INSPECTION PROCEDURE 35017

POST-DOCKETING DEVELOPMENT OF THE QUALITY ASSURANCE (QA) PROGRAM FOR DESIGN AND PROCUREMENT ACTIVITIES

PROGRAM APPLICABILITY: 2502

35017-01 INSPECTION OBJECTIVES

Determine if the applicant's QA program was appropriately translated from the FSAR into implementing procedures without substantive deviations for design and procurement activities. This procedure should precede Inspection Procedure 35021, "Post-Docketing COL QA Inspection of Design, Procurement and Construction." This procedure is to be used concurrent with Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and Section 50.55(e) Programs for Reporting Defects and Nonconformances."

35017-02 INSPECTION REQUIREMENTS

02.01 Examine QA activities related to the Design Process. Determine if the QA program being implemented for the project design activities in process is consistent with the items listed below. Where possible, selections should relate to individuals, activities and/or areas of implementation not previously selected for examination during the pre-docketing inspection. Review applicable guidance in Section 17.1-3 of NUREG 0800. Ensure the following:

a. The organization is staffed as described in the QA manual for quality assurance personnel and others performing activities affecting quality.

b. QA staff with oversight of design activities demonstrate knowledge of the QA program.

c. QA procedures to control current design activities are used to the extent applicable.

d. The design QA organization conducts review and approval activities in accordance with the appropriate procedures.

e. Internal/external audits of design activities have the following characteristics;

   (1) Are planned (100%).

   (2) Were conducted in a timely manner (100%).

   (3) Were effectively implemented (2 audits).

f. Audits of the following activities were performed and audit reports generated subsequent to the pre-docketing inspection:

(1) Applicant's engineering activities.

(2) Architect-engineer activities.

(3) Nuclear steam supply system (NSSS) provider design activities.

(4) At least one other applicant procured engineering contractor.

(5) Verify that records of corrective actions exist for the most current of the above reports where such action was indicated.

02.02 Review Design Control Implementation. Select one structural and one major mechanical component or system procurement specification and their related representative drawings and calculations for review. With the help of the person(s) responsible for preparation or review of the documents selected, ensure that:

a. QA procedures are readily available.

b. Engineers are knowledgeable of the QA program.

c. Procedures exist for review of calculations.

d. Procedures exist for review of drawings.

e. Procedures exist for review of specifications.

f. Procedures exist for review of quotations.

g. Training was conducted in design QA.

h. For one of the specifications selected for examination, determine if the person preparing or reviewing the specification can demonstrate the availability, use, and reference to data required to be translated from the Final Safety Analysis Report (FSAR), codes, standards or Regulatory Guides to the procurement document. Select three FSAR technical requirements which should have been translated to the procurement document and have him/her verify the appropriate delineation of these criteria within the procurement document.

02.03 Examine Procurement Activities. Determine if the implementation of the QA program for the activities listed below is consistent with status of procurement activities in process. Where possible selections should relate to individuals, activities and/or areas of the implemented QA program not previously selected for examination during the pre-docketing inspection.

a. The organization is staffed as described in the QA manual for QA personnel and others performing activities affecting quality.

b. QA or other staff personnel responsible for procurement demonstrate knowledge of QA program.

c. The current QA procedures to control the activities of procurement are in use to the extent applicable (examine one set).

d. Examine the schedule and records of internal/external QA program audits and determine that audits for procurement activities:

(1) Were planned (100%).

(2) Were conducted in a timely manner (100%).

(3) Were effectively implemented (2 audits).

e. Examine audit reports generated subsequent to the predocketing inspection and ascertain whether audits of the following activities were performed:

(1) Applicant's procurement activities.

(2) Architect engineer's procurement activities.

(3) NSSS supplier's procurement activities.

(4) Major supplier's procurement activities.

f. For the most recent of the reports in e. (1) to (4), verify that records of corrective actions exist, if such action was indicated.

02.04 Review Procurement Control Implementation. Select one structural and one major mechanical component procurement package (in process or completed) for review. With the assistance of the cognizant procurement supervisor or buyer and in reference to the selected procurement packages, determine if:

a. QA procedures for procurement control are readily available.

b. Purchasing agents and buyers are knowledgeable of QA program requirements.

c. Prior to requests for quotations:

(1) Drawings and specifications were reviewed and approved.

(2) Supplier capability was evaluated.

(3) Final procurement package was reviewed.

(4) Authorization to request quotations granted.

d. Subsequent to receipt of quotations:

(1) Quotation was compared to procurement package.

