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**PRE-LICENSING EVALUATION REPORT OF
U.S. DEPARTMENT OF ENERGY
MINED GEOLOGIC DISPOSAL SYSTEM
LICENSE APPLICATION ANNOTATED OUTLINE
CHAPTER 10.0, "QUALITY ASSURANCE"**

Prepared for

**Nuclear Regulatory Commission
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PRE-LICENSING EVALUATION REPORT

CHAPTER 10. QUALITY ASSURANCE

This chapter of the Pre-Licensing Evaluation Report documents the NRC staff review of DOE's quality assurance (QA) program to be applied to all phases of repository development, including site characterization. The review utilized Draft Regulatory Guide DG-3003, "Format and Content for the License Application for the High-Level Waste Repository (FCRG)" (Nuclear Regulatory Commission, 1990), to assess the DOE's Chapter 10.0, "Quality Assurance," of the Annotated Outline (AO) (U.S. Department of Energy, 1995). NUREG-1323, "License Application Review Plan for a Geologic Repository for Spent Fuel and High-Level Radioactive Waste" (LARP) (Nuclear Regulatory Commission, 1994), was used to assess DOE's Quality Assurance Requirements and Description (QARD), DOE/RW-0333P (U.S. Department of Energy, 1992), which is referenced in the AO.

Existing QA-related Open Items (OIs) were not addressed by Chapter 10.0 of this AO submittal.

10.1 Staff Review of the DOE QARD

10.1.1 General

In Chapter 10.0 of the AO, the DOE proposes to use the QARD as the QA requirements document for all phases of repository related activities.¹ The QARD has been reviewed and found to be acceptable by the NRC staff using the Review Plan for High-Level Waste Quality Assurance Program Descriptions (Nuclear Regulatory Commission, 1989), which is equivalent to LARP Chapter 10, Section 3.2.1. The history of staff review and acceptance of the QARD is as follows:

- DOE submittal for NRC review and acceptance of QARD Revision 0, incorporating changes resulting from the NRC informal review of QARD Draft OD (Roberts, 1992)
- NRC staff positions on QARD Revision 0 (Holonich, 1993)
- DOE transmittal of QARD Revisions 1 and 2 (Milner, 1995)
- NRC acceptance of QARD (Holonich, 1995)

10.1.2 Organization of the QA Program

The DOE organization for the design, construction, operation, and permanent closure of the proposed repository includes the DOE Office of Civilian Radioactive Waste Management (OCRWM) and the Civilian Radioactive Waste Management System Management and Operating Contractor (M&O). The national laboratories and U.S. Geological Survey and similar organizations supporting the repository program have recently been designated as M&O partners.

¹ Prior to the QARD, DOE had developed and NRC had accepted its predecessor documents, the "Quality Assurance Requirements Document" (DOE/RW-0214) and the "Quality Assurance Program Description Document" (DOE/RW-0215). An example of NRC acceptance of these documents can be found in Holonich (1991).

The Director of OCRWM, reporting to the Secretary of Energy, has responsibility for the repository program. Among several offices reporting to the Director is the Office of Quality Assurance, having responsibility for assisting the line organization, developing the QA program, and for overview of work subject to the QA program. The Office of Quality Assurance has a direct line of reporting to the Director of OCRWM. The Yucca Mountain Site Characterization Office is responsible for site characterization, evaluation of site suitability, producing an Environmental Impact Statement, and, if appropriate, producing a license application (LA). The organizational structure of OCRWM is provided in Figure 10.1.

10.1.3 Quality Assurance Program

The QARD is composed of eighteen sections corresponding to the eighteen criteria of 10 CFR Part 50, Appendix B, which is applicable to the geologic repository program through reference in 10 CFR Part 60, Subpart G. The QARD also contains supplements of requirements for specialized activities, currently focusing on site characterization activities, and appendices containing requirements that are specific to an individual program element. Appendix C provides requirements specifically addressing the Mined Geologic Disposal System.

The QARD serves as the top-level requirements document for all line organizations, including OCRWM, the M&O, and M&O partners. The line organizations develop implementing procedures that translate applicable QARD requirements into work processes. These organizations develop matrices identifying the implementing procedures which address individual QARD requirements, which are reviewed and approved by the OCRWM Office of QA. The QARD has provisions for identifying items subject to the QA program (the Q-List) and for identifying the portions of the QA program applicable to individual activities.

The implementation of the QA program at the affected organizations is assessed by DOE through audits, surveillances, and inspections. The NRC staff have assessed QA program implementation through observation of DOE QA audits and through independent NRC audits and field verification activities. Several NRC OIs are currently unresolved regarding QA program implementation.

10.1.4 Conclusion

The staff review of the DOE OCRWM QARD has verified that the criteria of Appendix B to 10 CFR Part 50 have been addressed.

