

# NRC INSPECTION MANUAL

DQASIP

## INSPECTION PROCEDURE 35060

### LICENSEE MANAGEMENT OF QA ACTIVITIES

PROGRAM APPLICABILITY: 2511, 2512

#### 35060-01 INSPECTION OBJECTIVE

To determine the status and effectiveness of licensee management and implementation of the corporate quality assurance program for ongoing activities of design, procurement and construction.

#### Inspection Schedule

| <u>Inspection</u> | <u>May Be Started</u> | <u>Must Be Started</u>                 | <u>Must Be Completed</u> |
|-------------------|-----------------------|--|--------------------------|
| Initial           |                       | Within six months<br>of issuance of CP |                          |
| Subsequent        |                       | Every 18 months                        |                          |

#### 35050-02 INSPECTION REQUIREMENTS

##### 02.01 Inspection Planning

- a. This procedure should be conducted at a frequency of every 18 months or at a minimum, twice during the construction program, and should be completed within 6 months of start date.
- b. This inspection should be planned to complement Inspection Procedure 37055 both in timing and scope. The inspection procedure completed first, should provide input to the other.
- c. The following items should be reviewed and/or evaluated as part of the inspection planning:
  1. QA commitments (SAR Chapter 17).
  2. Inspection history with particular emphasis on Inspection Procedure 35100 conducted over the previous year.
  3. 10 CFR 50.55(e) and 10 CFR Part 21 reports and resolutions.

4. Status of construction.

5. If the licensee utilizes an external A/E, contact RIV LCVIP and review the two most recent LCVIP inspections of that A/E and any responses available.
  6. Review recent Bulletins, Circulars, and Information Notices sent to the licensee.
- d. Inspection planning should be oriented toward assessing licensee QA program effectiveness.

02.02 Quality Assurance Program. The corporate quality assurance organization and its function shall be reviewed by use of interview(s) with QA management, observation of activities in process, and a review of documentation.

- a. QA Program Changes. Determine if there have been any changes since the previous NRC inspection. Where substantive changes have been made in areas 1 through 5 listed below, complete related inspection requirements.
  1. Organizational structure
    - (a) Why was the change instituted?
    - (b) What was the effect on QA effectiveness?
    - (c) Has QA independence been retained?
    - (d) Were substantive changes reported to the NRC?
  2. QA management personnel
    - (a) Review qualifications of replacement or new manager.
    - (b) Was there an impact on QA effectiveness?
    - (c) Was it reported to the NRC? (if it should have been)
  3. QA staff
    - (a) Considering project status, type of organization and assigned responsibilities, compare existing staff level and composition with previous inspection.
    - (b) If there has been a QA staff decrease - what area, why, and what is the impact on QA effectiveness?
    - (c) Is QA staff considered adequate? This must be supported by objective evidence of failure of QA effectiveness.
    - (d) Does QA staff responsibility include areas other than the units under construction?
  4. QA policy
    - (a) What is the change?
    - (b) How does it affect SAR commitments relative to organization structure, QA responsibilities and QA effectiveness?

- (c) Has independence of QA been retained?
- 5. QA procedures
  - (a) Review at least two different changes to QA procedures preferably in the areas of design, procurement or audit.
  - (b) Verify that changes were approved at appropriate management levels.
  - (c) Verify that document control requirements have been complied with; i.e. distribution, effectivity.
- b. Licensee Reviews of QA Program Effectiveness. Verify that the licensee has regularly reviewed the status and adequacy of the quality assurance program.
  - 1. Licensee effectiveness review
    - (a) Determine the means and criteria used to determine QA program effectiveness.
    - (b) Determine frequency of review.
  - 2. Recommendations and followup
    - (a) Review the two most recent periodic reports for compliance with procedural requirements.
    - (b) Verify that recommendations have been dispositioned in a timely manner.
- c. Corporate QA - Site QA interface
  - 1. Reporting
    - (a) Determine what QA/QC reports are compiled by the site QA and submitted to corporate QA.
      - (1) Type and intent of report.
      - (2) Information transmitted.
      - (3) Frequency.
    - (b) Ascertain corporate QA use of reports.
      - (1) Reporting problems to upper management and interface organizations (engineering, procurement) including followup of QA findings.
      - (2) Trend determination.
      - (3) Supplier evaluation.
      - (4) Feedback to site QA.

