INSPECTION PROCEDURE 35301

PREOPERATIONAL TESTING
QUALITY ASSURANCE

PROGRAM APPLICABILITY: 2509

35301-01 INSPECTION OBJECTIVES

01.01 Ascertain that the applicant has a QA program that will provide controls over the conduct of preoperational testing and related activities.

01.02 Ascertain that the applicant's QA program which covers preoperational testing activities has been developed consistent with Final Safety Analysis Report (FSAR) commitments and Regulatory requirements.

01.03 Ascertain that the applicant's QA program which covers preoperational testing activities has been implemented.

35301-02 INSPECTION REQUIREMENTS

02.01 Management of the QA Program and Quality Verification

a. Authorities and Responsibilities

1. QA Manual Review

(a) Determine that formal requirements relating to authorities and responsibilities of individuals or groups managing the quality assurance program or performing quality verification functions are in accordance with those set forth in the application.

(b) Determine that formal responsibility has been delegated for periodically or regularly auditing the status and adequacy of the QA program.

2. Implementation

(a) Verify, by direct questioning, of 50% of the key personnel utilized in the applicant's onsite QA organization, that they understand their basic responsibilities.

02.02 QA Surveillance and Inspection

a. Surveillance Responsibilities

1. Verify that requirements have been established (e.g., inspection frequencies) and procedures or checklists developed for a QA/QC organization to review and monitor the following activities on a regular basis:

- Conduct of testing
- Tracking of test deficiencies
- Test documentation
- Document control
- Control of measuring and test equipment
- Cleanliness control
- Field changes and modifications
- Maintenance during preoperational testing
- QA records

2. Verify that responsibilities for the QA surveillance activities identified above are specified in writing.

3. Select three recently completed QA surveillance activities. Review the documentation to determine that the surveillance activities were carried out in accordance with 02.a(1) above.

4. During systems turnover, verify by observation and document review of system turnover packages, that QA/QC surveillance of system turnover activities from construction to the preoperational test organization are being conducted in accordance with established procedures or checklists.

b. Corrective Actions

1. Determine that formal controls include requirements or features that will assure notification of individuals or groups responsible when significant deficiencies are identified during inspection.

2. Verify that responsibilities have been assigned in writing for assuring that corrective actions are taken for deficiencies identified during inspection.

3. Verify that requirements have been established for reinspection of deficient areas where appropriate.

02.03 Audits

a. Authorities and Responsibilities

1. Verify that responsibilities have been assigned in writing for the following:

- Overall management of the audit program.

- Approving audit procedures.
- Determining the adequacy of the qualifications of audit personnel.
- Determining the need for special training for audit personnel.
- Determining the independence of audit personnel.
- Assuring corrective actions are taken for deficiencies identified during audits.
- Determining when reaudits are required.
- Issuance of audit reports to management.
- Periodic review of the audit program to determine its status and adequacy.

2. Verify that subject areas to be audited and audit schedules have been defined.

3. Verify that methods or administrative channels have been defined for taking corrective actions when deficiencies are identified during audits.

4. Verify that requirements have been defined to require independence of audit personnel.

5. Verify that distribution requirements for audit reports have been defined.

b. Implementation

1. Verify, by direct questioning of 25% of the people that personnel assigned responsibility for audit functions understand the defined requirements.

2. Verify that the preoperational test program has been audited by reviewing available audit reports. Verify that personnel performing the audits were not involved in either the performance or the inspection of the activity audited.

3. Verify that corrective actions are being taken when deficiencies are identified.

02.04 Training and Qualification of QA Personnel

a. Qualification of Personnel. Verify by review of established administrative controls, including job position descriptions, that minimum educational, experience or qualification requirements have been established in writing for the following positions:

- Supervisory positions in the on-site QA organization.
- Supervisory positions in the off-site QA organization.
- QA surveillance and inspection personnel.
- QA auditors.

b. Implementation. Verify by review of personnel records that the following personnel meet the minimum educational, experience and qualification requirements established for the assigned positions:

1. Off-site QA supervisor (Audit) or equivalent

2. On-site QA supervisor

3. QA inspector

4. QA auditor

Give emphasis to verifying that replacement QA personnel or those newly assigned to the on-site organization, meet position requirements.

NOTE: If preoperational testing QA/QC personnel are the same as the operational QA personnel, perform Procedure No. 36301, II.5 in lieu of the above (II.4.b.(2), (3) and (4)).

c. Training

1. Verify that a training program has been established for QA auditors and inspectors which includes the following as a minimum:

- Overall company policies, procedures and instructions which establish its QA program.

- Procedures or instructions which implement the QA program related to specific job-related activities.

