INSPECTION PROCEDURE 35100

REVIEW OF QA MANUAL

PROGRAM APPLICABILITY: 2502, 2504

35100-01 INSPECTION OBJECTIVES

01.01 To determine if quality assurance plans, instructions, and procedures for specific safety-related activities have been implemented as outlined in the facility's QA manual.

01.02 To determine if quality assurance plans, instructions, and procedures conform to the QA program as described in the FSAR or the NRC-accepted quality assurance topical report.

35100-02 INSPECTION REQUIREMENTS

Review the facility QA manual, and implementing procedures, instructions, and drawings to determine if the QA program has been adequately implemented.

02.01 Assess the Organizational Structure and QA Personnel by reviewing the following:

a. Organizational structure and functional relationships.

b. Qualifications, responsibilities and duties of QA personnel, including independence from personnel having cost or scheduling responsibilities.

c. Indoctrination/training and retraining program for QA personnel.

d. Assignment of stop-process and stop-work authority to an onsite individual.

02.02 Assess Onsite Design Controls by ensuring that:

a. Procedures are in effect to ensure that design activities are carried out in a planned, controlled, and orderly manner, and to ensure that design changes are subject to design control measures commensurate with those applied to the original design.

b. Applicable design inputs are identified and their selection reviewed and approved.

c. Design activities are prescribed and accomplished in accordance with procedures of a type sufficient to ensure that applicable design inputs are correctly translated into specifications, drawings, procedures, or instructions.

d. Procedures requiring design analysis, such as physics, stress, thermal, hydraulic, and accident, shall be performed in a planned, controlled, and correct manner.

e. Procedures exist that identify the external interfaces between the onsite design organizations, including criteria designs, specifications, changes, technical direction, and approvals.

f. Procedures exist to ensure that design changes have the adequacy of design verification or checking by applicable methods.

02.03 Assess the Quality Requirements by ensuring the following:

a. Quality requirements, including appropriate material specifications, test reports, acceptance criteria, and required documentation, are specified in design and procurement documents.

b. Quality requirements are adequately specified.

c. Deviations from previously established requirements, including design changes, are adequately controlled and reviewed.

d. Quality documentation, including material certifications, test reports, receiving inspections, evaluations, and auditing results are generated and maintained to indicate that quality requirements have been met.

e. Identification and control of structures, systems and components (SSCs) covered by the facility's QA program; i.e., all safety-related, fire protection, environmental, and other items important to safety subject to the QA program.

02.04 Assess Document Control by ensuring that:

a. Documents relating to quality are adequately controlled.

b. Quality related documents are reviewed by qualified personnel for adequacy.

c. Provisions to ensure appropriate identification/listing and control of aggregate collection of quality assurance (including quality control) instructions and procedures known as the QA manual, including future revisions.

d. Provisions exist to ensure periodic review of the adequacy of the document control procedures.

e. Provisions exist to ensure that plant configurations are accurately reflected in as-built drawings.

02.05 Assess Work and Quality Inspection Procedures for the following:

a. Work and inspection procedures important to safety, including those of vendors and suppliers, have been established.

These procedures shall cover significant related activities such as process monitoring surveillances, inspection hold points, test programs, and the control of special equipment.

b. Procedures are complete, reviewed, approved and controlled; and that those performing QA activities have available to them the most recent and approved specifications, procedures, and instructions pertinent to activities audited, monitored, or inspected by them.

02.06 Assess Control of Material by reviewing the following:

a. Documented evidence that quality requirements are met prior to use or installation of material or equipment.

b. Identification and traceability of material and equipment, including status of inspection or tests performed, as required.

c. Handling, shipping, and storage procedures are established.

d. Identification and control of nonconforming material and components to preclude inadvertent use, including periodic inspections/surveillances to verify adequate control.

02.07 Assess Control of Processes by ensuring:

a. Procedures are provided to ensure suitably controlled work and inspection/surveillance conditions.

b. Procedures are provided for the control of special processes.

c. Special processes are performed by qualified personnel using qualified procedures in accordance with applicable requirements.

d. Procedures are provided for control and approval of supplier's special processes such as welding, nondestructive examinations, (NDE), heat treatment, electroplating, etc.

02.08 Assess Corrective Action by ensuring:

a. Procedures are established for identification and correction of conditions adverse to quality.

b. Procedures are established to preclude repetition of activities adverse to quality.

c. Provisions are established for escalating to higher management those corrective actions that are not adequate/timely.

d. A management system is established for overview of trends in conditions adverse to quality.