2. Review of Site QA Reporting

- (a) Selectively review an example of the reporting mechanism starting with a report submitted by site QA approximately 6 months prior to this inspection. See if the reports have identified problem areas, trends, corrective action and any licensee followup.
- (b) The inspectors may have to review other documentation to establish corporate QA effectiveness.
- (c) Determine if C1(a) and C1(b), above are adequate and effective.

02.03 Design. If the licensee performs his own Architect/Engineer services, utilize Section 02.03a of this procedure. If the licensee has contracted out the A/E function, then use Section 02.03b.

a. Design Licensee Acting As Own A/E

1. Design Assurance - Responsibility. Review the licensee's organizational structure and procedures to determine what organization is primarily responsible for design assurance: QA or design engineering. The review should establish:

- (a) Organizational responsibility for design verification
- (b) Compliance with NRC positions in relation to design verification - particularly independence
- (c) The interface between QA, project design, and design disciplines
- (d) Policy and responsibilities for review of site originated designs or changes
- (e) That if substantial changes in design assurance responsibilities, if any occurred, independence of design verification has not been compromised

2. Personnel Interview

(a) Management Interview. Interview at least three design organization managers, at least one from project and two from discipline groups. Determine adequacy in the following areas:

- (1) Their understanding of design verification
- (2) Their interface with design assurance and QA
- (3) Their implementation of design verification
- (4) Means of dispositioning design verification findings
- (5) Criteria for competency of design verifiers

b. Design Engineer Interview - Designer

- 1. Determine adequacy of designer understanding/implementation of procedures for the control of the design process.

2. Identify a recent design of two engineers (i.e., select from different disciplines, civil, mechanical, electrical, etc.) and have the individual discuss his handling of the following for design selected.
  - Design inputs, received and established
  - Design assumptions, received and established
  - Design interface with other disciplines/organizations.
  - Which "design documents" (SAR or other) are used as reference to check if design inputs and the design was prepared consistent with the SAR?
  - Design changes, prior and following release for use by others for design, manufacturing, or construction

c. Design Engineer Interview - Verification

1. If appropriate, continue with design documents selected in Section 02.03a2(b) above, but conduct verification interview separate from interview with the designer. Interview at least one design/engineer with design verification responsibilities from at least two discipline engineering groups; i.e., mechanical, electrical, and nuclear or others.
2. Determine adequacy in the following areas:
  - Their role in and understanding of design verification
  - Identify a recent design in which each served as the design verifier.
  - Review his qualifications to serve as a design verifier.
3. Design Verification. Review design packages identified in the preceding paragraph. For each of these, determine adequacy of the following:
  - (a) Documentation
    - (1) Design verification documentation conforms with procedural controls
    - (2) Traceability of design verifiers by an inventory of initials and/or signatures
    - (3) Documentation is adequate to provide objective evidence of verification
    - (4) Independence of the verifier
  - (b) Resolution of Disagreement. If the design verification resulted in questions by the verifier, review the dispositioning of the questions and ascertain adequacy. This latter aspect may require an interview with the verifier.

- (c) Verification of Computer Codes. Verify that there is a controlled program to assure that computer programs used in the design process are validated and that subsequent changes are also validated.

4. Management Review

- (a) Determine whether engineering design management has conducted regularly a review of the status and adequacy of those quality assurance functions their organization is performing; i.e., the design assurance and/or design verification function in accordance with the requirement of Criterion II of Appendix B.
- (b) Review the two most recent management reports.
- (c) Ascertain that applicable corrective actions have been initiated.

5. Design Interfaces

- (a) Interface Control Document. Verify that a current written interface control document exists and addresses:
  - (1) Identification of interfaces (internal and external)
  - (2) Responsibilities
  - (3) Communication access interfaces
  - (4) Documentation
- (b) Review of New Contract. For at least one design related contract issued (if issued) during the last year, review the procurement documents, design correspondence, and any other available documentation which can provide objective evidence of effective interface control. All documentation shall be correlated to assure that a change in design input or output is transmitted in a timely manner to all affected interfaces.
- (c) NSSS Interface. Review project records and documentation related to NSSS design activity to determine whether interface activities are effective. During this review of NSSS interface, note procedural requirements, interface contacts (by name), and specific instances of interface activities.
- (d) Site Design Interface. Review the site design interface. Coordinate this with the inspection of the corporate design organization.
  - (1) Verify that an effective system of reviewing site design changes has been implemented.
  - (2) Audit several site initiated design change records. Verify that the change was documented, reviewed by corporate design in an adequate and timely fashion, and that impact on other interfaces was considered.
  - (3) Review the design drawings to establish that affected drawings have been revised, or are adequately controlled such that the site change will be incorporated.

