

July 3, 2002

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Office of Licensing and Regulatory Compliance
U.S. Department of Energy
Yucca Mountain Site Characterization Office
P.O. Box 364629
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SUBJECT: PRECLOSURE AGREEMENT 6.01

Dear Mr. Ziegler:

During a Technical Exchange and Management Meeting held on July 24-26, 2001, the U.S. Nuclear Regulatory Commission (NRC) and the U.S. Department of Energy (DOE) reached agreement on a number of issues within the Preclosure area. By letter dated March 27, 2002, DOE provided information pertaining to Preclosure Agreement 6.01. The NRC staff has reviewed this information as it relates to the agreement and the results of the staff's review are enclosed.

In summary, the staff believes that the procedure provided by DOE does not fulfill the purpose of developing a procedure for identification and quality level categorization of structures, systems, and components important to safety, and engineered and natural barriers important to waste isolation. The NRC staff concern associated with Preclosure Agreement 6.01 is that DOE have an acceptable technical basis for its categorization process and that the process is consistent with 10 CFR Part 63. The agreement called for an update to DOE Procedure QAP-2-3, "Classification of Permanent Items," which DOE had used to develop its Q-List. In response to the agreement, DOE provided Procedure AP-2.22Q, Revision 0, ICN 0, "Classification Criteria and Maintenance of the Monitored Geologic Repository Q-List." In its letter dated March 27, 2002, DOE stated that Procedure AP-2.22Q supercedes Procedure QAP-2-3. Initial review of the document raised several NRC staff concerns and the guidelines provided in AP-2.22Q were discussed in the April 25-26, 2002, NRC/DOE technical exchange. NRC staff review identified that the guidance and criteria in AP-2.22Q are inadequate and incomplete for determining if a structure, system, or component is important to safety, and for assigning a quality level category. During the April 2002 Technical Exchange, DOE acknowledged the staff's concerns and stated that it plans to revise the procedure to address the concerns. Based on the NRC staff needing additional information for this agreement, Preclosure Agreement PRE 6.01 is listed as "need additional information."

J. Ziegler

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If you have any questions regarding this letter, please contact Mr. James Andersen of my staff. He can be reached at (301) 415-5717.

Sincerely,
/RA/

Janet R. Schlueter, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc: See attached distribution list

J. Ziegler

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Letter to J. Ziegler from J. Schlueter dated July 3, 2002

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NRC Review of DOE Documents Pertaining to Key Technical Issue Agreements

The U.S. Nuclear Regulatory Commission (NRC) goal of issue resolution during this interim pre-licensing period is to assure that the U.S. Department of Energy (DOE) has assembled enough information on a given issue for NRC to accept a license application for review. Resolution by the NRC staff during pre-licensing does not prevent anyone from raising any issue for NRC consideration during the licensing proceedings. Also, and just as importantly, resolution by the NRC staff during pre-licensing does not prejudice what the NRC staff evaluation of that issue will be after it's licensing review. Issues are resolved by the NRC staff during pre-licensing when the staff has no further questions or comments about how DOE is addressing an issue. Pertinent new information could raise new questions or comments on a previously resolved issue.

This enclosure addresses one NRC/DOE agreement made during the NRC/DOE Technical Exchange and Management Meeting on Pre-Closure Safety on July 24-26, 2001 (see NRC letter dated August 14, 2001, which summarized the meeting). By letter dated March 27, 2002, DOE submitted information to address Preclosure Agreement 6.01. The information submitted for this agreement is discussed below.

Preclosure Agreement 6.01

Wording of the Agreement: Provide the update to Quality Assurance Procedure QAP-2-3. DOE agreed to provide the procedure. The procedure will be available in February 2002.

NRC Review: In compliance with the requirements of 10 CFR Part 63, DOE in a potential license application for the proposed repository at Yucca Mountain, would be required to include a preclosure safety analysis identifying the structures, systems, and components important to safety and their design bases. In addition, 10 CFR Part 63 allows categorization of structures, systems, and components to an extent consistent with their importance to safety for the purpose of graded application of quality assurance programs. Prior to Preclosure Agreement 6.01 being reached, DOE developed (1) Procedure QAP-2-3, "Classification of Permanent Items," that defined a categorization process to determine appropriate quality levels for structures, systems, and components important to safety, and (2) a preliminary Q-List reported in Q-List, YMP/90-55Q. The NRC staff reviewed DOE Procedure QAP-2-3, Revision 10, May 1999, and the preliminary Q-List reported in Q-List, YMP/90-55Q, Revision 6, April 2000. The review generated several staff concerns, which were discussed at a July 24-26, 2001, NRC/DOE Technical Exchange and Management Meeting on Pre-Closure Safety. Subsequently, NRC generated a white paper, "Staff Review of DOE's Approach to Risk-Significance Categorization of Structures, Systems, and Components Important to Safety," which was transmitted to DOE by NRC letter dated September 28, 2001.

