University of California
Lawrence Livermore National Laboratory

YUCCA MOUNTAIN PROJECT

Page_____ Of_____

CHANGE NOTICE

CN No.: 2.0-0-3

Affected Document: 033-YMP-QP 2.0 "Assurance"

Prepared by: Jim Blink/Barbara Bryan

Approved by: N/A
(Technical Area Leader) (Date)

Approved by: David W. Short 11-26-90
(YMP QA Manager) (Date)

Approved by: [illegible] / FOR L. JARDINE 11/26/90
(YMP Project Leader) (Date)

Training Required: Yes ☐ No ☒

urrently Read as Follows:

Section 2.0.4: Add letter d. as below. As published.

CHANGED TO READ:

Section 2.0.4 STRUCTURE

d. Issue of Forms

All forms that appear as sample exhibits to quality procedures are provided as a convenience; their use is encouraged, but not mandatory. If another format is used to document a process as prescribed in the procedure, all prescribed information must be addressed. Participants are encouraged to contact Document Control to obtain the most current sample form.

Since the sample forms are not mandatory, changes to forms do not require a change notice action.

9210260212 921013
PDR WASTE
WM-11 PDR

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

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YUCCA MOUNTAIN PROJECT

CHANGE NOTICE

CN No.: 2.0-0-2

Affected Document: 033-YMP-QP 2.0, "Assurance" Rev. 0

Prepared by: David Short

Approved by: N/A
(Technical Area Leader) (Date)

Approved by: David W. Short 5/17/90
(YMP QA Manager) (Date)

Approved by: [illegible] 5/17/90
(YMP Project Leader) (Date)

Training Required: Yes ☒ No ☐
For Document Control Personnel

Currently Read as Follows:

Paragraph 2.0.4 c - Issue of Technical Implementing Procedures

"Technical Implementing Procedures are distributed at the discretion of the TIP's author to holders and non-holders of the YMP Quality Assurance Program Plan."

Changed to Read:

Add the following to the above paragraph:

"A controlled copy of each Technical Implementing Procedure (TIP) will be forwarded to the DOE Project Office QA Manager."

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YUCCA MOUNTAIN PROJECT

CHANGE NOTICE

CN No.: 2.0-0-1

Affected Document: 033-YMP-QP 2.0 Assurance Rev. 0

Prepared by: D. Short

Approved by: N/A
(Technical Area Leader) (Date)

Approved by: David W. Short 5/2/90
(YMP QA Manager) (Date)

Approved by: [illegible] 5/2/90
(YMP Project Leader) (Date)

Training Required: Yes ☐ No ☒

Currently Read as Follows:

1. Section 2.0.1, second paragraph, third sentence (as published)
2. Section 2.0.1, second paragraph, fourth sentence (as published)
3. Section 2.0.2, Quality Procedure definition, first sentence (as published)
4. Section 2.0.2, Administrative Procedure term and definition (as published)
5. Section 2.0.3, first sentence (as published)
6. Section 2.0.4b, first sentence (as published)

Changed to Read:

1. Section 2.0.1, second paragraph, third sentence: Procedures formulated to meet the QAPP requirements constitute the second tier and are published as Quality Procedures (QPs).
2. Section 2.0.1 second paragraph, fourth sentence: The third tier documents are work plans in the form of Scientific Investigation Plans, Activity Plans, and Technical Implementing Procedures. Technical Implementing Procedures are generic or specific technical procedures used to plan and direct specific work activities.
3. Section 2.0.2, Quality Procedure definition, first sentence: A Quality Procedure is a procedure that implements a set of requirements contained in the QAPP.

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

Currently Read as Follows:

7. Section 2.0.4c, (as published)

8. Section 2.0.6, second sentence: ... - Reviews and approval of QAPPs and QPs and review of APs.

9. Section 2.0.7, third paragraph, third sentence (as published)

Changed to Read:

4. Section 2.0.2, Administrative Procedure term and definition (deleted)

5. Section 2.0.3, first sentence: This procedure applies to all the requirements and procedures that collectively constitute the LLNL-YMP QAPP, QP, and TIP Manuals.

6. Section 2.0.4b, first sentence: Quality Assurance requirements and procedures are usually, but not necessarily, issued to all holders of the YMP Quality Assurance Program Plan.

7. Section 2.0.4c: Technical Implementing Procedures are distributed at the discretion of the TIPs author, with the concurrence of the Task Leader, to holders and non-holders of the LLNL-YMP Quality Assurance Program Plan.

8. Section 2.0.6, second sentence: ... - Review and approval of Quality Assurance program documentation. (Quality Assurance Program Plans, Quality Assurance Program Descriptions, Quality Assurance Manuals, and Quality Assurance implementing procedures.)

9. Section 2.0.7, third paragraph, third sentence: Management above or outside the QA organization is responsible for the readiness review activity; however, the QA organization may participate in the review.

Approved by: 2/4/89 YMP Project Leader

Approved by: 1/12/8 YMP Quality Assurance Manager

2.0.1 PURPOSE

This procedure assigns specific responsibilities to the YMP Quality Assurance Manager (QA Manager). This procedure also describes the structure, preparation and application of the Yucca Mountain Project (YMP) Quality Procedures (QP) Manual.

The requirements and procedures governing YMP quality assurance program consist of a three-tier system under which work for various sponsors can be controlled and documented. In the first tier, requirements generally applicable to the work performed for the DOE Project Office are identified in the Quality Assurance Program Plan (QAPP). Procedures formulated to meet the QAPP requirements constitute the second tier and are either published as Quality Procedures (QP), or as Administrative Procedures (AP). The third tier documents are work plans in the form of Scientific Investigation Plans and Technical Implementing Procedures and are generic or specific technical procedures used to plan and direct specific work activities.