Based on its review of the QARD and evaluation of the QARD, the staff concludes:

- (1) The organization of OCRWM and of affected organizations in the geologic repository program provide sufficient independence and authority to effectively carry out the OCRWM QA program, and provide access to management necessary to perform the QA functions.
- (2) The QA program describes requirements and controls that, when properly implemented, comply with the requirements of 10 CFR Part 60, Subpart G, and by reference, Appendix B of 10 CFR Part 50.

Accordingly, the staff concludes that the DOE OCRWM QA program is in compliance with applicable NRC regulations.

10.2 Staff Review of the License Application Annotated Outline

The organization of Chapter 10.0 of the AO follows the suggested outline in the FCRG. With the exception of the Introduction to Chapter 10.0 and Section 10.0.3, AO Chapter 10.0 contains only section headings.

Considering the history of the DOE QA program development and its acceptance by NRC, this edition of Chapter 10.0 of the AO should be considerably more developed than it is at this time. The DOE should have documented the acceptance history of the OCRWM QARD and described the measures that have been taken to determine the effectiveness of the QA program implementation for affected activities and organizations. In addition, the "Information Needs," identified in Section 10.1, will provide far less than the information requested in the FCRG. A more developed Chapter 10.0 of the AO would allow the NRC staff to make a more definitive determination of the acceptability of the chapter and of compliance to 10 CFR Part 60, Subpart G (see new OI OAO000PER1995Q001).

The NRC staff identified a generic issue regarding QA and the AO, although not specifically with Chapter 10.0 of the AO. The staff is not aware of any quality control or quality verification activities that have been applied to the development of the AO. In particular, the staff is concerned about the qualification of the data presented in the AO, what measures will be taken to qualify the data, and how DOE will ensure that only qualified data are presented in the LA (see new OI OAO000PER1995C001).

10.2.1 Introduction

Chapter 10.0 of the AO provides for descriptions of the application of the QA program to structures, systems, and components (SSCs) important to safety; identification of the analyses used to determine SSCs and the barriers important to waste isolation; the Q-List; and the QA program for items other than those important to safety and waste isolation. This format appears adequate to provide the information necessary for the NRC staff to determine if the QA programs will be applied to the appropriate items and activities. However, the QA program descriptions are not listed as Information Needs (see new OI OAO000PER1995Q001).

Section 10.0.3 of the AO indicates that the QA program applies to 10 CFR 60.131(a) items, that is, to radiological protection in the same fashion as items and activities important to safety and waste isolation. The NRC staff considers this to be appropriate.

10.2.2 QA Program for the Various Activities of the Geologic Repository

This section of the AO presently contains only sub-section headings. The list of headings is generally consistent with the FCRG. However, the staff identified several instances in which the headings do not appear to reflect the staff guidance of the FCRG (see new OI OAO000PER1995Q002). When the sub-sections are completed, they should provide sufficient information for the NRC staff to conduct an adequate review to determine compliance with 10 CFR Part 50, Appendix B, which is referenced in 10 CFR 60.152.

10.2.3 Implementation of the QA Program for Site Characterization

This section is not sufficiently developed to comment upon. As indicated above, DOE should have described the activities and actions that it has taken to determine the effectiveness of the QA program implementation for affected activities and organizations.

The NRC staff has conducted numerous verification activities in regard to the QA program implementation, including the following:

- Observing DOE audits to determine whether they effectively evaluate compliance and program implementation
- Conducting independent NRC audits of selected organizations and activities
- Conducting independent NRC in-field verification of DOE activities
- Observing DOE QA surveillance activities
- Participating in periodic meetings with DOE concerning QA and other issues

As a result of these verification activities, OIs have been identified and reported to DOE. At this time, several of the OIs remain unresolved pending further DOE action and NRC verification. At the time of this report, the NRC staff has found the DOE QA programs to be effectively implemented, with the exception of that of the M&O that has not yet been shown to be acceptable.

10.2.4 Conclusion

Chapter 10.0 of the AO is insufficiently developed to make any preliminary findings at the present time.

REFERENCES

Holonich, J.J., Nuclear Regulatory Commission, letter to John P. Roberts, U.S. Department of Energy, November 21, 1991.

Holonich, J.J., Nuclear Regulatory Commission, letter to D.E. Shelor, U.S. Department of Energy, March 8, 1993.

Holonich, J.J., Nuclear Regulatory Commission, letter to R.A. Milner, U.S. Department of Energy, June 6, 1995.

Milner, R.A., U.S. Department of Energy, letter to J.J. Holonich, Nuclear Regulatory Commission, March 9, 1995.

Nuclear Regulatory Commission, *Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions*, Revision 2, Nuclear Regulatory Commission, Washington, DC, 1989.

Nuclear Regulatory Commission, *Draft Regulatory Guide DG-3003, Format and Content for the License Application for the High-Level Waste Repository (FCRG)*, Nuclear Regulatory Commission, 1990.

