

**COMPLIANCE DETERMINATION STRATEGY  
RRT 7.4 PROCEDURE DEVELOPMENT**

**APPLICABLE REGULATORY REQUIREMENTS:**

10 CFR 60.21(c)(15)(iv)  
10 CFR 60.21(c)(15)(v)  
10 CFR 60.21(c)(15)(vi)  
10 CFR 60.21(c)(15)(vii)  
10 CFR 60.31(a)(1)(iv)  
10 CFR 60.31(a)(6)

**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(c) and Section 7.4 of 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 topic is considered to be related to radiological safety during the pre-closure period. 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 B, E, G, H, and I). It focuses on those procedures necessary to implement DOE's plans for the conduct of normal operations at the geologic repository. This would include, at a minimum, the following activities: start-up, receipt, handling, emplacement, inspection, testing, maintenance, and permanent closure. Understanding DOE's proposed procedures for repository operations is intended to lead to a determination as to whether the high-level radioactive waste will be received, handled, and stored in a manner that will assure public health and safety. (Review of DOE's procedures for any waste retrieval operations that may be necessary are addressed in Review Plan 4.5.2.) Therefore, the staff will conduct a Safety Review of the license application to determine compliance with the applicable regulatory requirements.

There appears to be no lack of certitude as to the methodology needed to determine or demonstrate compliance with the applicable regulatory requirements. Methodologies for preparing operational procedures for geologic repository operations are considered to be available because of the past and current experience in similar nuclear facility operations. Therefore, the type of review for this topic will be a (Type 3) Safety Review.

## **REVIEW STRATEGY:**

### **Acceptance Review:**

In conducting the Acceptance Review of the U.S. Department of Energy's (DOE's) program planned for developing procedures for normal geologic repository operations, the reviewer should determine if the information present in the license application for demonstrating compliance with the applicable regulatory requirements is complete in technical breadth and depth as identified in regulatory guide "Format and Content for the License Application for the High-Level Waste Repository (FCRG)." The reviewer should determine whether all appropriate information for the staff to review the applicable regulatory requirements is presented in a manner that would support a determination of whether there is reasonable assurance that the geologic repository can be operated in a manner that assures public health and safety.

The description of procedures provided in this section of the license application should be consistent with DOE's plans identified for normal repository operations described in Section 7.1 ("Plans for the Conduct of Normal Activities") of the license application. Thus, the review of the information contained in Section 7.4 will be performed in parallel with the review of the information contained in Section 7.1 of the license application. Therefore, during the Acceptance Review of Section 7.4, the reviewer should determine whether all appropriate descriptive information necessary for the staff to conduct a Safety Review of the procedures for normal GROA activities has been provided, and whether the information is both internally consistent, and consistent from section-to-section.

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

Finally, the reviewer should determine if DOE has either resolved all the NRC staff objections related to the applicable regulatory requirements, 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 statutory three-year period.

### **Safety Review:**

This regulatory requirement topic is limited to consideration of DOE's program planned for developing procedures that are applicable to the conduct of normal geologic repository operations during the pre-closure period. It focuses on those activities (waste receipt, waste emplacement, GROA maintenance and inspection, testing, etc.) that can be expected to take place on a routine basis (daily, weekly, annually). It is not concerned with other activities that would be conducted during the pre-closure period such as performance confirmation, radiation protection, emergency planning, and others. Moreover, this regulatory requirement topic is not concerned with any procedures describing any waste retrieval operations that might be necessary, also during the pre-closure. The review of these other pre-closure subjects will be addressed in those sections of the license application listed in Table 7.4-1.

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 assess the adequacy of data and information presented in the license application to support DOE's demonstration. The specific aspects of the license application on which a reviewer will focus are discussed below, and the Acceptance Criteria are identified in Section 3.0 of this review plan.