Although the staff provided a number of detailed comments on Procedure QAP-2-3, the primary concern was that the DOE identification of structures, systems and components important to safety and the process for quality level categorization as outlined in Procedure QAP-2-3 are qualitative in nature and based on answering checklist questions; they do not use the preclosure safety analysis results. In the July 2001 Technical Exchange, DOE indicated that the preliminary identification and categorization of structures, systems, and components

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important to safety is based on engineering judgment, project strategies, and preliminary calculations. In accordance with 10 CFR 63, preclosure safety analysis identifies structures, systems, and components important to safety. DOE stated that it will revise the procedure to reflect that items important to safety and their quality level categorization are consistent with the design and the preclosure safety analysis. The NRC staff concern associated with Preclosure Agreement 6.01 is that DOE have an acceptable technical basis for its categorization process and that the process is consistent with 10 CFR Part 63. This agreement pertains to Preclosure Topic 6: Identification of Structures, Systems, and Components Important to Safety; Safety Controls; and Measure to Ensure Availability of Safety Systems (the ten preclosure topics are described in an NRC letter dated April 27, 2001).

To address Preclosure Agreement 6.01, DOE provided Procedure AP-2.22Q, Revision 0, ICN 0, "Classification Criteria and Maintenance of the Monitored Geologic Repository Q-List. In its letter dated March 27, 2002, DOE stated that Procedure AP-2.22Q supercedes Procedure QAP-2-3 in its entirety. The purpose of Procedure AP-2.22Q is to establish the classification criteria, and the responsibilities and process for maintaining the *Q-List YMP/90-55Q*. Procedure AP-2.22Q contains the criteria for quality level classification of structures, systems, and components important to safety and engineered and natural barriers important to waste isolation. In the March 27, 2002, letter, DOE also stated that the process of classification that was in Procedure QAP-2-3 has been revised and is included in Section 12 of the DOE Preclosure Safety Analysis Guide, TDR-MGR-RL-000002, Rev 00, February 2002. At the April 25-26, 2002, NRC/DOE Technical Exchange on DOE's Pre-Closure Safety Analysis Guide (see NRC letter dated May 3, 2002, which summarized the meeting), DOE stated that the Preclosure Safety Analysis Guide is not intended to be a quality assurance controlled document. As a result, the staff noted the formal process for identification of structures, systems, and components important to safety and their categorization for quality assurance purposes that is in the Preclosure Safety Analysis Guide can no longer be referenced in Procedure AP-2.22Q. DOE clarified that it will revise the existing classification analyses, Q-List, and quality level classification of Q-List items based on AP-2.22Q.

The NRC staff conducted an initial review of Procedure AP-2.22Q and provided preliminary comments to DOE prior to the April 2002 Technical Exchange. The staff's comments were discussed at the Technical Exchange and those that need DOE consideration for incorporation in the procedure AP-2.22Q are presented below. The following comments are also summarized in the "Need Additional Information" section. The comment number below and the number in the "Need Additional Information" section correspond.

- 1) Procedure AP-2.22Q does not discuss how DOE plans to identify structures, systems, and components important to safety or waste isolation, or how DOE plans to categorize those structures, systems, and components. The purpose of procedure AP-2.22Q was to establish the responsibilities and process for maintaining the Q-List YMP/90-55Q. This process includes the Quality Level assignments to Q-List items (structures, systems, and components, and engineered and natural barriers) and maintenance of the Q-List. However, procedure AP-2.22Q does not address how DOE will determine whether an individual structure, system, or component is important to safety or waste isolation; or how quality levels are assigned to structures, systems, and components that have been determined to be important to safety or waste isolation. Procedure AP-2.22Q, Attachment 1, "Important to Safety Screening Criteria," only provides the screening criteria or definitions. These screening criteria and definitions

provide little, if any, direction to individuals preparing or revising the Q-List or the Quality Level categorizations of the structures, systems, and components on the Q-List.

During the April 2002 Technical Exchange, DOE indicated that the analyses used to determine whether an individual structure, system, or component is important to safety or waste isolation and the classification of those structures, systems, and components would be implemented and documented using the procedures referenced in AP-2.22Q (e.g., AP-3.12Q, AP-SIII.9Q and AP-III.10Q). The staff reviewed these procedures and found no direction for processing or using the criteria in Attachment 1 of AP-2.22Q for determining whether a structure, system, or component is "Q" or "Quality Level-1" or "Quality Level-2" or "Quality Level-3." The required guidance appears to be contained in Preclosure Safety Analysis Guide. The guide is not quality assurance controlled and, therefore, cannot be used to satisfy the requirements of 10 CFR 63.142(f).

Procedure AP-2.22Q should provide a description of the classification process in procedure AP-2.22Q or include information that indicates/explains: (1) how DOE intends to determine whether an individual structure, system, or component is important to safety or waste isolation; (2) how the classification process will be implemented; (3) the steps of the classification process; and (4) references to the implementing procedures, where applicable.

2) The Preclosure Safety Analysis Guide, identifies several deterministic "factors" for consideration when evaluating the risk significance of an event sequence and associated classification (pages 12-10 and 12-11). However, procedure AP-2.22Q does not identify or explain how these or other deterministic "factors" are considered during the categorization of structures, systems, and components important to safety or waste isolation. The NRC staff white paper, "Staff Review of DOE's Approach to Risk-Significance Categorization of Structures, Systems, and Components Important to Safety" states that a risk-informed approach to regulatory decision-making considers risk insights together with other factors (including deterministic approaches) to establish requirements that better focus the licensee and regulatory attention on design and operation issues commensurate with their importance to public health and safety.

