (e.g., scenario analysis methods are necessary to demonstrate compliance with the containment requirement of 40 CFR 191). A Key Technical Uncertainty also exists where (1) there is a lack of understanding about a condition or process, and (2) it is credible that the condition or process exists (or will exist) and could have either a significant adverse or favorable affect on repository performance.

Type 5 - High Potential Risk of Non-Compliance and Most Difficult to Resolve

These RRs/REOPs, a subset of the RRs/REOPs that pose a high potential risk of non-compliance, pose the highest potential risk because the risk is judged to be the most difficult to reduce. Therefore, there might be a high residual risk of non-compliance because very little can be done to reduce the risk or compensate for the risk using, for example, favorable site conditions or engineered features.

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Table B-1 Regulatory Requirements Related to the License Application

<u>PASSID</u>	<u>TOPIC</u>
RR0001	Important to Safety - Natural Phenomena and Environmental Conditions
RR0002	Retrievability of Waste
RR0003	Design for Safe Underground Operations and Rock Movement
RR0004	Radiation Exposures and Releases
RR0034	Design Bases Consistent with Site Characterization
RR0035	Radiological Protection
RR0037	Important to Safety - Dynamic Effects
RR0055	Land Ownership and Control
RR0056	Water Rights and Controls Outside the Controlled Area
RR0074	License Application and Content
RR0080	Important to Safety - Mining Regulations
RR0081	Important to Safety - Shaft Conveyances
RR0082	Design of Waste Treatment Facility
RR0083	Design to Prevent Underground Floods, Fires, and Explosions
RR0084	Underground Design Flexibility
RR0085	Design to Control Underground Water or Gas Intrusion
RR0086	Design of Underground Ventilation Normal Operations and Accident Conditions
RR0087	Design for Performance Confirmation Program Implementation
RR0088	Important to Safety - Fires and Explosions
RR0089	Important to Safety - Emergency Capability
RR0090	Important to Safety - Utility Services
RR0091	Important to Safety - Inspection, Testing, and Maintenance
RR0092	Important to Safety - Criticality Control
RR0093	Important to Safety - Instrument and Control
RR0094	Separation of Underground Facility Ventilation
RR0096	Control Releases from Underground Facility
RR1001	System Performance After Permanent Closure
RR1002	EBS Performance After Permanent Closure
RR1003	EBS Release of Radionuclides After Permanent Closure
RR2000	Groundwater Travel Time
RR2001	Favorable Conditions
RR2002	Adverse Condition - Flooding
RR2003	Adverse Condition - Human Activity Affecting Groundwater
RR2004	Adverse Condition - Change Surface Groundwater
RR2005	Adverse Condition - Deformation Affecting Groundwater
RR2006	Adverse Condition - Changes to Hydrology
RR2007	Adverse Condition - Changes in Hydrology Due to Climatic Conditions

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<u>PASSID</u>	<u>TOPIC</u>
RR2008	Adverse Condition - Groundwater Conditions Affecting the Engineered Barrier System
RR2009	Adverse Condition - Geochemical
RR2010	Adverse Condition - Groundwater not Reducing
RR2011	Adverse Condition - Dissolutioning
RR2012	Adverse Condition - Structural Deformation
RR2013	Adverse Condition - Earthquakes
RR2014	Adverse Condition - Earthquakes with Tectonic Processes
RR2015	Adverse Condition - Higher Magnitude Earthquakes
RR2016	Adverse Condition - Igneous Activity
RR2017	Adverse Condition - Extreme Erosion
RR2018	Adverse Condition - Naturally Occurring Materials
RR2019	Adverse Condition - Mining for Resources
RR2020	Adverse Condition - Drilling
RR2021	Adverse Condition - Complex Engineering Measures
RR2022	Adverse Condition - Geomechanical Properties of Underground Openings
RR2023	Adverse Condition - Water Table Rise
RR2024	Adverse Condition - Perched Water
RR2025	Adverse Condition - Gaseous Radionuclides
RR3006	Completeness and Accuracy of Information
RR3014	Tests and Performance Confirmation Program
RR3017	QA Implementation
RR3018	General Requirements for Trained and Certified Personnel
RR3019	Training and Certification Program
RR3020	Physical Requirements
RR3021	Emergency Planning Criteria

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**ATTACHMENT C TO TOP-001-11
COMPLIANCE DETERMINATION STRATEGY FORMAT**

[PASS ID AND TOPIC OF THE REGULATORY REQUIREMENT] (See TOP-001-11, Section 7.1.1)
Format is: RR2018 ADVERSE CONDITION - NATURALLY OCCURRING MATERIALS

PRIMARY REGULATORY CITATION (IF APPROPRIATE):

Format is 10CFR60.122 (c)(17)
(See TOP-001-11, Section 7.1.1)

PASS ID OF THE COMPLIANCE DETERMINATION STRATEGY:

Format is: RR2018/NS0001
(See TOP-001-11, Section 7.1.1)

TYPES OF REVIEW:

(See TOP-001-11, Section 7.1.3 and Attachment B)
(List the following as appropriate to the specific RR):

- Acceptance Review (Type 1)
- Procedural Review (Type 2)
- Safety Review (Type 3)
- Detailed Safety Review Supported by Analyses (Type 4)
- Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations (Type 5)

RATIONALE FOR TYPES OF REVIEW: (Only for those review types selected)

(See TOP-001-11, Section 7.1.4)
(See Appendix 1 to this attachment for example rationales).

Acceptance Review (Type 1) Rationale:

Procedural Review (Type 2) Rationale:

Safety Review (Type 3) Rationale:

Detailed Safety Review Supported by Analyses (Type 4) Rationale:

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Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations
(Type 5) Rationale:

REVIEW STRATEGY: (Only for those review types selected)

(See TOP-001-11, Section 7.1.5)

Acceptance Review (Type 1):

Procedural Review (Type 2):

Safety Review (Type 3):

Detailed Safety Review Supported by Analyses (Type 4):

Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations
(Type 5):

RATIONALE FOR REVIEW STRATEGY (OPTIONAL):

(See TOP-001-11, Section 7.1.6)

APPLICABLE REGULATORY ELEMENTS OF PROOF:

(See TOP-001-11, Section 7.1.7)

Type 2:

Type 3:

Type 4:

Type 5:

REFERENCES CITED:

(See TOP-001-11, Section 7.1.8)

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**APPENDIX 1 TO ATTACHMENT C
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EXAMPLE STANDARD RATIONALES FOR TYPES OF REVIEWS (these are to be modified to reflect the specific characteristics of the RR as discussed in section 7.1.4 of this TOP).

ACCEPTANCE REVIEW (TYPE 1) RATIONALE

This Regulatory Requirement is considered to be License Application related because, as specified in the License Application content requirements of 10 CFR 60.21 and the F&CRG, it must be addressed by DOE in its License Application. Therefore, the staff will conduct an Acceptance Review of the License Application for this Regulatory Requirement.

PROCEDURAL REVIEW (TYPE 2) RATIONALE

This Regulatory Requirement is considered to be related to procedural matters and not related to the technical aspects of radiological safety and waste isolation. It is not a Regulatory Requirement for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31 (i.e., Regulatory Requirements in Subparts E, G, H, and I and 10 CFR 60.21). Therefore, the staff will conduct a Procedural Review of the License Application to determine compliance with the Regulatory Elements of Proof for this Regulatory Requirement.

SAFETY REVIEW (TYPE 3) RATIONALE

This Regulatory Requirement is considered to be related to radiological safety and waste isolation. It is a requirement for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31 (i.e., Regulatory Requirements in Subparts E, G, H, I and 10 CFR 60.21). Therefore, the staff will conduct a Safety Review of the License Application to determine compliance with the Regulatory Elements of Proof for this Regulatory Requirement.

Additional rationale should include an explanation for why a Type 4 is not appropriate and assumptions about the site or DOE's design on which the Type 3 selection is based.

DETAILED SAFETY REVIEW SUPPORTED BY ANALYSES (TYPE 4) RATIONALE

The staff considers that there may be a high potential risk of non-compliance with this Regulatory Requirement because, for the Yucca Mountain site, the following key Technical Uncertainty(ies) might pose a high potential risk of non-compliance with the performance objective(s) specified below.

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Key Technical Uncertainty Topic:

(Description of Uncertainty)
(Performance objectives at risk and associated REOP PASS ID)
(Explanation of nature of risk)

**DETAILED SAFETY REVIEW SUPPORTED BY INDEPENDENT TESTS, ANALYSES,
OR OTHER INVESTIGATIONS (TYPE 5) RATIONALE**

The staff considers that there may be the highest potential risk of non-compliance with this Regulatory Requirement because, for the Yucca Mountain site, the following key Technical Uncertainty(ies) are the most difficult to resolve. Therefore, there might be a high residual risk of non-compliance with the performance objectives specified below because very little can be done to reduce the risk, or compensate for the risk using, for example, favorable site conditions or engineered features.

Key Technical Uncertainty Topic:

(Description of Uncertainty)
(Performance Objectives at risk and associated REOP PASS ID)
(Explanation of nature of risk)
(Description of resolution difficulty)

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**ATTACHMENT D TO TOP-001-11
EXAMPLE COMPLIANCE DETERMINATION STRATEGY**

RR2018 ADVERSE CONDITION - NATURALLY OCCURRING MATERIALS

PRIMARY REGULATORY CITATION:

10CFR60.122(c)(17)

PASS ID OF THE COMPLIANCE DETERMINATION STRATEGY:

RR2018/NS0001

TYPES OF REVIEW:

Acceptance Review (Type 1)
Safety Review (Type 3)

RATIONALE FOR TYPES OF REVIEW:

Acceptance Review (Type 1) Rationale:

This regulatory requirement is considered to be License Application-related because, as specified in the License Application content requirements of 10 CFR 60.21 and the Format and Content Regulatory Guide (Reference 1), it must be addressed by the DOE in its license application. Therefore, the staff will conduct an Acceptance Review of the License Application for this Regulatory Requirement.

Safety Review (Type 3) Rationale:

This regulatory requirement is related to radiological safety and waste isolation. Because this requirement is in 10 CFR 60, Subpart E, it is a requirement for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31 (i.e., regulatory requirements in Subparts E, G, H, I and 10 CFR 60.21). Therefore, the staff will conduct a safety review of the license application to determine compliance with the elements of proof for the regulatory requirement.

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This regulatory requirement, concerning a potentially adverse condition, focuses on the potential for future exploration and exploitation of naturally-occurring materials within the site relative to the surrounding region (geologic setting). Such exploration/exploitation activities must be considered in assessing (1) potential occurrences of human intrusion within and adjacent to the site and (2) the consequences of such intrusion on the capability of the proposed geologic repository to isolate wastes. This regulatory requirement focuses on the potential for future exploration/exploitation of naturally occurring materials within the site as well as those occurring beyond the site, the presence (or perceived presence) of which may precipitate activities that may affect isolation within the controlled area. Naturally occurring materials beyond the site must also be considered in making the resource value comparisons to other areas within the geologic setting as required by 10 CFR 60.122(c)(17)(ii).

The Yucca Mountain site is located in a natural resources-rich geologic setting that includes current gold production and exploration for hydrocarbons. Groundwater, however, is the only natural resource known to exist beneath and adjacent to the proposed site (Reference 2). Gold has been mined in the site vicinity (at Bare Mountain 16 kilometers to the west for over a century (Reference 3) and at Wahmonie 28 kilometers to the east (Reference 4)). Interest in gold exploration and exploitation in the site vicinity continues as five new mines and prospects have been located within 48 kilometers of the proposed repository site between January 1988 and July 1990 (Reference 4). In addition, oil exploration was conducted at three separate sites during 1991 within twenty-five kilometers of the proposed Yucca Mountain repository site (Reference 5). No exploitable hydrocarbon resources were encountered. The exploration holes were plugged and abandoned (Reference 12). Finally, private exploration for natural resources north and east of the site has been highly restricted for more than 30 years by the presence of weapons testing ranges. These restricted-entry areas include the Nellis Air Force Range and the Nevada Test Site. Based on the historical record (References 2, 6, 7 and 8), it is highly likely that exploration for precious metals and hydrocarbons in the vicinity will continue into the foreseeable future.

Given this information, the staff considers that human intrusion resulting from natural resources-related activities is potentially feasible adjacent to, and perhaps within, the controlled area following closure of the repository. With respect to groundwater, this potentially adverse condition may be shown to exist. There is no direct evidence of viable deposits of either gold or hydrocarbons beneath or immediately adjacent to the site. Even though resources may not be present at the proposed repository site, the mineral-rich local environment may yet encourage the exploration of Yucca Mountain and its environs based upon the perception that viable resources might be present.

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Groundwater as a potentially exploitable naturally occurring material is addressed within this regulatory requirement. However, the potential for foreseeable human activity (such as mining activities, military action and extensive irrigation) to adversely affect the groundwater flow system will be addressed under another regulatory requirement (RR 2003 - Adverse condition - Human Activity Affecting Groundwater - 10 CFR 60.122(c)(2)).

In its analysis of this regulatory requirement, the staff identified a Technical Uncertainty: The Ability to Predict the Likelihood of Future Human Intrusion. The inability to predict the probability of such intrusion is present because: (1) models do not exist which can predict the frequency of future drilling at a proposed high level radioactive waste repository site; (2) estimating such probabilities is intimately linked to the impossible task of forecasting human behavior; and (3) additional data will not resolve most of the pressing issues associated with this Technical Uncertainty (e.g., the exploitability/depth index of particular resources, and the future value of a resource) (Reference 10).

The staff considers that this Technical Uncertainty may not pose a high potential risk of non-compliance with the identified performance objective (10 CFR 60.112, Overall System Performance) and therefore is not, at present, a key Technical Uncertainty. Preliminary staff evaluations (Reference 11), as well as those evaluations sponsored by the NRC (References 13 and 14), appear to show that the potential consequences related to human intrusion, in terms of radionuclides released directly to the accessible environment as the result of such intrusion, would not exceed the limits of the EPA high-level waste health and safety standards (40 CFR Part 191). Indirect impacts of inadvertent human intrusion both within and outside the controlled area of the repository might include (1) the creation of preferential pathways for infiltrating waters or for released gaseous radionuclides and/or (2) the shortening of flow paths and potential radionuclide transport pathways through the unsaturated zone below the repository horizon. As indicated above, only limited analyses which calculate the potential indirect impacts of inadvertent human intrusion on the repository's capability to isolate waste have been attempted (References 13 and 14). The results of these preliminary analyses indicate that waste isolation will not be threatened by off-site activities associated with the exploration/exploitation of natural resources.

Therefore, based on these preliminary evaluations and the present lack of conflicting data, this regulatory requirement will be reviewed by the staff as a Type 3 (Safety Review). However, in light of (1) the uncertainties associated with human intrusion as cited above, (2) the limited scenario/consequence analyses conducted by, or at the direction of, the staff, and (3) the present and probable future interest/concerns expressed by many parties on the matter of human intrusion, it is likely that the type of review for this RR will be reconsidered. Should future analyses and/or data arise such that this initial assessment is questioned, the type of review this regulatory requirement should receive will be reassessed in light of this additional information (Reference 9).

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The Regulatory Elements of Proof (REOP) (see pages 26-29) are considered to fall within the criteria for a Type 3 review because they represent citations from 10 CFR Part 60 which are related to radiological health and safety. For each of these REOPs, the analysts drew the conclusion that a safety determination could be made by evaluating the technical information submitted by DOE in the License Application. Additionally, in the reviewers' opinion, the information to be reviewed would be such that no additional analyses or tests (Types 4 or 5 review) would be required because sufficient technical knowledge exists to allow for an adequate investigation and evaluation of the acquired information.

REVIEW STRATEGY:

Acceptance Review (Type 1):

In conducting the acceptance review of the potentially adverse condition [naturally occurring materials - 10 CFR 60.122(c)(17)], the reviewer should determine if the information presented in the license application and its references for demonstrating compliance with the naturally occurring materials potentially adverse condition requirement is complete in technical breadth and depth as identified in Reference 1. All appropriate information necessary for the staff to review the likelihood and effect of inadvertent human intrusion resulting from exploration or exploitation of naturally occurring materials on the performance objective (10 CFR 60.112) should be presented.

The information in the license application should be presented in a manner such that the assumptions, data, and logic leading to a demonstration of compliance with the requirement are clear and do not require the reviewer to make extensive analyses and literature searches. The reviewer should also determine that controversial information and appropriate alternative interpretations and models have been adequately described and considered.

Finally, the reviewer should determine if DOE has either resolved all the NRC staff objections to the license application that apply to this requirement or provided all the information requested in Section 1.6 of Reference 1 for unresolved objections. The reviewer should evaluate the effect of any unresolved objections, both individually and in combinations with others, on (1) the reviewer's ability to conduct a meaningful and timely review and (2) on the Commission's ability to make a decision regarding construction authorization within the three-year statutory period.

