

NRC INSPECTION MANUAL

IPSB

INSPECTION PROCEDURE 35021

POST-DOCKETING IMPLEMENTATION OF QUALITY ASSURANCE (QA) ACTIVITIES RELATED TO DESIGN, PROCUREMENT, AND CONSTRUCTION

PROGRAM APPLICABILITY: 2502

35021-01 INSPECTION OBJECTIVE

Determine if the applicant/constructor QA organization is executing the QA program in the areas of design, procurement and construction. Ensure that the QA program being implemented is consistent with the program described in the application for a COL.

This inspection procedure is a follow-up to Inspection Procedure 35017, "Post-Docketing Development of the Quality Assurance (QA) Program for Design and Procurement."

35021-02 INSPECTION REQUIREMENTS

02.01 Determine Status of Previous QA Findings. Identify the individuals assigned key positions and functions described by the QA program. Verify their work locations and the availability of applicant personnel during the period scheduled for the inspection.

When necessary, meet with applicant management to discuss any outstanding regulatory concerns from previous QA inspections. If necessary, arrange for subsequent detailed discussions in this regard by the principal inspector.

02.02 Licensee Surveillance of Vendors. Review selected applicant vendor surveillance QA procedures for adequacy. Verify that the applicant/contractor organization assigned responsibility for vendor surveillance and for measuring related QA program effectiveness exists.

- a. Identify the responsible QA individuals or groups.
- b. Select one procedure for each of the nine areas below and, with the assistance of the cognizant licensee QA individuals request the responsible person to demonstrate how they perform their assigned activity using these procedures to control vendor surveillance contractual activities as specified in NRC QA guidance.

(1) Control of Purchased Material, Equipment and Services:

- a) Conformance of items to procurement documents.
- b) Conformance of services to procurement documents.
- c) Assessment of quality-related activities.
- d) Source inspections and audits.

- (2) Identification and Control of Materials, Parts and Components.
 - a) Establishment of identification and control system.
 - b) Lineage traceability of items.
- (3) Control of Special Processes.
 - a) Establishment of process controls.
 - b) Qualification of personnel.
 - c) Qualification of procedures.
 - d) Qualification of equipment.
- (4) Inspection
 - a) Establishment of inspection program.
 - b) Independence of inspectors.
 - c) In-process inspections.
 - d) Option to inspect or monitor.
 - e) Recognition of hold points.
 - f) Sampling to verify acceptability.
 - g) Evaluation of inspection results.
- (5) Test Control
 - a) Establishment of test program.
 - b) Test requirements in test documents.
 - c) Test acceptance criteria.
 - d) Evaluation of test results.
 - e) Criteria for requiring retest.
- (6) Control of Measuring and Test Equipment (M&TE).
 - a) Calibration and control of M&TE.
 - b) Control of calibration standards.
 - c) Evaluation of discrepant items.
 - d) Maintenance of calibration status.
- (7) Handling, Storage and Shipping
 - a) Control of handling, lifting, rigging.
 - b) Control of storage of materials.
 - c) Control of storage of assemblies.
 - d) Control of shipping.
 - e) Control of cleaning.
 - f) Control of preservation.
 - g) Control of packaging.
- (8) Inspection, Test and Operating Status
 - a) Methods of indication of inspection status.
 - b) Methods of indication of test status.
 - c) Methods of indication of operating status.
- (9) Nonconforming Materials, Parts, Components
 - a) Control of nonconforming items.

- b) Control of nonconforming processes.
 - c) Identification and segregation nonconforming items.
 - d) Disposition of nonconforming items.
 - e) Inspection of repaired or reworked items.
 - f) Notification of parties affected by nonconformances.
- c. Review Records of Applicant Surveillance of Vendor Activities. Review vendor surveillance records for two (2) vendors and check if scope of surveillance, as appropriate, includes provisions to verify vendor performance of activities covered by (1) to (9) above.

02.03 Construction. This part of the inspection is accomplished by continuing the review that was begun in other QA procedures. Review the QA program construction procedures and verify the presence of the applicant's organization and individuals assigned responsibilities for performance or surveillance of related QA program effectiveness.

- a. Identification of responsible QA individuals or groups.
- b. Select one procedure for each of the 11 areas below, and with the assistance of the cognizant individuals responsible for executing (or assuring execution) the provisions of these procedures request the responsible person to demonstrate how they perform, or will perform, their assigned activity relating to these procedures. Also, assess how well the responsible individual understands the contents of procedures relating to his assigned execution or surveillance activities.

(1) Design Control

- a) Control field initiated design activities.
- b) Control all changes to design.

(2) Procurement Document Control

- a) Control of field initiated procurement actions.

(3) Control of Site Initiated Purchased Material, Equipment and Services

- a) Conformance of items to procurement documents.
- b) Conformance of services to procurement documents.
- c) Source inspections and audits.
- d) Documentation of evidence of conformance.
- e) Assessment of quality-related activities.

(4) Identification and Control of Materials, Parts and Components

- a) Establishment of identification and control system.
- b) Lineage traceability of items.

(5) Control of Special Processes

- a) Establishment of process controls.
- b) Qualification of personnel.
- c) Qualification of procedures.
- d) Qualification of equipment.

(6) Inspection

- a) Establishment of inspection program.
- b) Independence of inspectors.
- c) In-process inspections.
- d) Option to inspect or monitor.
- e) Recognition of hold points.
- f) Sampling to verify acceptability.
- g) Evaluation of inspection results.