In general, the reviewer will assess the adequacy of DOE's program planned for development of procedures for those geologic repository operations area (GROA) activities that provide for the safe handling of radioactive materials during all phases of normal repository operations. These routine activities would include but not be limited to the following: (1) start-up and testing; (2) waste receipt; (3) temporary waste storage; (4) waste transfer; (5) waste emplacement; (6) routine GROA maintenance; (7) routine GROA inspection and testing; (8) permanent closure (including decontamination, dismantling, and decommissioning); and (9) those purposes other than high-level radioactive waste disposal. In addition to the activities described above, DOE's description of procedures for normal GROA activities should address maintenance, surveillance, and periodic testing of all structures, systems, and components of the GROA that are important to safety as well as those important to waste retrievability.

In reviewing DOE's program planned for development of procedures for normal repository operations, the reviewer should determine whether the proper interfaces between GROA operators and the GROA physical facility are in place to permit the conduct of routine activities.

It should be noted that DOE may choose not to provide procedures at the time of the license application submittal. For those procedures not submitted, but necessary to normal repository operations, DOE should include a schedule indicating when the necessary procedures will be developed and submitted to the staff.

In order to conduct an effective review, the reviewer will rely on staff expertise and independently acquired knowledge, information, and data. For example, the reviewer should have knowledge and experience in operating procedures for other types of nuclear facilities. The reviewer should also be able to identify those variables that may significantly influence procedure implementation at the GROA and thus normal geologic repository operations. The reviewer should focus on additional data that can refine knowledge of the facility operations. The reviewer should perform, as necessary, any reviews needed to confirm the adequacy of the methodologies proposed to ensure that DOE's procedures for normal operations will assure public health and safety. Also, the reviewer should use specific documents (design drawings, reports, planning documents, and procedures) bearing on this topic, that were prepared by NRC, DOE, and others. These documents should be available to the reviewers in anticipation of the license application submittal and review.

Finally, as noted above, the plans for normal repository operations described in Section 7.1 of the license application will support the Safety Review of the information contained in Section 7.4 of the license application. This other section of the license application should be consulted as part of the Safety Review.

**Contributing Analysts:**

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**APPLICABLE REGULATORY REQUIREMENTS FOR EACH TYPE OF REVIEW:**

Type 1:

10 CFR 60.21(c)(15)(iv)  
10 CFR 60.21(c)(15)(v)  
10 CFR 60.21(c)(15)(vi)  
10 CFR 60.21(c)(15)(vii)  
10 CFR 60.31(a)(1)(iv)  
10 CFR 60.31(a)(6)

Type 3:

10 CFR 60.31(a)(1)(iv)  
10 CFR 60.31(a)(6)

**REFERENCES:**

U.S. 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 in effect.

**Table 7.4-1. Chapters/Sections of the License Application that May Support the Review of the "Procedure Development" Section of the License Application.**

<b>License Application</b>	
<b>Chapter/Section</b>	<b>Title</b>
<b>Performance Confirmation</b>	
Chapter 8.1	Performance Confirmation Program for the Natural Systems of the Geologic Setting
Section 8.2	Performance Confirmation Program for Structures, Systems, and Components of the GROA
Section 8.3	Performance Confirmation of Engineered Barrier Systems
<b>Radiation Protection</b>	
Section 4.2	Assessment of Compliance with Design Criteria for Surface Facilities
Section 4.3	Assessment of Compliance with Design Criteria for Shafts and Ramps
Section 4.4	Assessment of Compliance with Design Criteria for the Underground Facility
Chapter 4.5	Assessment of Integrated GROA Compliance with the Performance Objectives
Section 7.1	Description of Radiation Protection Program
<b>Waste Retrievability</b>	
Section 4.5.2	Assessment of Integrated GROA Compliance with the Performance Objectives: Retrievability of Waste
<b>Other</b>	
Section 2.7	Nuclear Material Control
Section 7.3	Organizational Structure, Management, and Administrative Controls
Section 7.6	Personnel Training Programs
Section 7.8	Identification of Operating Controls and Limits
Chapter 10.0	Quality Assurance