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Safety Review (Type 3):

In conducting the safety review, the reviewer will, at a minimum, determine the adequacy of the data and analyses presented in the license application to determine DOE's compliance with 10 CFR 60.122(c)(17). In general, the reviewer will assess the adequacy of DOE's investigations of naturally occurring materials, both identified and undiscovered, within the site and within the geologic setting, in the manner outlined in 10 CFR 60.122(a)(2)(i).

In addition, the reviewer will assess the adequacy of DOE's evaluation of the effect this potentially adverse condition may have on the ability of the site to isolate waste. Such evaluations by DOE should use analyses that are sensitive to the potentially adverse condition and assumptions which are not likely to underestimate its effects. This assessment will evaluate the adequacy of DOE's scenarios of future human activity that may result from the post-closure exploration and exploitation of naturally occurring materials at or adjacent to the site.

Those specific aspects of the license application on which a reviewer will focus are discussed in Reference 1, and the acceptance criteria will be identified in Section 3 of the License Application Review Plan. The reviewer will focus on those natural resources-related activities that could be associated with inadvertent human intrusion (e.g. from the future exploration or exploitation of gold or oil and such other naturally occurring materials that may be identified as exploitable).

In order to conduct an effective review, the reviewer will rely on his own expertise and independently-acquired knowledge, information, and data in addition to that provided by the DOE in its license application. For example, gold is known to occur near the site (References 4 and 7). Oil is being exploited in the county (Nye) within which the Yucca Mountain site is located (Reference 8) and exploration was conducted near the site in 1991 (Reference 12). Therefore, it is incumbent upon the reviewer to have acquired a body of knowledge regarding these and other such critical considerations in anticipation of conducting the safety review.

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Examples of specific review activities that will be required include: (1) confirmation that the applicant has fully considered the most recent exploration and exploitation activities within the geologic setting that are appropriate for the analysis and (2) confirmation that the current industry and government projections of natural resources potential within that region have been included within the applicant's considerations. If the applicant determines (and the staff concurs) that naturally occurring materials (whether identified or undiscovered) are present within the site, then the staff will determine if the applicant has adequately considered whether (a) economic extraction of such materials is feasible in the present or following closure and (b) that such materials have greater gross value or net value than the average for other areas of similar size that are representative of and located within the geologic setting.

Contributing Analysts:

NRC Staff: Pauline P. Brooks, Neil M. Coleman, Philip S. Justus, Harold E. Lefevre, James R. Park, Robert L. Johnson

CNWRA Staff: Patrick C. Mackin, Michael P. Miklas, John L. Russell

Date of Analyses: 02/26/92

RATIONALE FOR REVIEW STRATEGY (OPTIONAL):

Not applicable.

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APPLICABLE REGULATORY ELEMENTS OF PROOF:

Type 3:

REOP

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RR2018/EP0100
RR2018/EP0150
RR2018/EP0200
RR2018/EP0250
RR2018/EP0300
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REOP

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5. Oil & Gas Permit Notices, State of Nevada, Department of Minerals, Permit Numbers 605-607, issued December 14, 1990.
6. Miller, Bob. 1989. Letter to the Honorable James D. Watkins and Summary Statement of Geologic and Hydrologic Deficiencies Supporting Disqualification of the Yucca Mountain Potential Nuclear Waste Repository Site. Governor's Office, State of Nevada.
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9. U.S. Nuclear Regulatory Commission. Division of High Level Waste Management. Draft of April 26, 1991. Guidance for Selecting the Type of License Application Review Strategy (i.e., Compliance Determination Strategy) for a Regulatory Requirement.
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11. U.S. Nuclear Regulatory Commission. Division of High Level Waste Management. 1992. Staff consequence analyses of January 24, 1992, and January 30, 1992, associated with the development of the Compliance Determination Strategy Synopsis and Compliance Determination Strategy for Regulatory Requirement 2018 -Naturally Occurring Materials.
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13. Logsdon, Mark J. 1990. A Methodology for Assessing Ground Water Resources as a Potential Source of Human Intrusion. Adrian Brown Consultants, Inc., Denver, Colorado. Report to Center for Nuclear Waste Regulatory Analyses.
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**ATTACHMENT E TO TOP-001-11
EXPLANATION OF TECHNICAL UNCERTAINTY**

BACKGROUND:

Use of the term "uncertainty" is common in decision and operational analysis. Its application ranges from the context of decision making under varying degrees of uncertainty with regard to the environment or potential outcomes, to problems where there is a lack of knowledge associated with physical systems, technologies or processes.

The Nuclear Regulatory Commission (NRC) has used the term uncertainty in reference to Probabilistic Risk Assessment (NUREG 1150), high level waste repositories (NUREG CR-5211) and in evaluation of waste package performance (NUREG 5639). Additionally, uncertainty has been addressed in several SECY papers.

The NRC staff has defined uncertainty as follows:

Generally, uncertainty is associated with a perceived insufficiency in a specific item. There are three specific types of uncertainty:

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

Regulatory Uncertainty - Lack of certitude as to what is meant by the regulatory requirement or its regulatory elements of proof, or the adequacy, completeness and/or necessity of the requirement itself.

Technical Uncertainty - Lack of certitude as to how to demonstrate (DOE action) or determine (NRC action) compliance. This includes lack of certitude (even controversy) about: (1) methods for obtaining information, (2) methods for analyzing information, or (3) the understanding of conditions or processes. It also includes staff concerns with DOE's program documented as objections, comments, or questions.

Key Technical Uncertainty. A Technical Uncertainty which poses a high risk of non-compliance with a performance objective of 10 CFR Part 60. It may also be associated with reducing a high risk of non-compliance with a performance objective.

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For example, a Key Technical Uncertainty exists where there is a lack of certitude about a methodology is needed to either demonstrate or determine compliance with a performance objective (e.g., scenario analysis methods are necessary to demonstrate compliance with the containment requirement of 40 CFR 191). A Key Technical Uncertainty also exists where (1) there is a lack of understanding about a condition or process, and (2) it is credible that the condition or process exists (or will exist) and could have either a significant adverse or favorable affect on repository performance.

This attachment specifically addresses Technical Uncertainty. The term Technical Uncertainty has been addressed within many forums in the High Level Waste (HLW) Program. In an effort to deal with a range of sources and contexts for Technical Uncertainties, various authors have assigned modifiers (for example, high-order and low-order) or developed different "categories", "types" and "characteristics" to further refine the definition. This document is intended to explain NRC's definition of the term.

DISCUSSION:

The definition of Technical Uncertainty presented above is broad enough to allow its application to the full spectrum of technical issues. Technical Uncertainties (in contrast to Institutional and Regulatory Uncertainties) stem from data and/or techniques required to reach a conclusion as to whether a particular regulatory requirement has been met. A Technical Uncertainty considers the question of "how to" do something, and may also include issues related to a lack of adequate understanding of conditions or processes. In addition, if methods (models, analyses, techniques) exist to resolve a technical question but the supporting information has not been gathered or the methods have not been exercised (in other words, the question can be answered but the effort to do so has not been expended), then no Technical Uncertainty exists.

It will be necessary to recognize the importance and source of a Technical Uncertainty, including such factors as technical difficulty, relationship to performance objectives or design criteria and required timelines for uncertainty reduction in order to focus resources and schedules for uncertainty reduction. Such elaborations on the specifics of any Technical Uncertainty are compatible with the approved definition. In particular, some Technical Uncertainties are not specifically related to a performance objective of 10 CFR Part 60 and therefore may not pose a serious regulatory concern. Of those Technical Uncertainties which are related to a performance objective, those which pose a high potential risk of non-compliance are termed "key" Technical Uncertainties and are of high importance.

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Technical Uncertainties can be considered as belonging to one of three general types based on technical source, namely: data, model, or future states (See Table 1). Data type uncertainties are associated with limited knowledge about the existing state of the repository system. Model type uncertainties relate to a lack of accuracy in the conceptual description of the repository system or the mathematical approximation of that conceptual description. Future states type uncertainties relate to difficulty in describing the future environment within which the repository system will exist. This usage is consistent with the other NRC documents discussed above. In general, the method chosen to reduce a Technical Uncertainty will be related to its technical source. The many variations and refinements which have arisen for the term within the HLW Program all fit within the scope of the original definition and the general types of Technical Uncertainty shown in Table 1 (Table 1 contains examples and is not meant to be exhaustive). Attempts to categorize, by their nature, imply judgments. Judgments, by their nature, will result in disagreements. To minimize confusion concerning Technical Uncertainties, categorization beyond the approved definition and the three general types in Table 1 should be avoided.

Technical Uncertainties might be identified during the staff's development of Compliance Determination Strategies, Compliance Determination Methods, Uncertainty Reduction Methods, or Information Requirements; or they may be identified directly from technical review of DOE plans, designs, and results of investigations in the form of objections, comments, or questions.

CONCLUSIONS:

The staff's definition of Technical Uncertainty is broad enough to allow its application to the full spectrum of technical issues.

There are three general types of Technical Uncertainty based on technical source: data, model and future states. Consideration of the type may be useful in developing methods for reduction of Technical Uncertainties.

Key Technical Uncertainties are those which pose a high potential risk of non-compliance with a performance objective of 10 CFR Part 60.

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**TABLE 1
TECHNICAL UNCERTAINTY TYPES**

<u>TYPES</u>	<u>EXAMPLES</u>
Data	<ul style="list-style-type: none"> o Statistical uncertainty (e.g., small sample size, large dispersion in experimental/investigative results) o Degree to which test conditions reproduce the actual conditions o Measurement uncertainty (e.g., instrument sensitivity, error, drift, human error) o Data logging and upkeep o Accuracy of data derived from analogs o Data reduction uncertainties o Data applicability uncertainty (data acquisition conditions vs. conditions being analyzed) o Interpolation/extrapolation uncertainty o Uncertainty re impact of assumptions or simplifications o Theory uncertainties (e.g., applicability, inherent idealizations/simplifications) o Unknown processes or interactions of processes o Unknown variability of properties/processes
Model	<ul style="list-style-type: none"> o Incomplete/inaccurate understanding of processes being modeled o Uncertainty re impact of assumptions or simplifications o Application of model beyond its range of applicability o Theory uncertainties (e.g., applicability, inherent idealizations/simplifications) o Unknown processes or interactions of processes o Unknown variability of properties/processes o Mathematical uncertainties o Software reliability
Future States	<ul style="list-style-type: none"> o Predictive uncertainties (e.g., unknown repeatability of periodic processes, unpredictable processes or interactions of processes) o Uncertainties re future human behavior (e.g., political stability, societal norms) o Future value uncertainties (e.g., future resource value)

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Title TOP-001-11: Development of Compliance Determination Strategies

EFFECTIVITY AND APPROVAL

Revision 1 of this procedure became effective on 1/18/93. This procedure consists of the pages and changes listed below.

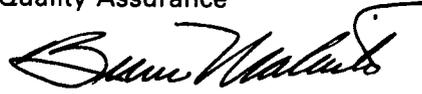
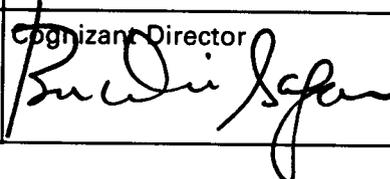
<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
A11	0	01/18/93

SUPERSEDED

Superseded by Revision 2, Chg. 0-12/31/93

Supersedes Procedure No. TOP-001-11, Revision 0

Approvals

Written By 	Date 1/15/93	Technical Review 	Date 1/15/93
Quality Assurance 	Date 1/18/93	Organizational Director 	Date 1/15/93

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DEVELOPMENT OF COMPLIANCE DETERMINATION STRATEGIES

1 PURPOSE

To provide guidance for the development of Compliance Determination Strategies (CDS) for the Yucca Mountain site. This procedure implements the appropriate requirements of Center for Nuclear Waste Regulatory Analyses (CNWRA) Quality Assurance (QA) Manual, Section 3.

2 REFERENCES

CNWRA TOP-001: Program Architecture Development and Maintenance.

3 DEFINITIONS

3.1 Compliance Determination Strategy (CDS). The general approach or overall plan of the Nuclear Regulatory Commission (NRC) for determination of compliance with the regulatory requirements associated with a Regulatory Requirement Topic (RRT). Each CDS establishes the scope and depth of the NRC compliance determination review for a RRT. NRC options in each case range from Acceptance Review to a Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations.

3.2 Format and Content Regulatory Guide (FCRG). The document prepared by the NRC to provide guidance to the Department of Energy (DOE) regarding the format and content of the license application.

3.3 License Application Review Plan (LARP). That document which provides detailed guidance to the NRC staff on how to conduct the license application review.

3.4 Technical Uncertainty. Lack of certitude as to how to demonstrate (DOE action) or determine (NRC action) compliance. This includes lack of certitude (even controversy) about: (i) methods for obtaining information, (ii) methods for analyzing information, or (iii) the understanding of conditions or processes. It also includes staff concerns with DOE's program documented as objections, comments, or questions.

3.5 Key Technical Uncertainty (KTU). A Technical Uncertainty which poses a high risk of noncompliance with a performance objective of 10 CFR Part 60. It may also be associated with reducing a high risk of noncompliance with a performance objective.

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For example, a Key Technical Uncertainty exists where there is a lack of certitude about a methodology that is needed to either demonstrate or determine compliance with a 10 CFR Part 60 performance objective (e.g., scenario analysis methods are necessary to demonstrate compliance with the overall system performance objective of 10 CFR 60.112). A Key Technical Uncertainty also exists where (i) there is a lack of understanding about a condition or process, and (ii) it is credible that the condition or process exists (or will exist) and could have either a significant adverse or favorable affect on repository performance.

3.6 Regulatory Requirement Topic (RRT). A set of one or more regulatory requirements pertaining to a topic of regulatory interest. Each RRT corresponds to an individual section of the Format and Content Regulatory Guide and an individual review plan in the License Application Review Plan.

4 BACKGROUND

In the conduct of Systematic Regulatory Analysis (SRA) in support of NRC's High-Level Waste Repository Licensing Program, the first step is the analysis of the regulatory requirements from 10 CFR Part 60 and the development of Regulatory Requirement Topics (RRT). The resulting number of RRTs, and the limited quantity of staff time and resources necessitate an evaluation of the level of resources to be applied to examining compliance with each of the RRTs based on technical urgency and difficulty, risk of non-compliance with repository performance objectives, and other factors.

The CDS establishes the scope and depth of the NRC compliance determination review for a given RRT for the Yucca Mountain site. The CDS controls the preparation of the Compliance Determination Method (CDM) for that RRT by defining any limits on the type and extent of the license application review. Portions of the CDSs and the CDMs will be included in the License Application Review Plan for the Yucca Mountain site.

The process of CDS development results in the definition of key technical uncertainties. These key technical uncertainties may result in the definition of research user needs, and ultimately in the initiation of research programs.

CDS development occurs in two steps. First, the types of review are chosen, then the review strategy is prepared. It is recognized that these steps may overlap.

The review strategy describes the type(s) of license application review for the subject RRT. It should not include descriptions of prelicensing review activities; however, it should recognize that analysis capability and research needed to support some of the license application reviews will be completed before DOE's submittal of the license application. The review strategy

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should define the scope and approach of the reviews and tests or analyses (if appropriate) to be used by the NRC and CNWRA staffs to review the license application and determine compliance with the associated RRT. Where possible, reviews, tests, and analyses should be identified that are appropriate for: (i) the specific nature of the RRT, (ii) the type of review selected, (iii) any key technical uncertainties that are associated with the RRT, and (iv) the methods to reduce, remedy, or compensate for the key technical uncertainties. The CDS review strategy is not intended to describe specifically how (i.e., step-by-step procedure) the reviews, tests, or analyses are to be performed, but rather to bound and guide the subsequent development of the CDM. The CDMs should prescribe how the review for compliance determination will be performed, including the details of the method (as in an NRC Standard Review Plan review procedure) and associated acceptance criteria.

Development of the CDSs and their incorporation into the LARP is an iterative process. The process must include a review of the associated portion of the FCRG to ensure that these two key regulatory products remain consistent.

The CDS will be reviewed and updated as needed based on new information and understanding.

5 RESPONSIBILITIES

5.1 The CNWRA Deputy Technical Director for Systems Engineering and Integration is responsible for preparation, revision, and implementation of this procedure.

5.2 Members of CDS Groups are responsible for developing CDSs in accordance with this procedure.

6 CDS GROUP MEMBERSHIP, TECHNICAL BACKGROUND, AND TRAINING

CDS group members shall be assigned by HLWM Division Directors, Branch Chiefs, Section Leaders, and CNWRA Element Managers, as appropriate. Members shall be familiar with background information pertinent to the RRT (see Attachment A) and the technical aspects of the CDS to be developed for the Yucca Mountain site, and shall be provided with general SRA training and with training in the use of this procedure.