(2) Technical exceptions were evaluated.

(3) Authorization of contract award follows procedures or instructions prescribed.

e. Records reflecting the above are available.

f. Training was conducted for procurement QA personnel.

02.05 Review Licensee Supplier Surveillance Activities. Determine if the applicant has assigned staff to be responsible for supplier surveillance. Determine if the records of completed surveillances related to the delegated activities listed below are sufficient to verify conformance to procurement documents. (Select two contracts for examination. When possible make selections from both a. and b. below).

a. Services

(1) Engineering

(2) Design

(3) Procurement

(4) Surveillance

(5) Audit

b. Material and Equipment

(1) Identification and control of material, parts and components

(2) Control of special processes

(3) Inspection

(4) Test control

(5) Control of measuring and test equipment

(6) Handling, storage and shipping

(7) Testing

(8) Nonconforming materials, parts, components

02.06 Pre-docketing QA Inspection Followup. Inspect each QA program implementation deviation documented in the pre-docketing inspection report and for which appropriate followup was not achieved or required prior to the docketing of the tendered application, complete the following. Refer to Inspection Procedure 35005, “Pre-Docketing COL QA Inspection ,” and repeat, as appropriate, the same inspection requirements selected for examination of QA program implementation which resulted in the identification of the deviation.

35017-03 INSPECTION GUIDANCE

General Guidance

The two to five months period after docketing should be established as the window for completion of this post-docketing inspection. Observations completed during the pre-docketing inspection and review will have indicated the status of the implemented QA program. If the pre-docketing results indicate that some activities could be lacking in substance or detail, the post-docketing inspection should be done early. If there were few potential problems identified during pre-docketing activities, the Region should plan to conduct the inspection during the fourth or fifth month after docketing. The four month

period after docketing should provide for the initiation of other design and procurement activities not underway during the pre-docketing reviews.

Specific Guidance

03.01 Examination of Design. The purpose of this section is to assess the adequacy of the ongoing QA program for control of applicant/contractor design activities.

a. The inspector need only verify that individual(s) actually performing specific QA functions are filling positions and performing activities described in the QA manual.

b. Assess the knowledge of the individuals by questioning QA personnel regarding the purpose and their general knowledge of the QA program.

c. Examine at least one controlled set of QA procedures in use in the design section. Select procedures that provide surveillance over delegated design activities and compare this set with the verified controlled copy.

d. This may be accomplished by discussion with the person(s) responsible for review and approval of the QA procedures.

e. This refers to QA program planned audits of the design section internal to the applicant's organization or external, as in the case of an architect-engineering firm. Timely is intended to mean that audits are scheduled prior to the completion of a major portion of the activity, and that they occur ± 15 days of schedule unless reasonable explanation is recorded.

f. If audit reports exist that have not been reviewed previously by the inspectors these may be considered. The audits may be pre-award evaluations or post-contract implementation audits. Normally, contracts would not be awarded prior to pre-award qualification of constructors and auditing may be necessary to provide for the initial qualification of a contractor.

   For the most current of the reviewed audit reports, the inspector should ask to see followup documentation, if applicable.

03.02 The review of design control implementation requires selection of documents which include two specifications, either completed or in process, and any related drawings and calculations . Using these documents, the inspector will examine the applicant/contractor design review process. The inspector will request the responsible lead engineer or supervisory engineer to produce the applicable QA procedures, explain their use for design control, and finally, produce documentation of the reviews and evidence that selected FSAR criteria were translated into the design output document. The inspector will also verify documentation of QA training conducted for design personnel.

03.03 and 03.04 The guidance in 03.01 also applies. As done above, the inspector will obtain assistance from the cognizant procurement supervisor or buyer. The individual will be asked to produce the QA procedures prescribed for control of the selected procurement packages, explain use of the procedures in the control process, and finally, produce documentation of the various reviews and evaluations required.

The inspector will also verify documentation of QA training conducted.

03.05 Supplier Surveillance. This section is applicable to any procurement package for equipment subject to QA program.

03.06 Predocketing QA Inspection Followup. Verify the status of corrective action commitments, adequacy of revised QA program procedures and instructions, and acceptability of program implementation or ongoing activities. The applicant should have responded to any substantive NRC concerns identified during the predocketing inspection. If other program deviations or unresolved items were identified in the inspection report issued subsequent to completion of the predocketing activity, a written reply to these items should have been received.

35017-04 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.

35017-05 REFERENCES

NUREG 0800, Section 17.1-3, “Quality Assurance Program”

END