

NRC INSPECTION MANUAL

NMSS/DWM/HLWB

INSPECTION PROCEDURE 78300

SUPPLIER/VENDOR INSPECTION (PRE-LICENSING AND CONSTRUCTION)

PROGRAM APPLICABILITY: MC 2300

78300-01 INSPECTION OBJECTIVES

01.01 To determine if vendors of items classified as important to safety or important to waste isolation comply with an established quality assurance (QA) program that satisfies the requirements of 10 CFR 63.142.

01.02 To determine if vendors that supply important-to-safety or important-to-waste isolation products or services have developed and implemented adequate programs to evaluate and correct conditions adverse to quality, including the reporting requirements of 10 CFR Part 21.

78300-02 INSPECTION REQUIREMENTS

02.01 Vendor/Supplier Inspection. Determine that procurement documents require that suppliers, contractors, and subcontractors implement documented QA programs with appropriate procedural controls consistent with the requirements of 10 CFR 63.142, before the initiation of work.

02.02 Procurement Document Control. Determine that applicable regulatory requirements, including controls for documenting and reporting deficiencies and maintaining adequate quality, are suitably included in procurement documents for material, equipment, and services, and that these requirements are appropriately implemented by the supplier.

02.03 Corrective Actions. Determine if nonconforming items and deficiencies were evaluated for potential adverse effects, including the performance of a root-cause analysis for significant conditions adverse to quality, and that appropriate 10 CFR Part 21 evaluation and notification of defects and nonconformances were performed.

78300-03 INSPECTION 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 Manual (QARD), DOE/RW-0333P. This inspection procedure applies to Systems, Structures, 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 shall 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.

For instances where first-of-its-kind components or equipment are used in specific applications, it may be necessary to perform an inspection of the manufacturer's facility, to gain confidence in the capability of the item to perform its intended function. Other instances that may prompt an inspection are those components or equipment identified by Part 21 reports, or construction deficiencies reported pursuant to 10 CFR 63.73.

If the supplier/vendor is purchasing commercial-grade items and dedicating them as a basic component, for use as important-to-safety or important-to-waste-isolation items, this process should be evaluated in accordance with Inspection Procedure 78290, "Commercial-Grade-Item Dedication."

03.01 Vendor/Supplier Inspection. Verify that the applicable procurement documents require that contractors and subcontractors have established and implemented acceptable QA program. The vendor's documented QA program shall implement the applicable quality requirements specified in DOE's Quality Assurance Requirements Description (QARD) before to the initiation of work. The extent of the QA program applicability will depend on the scope, nature, or complexity of the item or service being procured. The procurement document shall also specify that the supplier incorporate the appropriate QARD requirements into any subtier supplier-issued procurement document.

Verify that appropriate procedural controls have been established to assure that the procurement documents include a statement of work the contractor will perform, that identifies requirements such as: (i) applicable regulatory, design, technical, administrative, and reporting requirements; (ii) drawings; (iii) specifications; (iv) codes and standards; (v) test and acceptance requirements; (vi) access for audit or inspection by the purchaser; (vii) identification of documentation to be submitted to the purchaser or retained by the supplier (including retention times); and (viii) special process instructions that should be completed by the supplier(s).

03.02 Procurement Document Control. Verify that the applicable procurement documents require that contractors and subcontractors have established and implemented appropriate procedural controls for reporting and disposition of nonconformances.

Procurement document changes to the scope of work, technical requirements, QA program requirements, right of access, documentation requirements, nonconformances, and hold points shall be subject to the same degree of control as used in the preparation of the original documents. Changes made as a result of proposal/bid evaluations or pre-contract negotiations shall be incorporated into the procurement documents.

For selected items, identify the attributes to be inspected to assure that procedures adequately describe and control the manufacturing process; that critical in-process tests adequately verify those attributes that cannot be verified after subsequent assembly operations; and that prescribed tests are performed on the product to confirm performance-based requirements.

03.03 Corrective Actions. Verify that procurement documents include requirements for the supplier to report nonconformances and purchaser approval of the disposition of nonconformances. The corrective action program shall also contain appropriate provisions to ensure that conditions adverse to quality are promptly identified and corrected. Criteria for determining a significant condition adverse to quality shall be established and the responsible management shall evaluate significant conditions adverse to quality for their extent and impact. Significant conditions adverse to quality, the cause of the condition, and the corrective actions to preclude recurrence shall be documented and responsible management shall determine the root cause of the problem and take corrective action to prevent recurrence.

If applicable, verify that procurement documents include requirements for the supplier to establish and maintain a QA program that complies with the requirements of Part 21, regarding the reporting of defects and noncompliances. If it is known that a vendor/subcontractor has issued a 10 CFR Part 21 notification, verify the accuracy and completeness of the information submitted by the reporting party to the purchasers (for deviations, as defined by 10 CFR Part 21) and/or NRC (for deviations determined to be defects).

78300-04 INSPECTION RESOURCES

An initial inspection of supplier/vendor programs may be conducted approximately 1 year before submittal of an application, provided DOE issued a purchase order, to the supplier/vendor, that invokes the requirements of Part 21. This inspection will consist of one inspector at the supplier's facility for 1 week. Preparations for the inspection and documentation of the inspection will consist of 1 week. Depending on the number of vendors/suppliers, implementation of the first inspections may require 2-6 inspector-weeks.

After the construction authorization is issued and construction starts, annual inspections of the vendor/supplier program will be conducted by one inspector. Depending on the number of vendor/suppliers, annual inspections may require 2-6 inspector-weeks per year.

Once construction is complete and the operating license is issued, an annual inspection of vendors/suppliers facility will be conducted by one inspector which may require 2-6 inspector-weeks per year.

78300-05 REFERENCES

U.S. Nuclear Regulatory Commission, NUREG-1804, "Yucca Mountain Review Plan," Draft Revision 2.

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."

U.S. Code of Federal Regulations, 10 CFR Part 21, "Reporting of Defects and Noncompliances"

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

U.S. Nuclear Regulatory Commission, Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products."

U.S. Nuclear Regulatory Commission, Information Notice 89-70 and supplements, "Possible Indications of Misrepresented Vendor Products."

U.S. Nuclear Regulatory Commission, NRR Office Letter No. 1300, "Procedures For Handling 10 CFR Part 21 and 10 CFR 50.55(e) Notifications of Defects, Noncompliances, and Construction Deficiencies."

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