7 PROCEDURE

7.1 Using the CDS format (Attachment B), the CDS template (Attachment C), the example CDSs (Attachment D), and other approved CDSs as appropriate, develop the CDS as follows. (The template in Attachment C, which contains the appropriate standard language, is

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available on floppy disk to assist in CDS preparation. However, it is intended as a guide, and the staff should exercise judgment in its use. Some portions of procedure step 7.1.2 and step 7.1.7 are not applicable to those RRTs which are not based on specific requirements from 10 CFR Part 60.)

7.1.1 Record the RRT number, title, and the "APPLICABLE REGULATORY REQUIREMENTS" (if appropriate). This information may be obtained from the associated individual review plan in the LARP.

7.1.2 Determine the review type(s) to be applied to the RRT as a whole and to each individual regulatory requirement by referring to the detailed discussion of review type selection criteria in Attachment B. Prepare a list of the regulatory requirement citations by review type. This list shall be placed in the "APPLICABLE REGULATORY REQUIREMENTS FOR EACH REVIEW TYPE" section near the end of the CDS. Some considerations for the completion of this step include:

- All RRTs shall receive at least an acceptance review.
- NRC and CNWRA management shall be briefed to obtain their comments on CDS type selection prior to further development of the CDS. In some cases, such action may reduce the resources required to complete CDS preparation.
- When conducting review type selection, CDS development group leaders shall ensure that participation by appropriate staff from all disciplines associated with an RRT is obtained.
- Include considerations of NRC staff interpretation of 10 CFR Part 60, as appropriate, consistent with NUREG-0804.
- Consider any important design assumptions, or existing knowledge expected to be used by DOE in demonstrating compliance.
- List any standards or guides that can be used to evaluate designs, reviews, etc.

7.1.3 Complete the "TYPES OF REVIEW" section of the CDS by listing all the review types applicable to the RRT (this information was developed by executing step 7.1.2 above). When listing the review types, consider that all RRTs related to the license application will receive a Type 1 Acceptance Review, only general information RRTs and those topics not related to specific regulatory requirements from 10 CFR Part 60 will receive a Type 2 General Information Review, and any RRT related to radiological health and safety or waste

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isolation will receive at least a Type 3 review. It can, in addition, receive Types 4 and/or 5 reviews.

7.1.4 Complete the "RATIONALE FOR TYPES OF REVIEW" section by justifying the choice of review types. It is recognized that technical judgement will be needed where specific evidence is lacking. However, where judgement is used, the basis must be explained. The information to be included in this section is as follows.

- For each review type applicable to the RRT or its individual regulatory requirements, provide the rationale for selection of that review type. The standard rationales which are provided in the Attachment C template should be used as applicable. These standard rationales shall be modified as appropriate such that specific characteristics, aspects, system operating concepts, or conditions associated with the RRT, which influenced the selection of the individual review type, are addressed. Also, provide the assumptions for determining the type, if appropriate (e.g., design assumptions or existing knowledge). If these assumptions differ significantly from those made by DOE regarding the site, the difference should be discussed.
- For regulatory requirements with review Types 4 or 5, provide the topic and description of any associated KTU, the specific performance objective(s) which is at risk, and its citation(s), an explanation of the nature of the risk, and a description of the resolution difficulty. In deciding to assign review Types 4 and 5, it is important to note the criteria for a Type 4 and 5 review specified in Appendix 1 to Attachment B, namely the identification of KTUs, and that professional judgement might be needed where evidence does not exist. The section should close with a brief summary of the reasons for selecting a Type 4 or Type 5 review strategy.

7.1.5 Prepare the "REVIEW STRATEGY" text. The text shall be developed as follows.

- Consistent with the review type and rationale, include a general description of the evaluation method(s), if known, for each review type in the RRT. The scope and approach of reviews, tests, or analyses that are appropriate to the nature of the regulatory requirements and their associated KTUs shall be included, as appropriate. Specific uncertainty reduction methods, remedies, compensatory measures, models, tests, or reviews may be identified for specific regulatory requirements if: (i) they are standard practice; (ii) they now exist; or (iii) they are described in current NRC or CNWRA plans.

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- The activities outlined in the Review Strategy shall be compared to the associated section of the FCRG to ensure that the information requested in the LA will support the stated level of review. Any discrepancies identified in this process shall be addressed through the procedure for review of the FCRG.
- Include, as appropriate, discussions to clarify the scope of this review plan. (Note that information on integration will be addressed in future SRA work.)

7.1.6 Provide a "RATIONALE FOR REVIEW STRATEGY." This rationale shall consist of the following (as appropriate).

- If independent analyses or research are considered to be needed for a Type 4 or a Type 5 review, include the rationale for such efforts here. This should include or explain why the activities should be conducted by NRC rather than relying upon DOE studies.

OPTIONAL:

- If specific reviews, tests, or analyses are identified in the Type 4 and 5 reviews, there may be value in discussing why these were selected. Generally, Type 4 and 5 reviews are where selections are made on what and how to review, and therefore, where some additional rationale might be useful.

7.1.7 End the Rationale with the name(s) of the contributing analyst(s) and the date of the analysis.

7.1.8 Complete the "APPLICABLE REGULATORY REQUIREMENTS FOR EACH TYPE OF REVIEW" section by listing each regulatory requirement citation by its associated review type. This information is obtained from the results of step 7.1.2.

7.1.9 List the "REFERENCES" in the CDS in using the NRC publication style defined in NUREG-1379.

7.2 NRC and CNWRA staffs shall review the CDS. The CNWRA reviews shall be conducted as specified by QAP-002. When appropriate, after approval by the NRC and the CNWRA, the CDS shall be entered into the Program Architecture Database (PADB).

7.3 As appropriate, the NRC shall direct that integrating reviews are conducted of CDSs. These reviews shall ensure that CDSs are integrated programmatically and technically. Specific procedures shall be provided for the conduct of these integrating reviews.

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8 RECORDS

8.1 CDSs shall be maintained as QA Records in accordance with CQAM Section 17.

8.2 Review documentation developed by the CNWRA as a result of conducting CDS related activities shall be maintained as QA Records as specified in QAP-002.

8.3 Review documentation developed by the Division of HLWM shall be provided to the CNWRA for maintenance as QA Records in accordance with CQAM Section 17.

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**ATTACHMENT A TO TOP-001-11
EXAMPLE LIST OF PERTINENT BACKGROUND MATERIAL
FOR REVIEW TYPE SELECTION AND REVIEW STRATEGY DEVELOPMENT**

CDS Development Group members should be generally familiar with the relevant sections of the following documents, as necessary, to develop the CDS.

1. RRT Compilation Report.
2. Statement of considerations for 10 CFR Part 60.
3. Rationale and staff analysis of comments on proposed rule 10 CFR Part 60, NUREG-0804.
4. DOE's Site Characterization Plan for the Yucca Mountain Site (e.g., licensing strategies to resolve issues in Chapter 8, including DOE's performance allocations: this information provides insight on what DOE considers to be the important areas of repository performance), and periodic revisions and status reports.
5. DOE's Final Environmental Assessment for the Yucca Mountain site.
6. NRC staff's Site Characterization Analysis (SCA).
7. NRC staff's response to DOE's response to NRC's SCA.
8. Key site-specific topics listed under each review guide in the NRC staff's SCP Review Plan.
9. Identified Regulatory and Institutional Uncertainties in CNWRA 90-003; SECY-90-207, Enclosure 5; and SECY-91-225, Enclosure 3, which have not, to date, been excluded or otherwise resolved.
10. Technical Position topics listed in Enclosure 8 of SECY-88-285 and any revisions thereto.
11. Issued Staff Technical Positions and Staff Positions.
12. Major issues at the Yucca Mountain site listed in SECY-87-137 and any revisions thereto.
13. Associated sections of the Format and Content Regulatory Guide.

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14. DOE's Report of Early Site Suitability Evaluation of the Potential Repository Site at Yucca Mountain, Nevada.
15. Nuclear Waste Policy Act of 1982, as Amended.
16. 48 FR 28222 of June 21, 1983 (the source document for 10 CFR Part 60, Subpart E).
17. DOE's Test Prioritization Plan.
18. NRC and DOE performance assessment reports.
19. Draft License Application Review Plan

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**ATTACHMENT B TO TOP-001-11
COMPLIANCE DETERMINATION STRATEGY FORMAT**

RRT NUMBER AND TITLE

Format is: RRT 3.2.1.11 POTENTIALLY ADVERSE CONDITION: PRESENCE OF
NATURALLY OCCURRING MATERIALS

APPLICABLE REGULATORY REQUIREMENT(S) (IF APPROPRIATE):

Format is 10 CFR 60.122(c)(17)
(See TOP-001-11, Section 7.1.1)

TYPES OF REVIEW:

(See TOP-001-11, Section 7.1.3 and Appendix 1 to Attachment B)
(List the following as appropriate to the specific RRT):

Acceptance Review (Type 1)
General Information Review (Type 2)
Safety Review (Type 3)
Detailed Safety Review Supported by Analyses (Type 4)
Detailed Safety Review Supported by Independent Tests, Analyses, or Other
Investigations (Type 5)

RATIONALE FOR TYPES OF REVIEW: (Only for those review types selected)

(See TOP-001-11, Section 7.1.4)
(See Appendix 1 to Attachment B for example rationales).

Acceptance Review (Type 1) Rationale:

General Information Review (Type 2) Rationale:

Safety Review (Type 3) Rationale:

Detailed Safety Review Supported by Analyses (Type 4) Rationale:

**Detailed Safety Review Supported by Independent Tests, Analyses, or Other
Investigations (Type 5) Rationale:**

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REVIEW STRATEGY: (Only for those review types selected)

(See TOP-001-11, Section 7.1.5)

Acceptance Review:

General Information Review:

Safety Review:

Detailed Safety Review Supported by Analyses:

Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations:

RATIONALE FOR REVIEW STRATEGY:

(See TOP-001-11, Section 7.1.6)

APPLICABLE REGULATORY REQUIREMENTS FOR EACH TYPE OF REVIEW:

(See TOP-001-11, Section 7.1.8)

Type 1:

Type 2:

Type 3:

Type 4:

Type 5:

REFERENCES:

(See TOP-001-11, Section 7.1.9)

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**APPENDIX 1 TO ATTACHMENT B TO TOP-001-11
DEFINITION OF REVIEW TYPES AND CRITERIA
FOR REVIEW TYPE SELECTION**

There are five types of reviews. Each regulatory requirement must be assigned one or more of these review types. Each of the five review types is defined below. Selection criteria for assigning the review type to a particular regulatory requirement are also defined.

REVIEW TYPE DESCRIPTION:

Type 1 - Acceptance Review

This type of review is to determine if the LA is complete and acceptable for docketing and for conducting the compliance review in an effective and timely manner. This is not a review to determine adequacy. For RRTs based on 10 CFR 60.21(c), the acceptance review will be the only type of review conducted.

Type 2 - General Information Review

This type of review is to determine the adequacy of compliance with the general information requirements of 10 CFR Part 60 and with those requests for information in the license application which are not based on specific regulatory requirements from 10 CFR Part 60, but which support the staff's review and overall finding with respect to safety, as stated in 10 CFR 60.31(a).

Type 3 - Safety Review

This type of review is to determine the adequacy of the compliance demonstrations and associated system descriptions which are related to radiological health and safety or waste isolation. The focus of this review is primarily on the LA itself, although some references might also be reviewed if they contain essential compliance demonstration information. Generally, however, the detailed information supporting the compliance demonstration in the LA references will not be the focus of this type of review. The safety review might also be supported by simple verifications using handbooks, standard formula, or "back-of-the-envelope" calculations. However, detailed verifications using complex numerical modeling should not be used. A Type 3 review might eventually be changed if new information leads to a key technical uncertainty.

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Type 4 - Detailed Safety Review Supported by Analyses

This review is an expansion or extension of the Type 3 Safety Review in that it is a detailed review of the adequacy of selected detailed information supporting the compliance demonstration in the LA (i.e., "vertical slice" reviews of data, analyses, methods, and technical procedures). Specifically, Detailed Safety Reviews would focus on the level(s) of detail appropriate for the assessment of the key technical uncertainty(ies) associated with the regulatory requirement and how the key technical uncertainty is reduced, compensated for, or remedied.

The Detailed Safety Review should be supported, if relevant and needed, by analyses conducted by the staff of specific key technical uncertainties. Such analyses could include use of complex numerical models. Unless justified based on the unique nature of the key technical uncertainty, the detailed analyses methods would not be developed by the staff. Instead, the staff would use methods developed by DOE or other parties that have been reviewed and found acceptable by the staff. While this type of review requires the staff to obtain and become proficient in using a particular method or making minor modifications to the method, it does not require, for most cases, the extensive resources needed for the staff to develop its own independent method. (For special cases, such as where the staff may have concerns with DOE's data interpretation or method of analysis, the staff could modify DOE's method or use another party's method.) Independent investigations, including research, can also support Type 4 reviews if justified; however, these investigations would be lower priority than those supporting a Type 5 review.

It is important to note that a review type might eventually be changed to a lower or higher type should new information or lack of information either reduce the key technical uncertainty causing the risk of noncompliance, or lead to identifying a new key technical uncertainty.

Type 5 - Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations

This type of review further supports the Detailed Safety Review with either analyses, tests (laboratory or field), or other investigations conducted by the staff or using methods (e.g., numerical modeling) independently developed by the staff. Such independent investigations could focus on all or a part of a specific key technical uncertainty. This type of review might also further supplement the Detailed Safety Review by verifying some of the LA data or descriptions of conditions or processes with data collected by the staff or the understanding of conditions and processes obtained by the staff's own investigations (e.g., results of the Research Program). Furthermore, the understanding of processes may also support the staff's independent

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model development. In addition to analyses and tests, this type of review could, if appropriate, be supported by other kinds of investigations such as expert panel solicitations. The specific type of supporting investigations selected should be based on what is technically needed to address the key technical uncertainty(ies).

It should be emphasized, however, that the independent investigations conducted by the staff are for verification purposes and are not a substitute for data or analyses that DOE should be providing to support its compliance demonstration in the LA.

It is important to note that a review type might eventually be changed to a lower type should new information or lack of information either reduce the key technical uncertainty causing the risk of noncompliance, or lead to identifying a new key technical uncertainty.

REVIEW TYPE SELECTION CRITERIA:

Type 1 - LA Related

These are RRTs and their associated regulatory requirements for which DOE must demonstrate compliance in its LA, or which directly affect the content or submittal of the LA. These are also the RRTs and regulatory requirements that would be addressed in the staff's compliance review of the LA and for which findings will be made in the staff's Safety Evaluation Report.

Excluded from these requirements would be those not related to the LA, whether DOE regulatory requirements (e.g., Site Characterization Plan requirements in 10 CFR 60.16 and 10 CFR 60.17), NRC regulatory requirements [e.g., review of site characterization activities in 10 CFR 60.18 and construction authorization in 10 CFR 60.31(a), or other procedural regulatory requirements (e.g., participation of State governments and Indian tribes in 10 CFR Part 60, Subpart C)].

Type 2 - General Information Related

These are the general information requirements contained in 10 CFR 60.21(b), and for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31(a). Additionally, this review type is for requests for information in the license application which are not based on specific regulatory requirements from 10 CFR Part 60 but which support the staff's reviews and overall finding with respect to safety, as stated in 10 CFR 60.31(a).

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Type 3 - Radiological Safety and Waste Isolation Related

These are RRTs and their associated regulatory requirements for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31(a). These include those RRTs which embody Subparts E, G, H, and I.

Type 4 - High Potential Risk of Noncompliance with a Performance Objective of 10 CFR Part 60

These RRTs and their associated regulatory requirements are the subset of all those related to radiological health and safety or waste isolation for which there is a high potential risk of noncompliance with one or more of the performance objectives in 10 CFR 60.111, 60.112, or 60.113.

The high potential risk of noncompliance comes from the existence of key technical uncertainties.

A key technical uncertainty is a technical uncertainty which poses a high risk of noncompliance with a performance objective of 10 CFR Part 60. It may also be associated with reducing a high risk of noncompliance with a performance objective.

For example, a key technical uncertainty exists where there is a lack of certitude about a methodology that is needed to either demonstrate or determine compliance with a 10 CFR Part 60 performance objective (e.g., scenario analysis methods are necessary to demonstrate compliance with the overall system performance of objective 10 CFR 60.112). A key technical uncertainty also exists where: (i) there is a lack of understanding about a condition or process; and (ii) it is credible that the condition or process exists (or will exist) and could have either a significant adverse or favorable effect on repository performance.

Type 5 - High Potential Risk of Noncompliance and Most Difficult to Resolve

These RRTs and their associated regulatory requirements, a subset of those that pose a high potential risk of noncompliance, pose the highest potential risk because the risk is judged to be the most difficult to reduce. Therefore, there might be a high residual risk of noncompliance because very little can be done to reduce the risk or compensate for the risk using, for example, favorable site conditions or engineered features.