- (4) Verify that a means has been established to assure as-built drawings are controlled and updated to assure final design is correct. Determine if this is effective in assessing affect of design changes in overall design.

e. Design - External A/E

- (1) Design Assurance - Responsibility. Review the total licensee/AE contracted mechanism and determine the licensee organizational responsibilities for design assurance. This review should establish:
  - (a) The means by which the effectiveness of A/E design assurance is determined
  - (b) The responsibility for conduct of audits of A/E, the design function, and the role QA plays

f. Design Assurance Audits of A/E

(a) Audit Planning/Scheduling

- (1) Review the licensee audit plan/schedule and verify that a comprehensive audit plan is documented.
- (2) The frequency and scope of audits shall be sufficient to assure that representative design groups and safety functions are included.

(b) Auditor Qualifications. Review the licensee's procedure/practice for assigning personnel to perform audits of the A/E design function.

- (1) Determine how composition of the audit team(s) is decided.
- (2) Qualification requirements of auditors

(c) Review of Licensee Audits of A/E Design

- (1) Review the results of at least three licensee audits of the A/E design function conducted during the preceding year. Compare the audit plan with the record of audit findings to determine if the objective and scope established for the audit has been accomplished.
- (2) Verify auditor qualifications. Ascertain timeliness and adequacy of dispositioning of audit findings.
- (3) Compare licensee audit findings with LCVIP inspection findings.
- (4) Determine if the licensee has ever been audited or is planning to audit the design and engineering group by an independent audit agency.

3. Acceptability of Design Services

- (a) Determine how the licensee assures himself of the adequacy of A/E designs. The licensee must perform some activity (review, surveillance and/or audit) that can provide objective evidence of an effective overview of the A/E design adequacy. Audits of A/E design verifications should demonstrate effectiveness of the A/E program and compliance with NRC requirements. (Also see preceding Section 02.03b2(c).)
  - (b) Where audits do not assess adequacy of design, examine whether licensee "design reviews" (not verification) of an adequate sample of A/E drawings and specifications for each major activity are conducted.
4. Design Inputs. There are certain NRC requirements/positions that are transmitted to the licensee which can become design inputs.
- (a) Determine the licensee's procedure for transmitting NRC requirements to the A/E.
  - (b) Review licensee's method of determining A/E dispositioning of these requirements.
  - (c) Review licensee A/E dispositioning of several recent Bulletins, Circulars, or Information Notices applicable to the licensee's facility.

#### 02.04 Procurement

##### a. Quality Assurance Responsibilities

1. Review the organization charts, position descriptions, and practices related to procurement. Interview QA management to determine QA's role in procurement.
2. Interview procurement personnel, preferably a manager, to determine his knowledge of the system and to clarify the procurement/QA interface.
3. Integrate the findings of Items 1 and 2 (Section 02.04a) to determine adequacy in the following areas:
  - (a) QA procurement interface
  - (b) QA review of procurement documents
  - (c) QA inputs to procurements
  - (d) QA role in bid evaluation
  - (e) QA activity related to source evaluation
4. Review the manner in which the licensee performs surveys/reviews to maintain suppliers on the list and the frequency of a complete licensee re-review/survey of suppliers' QA.

##### b. Procurement Action Review

1. Item Contracts. Select two procurement actions (contracts) that were initiated subsequent to the previous NRC corporate inspection or ongoing contracts that have not been previously reviewed by the NRC. It is also acceptable to choose a contract which may have been reviewed previously if there are indications of significant quality problems with the contractor. To the extent possible, select one of a major nature and one of a lesser nature. Review the action to determine/evaluate adequacy of the following areas:

- (a) Procurement Documentation

- (1) Review the procurement documentation placing particular emphasis on technical requirements and quality assurance requirements.
    - (2) Verify that the documentation had been reviewed prior to release for bid. Ascertain the qualifications of the reviewer(s), and that all required reviews had been performed.
    - (3) Determine if subsequent changes to the technical or QA requirements were adequately reviewed before being transmitted to the bidder/contractor.
    - (4) Determine that purchaser notification points, hold points, and access rights had been incorporated in, or provided for, in the documentation.
    - (5) Verify that 10 CFR 21 and 10 CFR 50.55(e) reporting requirements were appropriately addressed.
    - (6) Review and evaluate the appropriateness of the QA and acceptance requirements in relation to the complexity and importance to safety of the item.
    - (7) Verify that the contractor is required to impose applicable QA requirements on subcontractors.

