

PRE-DOCKETING COMBINED LICENSE QUALITY ASSURANCE CONTROLS INSPECTION

PROGRAM APPLICABILITY: 2502

35005-01 INSPECTION OBJECTIVE

To determine whether the quality assurance (QA) program used in the development of an application for a combined license (COL) contains any substantial deviations.

35005-02 INSPECTION REQUIREMENTS

In order to facilitate NRR's technical review of a COL application, conduct a pre-docketing audit/inspection of the QA controls for preparation of the COL application. Assess the extent and effectiveness of the implementation of the QA program, with particular emphasis on the areas listed below:

02.01 Assess the QA Organization by reviewing the following:

- a. Organizational description and charts of the lines, interrelationships, and areas of responsibility and authority for all organizations performing quality-related activities,
- b. Organizational location, degree of independence from the performing organization, and authority of the individuals assigned the responsibility for performing QA functions,
- c. Organizational provisions for ensuring the proper implementation of the QA program.

02.02 Assess the QA Program by reviewing the following:

- a. Scope of the QA program,
- b. Provisions to ensure proper definition of the QA program,
- c. Programmatic provisions to ensure proper implementation of the QA program,

- d. Provisions to ensure adequacy of personnel qualifications.

02.03 Assess the Quality Assurance aspects of Design Control by reviewing the following:

- a. Scope of the program for design activities,
- b. The organizational structure, activity, and responsibility of the positions or groups responsible for design activities,
- c. Provisions to carry out design activities in a planned, controlled, and orderly manner,
- d. Provisions for interface control,
- e. Provisions to verify or check the technical adequacy of design documents,
- f. Provisions to control design changes.

02.04 Assess Procurement Document Control by reviewing the following:

- a. Provisions to ensure that applicable regulatory requirements, technical requirements, and QA program requirements are included or referenced in procurement documents,
- b. Provisions for review and approval of procurement documents.

02.05 Assess the use of Audits by reviewing the following:

- a. Provisions for audits to verify compliance with all aspects of the QA program and to determine the effectiveness of the QA program,
- b. Responsibilities and procedures for auditing, documenting, and reviewing audit results, and designating management levels to review and assess audit results.

35005-03 INSPECTION GUIDANCE

General Guidance

The application will not be docketed unless the established and implemented QA program has no substantive deviation from NRC QA guidance applicable to activities conducted prior to docketing. The Region must provide complete comments to NRR on QA Program quality before the application is assigned a docket number.

Although there is no regulatory requirement for a review of QA processes before an application is submitted, a pre-application review is likely to be beneficial to both the staff and the applicant since it will facilitate early identification of substantial QA issues and

support timely completion of the COL application review. A substantial deviation in QA controls (1) reflects a significant departure from established NRC and industry standards and (2) results in a lack of assurance of the integrity and reliability of the applicant's COL data or analyses.

Audit/Inspection Timing

The decision about when to perform this audit/inspection will be made on a case-by-case basis with agreement by the potential applicant.

- a. If the potential applicant has requested the conduct of a pre-submittal QA controls audit, the staff shall request information related to the QA controls applied to COL activities. A potential applicant may choose to submit a QA program description to more efficiently provide this QA control information.
- b. If an applicant did not submit a description of the COL QA controls before the application was submitted, the staff will schedule the audits/inspections required by this procedure immediately after the application is received.

Specific Guidance

The team will audit/inspect a suitable sample of in-process COL-related design and procurement activities to verify consistent implementation of QA controls. The staff will review the applicant's QA control framework to determine if the quality related activities are consistent with the guidance contained in Section 17.1-3 of NUREG-0800.

In particular, the staff will assess the following attributes of the QA control framework:

1. QA controls are applied to all COL related activities that would affect data or analyses used to design and construct future SSCs important to safety.
2. The QA control framework should be established such that the applicant retains the responsibility for the establishment and execution of all QA controls, including those aspects of the program delegated to contractors and consultants.
3. For applicants who delegate the authority for design to others (consultants, architect-engineering firms, nuclear steam system supply vendor), the staff will review the applicant's applicable procurement and vendor surveillance program instructions. Where the applicant has delegated design or procurement activities to others, the review shall examine the applicant's surveillance of contractor activities to assure that each delegated element of COL QA controls is being established and executed consistently.
4. The COL QA control framework should include programmatic measures to the extent necessary for personnel from the applicant's organization to make a determination during each phase of the project that an acceptable program has been established and is being implemented in accordance with the requirements of the program.

5. Preparation of analysis, calculations, design drawings, specifications and procurement documents, related verification reviews, and control of engineering documents and changes thereto are being controlled in a consistent manner

03.01 - 03.05 QA Controls Assessment Guidance: Guidance for assessing the attributes of the applicant's QA controls is provided in NUREG-0800, Sections 17.1-3, "Quality Assurance Program."

35005-04 RESOURCE ESTIMATE

This inspection procedure supports review of an COL application per the guidance contained in Section 17.1-3 of NUREG-0800. This inspection may be conducted independently by a team of regional inspectors, but a more efficient use of NRC resources would have the team include the members of NRR assigned the responsibility for the pre-docketing substantive review of the applicant's QA program. The resource estimate for this inspection procedure is approximately 200 hours of direct inspection effort.

35005-05 REFERENCES

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

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