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**ATTACHMENT C TO TOP-001-11
TEMPLATE FOR COMPLIANCE DETERMINATION STRATEGIES**

This template provides guidance on the format and content of the CDS. It contains recommended standard language for review type rationales and review strategies. This recommended language should be utilized with judgement and should be modified or added to, as appropriate, such that specific characteristics, aspects, system operating concepts, or scenarios are addressed. Italicized text provides explanation and guidance.

**COMPLIANCE DETERMINATION STRATEGY
REVIEW PLAN NO. AND TITLE**

APPLICABLE REGULATORY REQUIREMENT(S):

10 CFR 60.ZZ

TYPES OF REVIEW:

- Acceptance Review (Type 1)
- General Information Review (Type 2)
- Safety Review (Type 3)
- Detailed Safety Review Supported by Analysis (Type 4)
- Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations (Type 5)

RATIONALE FOR TYPES OF REVIEW: *Only for those review types selected.*

Acceptance Review (Type 1) Rationale:

This regulatory requirement topic is considered to be license application-related because, as specified in the license application content requirements of 10 CFR 60.21 and the regulatory guide "Format and Content for the License Application for the High-Level Waste Repository (FCRG)" it must be addressed by the U.S. Department of Energy (DOE) in its license application. Therefore, the staff will conduct an Acceptance Review of the license application for this regulatory requirement topic.

Add additional information/background, as appropriate.

General Information Review (Type 2) Rationale:

For general information requirements identified in 10 CFR Part 60:

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This regulatory requirement is related to the general information required in 10 CFR 60.21(b). It is a requirement for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31(a).

OR

For miscellaneous requests for information or (those not based on specific regulatory requirements from 10 CFR Part 60):

This FCRG topic is related to a request for information in the license application which is not based on a specific regulatory requirement from 10 CFR Part 60, but which supports the staff's reviews and overall finding with respect to safety, as stated in 10 CFR 60.31(a).

Add additional information/background, as appropriate.

Safety Review (Type 3) Rationale:

This regulatory requirement is considered to be related to radiological safety, retrievability, containment, or waste isolation [*pick one or more*]. It is a requirement for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31(a) (i.e., regulatory requirements in Subparts E, G, H, and I). Therefore, the staff will conduct a Safety Review of the license application to determine compliance with this regulatory requirement.

This regulatory requirement, concerning ... *repeat or paraphrase title of Review Plan*, focuses on ... *provide background*

Add additional information/background and assumptions, as appropriate, see Section 7.1.4.

Detailed Safety Review Supported by Analyses (Type 4) Rationale:

The staff considers that there may be a high potential risk of non-compliance with the applicable regulatory requirement(s) because, for the Yucca Mountain site, there are/is *(the following)* Key Technical Uncertainties(y).

These Key Technical Uncertainty(ies) is (are) considered to require a Type 4 review because there is a high risk of non-compliance with the performance objective(s) specified below. This concern of high risk of non-compliance will necessitate analysis above and beyond that required for a Type 3 safety review in order to assure that the uncertainties and potential effects on performance have been minimized to the extent practical.

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Key Technical Uncertainty Topic: *Title of KTU*

Description of Uncertainty:

Performance Objective at Risk: *Specify the title of the performance objective at risk and include the 10 CFR Part 60 citation parenthetically*

Explanation of Nature of Risk:

Description of Resolution Difficulty:

Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations (Type 5) Rationale:

The staff considers that there may be the highest potential risk of non-compliance with this Regulatory Requirement because, for the Yucca Mountain site, the following Key Technical Uncertainty is the most difficult to resolve. Therefore, there might be a high residual risk of non-compliance with the performance objective(s) specified below because very little can be done to reduce the risk, or compensate for the risk using, for example, favorable site conditions or engineered features.

Add additional information/background, as appropriate.

The potential for high residual risk of noncompliance in light of this Key Technical Uncertainty(ies) is sufficient that a detailed safety review supported by independent tests, analyses, or other investigations is justified.

Key Technical Uncertainty Topic: *Title of KTU*

Description of Uncertainty:

Performance Objective at Risk: *Specify the title of the performance objective at risk and include the 10 CFR Part 60 citation parenthetically*

Explanation of Nature of Risk:

Description of Resolution Difficulty:

REVIEW STRATEGY: *Only for those review types selected.*

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Acceptance Review:

In conducting the acceptance review of the ... *repeat or paraphrase title of Review Plan*, the reviewer should determine if the information present in the license application and its references for determining compliance with the applicable regulatory requirement(s) (or the FCRG) is complete in technical breadth and depth as identified in the FCRG. The reviewer should determine that all appropriate information necessary for the staff to review the ... *repeat or paraphrase title of Review Plan*... is presented such that the assessments required by the regulatory requirement(s) associated with total system and subsystem performance objectives or other technical criteria can be performed.

The reviewer should determine that the information presented in the license application is presented in such a manner that the assumptions, data, and logic leading to a demonstration of compliance with the requirement are clear and do not require the reviewer to conduct extensive analyses or literature searches. The reviewer should also determine that controversial information and appropriate alternative interpretations and models have been adequately described and considered.

Finally, the reviewer should determine if the U.S. Department of Energy (DOE) has either resolved all the NRC staff objections that apply to this requirement or provided all the information requested in Section 1.6.2 of the FCRG, for unresolved objections. The reviewer should evaluate the effects of any unresolved objections, both individually and in combinations with others, on: (1) the reviewer's ability to conduct a meaningful and timely review; and (2) the Commission's ability to make a decision regarding construction authorization within the three-year statutory period.

Add additional information/background, as appropriate.

General Information Review:

For General Information:

In conducting the general information review of the ... *repeat or paraphrase title of Review Plan*, the reviewer should determine if the information presented in the license application and its references is an acceptable demonstration of compliance with the applicable regulatory requirement(s).

Finally, the reviewer should determine if the information presented in the license application is presented in such a manner that the demonstration of compliance with the applicable regulatory requirements (or the FCRG) is clear. The review should also determine that contradictory information and appropriate alternative interpretations and models have been adequately described and considered.

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For miscellaneous requests for information (those not based on specific regulatory requirements from 10 CFR Part 60):

In conducting the general information review of the ... *repeat or paraphrase title of Review Plan*, the reviewer should determine if the information present in the license application and its references is sufficient/adequate to determining compliance with the information request made in the regulatory guide "Format and Content for the License Application for the High-Level Waste Repository (FCRG)."

Add additional information/background, as appropriate.

Safety Review:

This regulatory requirement is limited to consideration of ... *repeat or paraphrase title of Review Plan*. It is not concerned with ... *the title/number of other Review Plan(s)*. These ... *topics* ... will be covered under other review plans (*if possible, specify which ones they are*). Include, as appropriate, discussions to clarify scope of this review plan.

In conducting the safety review the reviewer should determine if the information presented in the license application and its references is an acceptable demonstration of compliance with the applicable regulatory requirement(s). At a minimum, the reviewer should determine the adequacy of the data and analyses presented in the license application to support DOE's demonstration of compliance with this regulatory requirement. Specifically, DOE will need to: (1) provide information ... *describe what the staff expects DOE to present in its license application – see FCRG. Also describe any underlying assumptions, axioms, or "givens"*, (2)

In general, the reviewer should assess the adequacy of the investigations of ... *repeat or paraphrase title of Review Plan topic*, both within the controlled area and outside the controlled area, as necessary. The specific aspects of the license application on which the reviewer will focus are discussed in the FCRG, and the acceptance criteria will be identified in Section 3.0 of this Review Plan.

In order to conduct an effective review, the reviewer will rely on his own expertise and independently acquired knowledge, information, and data such as the results of research activities being conducted by the NRC's Office of Nuclear Regulatory Research, in addition to that provided by the DOE in its license application. For example, ... *describe activities/investigations that are applicable to the topic* The reviewer should focus on additional data which can refine knowledge of the ... *condition – PAC or FAC* ..., and should perform, as necessary, additional analyses to confirm the resolution capabilities of the methodologies. It is incumbent upon the reviewer to have acquired a body of

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knowledge regarding these and other critical considerations in anticipation of conducting the review to assure that the ... *describe DOE's program* ... program is sufficient in scope and depth to provide the information to resolve the concerns.

Add additional information/background, as appropriate.

Detailed Safety Review Supported by Analysis: *Note that a separate paragraph is needed for each KTU.*

A detailed safety review and analysis will be needed for evaluation of the Key Technical Uncertainties regarding ... *specify Type 4 KTU*. This will ensure that DOE has adequately demonstrated Items (1)-(...), listed in the previous section (Safety Review, paragraph ...). *[Tie back to the second paragraph in the Safety Review, above.]* Activities performed in this Detailed Safety Review will help to assure that DOE has adequately addressed and resolved these Key Technical Uncertainty(ies) so that they do not lead to non-compliance with the performance objective (*specify which one(s)*).

Examples of specific review activities that will be required include: (1) ... *specify as appropriate, detailed reviews, supporting analyses, etc.*

For key technical uncertainties it may also be appropriate to assess the quality and traceability of data and information by also utilizing staff with expertise in review of quality assurance programs.

Add additional information/background, as appropriate.

Detailed Safety Review Supported by Independent Tests, Analyses or Other Investigations: *Note that a separate paragraph is needed for each KTU.*

A detailed safety review, independent modeling, and use of the results of staff investigations, will be needed for the Key Technical Uncertainties with ... *specify KTU*. This will ensure that DOE has adequately demonstrated Items (1)-(...) listed in the section on safety review (Safety Review, paragraph ...). *[Tie back to the second paragraph in the Detailed Safety Review, above.]*

For the Key Technical Uncertainty concerning ... *specify KTU*, the staff detailed review will be supported by ... *describe what the staff will do* In conducting this review, the staff must evaluate, for example, ... *provide examples*

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A detailed safety review of the Key Technical Uncertainty related to evaluation of *the KTU concerning...* will be supported by the results of staff investigations that may include ... *specify specific types*. It is anticipated that these results will allow *what?*

For key technical uncertainties it may also be appropriate to assess the quality and traceability of data and information by also utilizing staff with expertise in review of quality assurance programs.

Add additional information/background, as appropriate.

RATIONALE FOR REVIEW STRATEGY:

In view of the complexity of the key technical uncertainty(ies) addressed above, it is appropriate that the NRC conduct the independent activities described in order to (*select one or more of the following*) (1) develop the licensing tools and technical basis necessary to judge the adequacy of DOE's license application, (2) assure sufficient independent understanding of the basic physical processes taking place at the geologic repository, or (3) maintain an independent but limited confirmatory research capability under NRC suspices.

Contributing Analysts:

CNWRA:

NRC:

Date of Analysis:

APPLICABLE REGULATORY REQUIREMENTS FOR EACH TYPE OF REVIEW:

REFERENCES:

DOE (U.S. Department of Energy). 1988. *Site Characterization Plan: Yucca Mountain Site, Nevada Research and Development Area, Nevada*. Office of Civilian Radioactive Waste Management. DOE/RW-0199. 9 Volumes.

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NRC (U.S. Nuclear Regulatory Commission). 1989. *NRC Staff Site Characterization Analysis of the Department of Energy's Site Characterization Plan, Yucca Mountain Site, Nevada*. NUREG-1347.

Add additional REFERENCES, as appropriate.

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**ATTACHMENT D TO TOP-001-11
EXAMPLE COMPLIANCE DETERMINATION STRATEGIES**

The example CDSs provided in this attachment are intended only to reflect how the template in Attachment C may be used as guidance in CDS development. They are not the approved versions of these CDSs even though they are based on actual RRTs.

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EXAMPLE TYPE 3 COMPLIANCE DETERMINATION STRATEGY

COMPLIANCE DETERMINATION STRATEGY

10.0 QUALITY ASSURANCE

APPLICABLE REGULATORY REQUIREMENTS (IF APPROPRIATE):

10 CFR 60.150
10 CFR 60.151
10 CFR 60.152
10 CFR 60.21(c)(4)

TYPES OF REVIEW:

Acceptance Review (Type 1)
Safety Review (Type 3)

RATIONALE FOR TYPES OF REVIEW:

Acceptance Review (Type 1) Rationale:

This regulatory requirement topic is considered to be license application-related because, as specified in the license application content requirements of 10 CFR 60.21 and the regulatory guide "Format and Content for the License Application for the High-Level Waste Repository (FCRG)" it must be addressed by the U.S. Department of Energy (DOE) in its license application. Therefore, the staff will conduct an Acceptance Review of the license application for this regulatory requirement topic.

Safety Review (Type 3) Rationale:

This regulatory requirement is considered to be related to radiological safety, retrievability, containment, and waste isolation. It is a requirement for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31(a) (i.e., regulatory requirements in Subparts E, G, H, and I). Therefore, the staff will conduct a Safety Review of the license application to determine compliance with this regulatory requirement.

This regulatory requirement, concerning quality assurance, focuses on the scope, description and adequacy of quality assurance programs as they apply to a High-Level Waste repository. For the regulatory requirements associated with this review plan, the staff can make its safety determinations by evaluating the quality assurance program

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descriptions and associated information submitted in the license application. In the opinion of the analysts, no additional analyses (i.e., as in Type 4 or 5 Reviews) would be necessary because sufficient expertise and experience exist to allow for adequate investigations and evaluations of the submitted information. The criteria for quality assurance programs have been clearly identified and quality assurance programs meeting these criteria have been effectively implemented in commercial nuclear power plants for many years. Initial uncertainties regarding the application of quality assurance program criteria to scientific investigations have been resolved for the most part through NRC/DOE interaction and issuance of NUREGs 0856, 1297, and 1298.

REVIEW STRATEGY:

Acceptance Review:

In conducting the review of the quality assurance program, the reviewer should determine if the information presented in the license application and its references for determining compliance with the applicable regulatory requirements is complete in breadth and depth as identified in the FCRG.

The reviewer should determine that the information presented in the license application is presented in such a manner that the assumptions, data, and logic leading to a demonstration of compliance with the requirement are clear and do not require the reviewer to conduct extensive analyses or literature searches. The reviewer should also determine if the quality assurance program descriptions submitted cover all of the affected activities, i.e., site characterization, design and construction, performance confirmation, and operations, permanent closure, decontamination, and decommissioning. In addition, the reviewer should confirm that applicable criteria of 10 CFR Part 50, Appendix B are addressed in the quality assurance program descriptions.

An acceptance review for the implementation of the site characterization quality assurance program should verify that DOE has submitted evidence of DOE acceptance of these programs during prelicensing consultation.

Finally, the reviewer should determine if the U.S. Department of Energy (DOE) has either resolved all the NRC staff objections that apply to this requirement or provided all the information requested in Section 1.6.2 of the FCRG, for unresolved objections. The reviewer should evaluate the effects of any unresolved objections. The reviewer will evaluate the effects of any unresolved objections, both individually and in combinations with others, on: (1) the reviewer's ability to conduct a meaningful and timely review; and (2) the Commission's ability to make a decision regarding construction authorization within the three-year statutory period.

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Safety Review:

This regulatory requirement is limited to consideration of quality assurance.

In conducting the safety review, the reviewer should determine if the information presented in the license application and its references is an acceptable demonstration of compliance with the applicable regulatory requirements. At a minimum the reviewer should, determine the adequacy of the quality assurance program descriptions submitted in the license application to support DOE's compliance with the associated regulatory requirements for implementation quality assurance programs. Specifically, DOE will need to provide information with respect to the QA program that has been applied to activities affecting quality during site characterization; the QA program that will be applied to the structures, systems, and components important to safety and to the engineered and natural barriers important to waste isolation during the design and construction of the repository; the QA program that will be established and implemented for quality affecting activities associated with the performance confirmation program; the QA program that will be established and implemented for quality affecting activities associated with the operations, permanent closure, decontamination, and decommissioning phases of the repository operations; and the extent to which the completed and ongoing quality affecting activities were described in sufficient detail to allow a determination that the requirements of 10 CFR Part 50, Appendix B were satisfied.

The current version of the NRC Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions, Revision 2, March 1989, should be used as the basis for evaluating the sufficiency of the quality assurance program descriptions. The review plan has been applied extensively during site characterization, and provides criteria for determining compliance to quality assurance regulations, standards, and guidance, i.e., 10 CFR 60.152, 10 CFR Part 50, Appendix B, ANSI/ASME NQA-1 and applicable NUREGs (NRC, 1983; NRC, 1988a; NRC, 1988b). The reviewer will rely on personal expertise and knowledge of quality requirements and personal experience obtained in evaluating quality assurance program implementation during site characterization.

