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!CCA MOUNTAIN PROJECT

Quality Procedures

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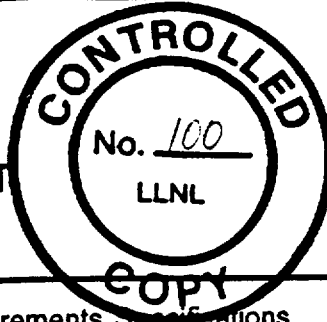
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Subject:
Preparation of Quality Assurance Requirements Specifications
and Approval of Subcontractor QA Programs

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Training Required: Yes ☐ No ☒

Comment: Incorporation of CNs and deletion of one requirement.

Approved by _W. L. Clarke_   _8/24/92_
Yucca Mountain Project Leader   Date

Approved by _Dean Wolfe_   _8/24/92_
YMP Quality Assurance Manager   Date

4.1.1 PURPOSE

This procedure establishes the methods for developing, approving, controlling and using Quality Assurance (QA) Requirements Specifications for subcontractors performing activities or providing services in support of the Yucca Mountain Project.

4.1.2 SCOPE

This procedure applies to activities and services that are subcontracted by the LLNL-YMP where the supplier is required to prepare and implement a Quality Assurance Program. As used in this procedure, the term subcontractor includes organizations performing activities or providing services under DOE Letter Agreements through various DOE Operating Offices.

4.1.3 DEFINITIONS

Generic QA Requirements Specification: A document containing relevant requirements from the LLNL-YMP Quality Assurance Program Plan that may be applicable to the activities of a subcontractor.

Subcontract QA Requirements Specification: A document derived from the Generic QA Requirements Specification that has been tailored to the specific requirements applicable to a subcontractor based upon the activities to be performed by that subcontractor.

4.1.4 RESPONSIBILITIES

The YMP Project Leader is responsible for approving the Generic QA Requirements Specification and Subcontract QA Requirements Specifications prepared for subcontractor activities.

The YMP QA Manager is responsible for preparing the Generic QA Requirements Specification, reviewing and approving Subcontract QA Requirements Specifications, and approving subcontractor QA Programs.

The Technical Area Leaders are responsible for reviewing and approving Subcontract QA Requirements Specifications for subcontractors performing activities within their area of responsibility.

The Task Leaders are responsible for preparing Subcontract QA Requirements Specifications for subcontractors whose activities they supervise.

4.1.5 PROCEDURE

4.1.5.1 Preparation of the Generic QA Requirements Specification

YMP QA MANAGER: 4.1.5.1.1   Prepares the Generic QA Requirements Specification. This document includes the requirements contained in the LLNL-YMP QAPP that may be applicable to subcontractors performing activities or services for the YMP. The Specification includes provisions for invoking only NQA-1 requirements, or those of other Nationally recognized QA

Program requirements documents. The completed specification is forwarded to the YMP Project Leader for approval. Upon approval the document is forwarded to the Local Records Center.

LOCAL RECORDS CENTER: 4.1.5.1.2 Assigns the approved Generic QA Requirements Specification a control number and distributes controlled copies of the Generic QA Requirements Specification to the following:

a. The YMP Project Leader;

b. The YMP QA Manager;

c. YMP Technical Area Leaders;

d. YMP Task Leaders.

4.1.5.2 Preparation of QA Requirements Specifications

TASK LEADER: 4..1.5.2.1 Prepares the draft Subcontract QA Requirements Specification. The draft specification is submitted to the cognizant Technical Area Leader and the QA Manager for review.

TECHNICAL AREA LEADER AND QA MANAGER:

4.1.5.2.2 Review the draft specification to assure an adequate inclusion of QA Program requirements taking into consideration the scope of work and any other pertinent considerations. Comments are submitted to the Task Leader.

TASK LEADER: 4.1.5.2.3 Resolves any comments and prepares the Subcontract QA Requirements Specification for approval. The final document is submitted to the cognizant Technical Area Leader, the QA Manager and the Project Leader for approval. Upon approval, the Subcontract QA Requirements Specification is submitted to the Local Records Center for distribution.

LOCAL RECORDS CENTER: 4.1.5.2.4 Assigns the approved Subcontracted QA Requirements Specification a control number and distributes controlled copies of the Subcontract QA Requirements Specification to the following:
a. The cognizant Technical Area Leader;

b. The cognizant Task Leader;

c. The QA Manager; and

d. The Resource Manager for inclusion in applicable procurement documents.

4.1.5.3 Approval of Subcontractor QA Programs

TASK LEADER: **4.1.5.3.1** Obtains a controlled copy of the Subcontractors Quality Assurance Program manual that has been modified, as necessary, to include requirements contained in the Subcontract QA Requirements Specification, and submits it to the QA Manager for review.

QA MANAGER: **4.1.5.3.2** Reviews the submitted QA Program manual to verify inclusion of the requirements specified in the Subcontract QA Requirements Specification. Comments are submitted to the Task Leader.

4.1.5.3.3 Conducts a prequalification QA Surveillance of the subcontractor's facility(ies).

TASK LEADER: **4.1.5.3.4** Coordinates with the subcontractor and the QA Manager to achieve satisfactory resolution of any comments on the QA Program and open items resulting from the prequalification QA Surveillance.

QA MANAGER: **4.1.5.3.5** Upon satisfactory resolution of comments and open items, submits a letter approving the subcontractor's QA Program to the cognizant Technical Area Leader and Task Leader. The letter specifies the number and revision level of the Subcontract QA Requirements Specification used as the source of requirements and any exceptions granted to the Specification's requirements.

TASK LEADER: **4.1.5.3.6** **Upon receipt of a letter approving the subcontractor's QA program from the QA Manager, provides a notification letter to the subcontractor indicating that the QA program is approved for use.**

4.1.5.4 Changes to QA Requirements Specifications

QA MANAGER: **4.1.5.4.1** Upon approval of each revision to the LLNL-YMP QAPP, reviews the Generic QA Requirements Specification to assure that it contains current requirements identified in the QAPP. If changes are necessary, they are processed in accordance with Section 4.1.5.1, or by Change Notice in accordance with 033-YMP-QP 2.1.

4.1.5.4.2 Notifies Task Leaders in writing that the Generic QA Requirements Specification has been revised.

TASK LEADERS: 4.1.5.4.3   Review existing Subcontract QA Requirements Specifications each time there is a change to the Generic QA Requirements Specification **or** a change to the scope of the subcontractor's activities. Changes to Subcontract QA Requirements Specifications are prepared in accordance with Section 4.1.5.2 or by Change Notice in accordance with 033-YMP-QP 2.1. If no changes to Subcontract QA Requirements Specifications are necessary, the QA Manager is notified in writing of that conclusion.

QA MANAGER: 4.1.5.4.4   Reviews subcontractor QA Programs to assure inclusion of requirements from revised Subcontract QA Requirements Specifications. Review and Approval are processed in accordance with Section 4.1.5.3.

4.1.6 RETAINED DOCUMENTATION

4.1.6.1 <u>QA Records</u>

QA MANAGER: 4.1.6.1.1   Submits the following documents that result from the implementation of this procedure as QA Records to the Local Records Center in accordance with 033-YMP-QP 17.0:

a. Approved Generic QA Requirements Specifications and revisions thereto;

b. Approved Subcontract QA Requirements Specifications and revisions thereto;

c. Memoranda approving specific subcontractor QA Programs;

d. Memoranda documenting reviews of subcontract QA Requirements Specifications where no revisions are necessary.