
INSPECTION PROCEDURE 78070

PROCUREMENT DOCUMENT CONTROL (PRE-LICENSING AND CONSTRUCTION)

PROGRAM APPLICABILITY: MC 2300

78070-01 INSPECTION OBJECTIVES

01.01 To determine if procurement documents adequately incorporate regulatory and design basis information for the procurement of material, equipment, and services and require contractors and subcontractors to implement Quality Assurance (QA) programs that meet the requirements of 10 CFR 63.142.

78070-02 INSPECTION REQUIREMENTS

02.01 Procurement Procedures. Determine if activities related to procurement are controlled by acceptable procedures that are adequately implemented.

02.02 Procurement Documents. Determine if applicable requirements, design basis, and other requirements necessary to assure adequate quality are suitably included or referenced in documents for the procurement of material, equipment, and services.

02.03 Suppliers'/Contractors' QA Programs. Determine if procurement documents require suppliers, contractors, and subcontractors to implement a QA program that meets the requirements of 10 CFR 63.142.

78070-03 INSPECTION GUIDANCE

General Guidance

This inspection procedure applies to the implementation of the U. S. Department of Energy's (DOE's) QA program during the design and construction of a geologic repository at Yucca Mountain. The DOE QA program is described in the Quality Assurance Requirements and Description (QARD) Manual, DOE/RW-0333P. This inspection procedure applies to structures, systems, and components (SSCs) important to safety, to design, characterization, and construction of barriers important to waste isolation, and to related activities described in the safety analysis report.

Selection of areas for evaluation during inspections should be based on the risk significance of the SSCs, related activities, and past performance. The scope of inspections should also consider the cumulative effect of failures related to low-risk-significant SSCs, regarding their potential effects on overall system performance and reliability.

Specific Guidance

03.01 Procurement Procedures. Review procedures used for procurement activities. Verify that procedures require the following information to be provided in procurement documents:

- a. Statement of work to be performed.
- b. Design basis or references to the design basis.
- c. Applicable regulatory, design, technical, administrative, and reporting requirements (e.g., 10CFR Part 21 reporting requirements).
- d. Drawings, specifications, codes, and industry standards.
- i. Identification of applicable QA program requirements.
- f. Test, inspection, and acceptance requirements.
- g. Provisions for establishing hold points.
- h. Access for audit or inspection by the purchaser and the U.S. Nuclear Regulatory Commission.
- i. Identification of documentation to be submitted to the purchaser or retained by the supplier, including any retention times.
- j. Schedule for submitting any documents to the purchaser for information, review, or acceptance.
- k. Requirements for reporting and dispositioning nonconformances.
- l. Special process requirements.
- m. Identification of any spare or replacement parts or assemblies and the appropriate technical and QA data required for ordering.

Verify that procedures require procurement documents to be prepared, reviewed, and approved in accordance with QA program requirements.

Verify that organizational responsibilities are described in procedures or other program documents that describe responsibilities for; (i) procurement planning; (ii) the preparation, review, and control of procurement documents; (iii) supplier evaluation and selection; (iv) bid evaluations; (v) and review and concurrence of suppliers' QA programs before initiation of activities. The involvement of the QA organization in the procurement process should also be described, including the requirement for the QA organization to review the procurement procedures and changes to the procedures.

03.02 Procurement Documents. Select a sample of procurement documents that have been issued to suppliers or contractors. Verify that the procurement documents include appropriate provisions to ensure material, equipment, or services meet the governing requirements and all applicable technical and QA program requirements, such as the information described in Section 03.01 above. Verify that all requirements in the procurement documents are correctly stated, inspectable, and controllable.

For the selected procurement documents, verify that audits of the suppliers or contractors were performed, and verify that the audits were adequate and pertinent for the material, equipment, or service being procured. Review the audits to verify that any areas of noncompliance identified were corrected. Verify that the suppliers are on the approved vendors list and that any restrictions assigned to the suppliers, if applicable, are referenced on the list and are appropriately accounted for in the procurement documents.

Verify that the procurement documents were reviewed and approved before issuance by affected organizations or disciplines, and by representatives from technical and QA organizations, in accordance with established procedures. These reviews should include considerations for applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements. Verify that comments resulting from the reviews were documented and resolved before approving the procurement document.

Verify that any changes to the procurement documents were reviewed by organizations affected by the change and were subject to the same degree of control as used in the preparation of the original documents. If any changes were incorporated into a procurement document as the result of proposal/bid evaluations or precontract negotiations, verify that an evaluation of the change was completed before awarding the contract. Verify that changes were evaluated against appropriate requirements, additional or modified design criteria, and analysis of exceptions or changes requested or specified by the supplier. Verify that evaluations include a determination of the impact such changes have on the intent of the procurement documents or quality of the material, equipment, or services to be furnished.

Verify that procurement documents include a statement that the provisions of Part 21 apply, if applicable.

Interview several persons who have reviewed procurement documents. Verify that the reviewers were not involved in the preparation of the documents. Verify that the reviewers are technically competent in the areas discussed in the procurement document in which they have completed reviews. Verify that the reviewers had available and used, as necessary, pertinent background information or data.

Verify that personnel performing the reviews have been trained and indoctrinated in QARD requirements and other applicable regulations before performing the reviews.

03.03 Suppliers'/Contractors' QA Programs. Select a sample of procurement documents that have been issued to suppliers or contractors. Verify that the procurement documents require the suppliers or contractor to have a documented QA program implementing the applicable sections of the QARD before starting work. Verify that procurement documents require suppliers to incorporate appropriate QARD requirements into any procurement documents issued to sub-suppliers. Verify if work is performed under the purchaser's or another affected organization's QA program. If work is performed under another affected organization's QA program, verify that the affected organization has been satisfactorily audited, is on the purchaser's qualified vendor's list, and that the work is adequately described and controlled in accordance with the requirements of the governing procurement documents.

78070-04 INSPECTION RESOURCES

An initial inspection of the design control program may be conducted approximately 1 year before submittal of an application. This inspection will consist of one inspector on site for 1 week. Preparations for the inspection, and documentation of the inspection will consist of 3 weeks. Implementation of the first inspection is 4 inspector-weeks.

After the construction authorization is issued and construction starts, at least semiannual inspections of the procurement document control program will be conducted by one inspector, for a total of 4 inspector-weeks per year.

After the operating license is issued, at least an annual inspection will be conducted by one inspector, for a total of 0.5 inspector-week per year.

78070-05 REFERENCES

U.S. Code of Federal Regulations, 10 CFR Part 63, "Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada."

Agency, "Yucca Mountain Review Plan, "NUREG XXXX, Draft Revision 1, dated August 2000.

U. S. Department of Energy's "Quality Assurance Requirements and Descriptions (QARD)," DOE/RW-0333P, latest revision accepted by NRC.

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