(7) Test Control

- a) Establishment of test program.
- b) Test requirements in test documents.
- c) Test acceptance criteria.
- d) Evaluation of test results.
- e) Criteria for requiring retest.

(8) Control of M&TE

- a) Calibration and control of M&TE.
- b) Control of calibration standards.
- c) Evaluation of discrepant items.
- d) Maintenance of calibration status.

(9) Handling, Storage, and Shipping

- a) Control of handling, lifting, rigging.
- b) Control of storage of materials.
- c) Control of storage of assemblies.
- d) Control of shipping.
- e) Control of cleaning.
- f) Control of preservation.
- g) Control of packaging.

(10) Inspection, Test and Operating Status

- a) Methods of indication of inspection status.
- b) Methods of indication of test status.
- c) Methods of indication of operating status.

(11) Nonconforming Materials, Parts, Components

- a) Control of nonconforming items.
- b) Control of nonconforming processes.
- c) Identification and segregation nonconforming items.
- d) Disposition of nonconforming items.
- e) Inspection of repaired or rework.
- f) Notification of parties affected by nonconformances.

02.04 Review of Vendor Surveillance/Construction Audits. Obtain one audit report for each of the following categories. With the assistance of the responsible licensee individual, review the audit reports against the Final Safety Analysis Report (FSAR) and the NRC QA guidance for adequacy .

- a. Architect-Engineer (A-E) vendor surveillance.
- b. Nuclear steam supply system (NSSS) provider, vendor surveillance.

- c. Surveillance of one major equipment or material vendor.
- d. Constructor's onsite QA manual development/implementation, as appropriate.
- e. Internal audit of applicant (or consultant) surveillance activities.

02.05 Review of Corrective Actions. For each audit report reviewed in 02.04 above, review the corrective actions recommended and taken, and the timeliness.

35021-03 INSPECTION GUIDANCE

General Guidance

This inspection should be scheduled for about three or four weeks after the issue of the draft safety evaluation report for the application.

Specific Guidance

03.01 Status of Previous QA Findings. The inspection should begin with a brief meeting with cognizant members of management and individuals responsible for key QA functions in those areas of the QA program included in the scope of the inspection. The meeting is considered an important and necessary activity which is required to ensure effective and expeditious completion of subsequent inspector examinations of the QA program being implemented.

During the meeting with the applicant, the inspector shall define in broad terms the scope of the inspection; identify the inspection responsibilities assigned to each inspector; and identify Inspection Procedure 35021 and Section 17.1-3 of NUREG 0800 as the guidance documents for the inspection.

At the meeting the applicant should be asked to provide an update of the status of project activities to allow the team to assess the desirability of performing examinations in new areas of program activity.

03.02 Licensee Surveillance of Vendors.

There will be wide variations in applicant involvement in this area. The applicant may retain total control or may delegate part of all of the function to the major contractors. However, as a minimum, the applicant must have QA procedures in effect for control of vendor activities and for the purpose of measuring the effectiveness of whatever vendor surveillance method used.

- a. In this requirement, it should only be necessary to identify the individual directly responsible for this function. It should have been determined previously that the individual is qualified and aligned in the organization as described in the QA manual or FSAR.
- b. This review is best conducted with the direct assistance of the cognizant individual identified in section a. above. This will save time and also, enable the inspector to evaluate the responsible individual's knowledge and familiarity with the procedures. The procedures may also serve the procurement functions, such as preparation of bid packages. However, in reviewing the activity discussed by the

procedures with the responsible surveillance individual(s), it must be clearly established how they are used for control of vendor performance.

The emphasis of this requirement is the control of vendor performance. Should a procedure selected from any group not be adequate, an alternate procedure should be reviewed prior to final judgement on overall adequacy.

03.03 Construction. This portion of the inspection is accomplished in the same general manner as a vendor surveillance described above. In most projects, construction is totally contracted and the QA program delegated to the constructor or A-E. In a number of projects the applicant contracts construction but manages the work and QA program. Also, the applicant may be his own A-E or constructor. In any case, the applicant must have a minimum program of QA procedures for control of construction activities and measurement of the effectiveness of the program in effect for construction.

- a. This refers to the corporate or project QA individual or group who is expected to be knowledgeable of the QA system for construction.
- b. Same as guidance for vendor surveillance except, keep in mind that these procedures are for control of onsite construction activities and measuring the effectiveness of the implemented QA program onsite, if and when construction commences. The individual requirements should be clear as stated.

03.04 Review of Vendor Surveillance/Construction Audits. If a single report of one type of audit is not of sufficient scope to make a judgement of adequacy, additional reports of the type should be reviewed. If the audit team leader is available, it is preferable that he assist the inspector in review and understanding of the reports. Otherwise, the cognizant corporate QA individual(s) should assist. Each report should be compared generally with the reference standard for audits, keeping in mind that these may be internal or external audits, or both.

03.05 Review of Corrective Actions. This requires the inspector to verify responses of the audited organization, to the audit reports and of course any followup actions indicated for either audited or auditing organizations. The reference standard should be used for guidance in this effort.

35021-04 RESOURCE ESTIMATE

This inspection procedure supports the review of a COL application per the guidance contained in Section 17.1-3 of NUREG 0800. The resource estimate for this inspection procedure is approximately 240 hours of direct inspection effort.

35021-05 REFERENCES

NUREG 0800, Section 17.1-3, "Quality Assurance Program"

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