The safety review of the implementation of quality assurance programs will primarily focus on determinations whether they have been effectively implemented during site characterization. This review will include evaluations of: (i) all data and data analysis contributing to the license application have been developed or qualified under acceptable quality assurance programs; (ii) scientific and engineering computer codes have been adequately documented in terms of verification and model validation; and (iii) peer reviews have been conducted in accordance with quality program requirements. These determinations will be made based on evidence submitted by DOE of the effective implementation of quality assurance programs during site characterization. The NRC staff's documented observations during site characterization quality assurance

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implementation activities will contribute to the ability to determine the adequacy of the evidence submitted by DOE.

The specific aspects of the license application on which the reviewer will focus are discussed in the FCRG, and the acceptance criteria will be identified in Section 3.0 of this Review Plan.

In order to conduct an effective review, the reviewer will rely on his own expertise and independently acquired knowledge, information, and data in addition to that provided by the DOE in its license application. It is incumbent upon the reviewer to have acquired a body of knowledge regarding these and other critical considerations in anticipation of conducting the review to assure that the quality assurance program is sufficient in scope and depth to provide the information to resolve the concerns.

RATIONALE FOR REVIEW STRATEGY:

By agreement between DOE and NRC (Linehan, 1989), DOE prelicensing quality assurance program adequacy and implementation effectiveness are continuously evaluated by DOE and NRC staff. This action was taken to provide greater assurance that information submitted in a license application will be acceptable from the quality assurance perspective. This process of continuous quality assurance evaluation will provide the primary basis for the staff determination of site characterization quality assurance program implementation effectiveness.

Contributing Analysts:

CNWRA: Robert Brient

NRC: Kenneth Kalman, John Buckley

Date of Analysis: 05/27/92

APPLICABLE REGULATORY REQUIREMENTS FOR EACH REVIEW TYPE:

Type 1:

10 CFR 60.150
10 CFR 60.21(c)(4)
10 CFR 60.151
10 CFR 60.152

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Type 3:

10 CFR 60.150
10 CFR 60.21(c)(4)
10 CFR 60.151
10 CFR 60.152

REFERENCES:

American Society of Mechanical Engineers. ANSI/ASME NQA-1-1986, Quality Assurance Program Requirements for Nuclear Facilities.

J. Linehan to R. Stein, letter dated August 4, 1989. Transmittal of Meeting Minutes from July 6, 1989 QA Meeting and July 6-7, 1989 Design Control Meeting.

U.S. Nuclear Regulatory Commission. 1983. NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management.

U.S. Nuclear Regulatory Commission. 1988a. NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories.

U.S. Nuclear Regulatory Commission. 1988b. NUREG-1298, Qualification of Existing Data for High-Level Waste Repositories.

U.S. Nuclear Regulatory Commission. 1989. Division of High-Level Waste Management. Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions, Revision 2.

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EXAMPLE TYPE 3 COMPLIANCE DETERMINATION STRATEGY

COMPLIANCE DETERMINATION STRATEGY

4.3 ASSESSMENT WITH DESIGN CRITERIA FOR SHAFTS AND RAMPS

APPLICABLE REGULATORY REQUIREMENTS:

10 CFR 60.130
10 CFR 60.131(a)
10 CFR 60.131(b)
10 CFR 60.134
10 CFR 60.137

TYPES OF REVIEW:

Acceptance Review (Type 1)
Safety Review (Type 3)

RATIONALE FOR TYPES OF REVIEW:

Acceptance Review (Type 1) Rationale:

This regulatory requirement topic is considered to be license application-related because, as specified in the license application content requirements of 10 CFR 60.21 and the regulatory guide "Format and Content for the License Application for the High-Level Waste Repository (FCRG)" it must be addressed by the U.S. Department of Energy (DOE) in its license application. Therefore, the staff will conduct an Acceptance Review of the license application for this Regulatory Requirement.

Safety Review (Type 3) Rationale:

This regulatory requirement is related to radiological safety, retrievability, and waste isolation. It is a requirement for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31(a) (i.e., regulatory requirements in Subparts E, G, H, and I). Therefore, the staff will conduct a safety review of the license application to determine compliance with this regulatory requirement.

This regulatory requirement, concerning assessment of design criteria for shafts and ramps, focuses on the strategies for assessment of these criteria.

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There appears to be no lack of certitude as to the methodology needed to determine or demonstrate compliance with the preclosure regulatory requirements on the design of shafts and ramps for the geologic repository operations area (GROA). Factors considered in making this determination include the nature of the Yucca Mountain tuff and the available drilling and boring technologies. Therefore, the safety review for the preclosure portion of this requirement will be a Type 3 Review.

Review of the post-closure portion of this requirement, however, demands consideration of the performance of seals (and backfill materials) for shafts, ramps and boreholes, and the impact of repository-generated thermal loads on the long-term performance of these repository features. For example, in order to have confidence in applying current sealing technology to the repository environment, two technical uncertainties relevant to the effectiveness and performance of seals remain to be resolved. These uncertainties are: (1) whether the seals will remain effective over thousands of years (seal long-term performance), and (2) whether technology exists to effectively install seals such that the intended performance of seals can be achieved.

Experience on long-term performance of seals is currently lacking. Although available observations of the performance of some seal materials (for example, low permeability cements) seem to indicate that these components may have great durability (Osende, 1985; and Rissler, 1978), it is also uncertain what impact thermal loads will have on their performance. Also, other observations (Roy and Langton, 1983 and 1986), about deterioration of high quality cement grouts in dam foundations within a decade after installation seem to indicate otherwise. Considerable uncertainty exists related to the installation of seals in the underground excavations (Schaffer and Daemen, 1987). This is especially true in the determination of optimum grouting conditions and preferable grouting pressures to seal fractures that may have been dilated and/or created around the excavations due to construction to prevent the fractured zone around the excavations from becoming dominant bypass flowpaths around the seals and thereby negating the effectiveness of the seals. At the present time, the net contribution of seals to the overall system performance of the geologic repository is yet to be established. However, preliminary assessment by the U.S. Department of Energy (DOE), based on the current knowledge of the site and simplified analyses, is that the contribution of seal performance to overall system performance of the geologic repository may not be significant (Fernandez, 1991; and U.S. DOE, 1988). Therefore, the technical uncertainties mentioned above do not appear to pose a risk of noncompliance with the performance objectives based on current knowledge and, as a result, are not considered key-technical uncertainties.

Accordingly, a Type 3 Review has also been selected for the post-closure portion of this requirement based on the following assumptions:

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- (1) the impacts of repository-generated thermal loads on the long-term performance of seals and backfill materials will be evaluated as part of the review of compliance with the pertinent performance objectives; and
- (2) that DOE preliminary assessments, that the net contribution of seals to overall system performance is negligible, will be substantiated.

Ongoing research associated with thermal loading is expected to address performance of seals for shafts and boreholes and backfill. If future research or site studies indicate that uncertainties regarding seal performance or the relative effects of thermal loads cannot be adequately bounded, the strategy for compliance determination will be revised so that a finding regarding the adequacy of shaft and borehole seals can be made with reasonable assurance.

REVIEW STRATEGY:

Acceptance Review:

In conducting the acceptance review of the assessments of design criteria for shafts and ramps, the reviewer should determine if the information presented in the license application and its references for demonstrating compliance with the applicable regulatory requirements is complete in technical breadth and depth as identified in the Format and Content Regulatory Guide. The reviewer should determine that all appropriate information necessary for the staff to conduct the assessment of design, criteria for shafts and ramps is presented such that the assessments required by the regulatory requirements associated with total and subsystem performance objectives can be performed. These include assessing the potential for creating preferential pathways for either: (i) the inward movement of water and water vapor to contact the waste packages; or (ii) the outward migration of radionuclides through shafts, ramps and boreholes to the accessible environment. In addition, the license application should include an assessment demonstrating that the design does not compromise the ability of the geologic repository to meet the performance objectives for the period following permanent closure [i.e., 10 CFR 60.112 and 60.113(a)] and for the period before permanent closure [i.e., 10 CFR 60.111(a) and 60.111(b)].

The reviewers should determine that the information presented in the license application is presented in such a manner that the assumptions, data, and logic leading to a demonstration of compliance with the requirement are clear and do not require the reviewer to make extensive analyses or literature searches. The reviewer should also determine that controversial information and appropriate alternative interpretations and models have been adequately described and considered.

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Finally, the reviewer should determine if the U.S. Department of Energy (DOE) has either resolved all the NRC staff objections that apply to this requirement or provided all the information requested in Section 1.6.2 of the FCRG, for unresolved objections. The reviewer should evaluate the effects of any unresolved objections, both individually and in combinations with others, on: (i) the reviewer's ability to conduct a meaningful and timely review; and (ii) the Commission's ability to make a decision regarding construction authorization within the three-year statutory period.

Safety Review:

In conducting the safety review, the reviewer should determine if the information presented in the license application and its references is an acceptable demonstration of compliance with the applicable regulatory requirements. At a minimum the reviewer should, determine the adequacy of the data and analyses presented in the license application to support DOE's demonstration of compliance with this regulatory requirement topic. Specifically, DOE will need to: provide information demonstrating compliance for each shaft or ramp structure, system or component important to safety with applicable general and specified design requirements from 10 CFR Part 60; justifying use and compliance with applicable design parameters and industry codes and methods; acceptability of accident analyses; use of appropriate margins of safety in design; acceptability of models used to perform analyses; description of field, in-situ, and laboratory tests, and natural analog studies; variability and uncertainty of data and propagation of errors; use of assumptions and sensitivity of model results to uncertainties; and interpretations of input and output data. These requirements are discussed in more detail in the FCRG.

Those specific aspects of the license application on which a reviewer will focus are discussed in the Format and Content Regulatory Guide, and the detailed acceptance criteria will be identified in Section 3.0 of this Review Plan.

In order to conduct an effective review, the reviewer will rely on his or her own expertise and independently acquired knowledge, information, and data in addition to that provided by the DOE in its license application. Therefore, it is incumbent upon the reviewer to have acquired a body of knowledge regarding critical considerations in anticipation of conducting the safety review.

Of primary interest is the performance of the seals for shafts, ramps and boreholes. For determining compliance with other regulatory requirements, it is expected that current technology is sufficient. The reviewer will assess the adequacy of DOE's evaluation of the degree to which the shafts and ramps and their seals may be preferential pathways for the movement of groundwater to contact the waste packages, as specified in 10 CFR 60.134(b)(1). DOE's evaluation should include a demonstration that the degree to which

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groundwater movement is impeded by the shafts and ramps and their seals and backfill is equal to or greater than the degree to which groundwater movement is impeded by the undisturbed geologic setting. DOE's evaluation of the design of seals for shafts and boreholes should also demonstrate that, following permanent closure, the seals do not become pathways that compromise the geologic repository's ability to meet the performance objectives, per 10 CFR 60.134(a). In addition, DOE must demonstrate that the materials and placement methods for seals for shafts, ramps, and boreholes must reduce to the extent practicable radionuclide migration through existing pathways, as specified in 10 CFR 60.134(b)(2). Factors which should be considered are methods of construction and the dimensions and properties of the resulting disturbed zone along with materials and placement methods for seals. Also, if the seals for shafts, ramps, and boreholes are made much better than the adjacent geologic media, any potential negative effects of low permeability zones in the presence of high permeability zones of the geologic setting should be investigated.

Other design criteria, which derive from citations in 10 CFR Part 60 other than 10 CFR 60.134, result in acceptance criteria generally related to ensuring that performance objectives will be met. The reviewer should determine compliance with these other design criteria from the perspective of the design of shafts and ramps. For example, for determining compliance with 10 CFR 60.130, the reviewer will determine that the design includes any safety features needed to achieve the 10 CFR Part 60 performance objectives. For determining compliance with 10 CFR 60.131(a) and 10 CFR 60.131(b), the reviewer will determine that the shafts and ramps designs meet the general design criteria for the GROA, respectively. For 10 CFR 60.137, the reviewer will determine whether or not the shafts and ramps designs will permit the implementation of the performance confirmation program.

The information in this section of the license application will be cross-referenced to information and analyses submitted for the sections 60.111(a) (Protection Against Radiation Exposure and Releases of Radioactive Material), 60.111(b) (Retrievability of Waste), 60.112 (Overall System Performance Objective After Permanent Closure), and 60.113 (Engineered Barrier System Performance After Permanent Closure).

RATIONALE FOR REVIEW STRATEGY:

The review strategy provides a standard approach to the review of structures such as shafts and ramps while taking into account the additional requirements for protection of public health and safety from radiological considerations.

Contributing Analysts:

CNWRA: A.H. Chowdhury, J.P. Hageman, S. Hsiung, H. Karimi, E. Tschoepe.

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NRC: B.N. Jagannath, M. Nataraja.

Date of Analyses: 08/20/92

APPLICABLE REGULATORY REQUIREMENTS FOR EACH REVIEW TYPE:

Type 1:

10 CFR 60.130
10 CFR 60.131(a)
10 CFR 60.131(b)
10 CFR 60.134
10 CFR 60.137

Type 3:

10 CFR 60.130
10 CFR 60.131(a)
10 CFR 60.131(b)
10 CFR 60.134
10 CFR 60.137

REFERENCES:

Fernandez, J. A. 1991. *Sealing Concepts and Design Approach*. Presentation to Nuclear Waste Technical Review Board Panel on Structural Geology and Geoengineering. November 12-13, 1991.

Osende, J. 1985. The Durability of Cement Grouts. *Fifteenth Congress on Large Dams Transactions*. pp.759-766, Q. 58, R. 43, Volume 3, Lausanne, Switzerland, International Commission on Large Dams, Paris, June 1985.

Rissler, A. 1978. *Determination of the Water Permeability of Jointed Rock*. English Edition of Vol. 5, Institute for Foundation Engineering, Soil Mechanics, Rock Mechanics and Water Ways Construction. Aachen, F.R.G.: RWTH (University).

Roy, D.M. and C.A. Langton. 1983. *Characterization of Cement-Based Ancient Building Materials in Support of Repository Seal Materials Studies*. Office of Nuclear Waste Isolation. BMI/CNWI-523. Columbus, OH: Battelle Memorial Institute.

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Roy, D.M. and C.A. Langton. 1986. *Ancient Concrete Studies as Analogs of Cementitious Sealing Materials for a Tuff Repository*. Materials Research Laboratory. Unnumbered Technical Report. University Park, PA: Pennsylvania State University.

Schaffer, A. and J.J.K. Daemen. 1987. *Experimental Assessment of the Sealing Effectiveness of Rock Fracture Grouting*. NUREG/CR-4541. Washington, DC: U.S. Nuclear Regulatory Commission (NRC).

U.S. Department of Energy. 1988. *Site Characterization Plan*. Chapter 8.3.3. Seal Program. Yucca Mountain Site. Nevada Research and Development Area. DOE/RW-0199. NV: DOE.

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EXAMPLE TYPE 5 COMPLIANCE DETERMINATION STRATEGY

COMPLIANCE DETERMINATION STRATEGY

**3.2.1.9 POTENTIALLY ADVERSE CONDITION: EVIDENCE OF IGNEOUS
ACTIVITY**

APPLICABLE REGULATORY REQUIREMENTS:

10 CFR 60.122(c)(15)
10 CFR 60.21(c)(1)(ii)(B)
10 CFR 60.21(c)(1)(ii)(F)

TYPES OF REVIEW:

Acceptance Review (Type 1)
Safety Review (Type 3)
Detailed Safety Review Supported by Analysis (Type 4)
Detailed Safety Review Supported by Independent Tests, Analyses, or Other
Investigations (Type 5)

RATIONALE FOR TYPES OF REVIEW:

Acceptance Review (Type 1) Rationale:

This regulatory requirement is considered to be license application-related because, as specified in the license application content requirements of 10 CFR 60.21 and the regulatory guide "Format and Content for the License Application for the High-Level Waste Repository (FCRG)" it must be addressed by the U.S. Department of Energy (DOE) in its license application. Therefore, the staff will conduct an Acceptance Review of the license application for this regulatory requirement topic.

Safety Review (Type 3) Rationale:

This regulatory requirement is considered to be related to containment and waste isolation. It is a requirement for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31(a) (i.e., regulatory requirements in Subparts E, G, H, and I). Therefore, the staff will conduct a safety review of the license application to determine compliance with this regulatory requirement.

This regulatory requirement, concerning evidence of igneous activity, focuses on characterization of the Yucca Mountain site as it relates to igneous activity.

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The Yucca Mountain site is located in an area of the Basin and Range physiographic province which has experienced extensive tertiary volcanic and magmatic activity of both silicic and basaltic affinities, and Quaternary basaltic volcanic activity has occurred near the site (DOE, 1988, pp. 1-88 - 1-99). Therefore, this potentially adverse condition exists for the Yucca Mountain site. There are also concerns about determining the degree to which the condition is present, or may be present and undetected.

Detailed Safety Review Supported by Analysis (Type 4) Rationale:

The staff considers that there may be high potential risk of noncompliance with the following applicable regulatory requirements because, for the Yucca Mountain site, there is a key technical uncertainty.