Nuclear Regulatory Commission, *License Application Review Plan for a Geologic Repository for Spent Nuclear Fuel and High-Level Radioactive Waste (LARP) Draft Review Plan*, NUREG-1323, Revision 0, Nuclear Regulatory Commission, Washington, DC, 1994.

Roberts, J.P., U.S. Department of Energy, letter to J.J. Holonich, Nuclear Regulatory Commission, December 21, 1992.

U.S. Department of Energy, *Department of Energy Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program (QARD)*, DOE/RW-0333P, Revision 0, U.S. Department of Energy, Washington, DC, 1992.

U.S. Department of Energy, *Mined Geologic Disposal System License Application Annotated Outline*, YMP/94-05, Revision 0, U.S. Department of Energy, Office of Civilian Radioactive Waste Management, Las Vegas, NV, 1995.

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OPEN ITEM STANDARD REPORT

OITSID: OAO000PER1995Q001

REPORT DATE: 13 Jul 1995

STATUS: Open

DATE RESOLVED:

TOPIC OF THE OPEN ITEM/UNCERTAINTY: License Application Annotated Outline (LAAO) is incomplete considering the amount of activity that has taken place.

RESPONSIBLE BRANCH/SECTION: HLUR/HLW & QA

ACTION AGENCY: DOE

IDENTIFICATION DATE: 13 Jul 1995

SOURCE TYPE: Pre-Licensing Evaluation Report (PER)

SOURCE DOCUMENT: PER 7/1995

DOE ACTIVITY CODE/WBS NO.: N/A

UNCERTAINTY TYPE: Technical

SPECIFIC TECHNICAL TYPE: Question on AO

TEXT: Chapter 10.0 of the AO is generally poorly written, contains editorial errors, and should be developed more fully in those areas where significant activity has taken place. Specifically,

- The DOE has available a significant history of QA program development and implementation that should have been included in AO Chapter 10.0. The greatest value of the AO will be realized if the AO is developed as much as possible at the time of its issuance.
- The information need identified in AO Section 10.1 is not sufficient to provide a complete LA for QA.

RATIONALE/BASIS: This question communicates to DOE the desire of the NRC Staff to be able to review versions of the AO as complete as possible at the time of their issuance.

RECOMMENDATIONS: DOE should provide the AO in a form and with the contents as up-to-date as possible.

UNCERTAINTY RESOLUTION METHOD TYPE:

RATIONALE FOR UNCERTAINTY RESOLUTION METHOD SELECTION:

HISTORY:

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CROSS REFERENCE

CITATION: 10 CFR 60 Subpart G

LARP (REVIEW PLAN) NUMBER: 10

REFERENCES:

Nuclear Regulatory Commission, *Draft Regulatory Guide DG-3003, Format and Content for the License Application for the High-Level Waste Repository (FCRG)*, Nuclear Regulatory Commission, Washington, DC, 1990.

U.S. Department of Energy, *Mined Geologic Disposal System License Application Annotated Outline*, YMP/94-05, Revision 0, U.S. Department of Energy, Office of Civilian Radioactive Waste Management, Las Vegas, NV, 1995.

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OPEN ITEM STANDARD REPORT

OITSID: OAO000PER1995C001

REPORT DATE: 11 Jul 1995

STATUS: Open

DATE RESOLVED:

TOPIC OF THE OPEN ITEM/UNCERTAINTY: Quality controls applied to license application annotated outline development (LAAO).

RESPONSIBLE BRANCH/SECTION: HLUR/HLW & QA

ACTION AGENCY: DOE

IDENTIFICATION DATE: 11 Jul 1995

SOURCE TYPE: Pre-Licensing Evaluation Report (PER)

SOURCE DOCUMENT: PER 7/1995

DOE ACTIVITY CODE/WBS NO.: N/A

UNCERTAINTY TYPE: Technical

SPECIFIC TECHNICAL TYPE: Question on QA program implementation

TEXT: DOE is required to implement its QA program so that all activities affecting quality are appropriately controlled. The NRC Staff is not aware of any QA program controls or quality verification activities that have been applied to the development of the LAAO.

In addition, the qualification status of the data contained in the annotated outline (AO) is unknown. The NRC Staff is not aware of any provisions made (i) to ensure that only qualified data are used in the LA and (ii) to prevent unqualified data used in the AO from being used in the LA.

RATIONALE/BASIS: While quality controls over site characterization activities and data acquisition have been routinely evaluated by DOE and NRC staffs, the application of controls over the use of that data, particularly in the AO and eventually in the LA, has not been apparent. Most of the site characterization data currently available to DOE were not collected under an acceptable QA program, nor has it been qualified under an acceptable QA program. Generally, the data used in the AO appear to be unqualified. The AO makes no claims or disclaimers to the qualification status of the data used in the AO.