It is the philosophy of the YMP that quality assurance is a line responsibility. Each requirement and procedure is, therefore, written with the objective of being understandable and applicable at the working level.

Activities that affect quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that all prerequisites for a given activity are satisfied.

2.0.2 TERMS AND DEFINITIONS

Quality Assurance Program Plan (QAPP): Quality requirements which specify what is to be done not how. The QAPP is based on requirements specified by the Yucca Mountain Project Office.

Quality Procedure (QP): A Quality Procedure is a procedure that implements a set of requirements contained in the QAPP or a set of requirements contained in the YMP quality related Administrative Procedures. A QP is applicable to all YMP personnel.

Scientific Investigation Plans (SIP): Documents which describe the scientific investigation performed in support of the waste package design for the Yucca Mountain Project. Each SIP is subdivided into one or more subtasks or activities.

Technical Implementing Procedures (TIP): Detailed procedures which provide instructions for repetitive operations.

Administrative Procedures (AP): An Administrative Procedure is a procedure that implements a set of requirements of LLNL-YMP's Project Management Plan or a set of requirements of YMP's Administrative Procedures. An AP is applicable to all YMP personnel.

2.0.3 SCOPE

This procedure applies to all the requirements and procedures that collectively constitute the YMP QAPP and the QP, AP and TIP Manuals.

2.0.4 STRUCTURE

a. Relationship to Other Standards

There is a one-on-one relationship of the numbers and the titles of the quality assurance elements in the Quality Assurance Program Requirements for Nuclear Facilities (NQA-1) and this three-tier set of QA requirements and procedures. There are two title differences: Element 2 is called "Assurance" in this Program rather than "Quality Assurance Program", and Element 5 is titled "Technical Implementing Procedures" instead of "Instructions, Procedures, Plans and Drawings."

b. Issue of Requirements and Procedures

Quality Assurance requirements and procedures are issued to all holders of the YMP Quality Assurance Program Plan.

Requirements and procedures are subject to review and approval as described in Procedure No. 033-YMP-QP 2.1, "Preparation, Approval and Revision of Quality Procedures and Requirements".

c. Issue of Technical Implementing Procedures

Technical Implementing Procedures are distributed at the discretion of the TIP's author to holders and non-holders of the YMP Quality Assurance Program Plan.

2.0.5 CONTROL OF ISSUE

The three-tier set of YMP requirements and procedures is considered to be a controlled quality assurance document. All requirements and procedures and their revisions are controlled. There is a record of issue of each copy of this document. This record contains the number assigned to each individual document holder and the contents, including revision numbers, for each copy. The record also indicates how superseded issues were handled.

2.0.6 RESPONSIBILITIES AND AUTHORITIES

The YMP Quality Assurance Manager (QA Manager) is responsible for and has the authority to:

- maintain the control system for the issuance and revision of the YMP Quality Assurance Program documents.
- verify that the YMP Quality Assurance Program remains responsive to the requirements, is implemented correctly, and continues to be effective.
- establish a program to train, qualify, and certify personnel in quality assurance methods. This program is described in Procedure No. 033-YMP-QP 2.9, "Training".
- review the implementation of the YMP Quality Assurance Program.
- perform other duties that are specifically delineated in other requirements and procedures of the YMP Quality Assurance Program documents. This includes the responsibility and authority to stop work which is not in compliance with the requirements of the QAPP.

The QA Manager is also responsible for and has the authority to conduct suitable overview of the QA activities of all organizations (including Subcontractors doing supportive work) under YMP purview. Overview includes the following as appropriate:

- Review and approval of QAPPs and QPs and review of APs.
- Surveillance of activities affecting quality to verify compliance with requirements.
- Performance of quality audits to verify the adequacy and compliance of QA Programs.

Procedures are established by the QA Manager for the review of QA program documentation of organizations under YMP purview for adequacy, completeness and relevance. The procedures identify the types of documents to be submitted for review and approval, assign responsibility for review, and identify the methods for documenting review and approval action. Reviews of QA program documentation are recorded on checklists or other forms that specify the criteria for acceptability and indicate conformance or nonconformance. Such review and approval procedures for YMP subcontractors are consistent with the procedures found in Procedure No. 033-YMP-QP 4.0, "Procurement Control and Documentation."

2.0.7 MANAGEMENT ASSESSMENTS AND READINESS REVIEWS

Management assessments are conducted at least annually to determine the effectiveness of the system and the management controls that have been established to achieve and assure quality and to assess the adequacy of resources and personnel provided to the QA program. Management verifies that the QA program is being effectively implemented and that personnel are trained to the QA requirements of the program.

Management assessments are conducted in accordance with Procedure No. 033-YMP-QP 2.3 "Management Assessments" which prescribes the planning, organizing, performing, and documenting of the management assessments. This procedure prescribes analysis and reporting of results and the tracking of recommendations that result from the management assessments. Copies of all management assessments are provided to the DOE Project Offices. Management above or outside the QA organization is responsible for the management assessment activity.

Management performs readiness reviews, as deemed appropriate in accordance with Procedures 033-YMP-QP 2.6 "Readiness Review." Readiness reviews apply to major scheduled/planned activities which could affect quality. Management above or outside the QA organization is responsible for the readiness review activity.