The KTU is considered to require a Type 4 review because there is a high risk of noncompliance with the performance objective specified below. This concern of high risk of noncompliance will necessitate analysis above and beyond that required for a Type 3 review in order to assure that the uncertainty and potential effects on performance have been minimized to the extent possible.

Key Technical Uncertainty Topic: Low Resolution of Exploration Techniques to detect and evaluate igneous features.

Description of Uncertainty: Geologic conditions at the Yucca Mountain site render low resolution results from most geophysical techniques. For example, standard reflection and refraction techniques may produce poor records of the subsurface in the Yucca Mountain region because of problems related to transmitting sufficient energy through the rock units. Teleseismic tomographic techniques such as those used by Evans and Smith (1992) have resolution capabilities on the order of kilometers. In addition, if dikes are assumed to be the prevalent volcanic/magmatic feature in the region, their commonly vertical orientation would make them difficult to detect in the subsurface using standard vertical drilling techniques.

Many features which are presumed to have a bearing on understanding magmatic processes, such as the zone of possible partial melt of Evans and Smith (1992), cannot be sampled directly (see the Key Technical Uncertainty related to Inability to Sample Igneous Features) and therefore can only be evaluated through indirect measurements. In addition, many properties, such as heat flow, are known to have some relationship to igneous processing, but the exact relationship is poorly understood. Therefore, processes, features, and characteristics related to igneous activity have a degree of uncertainty which is difficult to quantify.

Performance Objective at Risk: Total System Performance Objective (10 CFR 60.112)

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Explanation of Nature of Risk: Magmatic activity is a process which, if it occurred, has the potential for causing noncompliance with 10 CFR 60.112 even without considering coupled effects or the effects of other processes and events. To date, most probability and consequence analyses, have not considered coupled effects, such as effects on groundwater flow and transport, which increase the risk of noncompliance with 10 CFR 60.112. Direct disruption of the repository has received the most attention even though this is a relatively low probability event. However, volcanic activity in the vicinity of the repository, with resultant effects on coupled processes, has a higher probability of occurring and may cause a significant change to the complementary cumulative distribution function (CCDF). The uncertainty and risk associated with this Key Technical Uncertainty lies in the fact that determining the presence or absence of volcanic/magmatic features and processes, or determining the degree to which these features and processes may be present and undetected, could be severely impaired. In addition, little effort has been given to investigation and evaluation of the effects when the activity is not directly within the repository block. Therefore, understanding of the processes, features, and characteristics related to igneous activity, both direct and secondary, has a degree of uncertainty which is extremely hard to quantify.

Description of Resolution Difficulty: This uncertainty can best be addressed through the use of an integrated exploration program which employs multiple investigative techniques. In addition, various state-of-the-art techniques can be employed to improve the detection capabilities of the methods applied (Jones *et al.*, 1987). Although such procedures can minimize the uncertainty related to detection problems, some uncertainty will still be carried into subsequent analyses. If an integrated exploration program is not conducted by the DOE, the staff would consider this Key Technical Uncertainty to require a Type 5 review.

Detailed Safety Review Supported by Independent Tests, Analysis, or Other Investigations (Type 5) Rationale:

The staff considers that there may be the highest potential risk of noncompliance with this Regulatory requirement because, for the Yucca Mountain site, the following Key Technical Uncertainties are the most difficult to resolve. Therefore, there might be a high residual risk of noncompliance with the performance objectives specified below because very little can be done to reduce the risk, or compensate for the risk using, for example, favorable site conditions or engineered features.

Modeling exercises are already underway in an attempt to quantify and, reduce the uncertainty related to conceptual models. It is recognized that most of this modeling has and will be done under performance assessment. However, the interplay between performance assessment staff and geologists and volcanologists providing input cannot be stressed too strongly.

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The potential for high residual risk of noncompliance in light of these Key Technical Uncertainties is sufficient that a detailed safety review supported by independent tests, analyses, or other investigations is justified.

Key Technical Uncertainty Topic: Inability to Sample Igneous Features.

Description of Uncertainty: Many features related to volcanic/magmatic activity cannot be directly sampled. For example, the large low-velocity zone in the mantle, interpreted by Evans and Smith (1992) as a possible partial melt and the potential source for basaltic volcanism in Crater Flat, is known only from imaging by teleseismic tomography. This Key Technical Uncertainty stems from the fact that many features determined from low-resolution geophysical techniques cannot be sampled, so considerable judgment will be required in interpretation of anomalies detected by geophysical methods. The low velocity zone of Evans and Smith (1992), has several possible explanations, as does the seismic "bright spot" discussed by Brocher *et al.* (1990). In addition, other variables such as magma temperature and volatile content can only be constrained through detailed studies of past eruptions. Key Technical Uncertainties may also exist relative to adequacy of age dating techniques for representing temporal distribution of volcanic/magmatic events.

Performance Objective at Risk: Total System Performance Objective (10 CFR 60.112)

Explanation of Risk: Because of the inability to sample features, description of the characteristics of interpreted features is uncertain and can vary based on the model chosen. This means conceptual and mathematical models for use in performance assessment can never be completely verified or validated.

Description of Resolution Difficulty: As this problem is directly related to the amount of data available, the solution may involve use of subjective judgement in addition to objective data. Subjective judgement will be used to interpret the nature of the volcanic/magmatic features as well as for projecting the resultant effects of these features. The staff knows of no feasible technique to resolve the uncertainties related to inability to sample volcanic/magmatic features.

Key Technical Uncertainty Topic: Development and use of conceptual Tectonic Models as related to Igneous Activity.

Description of Uncertainty: The geologic data at Yucca Mountain are, and will most likely remain, permissive for the development of multiple geologic models to describe the presence and origin of many volcanic/magmatic and tectonic features. The choice of a conceptual geologic model can have a significant effect on interpretation of the hazards which may affect the repository. For example, currently available models include one

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assuming a northwest trending controlling structural feature (Crowe and Perry, 1990), and another assuming a north-northeast controlling structural feature (Smith *et al.*, 1990). These two models are mutually exclusive; however, existing data can be used to support either model. While it may be possible to determine a preferred model, the staff does not believe that either of these two models can be eliminated from consideration at the present time. The choice of one could strongly affect the results of performance calculations for assessing potential volcanic hazards in the vicinity of Yucca Mountain. Because of this range in permissible models and the associated uncertainties, this Key Technical Uncertainty is considered to involve a Type 5 review.

Performance Objective at Risk: Total System Performance Objective (10 CFR 60.112)

Explanation of Risk: By definition, models are a simplification of reality, and both conceptual and mathematical models will be used in the high-level waste program. The conceptual model selected can have a significant effect on the scope of the field investigation program and on interpretation of the data obtained. In addition, the regulatory requirement itself relates to more than just the presence of certain features; it also requires an assessment of what may be present and undetected. Without a conceptual model of what is being investigated, it is impossible to comply with either the regulatory requirements for this potentially adverse condition [10 CFR 60.122 (c) (15)] or the regulatory requirement related to overall system performance (10 CFR 60.122). Conceptual models can be used to describe the assumed physical and chemical processes which have, are, or will be taking place within the system under consideration; mathematical models are used in performance assessment to "predict" the behavior of the system. It is impossible to completely sample and describe any physical system which is as complex as that represented by igneous activity in the vicinity of Yucca Mountain. Because uncertainty will exist in the data and parameters, there will be an inherent uncertainty in the understanding of the physical system being represented by the model and a consequent inherent uncertainty in the correctness or validity of any conceptual model used. This uncertainty will be propagated through the performance assessments along with the mathematical model uncertainties, introducing an unknown amount of uncertainty in final results from performance assessment analyses.

Description of Resolution Difficulty: The Key Technical Uncertainty related to conceptual models is considered to require a Type 5 review because very little can be done to reduce the risk of noncompliance. According to Davis *et al.* (1990), there is currently no methodology designed to quantify the uncertainty in conceptual models. Also, selection of the model(s) to be used will be based, at least in part, on subjective judgement of experts and can, at best, be formalized and documented only to the extent that the assumptions used are clear, reasonable and traceable.

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Summary:

The reasons for a Type 5 review, related mainly to concerns about the inability to sample volcanic/magmatic feature and alternative conceptual models, can be summarized as follows:

- (1) Quantitative knowledge about volcanic/magmatic processes in the Yucca Mountain area is, and most likely will remain, rudimentary for both the deep and shallow subsurface. The ability to substantially improve on this knowledge base will be severely hampered by the low-resolution capabilities of the exploration techniques and the inability to adequately sample volcanic/magmatic features.
- (2) Alternative conceptual models of volcanic/magmatic processes may remain at the time of licensing.
- (3) Alternative conceptual models linking volcanic/magmatic processes with tectonic activity may remain at the time of licensing.
- (4) The alternative models for addressing probability of volcanic/magmatic activity and potential effects from this activity may span orders of magnitude.
- (5) The effects of volcanic/magmatic activity on the ability to demonstrate compliance with the overall system performance objective will be a highly contentious point during the hearing process.

REVIEW STRATEGY:

Acceptance Review:

In conducting the acceptance review of the potentially adverse condition (PAC) concerning evidence of igneous activity, the reviewer should determine if the information presented in the license application and its references for determining compliance with the igneous activity PAC requirement is complete in technical breadth and depth as required by the FCRG. The reviewer should determine that all appropriate information necessary for the staff to review the likelihood and type of hazard posed by this PAC is presented such that the assessments required by the regulatory requirements associated with total system and subsystem performance objectives can be performed.

The reviewer should determine that the information presented in the license application is presented in such a manner such that the assumptions, data, and logic leading to a demonstration of compliance with the requirements are clear and do not require the reviewer to conduct extensive analyses or literature searches. The reviewer should also

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determine that controversial information and appropriate alternative interpretations and models have been adequately described and considered.

Finally, the reviewer should determine if the U.S. Department of Energy (DOE) has either resolved all the NRC staff objections that apply to this requirement or provided all information requested in Section 1.6.2 of the FCRG, for unresolved objections. The reviewer should evaluate the effects of any unresolved objections, both individually and in combination with others, on: (1) the reviewer's ability to conduct a meaningful and timely review; and (2) the Commission's ability to make a decision regarding construction authorization within the three-year statutory period.

Safety Review:

This regulatory requirement is limited to consideration of evidence concerning igneous activity that has occurred in the area of the Yucca Mountain site. Although the regulatory requirement is limited to that activity which occurred since the start of the Quaternary Period, evidence of pre-Quaternary activity will require examination to demonstrate a sufficient understanding of igneous activity in the vicinity of the site. It is not concerned with projections of type, probability, and effects of igneous activity during the intended period of performance. These topics will be covered under other Review Plans which deal with performance assessment such as those represented in Sections 5.0 and 6.0 of the LARP.

In conducting the safety review, the reviewer should determine if the information presented in the license application and its references is an acceptable demonstration of compliance with the applicable regulatory requirements. At a minimum the reviewer should, determine the adequacy of the data and analyses presented in the license application to support DOE's demonstration of compliance with 10 CFR 60.21(c)(1)(ii)(B). Specifically, the DOE will be required to: (1) provide information to determine whether, and to what degree, the PAC is present; (2) provide information to determine to what degree the PAC is present, but undetected; (3) assure the sufficiency of the lateral and vertical extent of data collection; and (4) evaluate the information presented under (1) and (2), with assumptions and analysis methods that adequately describe the presence of the PAC and ranges of relevant parameters. For purposes of determining the presence or absence of this PAC, investigations should extend from the surface to a depth sufficient to determine critical pathways for radionuclide migration from the underground facility, and to a depth sufficient to demonstrate a suitable understanding of igneous processes such that reasonable bounds can be placed on the different conceptual models.

In general, the reviewer should assess the adequacy of the investigations of the PAC for evidence of igneous activity, both within the controlled area and outside the controlled area, as necessary. The specific aspects of the license application on which the reviewer

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will focus are discussed in the FCRG, and the acceptance criteria will be identified in Section 3.0 of this Review Plan.

In order to conduct an effective review, the reviewer will rely his own expertise and independently-acquired knowledge, information, and data such as the results of research activities being conducted by the NRC Office of Regulatory Research, in addition to that provided by the DOE in its license application. For example, teleseismic data have indicated a large low velocity zone beneath the site, which could indicate, among other things, a zone of partial melting and a source for basaltic magma (Evans and Smith, 1992). The reviewer should peruse this geophysical information plus relevant data from follow-up studies to refine this information. It is incumbent upon the reviewer to have acquired a body of knowledge regarding these and other critical considerations in anticipation of conducting the review to assure that the igneous activity exploration program is sufficient in scope and depth to provide the information necessary to resolve the concerns.

Detailed Safety Review Supported by Analysis:

A detailed safety review and analysis will be needed for evaluation of the Key Technical Uncertainty regarding poor resolution capability of exploration techniques to determine and evaluate igneous features and processes. This will ensure that the DOE has adequately handled Items (1)-(4) listed above in the previous section (Safety Review, second paragraph). Activities performed in this Detailed Safety Review will help to assure that DOE has adequately addressed and resolved this Key Technical Uncertainty so that it does not lead to noncompliance with the total system performance objective.

Examples of specific review activities that will be required include: (1) review and analysis of the geophysical tests which have been conducted in the vicinity of Yucca Mountain to assess the characteristics and distribution of volcanic/magmatic features; (2) review and analysis of results of field mapping programs to assess the distribution and characteristics of volcanic/magmatic features; (3) review of information provided by the drilling programs; and (4) review of the leveling and global positioning satellite (GPS) studies. The analysis should focus on the sensitivity, resolution and detection capabilities of the different techniques; and the degree to which the separate techniques can provide independent assessments of the various features and characteristics of concern; and the degree to which the techniques provide information which either corroborates or contradicts results of the other techniques.

It may also be appropriate to assess the quality and traceability of data and information by utilizing staff with expertise in review of quality assurance programs.

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Detailed Safety Review Supported by Independent Tests, Analysis, or Other Investigations:

A detailed safety review, independent modeling, and the use of the results of staff investigations will be needed for the Key Technical Uncertainties related to conceptual models and the inability to sample igneous features. This will ensure that the DOE has adequately demonstrated Items (1)-(4) listed in the section on safety review (Safety Review, second paragraph).

For the Key Technical Uncertainties concerning development and use of conceptual tectonic models and the inability to sample igneous features, the staff detailed review will be supported by conceptual and numerical models developed by the staff through Iterative Performance Assessment to determine if models being used by the DOE provide an adequate explanation of the phenomenon of igneous activity. Independent field investigations and laboratory analyses may be required to support the conceptual and numerical models. In conducting this review, the staff must evaluate the different conceptual models to determine if they are consistent with the models being proposed for other related processes. For example, while it is generally accepted that detachment faults are present in the area of Yucca Mountain, the models proposed to date do not provide an adequate explanation of the relationship between conduits for volcanic activity and the detachment. Through various modeling exercises, the staff may develop a range of structural models and attempt to determine the relationships necessary for dikes to be propagated through the structures.

When reviewing and creating models, it should be recognized that, in addition to field and analytical data, subjective judgement will also be required. It is important that the assumptions necessary for the different models be carefully documented and thoroughly reviewed. Bounding assessments, field data, and the results of research activities should be included to narrow and distinguish between the models proposed. It is anticipated that several conceptual models may be reasonable at the time of licensing. In reviewing these models, the staff must assure that they reflect the degree of resolution of the experimental and investigative methods, including what could be present but undetected due to the limitations of the methods applied. The staff must also assure that the models used incorporate all appropriate field data and assumptions.

RATIONALE FOR REVIEW STRATEGY:

In view of the complexity of the key technical uncertainty addressed above, it is appropriate that the NRC conduct the independent activities described in order to (1) develop the licensing tools and technical basis necessary to judge the adequacy of DOE's license application, (2) assure sufficient independent understanding of the basic physical

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processes taking place at the geologic repository, and (3) maintain independent but limited confirmatory research capability under NRC auspices.