02.09 Assess Test Control and Control of Test Equipment by reviewing the following:

a. Procedures are established to ensure that acceptance criteria are specified, test requirements (including prerequisites) have been met, evaluation of results are documented, and deficiencies have been detected and reported to the appropriate level of management.

b. Procedures are established to ensure adequate control, calibration and adjustment of measuring and test equipment.

c. An adequate method exists for establishing traceability of an inspected/tested work activity to the instrument used for acceptance purposes.

02.10 Assess Quality Records by ensuring that:

a. Procedures are established to ensure that evidence of activities affecting quality are documented by qualified personnel.

b. Procedures are established to ensure that specified documentation for procured items has been received at the site and has been reviewed.

c. Provisions are made to ensure that quality records are legible, adequate, retrievable, adequately protected and refer to markings, identification tags, or other means of identifying materials and components important to safety within a reasonable time after conclusion of the applicable quality-effecting activities.

d. Procedures for review of quality records by qualified personnel, including records of appropriate subsequent corrective action if needed.

e. Procedures are established to ensure that records are stored in a manner which precludes deterioration.

02.11 Assess Audits by reviewing the following:

a. Procedures and/or checklists for audits.

b. Scope and purpose of audits to be performed, including audits of the status and adequacy of the site QA program.

c. Frequency (or schedule) of audits, audit criteria, basis for reaudit, management review and assessment, corrective action (and followup), documentation of results of audits, management review and followup of corrective action.

d. Qualifications and responsibilities of auditors, including those of contractors.

e. An overall plan by which management ensures that the audit program addresses all aspects of quality-affecting activities.

35100-03 INSPECTION GUIDANCE

General Guidance

a. The applicant provides a description of the facility QA program (Section 17 of the FSAR or a QA topical report) to be established and executed during construction. This program is based on the requirements contained in Appendix B to 10 CFR 50. The determination of the adequacy of this QA program description is the responsibility of NRR. If the inspector, during review of the QA manual, considers the QA program (as described) to be deficient, the matter should be referred to NRR for resolution.

b. It is the responsibility of the applicant or licensee to establish and execute a QA program for facility construction.

This inspection procedure requires the inspector to determine if the applicant or licensee has established (written, reviewed, and approved) effective QA instructions, procedures, plans, and schedules in a timely manner which are in conformance with the facility FSAR, particularly the QA program described in Section 17 of the FSAR. The applicant or licensee is required to establish adequate procedures for any activity important to safety before the start of that activity. These documents may be developed by the applicant or licensee or delegated to others. This aggregate collection of documents is referred to as the "QA manual."

c. Quality requirements imposed on the licensee by NRC relate to activities important to safety as defined in 10 CFR Part 50. Specific requirements committed to by the licensee are included in the FSAR. Consequently, the above two documents are to be used by the inspector to determine construction quality requirements and commitments.

d. This inspection procedure is concerned with the adequacy of quality-related procedures which have been established by the licensee or his delegates; other construction inspection procedures are concerned with the execution of these procedures.

e. The intent of items 02.02 through 02.11 in Section 02 of this procedure is to provide the inspector with a "checklist" of inspection requirements to aid in determining whether adequate QA instructions and procedures have been established in the QA manual. It should be noted that these QA procedures do not establish construction quality requirements but provide a means to ensure that established quality requirements have been met during facility construction. Since QA personnel perform an audit/monitor/surveillance function, the assurance of adequacy of construction activities important to safety is proportional to the adequacy of the procedures used by QA personnel.

Specific Guidance

03.01 Organizational Structure and QA Personnel

a. The organizational structure described in the QA manual is to conform to the description in the QA program (FSAR, Section 17).

b. Qualifications, responsibilities, and duties of QA personnel are to be defined sufficiently to ensure adequately qualified personnel with appropriate responsibilities. It is necessary to review both the licensee/contractor organizational charts and descriptions of duties and responsibilities to ensure that the "independence and freedom of action" requirements are met.

c. No specific guidance

d. Whenever construction activities are in progress at the site, established procedures shall require at least one QA person on site with authority to stop any activity which does not conform to applicable quality requirements. This authority may be delegated and/or go through other organizational components, provided that this stop-process or stop-work authority is not abrogated, delayed, or diminished by this delegation or routing.

03.02 Onsite Design Controls. No specific guidance.

03.03 Quality Requirements. No specific guidance

03.04 Document Control

a. "Adequately controlled" includes the turnover/retention of contractor and consultant quality records associated with safety-related materials, components, and systems.