- (b) Source Selection

- (1) Determine how source selection was accomplished. Verify that procedural requirements were met.
    - (2) Verify that source selection was based on objective evidence.
    - (3) Review the accepted bid to determine what, if any, exceptions to the requirements were specified. Verify that these exceptions were reviewed and accepted by appropriate licensee organizations and that the procurement documentation was changed.

- (c) Supplier Performance Evaluation

- (1) Determine how the licensee evaluates the supplier performance; i.e., who, how often, and specific techniques such as audit, surveillance, or source inspection.

- (2) Review any reports, audits, or notifications related to the contract being reviewed. Correlate these with receiving inspection reports.
    - (3) Ascertain effectiveness of licensee evaluations, what actions were taken by licensee, and what corrective actions were implemented by the contractor.
  - (d) Item Acceptance
    - (1) Determine what constitutes acceptance of the item by the licensee and evaluate applicability to the procurement.
    - (2) If a certificate of conformance (or some other paper which essentially accomplishes the same function) is the sole means used for acceptance, verify that the item in question meets requirements of Section 03, "Guidance."
    - (3) If a certificate of conformance (COC) is used as a basis of acceptance, determine licensee procedure for verification of supplier QA system to support COCs.
- 2. Service Contracts. Select one procurement action that was initiated subsequent to the previous NRC corporate inspection. Review the action to determine/evaluate adequacy in the following areas:
  - (a) Procurement Documentation. See Section 02.04b1(a).
  - (b) Source Selection. See Section 02.04b1(b).
  - (c) Supplier Performance Evaluation. See Section 02.04b1(c).
- c. Supplier Control
  - 1. Audits
    - (a) Review the overall supplier audit program for the previous year.
      - (1) Determine how many scheduled supplier audits were actually conducted.
      - (2) Determine how many scheduled supplier audits were deferred or cancelled and the reasons for deferral or cancellation.
      - (3) Review the means to compensate for cancellation.
    - (b) Select three supplier audit reports for review.
      - (1) Determine the qualifications of the audit team members.
      - (2) Review the audit findings and followup actions.
  - 2. Approved Supplier Status. Review the licensee-approved supplier program/procedure.
    - (a) Ascertain by interview or documentation review how many, if any, suppliers were added to the list and how many, if any, were removed from the list during the last year.

- (b) Review the documentation supporting the addition of a supplier to the list.
- (c) Review the circumstances and documentation related to the removal of a supplier from the approved list.
  - (1) Verify by review of the list that the supplier has been removed and that the removal has been effective.
  - (2) If a supplier had been removed and was subsequently reinstated verify that objective evidence is available to support the action.
  - (3) Determine that the licensee has instituted additional action to include generic aspects such as notification of CASE, if applicable.

d. Corporate/Site Procurement Interface

1. Site Procurement

- (a) Determine what authority has been delegated to the site for procurement activities.
- (b) Ascertain what controls are imposed on site procurement. Verify that these controls are implemented.

2. Site Reports

- (a) Determine what site reports related to procurement are received at corporate office.
- (b) Investigate the use of these reports. Are they used for trend analysis, supplier evaluations, as input to approved vendor list, or others?

02.05 Audits

- a. Audit Program. Review the QA program audit procedures, records and schedules and interview QA management to ascertain the following items:

1. Scope

- (a) The QA audit program encompasses internal and external organizations and functions.
- (b) The audit program extends to all elements of the QA program within a reasonable time period.

2. Auditors

- (a) The QA audit staff is sufficient in number to effectively conduct planned audits.
- (b) How the audit team size and composition is determined
  - (1) Are specialists from other organizations routinely assigned to audit teams?

- (2) What determines the number of persons on an audit team?
    - (c) The auditors have training and experience in auditing sufficient to meet qualification requirements.
  - 3. Schedule
    - (a) Proposed audit schedule for the succeeding 12 months.
    - (b) Audits accomplished in the preceding 12 months.
      - (1) How many scheduled audits were completed?
      - (2) If any were cancelled, or deferred, why? How were they made up?
    - (c) By comparing (a) and (b), above, determine if the full scope of QA elements was encompassed.
- b. Audit Reviews. Select five audits performed during the previous year. If possible include one QA audit of design, procurement, and document control for this review.
  - 1. Planning. Review the audit plan/checklist for applicability to the QA element audited.
    - (a) Determine the audit team members. Verify qualification records.
    - (b) Determine number of days allotted to conduct the audit.
    - (c) Is the plan/checklist complete?
  - 2. Findings. Review the audit reports and verify:
    - (a) That audit findings were reported to upper management and the organizations audited.
    - (b) Corrective actions as required were initiated in a timely manner.
    - (c) Followup and reaudit by QA.