Contributing Analysts:

CNWRA: G. Stirewalt and S. Young

NRC: J.S. Trapp

Date of Analysis: September 11, 1992

APPLICABLE REGULATORY REQUIREMENTS FOR EACH REVIEW TYPE:

Type 1:

10 CFR 60.122(c)(15)
10 CFR 60.21(c)(1)(ii)(B)
10 CFR 60.21(c)(1)(ii)(F)

Type 3:

10 CFR 60.122(c)(15)
10 CFR 60.21(c)(1)(ii)(B)
10 CFR 60.21(c)(1)(ii)(F)

Type 4:

10 CFR 60.122(c)(15)
10 CFR 60.21(c)(1)(ii)(B)
10 CFR 60.21(c)(1)(ii)(F)

Type 5:

10 CFR 60.122(c)(15)
10 CFR 60.21(c)(1)(ii)(B)
10 CFR 60.21(c)(1)(ii)(F)

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Title

DEVELOPMENT OF COMPLIANCE DETERMINATION STRATEGIES

EFFECTIVITY

Revision 2 of this procedure became effective on 12/29/93.
This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change No.</u>	<u>Date Effective</u>
All	<i>DA</i>	12/29/93

SUPERSEDED

Supersedes Procedure No. TOP-001-11, Rev. 1

Approvals			
Written by R. Brient <i>R. Brient</i>	Date <u>12/29/93</u>	Technical Review Not required	Date
Quality Assurance B. Mabrito <i>B. Mabrito</i>	Date <u>12/29/93</u>	Cognizant Director B. Sagar <i>B. Sagar</i>	Date <u>12/29/93</u>

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DEVELOPMENT OF COMPLIANCE DETERMINATION STRATEGIES

1 PURPOSE

To provide guidance for the development of Compliance Determination Strategies (CDS) for the Yucca Mountain site. This procedure implements the appropriate requirements of the Center for Nuclear Waste Regulatory Analyses (CNWRA) Quality Assurance (QA) Manual, Section 3.

2 DEFINITIONS

2.1 **Applicable Regulatory Requirements.** The individual citations from 10 CFR Part 60 associated with a Regulatory Requirement Topic (RRT).

2.2 **Compliance Determination Strategy (CDS).** The general approach or overall plan of the Nuclear Regulatory Commission (NRC) for determination of compliance with the regulatory requirements associated with a RRT. Each CDS establishes the scope and depth of the NRC compliance determination review for a RRT. NRC options in each case range from Acceptance Review to a Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations.

2.3 **Format and Content Regulatory Guide (FCRG).** The document prepared by the NRC to provide guidance to the Department of Energy (DOE) regarding the format and content of the license application (LA).

2.4 **License Application Review Plan (LARP).** That document which provides detailed guidance to the NRC staff on how to conduct the license application review.

2.5 **Technical Uncertainty:** Lack of certitude as to how to demonstrate (DOE action) or determine (NRC action) compliance. This includes lack of certitude (even controversy) about: (i) methods for obtaining information, (ii) methods for analyzing information, or (iii) the understanding of conditions or processes. It also includes staff concerns with DOE's program documented as objections, comments, or questions.

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2.6 Key Technical Uncertainty (KTU). A Technical Uncertainty which poses a high risk of noncompliance with a performance objective of 10 CFR Part 60. It may also be associated with reducing a high risk of noncompliance with a performance objective.

For example, a KTU exists where there is a lack of certitude about a methodology that is needed to either demonstrate or determine compliance with a 10 CFR Part 60 performance objective (e.g., scenario analysis methods are necessary to demonstrate compliance with the overall system performance objective of 10 CFR 60.112). A KTU also exists where (i) there is a lack of understanding about a condition or process, and (ii) it is credible that the condition or process exists (or will exist) and could have either a significant adverse or favorable affect on repository performance.

2.7 Regulatory Requirement Topic (RRT). A set of one or more regulatory requirements pertaining to a topic of regulatory interest. Each RRT corresponds to an individual section of the FCRG and an individual review plan in the LARP.

3 BACKGROUND

In the conduct of Systematic Regulatory Analysis (SRA) in support of NRC's High-Level Waste (HLW) Repository Licensing Program, the first step is the analysis of the regulatory requirements from 10 CFR Part 60 and the development of RRT. The resulting number of RRTs, and the limited quantity of staff time and resources necessitate an evaluation of the level of resources to be applied to examining compliance with each of the RRTs based on technical urgency and difficulty, risk of noncompliance with repository performance objectives, and other factors.

The CDS establishes the scope and depth of the NRC compliance determination review for a given RRT for the Yucca Mountain site. The CDS controls the preparation of the Compliance Determination Method (CDM) for that RRT by defining any limits on the type and extent of the license application review. Portions of the CDSs and the CDMs will be included in the LARP for the Yucca Mountain site.

The process of CDS development results in the definition of KTUs. These KTUs may result in the definition of research user needs, and ultimately in the initiation of research programs.

CDS development occurs in two steps. First, the types of review are chosen, then the review strategy is prepared. It is recognized that these steps may overlap.

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The review strategy describes the type(s) of license application review for the subject RRT. It should not include descriptions of precicensing review activities; however, it should recognize that analysis capability and research needed to support some of the license application reviews will be completed before DOE's submittal of the license application. The review strategy should define the scope and approach of the reviews and tests or analyses (if appropriate) to be used by the NRC and CNWRA staffs to review the license application and determine compliance with the associated RRT. Where possible, reviews, tests, and analyses should be identified that are appropriate for: (i) the specific nature of the RRT, (ii) the type of review selected, (iii) any KTUs that are associated with the RRT, and (iv) the methods to reduce, remedy, or compensate for the KTUs. The CDS review strategy is not intended to describe specifically how (i.e., step-by-step procedure) the reviews, tests, or analyses are to be performed, but rather to bound and guide the subsequent development of the CDM. The CDMs should prescribe how the review for compliance determination will be performed, including the details of the method (as in an NRC Standard Review Plan review procedure) and associated acceptance criteria.

Development of the CDSs and their incorporation into the LARP is an iterative process. The process must include a review of the associated portion of the FCRG to ensure that these two key regulatory products remain consistent.

The CDS will be reviewed and updated as needed based on new information and understanding.

4 RESPONSIBILITIES

4.1 The CNWRA Deputy Technical Director for Systems Engineering and Integration is responsible for preparation, revision, and implementation of this procedure.

4.2 Members of CDS Groups are responsible for developing CDSs in accordance with this procedure.

5 CDS GROUP MEMBERSHIP, TECHNICAL BACKGROUND, AND TRAINING

CDS group members shall be assigned by HLWM Division Directors, Branch Chiefs, Section Leaders, and CNWRA Element Managers, as appropriate. Members shall be familiar with background information pertinent to the RRT (see Attachment A) and the technical aspects of the CDS to be developed for the Yucca Mountain site, and shall be provided with general SRA training and with training in the use of this procedure.

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6 PROCEDURE

6.1 Using the CDS format (Attachment B), the CDS template (Attachment C), and other approved CDSs as appropriate, develop the CDS as follows. (The template in Attachment C, which contains the appropriate standard language, is available on floppy disk to assist in CDS preparation. However, it is intended as a guide, and the staff should exercise judgment in its use.

6.1.1 Record the RRT number, title, and the "APPLICABLE REGULATORY REQUIREMENTS". This information may be obtained from the associated individual review plan in the LARP.

6.1.2 Determine the review type(s) to be applied to the RRT as a whole and to each individual regulatory requirement by referring to the detailed discussion of review type selection criteria in Attachment B. Prepare a list of the regulatory requirement citations by review type. This list shall be placed in the "APPLICABLE REGULATORY REQUIREMENTS FOR EACH REVIEW TYPE" section near the end of the CDS. Some considerations for the completion of this step include:

- All RRTs shall receive at least an acceptance review.
- NRC and CNWRA management shall be briefed to obtain their comments on CDS type selection prior to further development of the CDS. In some cases, such action may reduce the resources required to complete CDS preparation.
- When conducting review type selection, CDS development group leaders shall ensure that participation by appropriate staff from all disciplines associated with an RRT is obtained.
- Include considerations of NRC staff interpretation of 10 CFR Part 60, as appropriate, consistent with NUREG-0804.
- Consider any important design assumptions, or existing knowledge expected to be used by DOE in demonstrating compliance.
- List any standards or guides that can be used to evaluate designs, reviews, etc.

6.1.3 Complete the "TYPES OF REVIEW" section of the CDS by listing all the review types applicable to the RRT (this information was developed by executing step 6.1.2 above). When

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listing the review types, consider that all RRTs related to the license application will receive a Type 1 Acceptance Review, only general information RRTs will receive a Type 2 General Information Review, and any RRT associated with the Safety Analysis Report of the LA (related to radiological health and safety or waste isolation) will receive at least a Type 3 review. It can, in addition, receive Types 4 and/or 5 reviews.

6.1.4 Complete the "RATIONALE FOR TYPES OF REVIEW" section by justifying the choice of review types. It is recognized that technical judgement will be needed where specific evidence is lacking. However, where judgement is used, the basis must be explained. The information to be included in this section is as follows.

- For each review type applicable to the RRT or its individual regulatory requirements, provide the rationale for selection of that review type. The standard rationales which are provided in the Attachment C template should be used as applicable. These standard rationales shall be modified as appropriate such that specific characteristics, aspects, system operating concepts, or conditions associated with the RRT, which influenced the selection of the individual review type, are addressed. Also, provide the assumptions for determining the type, if appropriate (e.g., design assumptions or existing knowledge). If these assumptions differ significantly from those made by DOE regarding the site, the difference should be discussed.
- For regulatory requirements with review types 4 or 5, provide the topic and description of any associated KTU, the specific performance objective(s) which is at risk, and its citation(s), an explanation of the nature of the risk, and a description of the resolution difficulty. In deciding to assign review Types 4 and 5, it is important to note the criteria for a Type 4 and 5 review specified in Appendix 1 to Attachment B, namely the identification of KTUs, and that professional judgement might be needed where evidence does not exist. The section should close with a brief summary of the reasons for selecting a Type 4 or Type 5 review strategy.

6.1.5 Prepare the "REVIEW STRATEGY" text. The text shall be developed as follows.

- Consistent with the review type and rationale, include a general description of the evaluation method(s), if known, for each review type in the RRT. The scope and approach of reviews, tests, or analyses that are appropriate to the nature of the regulatory requirements and their associated KTUs shall be included, as

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appropriate. Specific uncertainty reduction methods, remedies, compensatory measures, models, tests, or reviews may be identified for specific regulatory requirements if: (i) they are standard practice, (ii) they now exist, or (iii) they are described in current NRC or CNWRA plans.

- The activities outlined in the Review Strategy shall be compared to the associated section of the FCRG to ensure that the information requested in the LA will support the stated level of review. Any discrepancies identified in this process shall be addressed during review of the FCRG.
- Include, as appropriate, discussions to clarify the scope of this review plan. (Note that information on integration will be addressed in future SRA work.)

6.1.6 Provide a "RATIONALE FOR REVIEW STRATEGY." This rationale shall consist of the following (as appropriate).

- If independent analyses or research are considered to be needed for a Type 4 or a Type 5 review, include the rationale for such efforts here. This should include or explain why the activities should be conducted by NRC rather than relying upon DOE studies.

OPTIONAL:

- If specific reviews, tests, or analyses are identified in the Type 4 and 5 reviews, there may be value in discussing why these were selected. Generally, Type 4 and 5 reviews are where selections are made on what and how to review, and therefore, where some additional rationale might be useful.

6.1.7 End the Rationale with the name(s) of the contributing analyst(s) and the date of the analysis.

6.1.8 Complete the "APPLICABLE REGULATORY REQUIREMENTS FOR EACH TYPE OF REVIEW" section by listing each regulatory requirement citation by its associated review type. This information is obtained from the results of step 6.1.2.

6.1.9 List the "REFERENCES" in the CDS in using the NRC publication style defined in NUREG-1379. References associated with the rationales shall be listed separately from those

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associated only with the Review Strategies, since only Review Strategies are to be included in the LARP.

6.2 NRC and CNWRA staff shall review the CDS. The CNWRA reviews shall be conducted as specified by QAP-002. When appropriate, after approval by the NRC and the CNWRA, the CDS shall be entered into the Regulatory Program Database (RPD).

6.3 As appropriate, the NRC shall direct that integrating reviews are conducted of CDSs. These reviews shall ensure that CDSs are integrated programmatically and technically. Specific guidance shall be provided for the conduct of these integrating reviews.

7 RECORDS

7.1 CDSs shall be maintained as QA Records in accordance with CQAM Section 17.

7.2 Review documentation developed by the CNWRA as a result of conducting CDS related activities shall be maintained as QA Records as specified in QAP-002.

7.3 Review documentation developed by the Division of HLWM shall be provided to the CNWRA for maintenance as QA Records in accordance with CQAM Section 17.

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**ATTACHMENT A TO TOP-001-11
EXAMPLE LIST OF PERTINENT BACKGROUND MATERIAL
FOR REVIEW TYPE SELECTION AND REVIEW STRATEGY DEVELOPMENT**

CDS Development Group members should be generally familiar with the relevant sections of the following documents, as necessary, to develop the CDS.

1. Statement of considerations for 10 CFR Part 60.
2. Rationale and staff analysis of comments on proposed rule 10 CFR Part 60, NUREG-0804.
3. DOE's Site Characterization Plan (SCP) for the Yucca Mountain Site (e.g., licensing strategies to resolve issues in Chapter 8, including DOE's performance allocations: this information provides insight on what DOE considers to be the important areas of repository performance), and periodic revisions and status reports.
4. DOE's Final Environmental Assessment for the Yucca Mountain site.
5. NRC staff's Site Characterization Analysis (SCA).
6. NRC staff's response to DOE's response to NRC's SCA.
7. Key site-specific topics listed under each review guide in the NRC staff's SCP Review Plan.
8. Identified Regulatory and Institutional Uncertainties in SECY-90-207, Enclosure 5; and SECY-91-225, Enclosure 3, which have not, to date, been excluded or otherwise resolved.
9. Technical Position topics listed in Enclosure 8 of SECY-88-285 and any revisions thereto.
10. Issued Staff Technical Positions and Staff Positions.
11. Major issues at the Yucca Mountain site listed in SECY-87-137 and any revisions thereto.

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12. Associated sections of the Format and Content Regulatory Guide.
13. DOE's Report of Early Site Suitability Evaluation of the Potential Repository Site at Yucca Mountain, Nevada.
14. Nuclear Waste Policy Act of 1982, as Amended.
15. 48 FR 28222 of June 21, 1983 (the source document for 10 CFR Part 60, Subpart E).
16. DOE's Test Prioritization Plan.
17. NRC and DOE performance assessment reports.
18. License Application Review Plan.

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**ATTACHMENT B TO TOP-001-11
COMPLIANCE DETERMINATION STRATEGY FORMAT**

RRT NUMBER AND TITLE

Format is: RRT 3.2.1.11 POTENTIALLY ADVERSE CONDITION: PRESENCE OF NATURALLY OCCURRING MATERIALS.

1.0 APPLICABLE REGULATORY REQUIREMENT(S) (IF APPROPRIATE):

Format is 10 CFR 60.122(c)(17)
(See TOP-001-11, Section 6.1.1)

TYPES OF REVIEW:

(See TOP-001-11, Section 6.1.3 and Appendix 1 to Attachment B)
(List the following as appropriate to the specific RRT):

Acceptance Review (Type 1)
General Information Review (Type 2)
Safety Review (Type 3)
Detailed Safety Review Supported by Analyses (Type 4)
Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations (Type 5)

RATIONALE FOR TYPES OF REVIEW: (Only for those review types selected)

(See TOP-001-11, Section 6.1.4)
(See Appendix 1 to Attachment B for example rationales).

Acceptance Review (Type 1) Rationale:

General Information Review (Type 2) Rationale:

Safety Review (Type 3) Rationale:

Detailed Safety Review Supported by Analyses (Type 4) Rationale:

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Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations (Type 5) Rationale:

- 2.0 REVIEW STRATEGY:** (Only for those review types selected)
(See TOP-001-11, Section 6.1.5)
- 2.1 Acceptance Review:**
- 2.2 Compliance Review** (as appropriate, sequentially numbered)
- 2.2.n General Information Review:**
- 2.2.n Safety Review:**
- 2.2.n Detailed Safety Review Supported by Analyses:**
- 2.2.n Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations:**

RATIONALE FOR REVIEW STRATEGY:

(See TOP-001-11, Section 6.1.6)

Contributing Analysts:

APPLICABLE REGULATORY REQUIREMENTS FOR EACH TYPE OF REVIEW:

(See TOP-001-11, Section 6.1.8)

Type 1:

Type 2:

Type 3:

Type 4:

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Type 5:

6.0 REFERENCES:

(See TOP-001-11, Section 6.1.9)

References for Rationales:

References for Review Strategies:

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**APPENDIX 1 TO ATTACHMENT B TO TOP-001-11
DEFINITION OF REVIEW TYPES AND CRITERIA
FOR REVIEW TYPE SELECTION**

There are five types of reviews. Each regulatory requirement must be assigned one or more of these review types. Each of the five review types is defined below. Selection criteria for assigning the review type to a particular regulatory requirement are also defined.

REVIEW TYPE DESCRIPTION:

Type 1 - Acceptance Review

This type of review is to determine if the LA is complete and acceptable for docketing and for conducting the compliance review in an effective and timely manner. This is not a review to determine adequacy.

Type 2 - General Information Review

This type of review is to determine the adequacy of compliance with the general information requirements of 10 CFR Part 60.