03.05 Work and Quality Inspection Procedures. No specific guidance.

03.06 Control of Material. Procedures must be sufficiently complete, appropriate, and adequate to ensure that only material meeting applicable requirements is used and that this information is adequately documented and retained. (Material issue control procedures are included in this category, and applicable requirements are specified in the facility FSAR).

In regard to quality certification (Appendix B to 10 CFR 50, Criterion VII), when quality documentation in the form of certification is used at the site in lieu of original records establishing quality of materials or components important to safety, the following guidelines should be used:

a. The certification shall specifically identify the purchased material or equipment, such as by citing the purchase order number.

b. The certification shall identify the specific procurement requirements met by the purchased material or equipment, such as by citing codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on site, a copy of the purchase order and procurement specifications or drawings, together with a suitable conformance statement. The procurement requirements identified should include any approved changes, waivers, or deviations applicable to the subject material or equipment.

c. The certification shall identify any procurement requirements which have not been met, together with an explanation and the means used to resolve the nonconformances.

d. The certification shall be attested to by a person who is responsible for this QA function and whose function and position are described in the purchaser's or supplier's QA program. (The architect-engineer or construction management organization usually has this information for major suppliers.)

e. The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the purchaser's or supplier's QA program.

f. Means should be provided by the licensee to verify the validity of certificates, and to determine the effectiveness of the certification system when desired, such as during the performance of audits.

Typical certifications are manufacturer's certifications that a product (usually consumables, such as weld rod and fly ash), if tested, would exhibit the product characteristics shown on the certification document. Typical certifications are acceptable only if the using-agency can demonstrate that the product was manufactured under a process control system which provides for product control and process records which can establish that the product was manufactured within the characteristic limits identified on the typical certification.

03.07 Control of Processes. No inspection guidance

03.08 Corrective Action. Deficiency reporting based on the requirements of 10 CFR Part 50.55(e) is designed to provide the NRC staff with prompt notification and timely information of deficiencies encountered during construction of nuclear power plants. The intent of the rule is to provide a basis for evaluation on the part of the NRC with respect to potential safety consequences of deficiencies and the need for further action by NRC.

a. The following matters merit particular attention:

   1. Prompt notification.

   2. Distribution of reports.

   3. Insufficient report information.

   4. Failure to report.

b. In most cases, the above problems reflect a lack of understanding of the reporting requirements and failure to recognize the collective set of conditions defined by the regulation which must exist as a basis for "required" reporting. Additional guidance on the above matter is given below:

   1. It should be made clear to licensees that reports are to be sent to Headquarters and the regional office.

   2. It should be emphasized that reports must include all the information specified by the rule, especially an analysis of the safety implications of the deficiencies.

   3. The licensee should be encouraged to discuss a potential report with the responsible inspector whenever he feels in doubt. It is appropriate for the inspector to indicate his views with regard to whether or not a deficiency is reportable but the licensee must always be informed that the ultimate responsibility is the licensee's and that the inspector's judgment may change during a future inspection wherein he has an opportunity to fully review circumstances associated with a deficiency. In "borderline" cases, the inspector should always encourage reporting.

c. The nature of the reporting rule requires that the licensee make a judgment; and it follows that if the licensee decides, on the basis of appropriate consideration of the facts, that a deficiency is not reportable, he has satisfied the intent of the rule and should not be cited for failure to report a deficiency which the inspector feels is reportable. However, in this event (and the licensee should be clearly informed) there must be documentation available for the inspector's review which clearly establishes that the licensee had promptly initiated analysis of the deficiency at the appropriate level and expertise of management and made the decision not to report. It should be explained to the licensee that the lack of records as discussed above, leaves the inspector in a position of not knowing whether the licensee had simply overlooked the reporting requirement rule or had considered the deficiency to be not reportable.

d. In the event a licensee habitually "evaluates" cases as nonreportable, the matter should be reviewed by regional supervision.

03.09 Test Control and Control of Test Equipment.

a. No specific guidance

b. The procedure should include, but not necessarily be limited to, specified calibration intervals, accuracy within specified limits, accuracy and traceability of equipment by marking (e.g., serial numbers) for identification, adequate means to readily establish calibration status of equipment (e.g., tags or labels), and disposition of previously inspected material when test equipment is discovered to be outside of the specified limits.

03.10 Quality Records. No specific guidance.

03.11 Audits. No inspection guidance

35100-04 RESOURCE ESTIMATE

This 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 200 hours of direct inspection effort.

35100-05 REFERENCES

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

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