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SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

SUPPLEMENT No. 2

OVERVIEW OF QUALITY ASSURANCE ACTIVITIES

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**U.S. Department of Energy
Office of Civilian Radioactive Waste Management
Office of Geologic Repositories**

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SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

Overview of Quality Assurance Activities

1.0 GENERAL

This Supplement provides amplified requirements for the overview of quality assurance activities. It supplements the OGR QA Plan and OCRWM Quality Assurance Management Policies and Requirement (DOE/RW-0032), Section 5.7. The requirements in this Supplement are to be used in conjunction with the requirements embodied or referenced in the governing QA plans and procedures.

2.0 PURPOSE

The purpose of this Supplement is to specify requirements for the overview of quality assurance activities performed on geologic repository projects.

3.0 SCOPE

The requirements of this Supplement are applicable to all quality levels 1 or 2 activities. These requirements apply to HQ-OGR overview of the activities of the project offices; the project offices overview of the activities of their contractors; and contractor overview of subcontractor activities. The requirements of this Supplement are not intended to be applicable to internal quality audits and surveillances.

4.0 DEFINITIONS

4.1 Overview. An analysis and assessment by management of the scope, status, adequacy and effectiveness of Program quality achievement and assurance activities. Overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveillances, as appropriate.

5.0 REQUIREMENTS

5.1 Overview

Each project organization is to perform overview of the quality assurance activities of all project participants under its purview including contractors doing supportive work.

Overview is to include, as appropriate:

- (a) The review and approval of participant quality assurance plans and administrative procedures;

- (b) Surveillance of participant activities affecting quality to verify compliance with requirements.
- (c) Performance of quality audits to verify the adequacy and compliance of participant programs.

5.2 Review and Approval of Participant QA Programs

Procedures are to be established for the review of participant QA program documentation for adequacy, completeness and relevance. The overview procedures shall identify the types of documents to be submitted by the participant for review and approval, assign project responsibility for review, and identify the methods for documenting review and approval action.

5.3 Surveillance

Procedures are to be established for planning, scheduling, performing, and documenting surveillance of participant activities affecting quality. The surveillance shall be performed by personnel who are not directly responsible for performing the work involved in the activities affecting quality. Surveillances are to be performed to written check lists or surveillance plans whenever practicable. All deficiencies, non-conformances, and potential quality problems identified during the surveillance are to be documented and monitored until verification of effective corrective action is made.

5.4 Quality Audits

Procedures to be established for the planning, scheduling, performing and reporting of quality assurance audits of participant QA programs. Audit schedules are to be developed annually and updated as changes occur. Audits of organizations common to more than one project are to be coordinated whenever practicable to conserve resources and maintain consistency. Checklists or plans shall be prepared in advance and used during audits. Audit results are to be documented. All deficiencies, non-conformances, and potential quality problems identified during the audit are to be documented and monitored until verification of effective corrective action is made, and root causes of deficiencies determined. An analysis of audit results and surveillance findings is to be performed to identify quality trends.

Audits will be performed by trained and qualified personnel and led by certified personnel not directly responsible for the activity being audited. Audit teams should include, whenever possible, a representative trained and/or qualified in the technology being audited.

5.5 Records

Records of overview activities referred to in this supplement shall be retained as lifetime QA records.

5.5.1 QA Program Review Records

Reviews of participant QA program documentation shall be recorded on checklists or other forms that specify the criteria for acceptability and indicate conformance or nonconformance.

5.5.2 Surveillance Records

Surveillance of participant activities shall be documented in reports that, as a minimum, include:

- (a) Identification of the organization(s), activities, and/or items under surveillance.
- (b) Description of any deficiencies, nonconformances, and potential quality problems identified during the surveillance.
- (c) Specification of recommended and/or approved corrective action resulting from the surveillance.

5.5.3 Audit Records

Audits of participant activities shall be documented in plans, checklists, and reports that, as a minimum, include:

- (a) Identification of the organization(s), activities, and/or items audited and the individuals contacted during the audit(s).
- (b) Description of any deficiencies, nonconformances, and potential quality problems identified during the audit(s).
- (c) Specification of recommended and or approved corrective action resulting from the audit(s).