Type 3 - Safety Review

This type of review is to determine the adequacy of the compliance demonstrations and associated system descriptions which are associated with the Safety Analysis Report of the LA (i.e., related to radiological health and safety or waste isolation). The focus of this review is primarily on the LA itself, although some references might also be reviewed if they contain essential compliance demonstration information. Generally, however, the detailed information supporting the compliance demonstration in the LA references will not be the focus of this type of review. The safety review might also be supported by simple verifications using handbooks, standard formula, or "back-of-the-envelope" calculations. However, detailed verifications using complex numerical modeling should not be used. A Type 3 review might eventually be changed if new information leads to identification of a KTU.

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Type 4 - Detailed Safety Review Supported by Analyses

This review is an expansion or extension of the Type 3 Safety Review in that it is a detailed review of the adequacy of selected detailed information supporting the compliance demonstration in the LA (i.e., "vertical slice" reviews of data, analyses, methods, and technical procedures). Specifically, Detailed Safety Reviews would focus on the level(s) of detail appropriate for the assessment of the KTU(s) associated with the regulatory requirement and how the KTU is reduced, compensated for, or remedied.

The Detailed Safety Review should be supported, if relevant and needed, by analyses conducted by the staff of KTUs. Such analyses could include use of complex numerical models. Unless justified based on the unique nature of the KTU, the detailed analysis methods would not be developed by the staff. Instead, the staff would use methods developed by DOE or other parties that have been reviewed and found acceptable by the staff. While this type of review requires the staff to obtain and become proficient in using a particular method or making minor modifications to the method, it does not require, for most cases, the extensive resources needed for the staff to develop its own independent method. (For special cases, such as where the staff may have concerns with DOE's data interpretation or method of analysis, the staff could modify DOE's method or use another party's method.) Independent investigations, including research, can also support Type 4 reviews if justified; however, these investigations would be lower priority than those supporting a Type 5 review.

It is important to note that a review type might eventually be changed to a lower or higher type should new information or lack of information either mitigate the KTU causing the risk of noncompliance, or lead to identifying a new KTU.

Type 5 - Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations

This type of review further supports the Detailed Safety Review with either analyses, tests (laboratory or field), or other investigations conducted by the staff or using methods (e.g., numerical modeling) independently developed by the staff. Such independent investigations could focus on all or a part of a specific KTU. This type of review might also further supplement the Detailed Safety Review by verifying some of the LA data or descriptions of conditions or processes with data collected by the staff or the understanding of conditions and processes obtained by the staff's own investigations (e.g., results of the research Program). Furthermore, the understanding of processes may

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also support the staff's independent model development. In addition to analyses and tests, this type of review could, if appropriate, be supported by other kinds of investigations such as expert panel solicitations. The specific type of supporting investigations selected should be based on what is technically needed to address the KTU(s).

It should be emphasized, however, that the independent investigations conducted by the staff are for verification purposes and are not a substitute for data or analyses that DOE should be providing to support its compliance demonstration in the LA.

It is important to note that a review type might eventually be changed to a lower type should new information or lack of information either mitigate the KTU causing the risk of noncompliance, or lead to identifying a new KTU.

REVIEW TYPE SELECTION CRITERIA:

Type 1 - LA Related

These are RRTs and their associated regulatory requirements for which DOE must demonstrate compliance in its LA, or which directly affect the content or submittal of the LA. These are also the RRTs and regulatory requirements that would be addressed in the staff's compliance review of the LA and for which findings will be made in the staff's Safety Evaluation Report.

Excluded from these requirements would be those not related to the LA, whether DOE regulatory requirements (e.g., SCP requirements in 10 CFR 60.16 and 10 CFR 60.17), NRC regulatory requirements [e.g., review of site characterization activities in 10 CFR 60.18 and construction authorization in 10 CFR 60.31(a), or other procedural regulatory requirements (e.g., participation of State governments and Indian tribes in 10 CFR Part 60, Subpart C)].

Type 2 - General Information Related

These are the general information requirements contained in 10 CFR 60.21(b), and for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31(a).

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Type 3 - Radiological Safety and Waste Isolation Related

These are RRTs and their associated regulatory requirements for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31(a). These include those RRTs which embody Subparts E, G, H, and I and 10 CFR 60.21(c).

Type 4 - High Potential Risk of Noncompliance with a Performance Objective of 10 CFR Part 60

These RRTs and their associated regulatory requirements are the subset of all those related to radiological health and safety or waste isolation for which there is a high potential risk of noncompliance with one or more of the performance objectives in 10 CFR 60.111, 60.112, or 60.113.

The high potential risk of noncompliance comes from the existence of KTUs.

A KTU is a technical uncertainty which poses a high risk of noncompliance with a performance objective of 10 CFR Part 60. It may also be associated with reducing a high risk of noncompliance with a performance objective.

For example, a KTU exists where there is a lack of certitude about a methodology that is needed to either demonstrate or determine compliance with a 10 CFR Part 60 performance objective (e.g., scenario analysis methods are necessary to demonstrate compliance with the overall system performance of objective 10 CFR 60.112). A KTU also exists where: (i) there is a lack of understanding about a condition or process; and (ii) it is credible that the condition or process exists (or will exist) and could have either a significant adverse or favorable effect on repository performance.

Type 5 - High Potential Risk of Noncompliance and Most Difficult to Resolve

These RRTs and their associated regulatory requirements, a subset of those that pose a high potential risk of noncompliance, pose the highest potential risk because the risk is judged to be the most difficult to reduce. Therefore, there might be a high residual risk of noncompliance because very little can be done to reduce the risk or compensate for the risk using, for example, favorable site conditions or engineered features.

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**ATTACHMENT C TO TOP-001-11
TEMPLATE FOR COMPLIANCE DETERMINATION STRATEGIES**

This template provides guidance on the format and content of the CDS. It contains recommended standard language for review type rationales and review strategies. This recommended language should be utilized with judgement and should be modified or added to, as appropriate, such that specific characteristics, aspects, system operating concepts, or scenarios are addressed. Italicized text provides explanation and guidance.

**COMPLIANCE DETERMINATION STRATEGY
REVIEW PLAN NO. AND TITLE**

1.0 APPLICABLE REGULATORY REQUIREMENT(S);

10 CFR 60.ZZ

TYPES OF REVIEW:

Acceptance Review (Type 1)

General Information Review (Type 2)

Safety Review (Type 3)

Detailed Safety Review Supported by Analysis (Type 4)

Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations (Type 5)

RATIONALE FOR TYPES OF REVIEW: *Only for those review types selected.*

Acceptance Review (Type 1) Rationale:

This regulatory requirement topic is considered to be license application-related because, as specified in the license application content requirements of 10 CFR 60.21 and the regulatory guide "Format and Content for the License Application for the High-Level Waste Repository (FCRG)" it must be addressed by the U.S. Department of Energy (DOE) in its license application. Therefore, the staff will conduct an Acceptance Review of the license application for this regulatory requirement topic.

Add additional information/background, as appropriate.

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General Information Review (Type 2) Rationale:

For general information requirements identified in 10 CFR Part 60:

This regulatory requirement is related to the general information required in 10 CFR 60.21(b). It is a requirement for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31(a).

Add additional information/background, as appropriate.

Safety Review (Type 3) Rationale:

This regulatory requirement is considered to be related to radiological safety, retrievability, containment, or waste isolation [*pick one or more*]. It is a requirement for which compliance is necessary to make a safety determination for construction authorization as defined in 10 CFR 60.31(a) (i.e., regulatory requirements in Subparts E, G, H, and I). Therefore, the staff will conduct a Safety Review of the license application to determine compliance with this regulatory requirement.

This regulatory requirement, concerning ... *repeat or paraphrase title of Review Plan*, focuses on ... *provide background* ...

Add additional information/background and assumptions, as appropriate, see Section 6.1.4.

Detailed Safety Review Supported by Analyses (Type 4) Rationale:

The staff considers that there may be a high potential risk of noncompliance with the applicable regulatory requirement(s) because, for the Yucca Mountain site, there are/is (*the following*) Key Technical Uncertainty(y).

These Key Technical Uncertainty(ies) is (are) considered to require a Type 4 review because there is a high risk of noncompliance with the performance objective(s) specified below. This concern of high risk of noncompliance will necessitate analysis above and beyond that required for a Type 3 safety review in order to assure that the uncertainties and potential effects on performance have been minimized to the extent practical.

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Key Technical Uncertainty Topic: *Title of KTU*

Description of Uncertainty: ...

Performance Objective at Risk: *Specify the title of the performance objective at risk and include the 10 CFR Part 60 citation parenthetically*

Explanation of Nature of Risk: ...

Description of Resolution Difficulty: ...

Detailed Safety Review Supported by Independent Tests, Analyses, or Other Investigations (Type 5) Rationale:

The staff considers that there may be the highest potential risk of noncompliance with this Regulatory Requirement because, for the Yucca Mountain site, the following KTU is the most difficult to resolve. Therefore, there might be a high residual risk of noncompliance with the performance objective(s) specified below because very little can be done to reduce the risk, or compensate for the risk using, for example, favorable site conditions or engineered features.

Add additional information/background, as appropriate.

The potential for high residual risk of noncompliance in light of this KTU(s) is sufficient that a detailed safety review supported by independent tests, analyses, or other investigations is justified.

Key Technical Uncertainty Topic: *Title of KTU*

Description of Uncertainty: ...

Performance Objective at Risk: *Specify the title of the performance objective at risk and include the 10 CFR Part 60 citation parenthetically*

Explanation of Nature of Risk: ...

Description of Resolution Difficulty: ...

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2.0 REVIEW STRATEGY: *Only for those review types selected.*

2.1 Acceptance Review:

To determine whether this section of the Department of Energy's (DOE's) license application is acceptable for docketing, the staff will determine whether the information submitted is consistent with that identified in the corresponding section of the Regulatory Guide "Format and Content for the License Application for the High-Level Waste Repository" (FCRG).

Before the receipt of the license application, the staff will have conducted prelicensing reviews of DOE's program, including technical reviews and quality assurance reviews and audits. The staff will have documented its concerns, resulting from these prelicense application reviews, as open items. Some of these open items, referred to as objections to license application submittal, may be critical to the staff's license application review, because lack of acceptable DOE resolution would prevent NRC from conducting a meaningful review. Therefore, as part of its *Acceptance Review* for docketing, the staff will evaluate how significant any unresolved objection to license application submittal is, to the effective conduct of licensing activities, using the criteria given in Section 3.1 of this review plan.

Add additional information/background, as appropriate.

2.2 Compliance Review

2.2.1 General Information Review:

For General Information:

In conducting the general information review of the ... *repeat or paraphrase title of Review Plan*, the reviewer should determine if the information presented in the license application and its references is an acceptable demonstration of compliance with the applicable regulatory requirement(s).

Finally, the reviewer should determine if the information presented in the license application is presented in such a manner that the demonstration of compliance with the applicable regulatory requirements (or the FCRG) is clear. The reviewer should also

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determine that contradictory information and appropriate alternative interpretations and models have been adequately described and considered.

Add additional information/background, as appropriate.

2.2.2 Safety Review:

This regulatory requirement is limited to consideration of ... *the title/number of other Review Plan(s)*. It is not concerned with ... *title of similar but unrelated Review Plan(s)*. These ...*topics* ... will be covered under other review plans (*if possible, specify which ones they are*). Include, as appropriate, discussions to clarify scope of this review plan.

In conducting the safety review the reviewer should determine if the information presented in the license application and its references is an acceptable demonstration of compliance with the applicable regulatory requirement(s). At a minimum, the reviewer should determine the adequacy of the data and analyses presented in the license application to support DOE's demonstration of compliance with this regulatory requirement. Specifically, DOE will need to: (1) provide information ...*describe what the staff expects DOE to present in its license application - see FCRG. Also describe any underlying assumptions, axioms, or "givens"*, (2) ...

In general, the reviewer should assess the adequacy of the investigations of ... *repeat or paraphrase title of Review Plan topic*, both within the controlled area and outside the controlled area, as necessary. The specific aspects of the license application on which the reviewer will focus are discussed in the FCRG, and the Acceptance Criteria will be identified in Section 3.0 of this Review Plan.

In order to conduct an effective review, the reviewer will rely on his own expertise and independently acquired knowledge, information, and data such as the results of research activities being conducted by the NRC's Office of Nuclear Regulatory Research, in addition to that provided by the DOE in its license application. For example, ... *describe activities/investigations that are applicable to the topic* The reviewer should focus on additional data which can refine knowledge of the ... *condition - PAC or FAC* ..., and should perform, as necessary, additional analyses to confirm the resolution capabilities of the methodologies. It is incumbent upon the reviewer to have acquired a body of knowledge regarding these and other critical considerations in anticipation of conducting the review to assure that the ... *describe DOE's program* ... program is sufficient in scope and depth to provide the information to resolve the concerns.

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Add additional information/background, as appropriate.

2.2.3 Detailed Safety Review Supported by Analysis: Note that a separate paragraph is needed for each KTU.

A detailed safety review and analysis will be needed for evaluation of the Key Technical Uncertainties regarding ... *specify Type 4 KTU*. This will ensure that DOE has adequately demonstrated Items (1)-(…), listed in the previous section (Safety Review, paragraph …). *[Tie back to the second paragraph in the Safety Review, above.]* Activities performed in this Detailed Safety Review will help to assure that DOE has adequately addressed and resolved these Key Technical Uncertainty(ies) so that they do not lead to noncompliance with the performance objective *[specify which one(s)]*.

Examples of specific review activities that will be required include: (1) ... *specify as appropriate, detailed reviews, supporting analyses, etc.*

For key technical uncertainties it may also be appropriate to assess the quality and traceability of data and information by also utilizing staff with expertise in review of quality assurance programs.

Add additional information/background, as appropriate.

2.2.4 Detailed Safety Review Supported by Independent Tests, Analyses or Other Investigations: Note that a separate paragraph is needed for each KTU.

A detailed safety review, independent modeling, and use of the results of staff investigations, will be needed for the Key Technical Uncertainties with ... *specify KTU*. This will ensure that DOE has adequately demonstrated Items (1)-(…) listed in the section on safety review (Safety Review, paragraph …). *[Tie back to the second paragraph in the Detailed Safety Review, above.]*

For the Key Technical Uncertainty concerning ... *specify KTU*, the staff detailed review will be supported by ... *describe what the staff will do* ... In conducting this review, the staff must evaluate, for example, ... *provide examples*...

A detailed safety review of the Key Technical Uncertainty related to evaluation of *the KTU concerning*... will be supported by the results of staff investigations that may include ... *specify specific types*. It is anticipated that these results will allow *what?*

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For key technical uncertainties it may also be appropriate to assess the quality and traceability of data and information by also utilizing staff with expertise in review of quality assurance programs.

Add additional information/background, as appropriate.

RATIONALE FOR REVIEW STRATEGY:

In view of the complexity of the key technical uncertainty(ies) addressed above, it is appropriate that the NRC conduct the independent activities described in order to (*select one or more of the following*) (1) develop the licensing tools and technical basis necessary to judge the adequacy of DOE's license application, (2) assure sufficient independent understanding of the basic physical processes taking place at the geologic repository, or (3) maintain an independent but limited confirmatory research capability under NRC auspices.

Contributing Analysts:

NRC:

CNWRA:

APPLICABLE REGULATORY REQUIREMENTS FOR EACH TYPE OF REVIEW:

Type 1:

10 CFR 60.abc

6.0 REFERENCES:

References for Rationales:

U.S. Department of Energy. 1988. *Site Characterization Plan: Yucca Mountain Site, Nevada Research and Development Area, Nevada*. Office of Civilian Radioactive Waste Management. DOE/RW-0199. 9 Volumes.

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References for Review Strategies:

Nuclear Regulatory Commission, Format and Content for the License Application for the High-Level Waste Repository. Office of Nuclear Regulatory Research. (Refer to the "Products List" for the Division of High-Level Waste Management to identify the most current edition of the FCRG in effect.)

Add additional REFERENCES, as appropriate.

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Title **DEVELOPMENT OF COMPLIANCE DETERMINATION STRATEGIES**

EFFECTIVITY

Revision 3 of this procedure makes this procedure obsolete. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change No.</u>	<u>Date Effective</u>
1	0	12/08/2000

NOTE: This procedure, TOP-001-011, has been withdrawn from use at the CNWRA.

Please remove and destroy the referenced procedure in your notebook/holder and return the acknowledgment page to CNWRA Document Control with your signature and date.

SUPERSEDED

Supersedes Procedure No. N/A

Approvals			
Written by <i>David Turner</i> David Turner	Date <i>12/08/2000</i> 12/08/2000	Technical Review <i>Pat Mackin</i> Pat Mackin	Date <i>12/11/2000</i> 12/11/2000
Quality Assurance <i>Bruce Mabrito</i> Bruce Mabrito	Date <i>12/18/2000</i> 12/18/2000	Cognizant Director <i>Budhi Sagar</i> Budhi Sagar	Date <i>12/18/2000</i> 12/18/2000