## 35060-03 INSPECTION GUIDANCE

### 03.01 General Guidance

Note: The guidance below refers to Section 02.01, above.

- a. The intent of this inspection is to determine the effectiveness of the licensee's QA program, especially in the areas of design and procurement, as it affects construction. There are several areas of this procedure which are subjective in nature. Therefore, inspection planning is an important prerequisite to the conduct of the inspection.
- b. It is essential that the inspection be conducted on a team basis with an inspection team leader in charge. It is suggested that the team leader be a section chief with

in-depth knowledge of NRC policies and positions and experience auditing licensee organizations.

### 03.02 Specific Guidance

Note: The guidance below refers to specific subsections of Section 02, above.

02.02a. Interviews of corporate quality assurance organization should include the senior executive responsible for quality assurance.

02.02b. Criterion II of 10 CFR 50, Appendix B specifies that the licensee shall do this. Program audits by the QA organization do not satisfy this requirement.

02.02c2c.2. The selective review may result in identification of inspector concerns. The inspector may then use this as the basis of an expanded review - both forward and backward in time.

02.03. When reviewing design activities of those licensees that are member companies of a utility holding company which has an engineering service arm, an inspection and interviews should be conducted at the Service Company headquarters.

The inspection team should include inspectors qualified in the disciplines of mechanical, electrical, and civil engineering whenever possible.

The basic guidance for QA during design is contained in the following:

ANSI N45.2.11-1974, Quality Assurance Requirements for the Design of Nuclear Power Plants

RG 1.64 Rev. 2, Quality Assurance Requirements for the Design of Nuclear Power Plants.

QAB, Position Statement No. 2 - "Time of Design Verification" (July 1975)

QAB, Position Statement No. 6 - "SAR as a Design Document" (December 1976)

QAB, Position Statement No. 10 - "Design Control Flexibility in Timeliness for Design Verification"

02.03b3. In addition to the requirements of ANSI N45.2.11, the inspector should use applicable provisions of ANSI N45.2.12 and ANSI N45.2.13 for this part of the inspection.

02.04. The extent of the licensee's procurement responsibilities and activities will vary depending on the licensee's capability and contractual arrangements. Inspection planning by the inspection team should identify which of the items can be effectively inspected at the licensee corporate office. For those items which cannot be effectively inspected at the corporate office, the inspector may arrange to accompany licensee personnel on an audit/inspection of a licensee contractor.

The basic guidance for procurement is contained in:

ANSI N45.2.13 - 1976 - "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants"

RG 1.123 Rev. 1, - "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants"

NUREG 0302 Rev. 1, "Questions/Answers at Public Regional Meetings to Discuss 10 CFR Part 21"

02.04b1(d). Refer to IE Manual Guidance, 10 CFR 50, Appendix B (VII), on the use of Certificates of Conformance.

02.04c2. Utilization of Coordinating Agency for Supplier Evaluation (CASE) Index to approve certain vendors is based on CASE Topical Report (CASE-TR 1, Rev. 1A) approved by NRR in a letter to industry dated 6/23/78. The inspector should review the restrictions on acceptability of CASE.

Additional guidance is in ANSI N45.2.13

02.05. Audits. Basic guidance related to audits is contained in:

RG 1.44/ANSI N45.2.12 - , "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants"

ANSI N45.2.23 - "Qualifications of Auditors"

## 35060-03 REFERENCES

### Regulations/SAR

10 CFR Part 50 (General)  
10 CFR Part 50, Appendix B  
SAR, Chapter 17  
SAR, other Chapters, as appropriate

### NRC Guidance

WASH 1283, Rev. 1 (Gray QA Book)  
WASH 1390 (Green QA Book)  
Regulatory Guides (1.28, 1.64, 1.144, 1.123 and others, as appropriate) which endorse ASME/ANSI N45.2 series QA standards.  
Quality Assurance Branch Position 10 (Timeliness of Design Review)

END