2. Verify that responsibilities have been assigned in writing for the training activities identified in a. above.

3. Verify that two selected quality assurance inspectors have received the training identified above.

35301-03 INSPECTION GUIDANCE

03.01 Management of the QA Program and Quality Verification

a.1(a) It is the responsibility of the licensee to establish in writing the authorities and duties of persons and organizations performing QA functions. ANSI N18.7-1976 makes the point that QA, in the broad sense, includes both: (1) the line organizational units (test, operations, maintenance and other groups) assigned the responsibility for performing certain work functions or activities in accordance with established requirements and; (2) quality verification functions (personnel responsible for verifying that established controls are being implemented and are adequate). The inspection effort should be directed in this section to QA management and quality verification functions (typically performed by the QA/QC group(s) or department).

a.1(b) Criterion II of Appendix B to 10 CFR 50 requires the licensee to regularly review the status of the QA program. Inherent in this review requirement is the requirement for the licensee to evaluate the adequacy of the QA program. The inspection effort should be directed to assuring that responsibility has been established in writing for accomplishing a regular review of the program.

a.2(a) The type and depth of the questioning should be designed to assure that key personnel understand their general and basic responsibilities as presented in the QA Manual.

03.02 QA Surveillance and Inspection

a. Surveillance Responsibilities. Criterion X of Appendix B requires that a program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Such inspections must be performed by individuals other than those who performed the activity being inspected. Criterion XVI of Appendix B requires that measures shall be established to assure that conditions adverse to quality such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified. The inspection effort should be directed to determining that an on-site QA/QC organization has been assigned responsibility for surveillance of preoperational test activities. Preoperational test activities that will require inspection should be identified and appropriate procedures or checklists developed for the conduct of that surveillance.

b. Corrective Actions. Individuals assigned responsibility for regular review of the status of the program need and require certain types of information to fulfill their responsibilities. The applicant's QA manual should recognize this need and require the review of significant deficiencies disclosed during the operating life of the facility by designated individuals to determine what corrective actions, if any, should be applied to the QA program and manual. Other types of deficiencies may disclose weaknesses or inadequacies in any number of areas covered by the QA manual and preoperational test control procedures and should also be required to be reviewed for the reasons stated above. For example, a history of repeated minor deficiencies could be indicative of a more serious problem.

Procedures should be established to assure that deficiencies will be reported to responsible line supervision for resolution. A formal system should be established for documenting and tracking deficiencies including corrective action taken.

Where identified deficiencies indicate that there has been a breakdown in preoperational test administrative controls or in QA/QC, requirements for reinspection to verify that corrective actions have been effective should be specified. The inspection effort should be directed to determine that requirements and responsibilities for reinspection, where appropriate, have been established.

03.03 Audits

a.1 Safety-related activities performed during preoperational testing should be audited to verify conformance to test commitments and administrative controls for testing and other safety-related activities (e.g., maintenance and modification). Section 17 of the FSAR will normally address or identify many of the audit program requirements (e.g., audits will be conducted using procedures; auditors will be independent, etc.).

The inspection effort should be directed at assuring that the licensee's audit program provides for formal designations of responsibilities to manage and implement the program. The construction, operations, or a separate audit organization could perform the required audits.

a.2 A listing of audit subjects and schedules should exist for auditing all segments of the applicant's QA program requirements applicable during preoperational testing.

a.3 Audits may and probably will disclose deficiencies that will require corrective action. The licensee's program should formally define his methods for handling such deficiencies including the documentation requirements relating to completed corrective actions. The program should also identify which personnel in his organization are to receive documentation relating to corrective actions.

b.2 Early in the preoperational phase at the plant one or more audits should be performed to determine if an adequate preoperational testing program has been established. The audit report(s) should reflect that the overall test program has been reviewed for conformance to commitments contained in Sections 14 and 17 of the FSAR (e.g., test controls, test plans and schedules, assignment of testing responsibilities, training and qualification of test personnel and plans for on-site QA surveillance and inspection).

03.04 Training and Qualification of QA Personnel

a. Qualification of Personnel. General statements are found in the FSAR and industry standards which require QA personnel to have the "...education and experience qualifications commensurate with the complexity or special nature of the activities to be inspected or audited..."

In translating these general requirements to those that should be specifically required for QA/QC organization personnel, the following guidance is provided:

The on-site QA supervisor should be required to have the equivalent of an engineering degree, and quality assurance experience in testing or inspection including at least one year at a nuclear power plant.

The off-site QA principal responsible for preoperational testing audits should have a testing or operations/engineering background, QA experience, a thorough understanding of the applicant's QA policy and be QA program oriented.

Personnel involved in the performance, evaluation or supervision of non-destructive testing of safety-related items should meet the qualification requirements set forth in ANSI/ASME N45.2.6-1978 and as specified in SNT-TC-1A and supplements (Society of Non-destructive Testing - Technical Council). These qualification requirements have been defined in terms of three levels of capability, i.e., Levels I, II and III. The education and experience requirements for a qualification Level certification are set forth in Section 3.5 of ANSI/ASME N45.2.6-1978.

Qualification requirements similar to those specified in ANSI/ASME N45.2.6-1978 for Level I, II and III inspectors should be defined and established for QA/QC inspectors and auditors.

35301-04 REFERENCES

ANSI N18.7-1976; Section 17 of the FSAR; Appendix B of 10 CFR 50

END