As the AO is iteratively developed, more qualified data should become available and be incorporated into the AO and eventually into the LA. The NRC staff questions how the qualified data will be differentiated from the unqualified so the LA will contain only qualified data and allow the staff to be aware of the qualification status of data in future AO reviews.

RECOMMENDATIONS: DOE should inform NRC of its methods to maintain clear identification of qualified data through its use in the AO and LA.

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UNCERTAINTY RESOLUTION METHOD TYPE:

RATIONALE FOR UNCERTAINTY RESOLUTION METHOD SELECTION:

HISTORY:

CROSS REFERENCE

CITATION: 10 CFR 60 Subpart G

LARP (REVIEW PLAN) NUMBER: 10

REFERENCES:

U.S. Department of Energy, *Mined Geologic Disposal System License Application Annotated Outline*, YMP/94-05, Revision 0, U.S. Department of Energy, Office of Civilian Radioactive Waste Management, Las Vegas, NV, 1995.

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OPEN ITEM STANDARD REPORT

OITSID: OAO000PER1995Q002

REPORT DATE: 11 Jul 1995

STATUS: Open

DATE RESOLVED:

TOPIC OF THE OPEN ITEM/UNCERTAINTY: License Application Annotated Outline (LAAO) Chapter 10.0 headings do not reflect NRC guidance

RESPONSIBLE BRANCH/SECTION: HLUR/HLW & QA

ACTION AGENCY: DOE

IDENTIFICATION DATE: 11 Jul 1995

SOURCE TYPE: Pre-Licensing Evaluation Report (PER)

SOURCE DOCUMENT: PER 7/1995

DOE ACTIVITY CODE/WBS NO.: N/A

UNCERTAINTY TYPE: Technical

SPECIFIC TECHNICAL TYPE: Question over AO Chapter 10.0 format

TEXT: The outline headings in AO Section 10.1 do not appear to reflect the NRC guidance.

1) The titles used for Sections 10.1.1.1, "Applicable Provisions of 10 CFR Part 50, Appendix B (as specified in the QARD) That Have Been Applied to Activities Affecting Quality During Site Characterization of the Geologic Repository" and 10.1.1.2, "Provisions Sufficiently Detailed to Respond to NRC's Review Plan for High-Level Waste Repository QA Program Descriptions," are inappropriate. The NRC guidance indicates that QA program descriptions should have the attributes of: (i) addressing applicable 10 CFR 50, Appendix B criteria, and (ii) sufficient detail to satisfy the NRC Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions (currently Chapter 10 of the LARP). The NRC staff suggests that AO Sections 10.1.1.1 and 10.1.1.2 be deleted and that the various QA program descriptions be in Sections 10.1.1.x.

2) AO Section 10.1.1.1.1 indicates that QA program descriptions of only three of the subcontractors/affected organizations involved in site characterization will be provided. Descriptions for all affected organizations should be included or referenced.

3) AO Sections 10.1.2, 10.1.3, and 10.1.4 separate the portions of the QA program identical to the site characterization QA program from those portions that are unique to the other activities. The guidance was not to separate the two, but to avoid repeatedly identifying portions already covered under the site characterization QA program. The NRC staff suggests that AO Sections 10.1.2, 10.1.3, and 10.1.4 have single QA program descriptions with cross references to the site characterization QA program descriptions when specific requirements are identical.

RATIONALE/BASIS: This question refers DOE to the FCRG so that, when AO text is developed for these sections, the content is meaningful both to DOE and to the NRC staff.

RECOMMENDATIONS: DOE should restructure AO Chapter 10.0 Table of Contents and headings to reflect the guidance of the NRC in the FCRG. Future iterations of the AO should be in accordance with the LARP.

UNCERTAINTY RESOLUTION METHOD TYPE:

RATIONALE FOR UNCERTAINTY RESOLUTION METHOD SELECTION:

HISTORY:

CROSS REFERENCE

CITATION: 10 CFR 60 Subpart G

LARP (REVIEW PLAN) NUMBER: 10

REFERENCES:

Nuclear Regulatory Commission, *Draft Regulatory Guide DG-3003, Format and Content for the License Application for the High-Level Waste Repository (FCRG)*, Nuclear Regulatory Commission, Washington, DC, 1990.

Nuclear Regulatory Commission, *License Application Review Plan for a Geologic Repository for Spent Nuclear Fuel and High-Level Radioactive Waste (LARP) Draft Review Plan*, NUREG-1323, Revision 0, Nuclear Regulatory Commission, Washington, DC, 1994.

U.S. Department of Energy, *Mined Geologic Disposal System License Application Annotated Outline*, YMP/94-05, Revision 0, U.S. Department of Energy, Office of Civilian Radioactive Waste Management, Las Vegas, NV, 1995.