Procedure AP-2.22Q should be revised to address how these and other deterministic "factors" are going to be considered and consistently incorporated into the classification process.

3) The quality assurance requirements identified in 10 CFR 63.142 (application of quality assurance controls) cannot be graded for important to safety structures, systems, and components categorized as Quality Level-1. Procedure AP-2.22Q, Section 5.1, paragraph 2, states "The QARD [Quality Assurance Requirements and Description] controls are applied on a graded basis to structure, system, or component items that are classified as QL [Quality Level]-1, QL-2, or QL- 3. The decisions made on the extent of QA [quality assurance] controls will be based on the item classification." The first statement is not correct in that the quality assurance requirements identified in 10 CFR 63.142 (application of quality assurance controls) cannot be graded for structures, systems, and components categorized as Quality Level-1 (Regulatory Guide 1.176). Further, the extent to which these controls are applied, consistent with their importance to safety, is not adequately defined. Additionally, DOE document DOE/RW-0333P, "Quality Assurance Requirements and Description," Revision 11, March 2002,

does not contain the necessary provisions to allow for the classification of important to safety structures, systems, and components.

Section 5.1 paragraph 2 of Procedure AP-2.22Q, should provide a better explanation of how the quality assurance controls are applied, consistent with their importance to safety. DOE document DOE/RW-0333P should include the necessary provisions to allow for the classification of important to safety structures, systems, and components.

4) Procedure AP-2.22Q does not currently require DOE to submit any quality assurance records as part of their classification process. There are several records associated with Procedure AP-2.22Q (e.g., the 10 CFR 63.44 review and evaluation; the 10 CFR 63.142(d)(2)(i) design review; the Q-List, a design output document; the inter-disciplinary reviews and comments and resulting resolutions; the approvals of the Q-List and subsequent revisions, etc.). The staff understands that these quality assurance records for categorization will be submitted under procedures referenced in Procedure AP-2.22Q (e.g., AP-3.12Q, AP-5111.9Q and AP-111.1Q). DOE should indicate and reference in Procedure AP-2.22Q which procedures generate quality assurance records associated with the classification process.

Procedure AP-2.22Q should indicate where the quality assurance records are generated and reference the applicable procedure(s).

5) Procedure AP-2.22Q does not address how DOE plans to reassess the safety classification of structures, systems, and components important to safety or waste isolation or the safety or risk (Quality Level) categorization of those structures, systems, and components in the event new information is obtained or design changes are made.

Procedure AP-2.22Q should either indicate how the requirements identified in 10 CFR 63.44 will be addressed, with respect to the reclassification of important to safety structures, systems, and components (due to the introduction of new information or design changes), or clearly reference the procedure(s) that will satisfy the requirements identified in 10 CFR 63.44.

6) Procedure AP-2.22Q does not clearly indicate how the independent verification of design outputs will be accomplished for the Q-List and the analyses used to categorize important to safety structures, systems, and components; as required by both 10 CFR 63.142(d)(i) and DOE document DOE/RW-0333P, Section 3.2.4.

Procedure AP-2.22Q should to indicate the process and documentation requirements for independent design review or reference the procedure or procedures that describe and document independent verification.

Additional Information Needed:

The NRC staff review of Procedure AP-2.22Q determined that DOE should address the following areas. These items should correspond in numbering to the comments above.

1) Procedure AP-2.22Q should provide a description of the classification process or include information that indicates/explains: (1) how DOE intends to determine whether an individual

structure, system, or component is important to safety or waste isolation; (2) how the classification process will be implemented; (3) the steps of the classification process; and (4) references to the implementing procedures, where applicable.

2) Procedure AP–2.22Q should address how the deterministic factors identified in the Preclosure Safety Analysis Guide, (pages 12-10 and 12-11) and other deterministic factors will be considered and consistently incorporated into the classification process when evaluating the risk significance of an event sequence and classification.

3) Section 5.1, paragraph 2 of Procedure AP–2.22Q, should provide a better explanation of how the quality assurance controls are applied, consistent with their importance to safety. DOE document DOE/RW–0333P should include the necessary provisions to allow for the classification of important to safety structures, systems, and components.

4) Procedure AP–2.22Q should indicate where the quality assurance records are generated and the applicable procedure(s).

5) Procedure AP–2.22Q should either indicate how the requirements identified in 10 CFR Part 63.44 will be addressed, with respect to the reclassification of important to safety structures, systems, and components (due to the introduction of new information or design changes), or clearly reference the procedure(s) that will satisfy the requirements identified in 10 CFR 63.44.

6) Procedure AP–2.22Q should indicate how the independent verification of design outputs, required by 10 CFR 63.142(d)(i) and DOE document DOE/RW–0333P, Section 3.2.4, will be accomplished and documented.

Status of Agreement: Preclosure Agreement 6.01 is listed as “need additional information.”