RAS J-94

NRC INSPECTION MANUAL

CQV

INSPECTION PROCEDURE 35101

QA PROGRAM IMPLEMENTATION INSPECTION FOR OPERATIONAL PROGRAMS

PROGRAM APPLICABILITY: 2504

35100-01 INSPECTION OBJECTIVES

Verify that the Licensee has a quality assurance (QA) program that is in conformance with the Quality Assurance Program Description (QAPD) in the areas of: (1) organizational structure, functional relationships, and training (2) onsite design (or design change) controls, (3) quality requirements, (4) document control, (5) work and quality inspection, (6) control of material, (7) control of special processes, (8) corrective action, (9) test control and control of test equipment, (10) quality records, (11) audits, and (12) process for reporting changes to the QA program description.

35100-02 BACKGROUND

NUREG 0800, Standard Review Plan, Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," provides extensive guidance concerning all phases of this procedure. Quality requirements related to safety-related activities are defined in 10 CFR Part 50, Appendix B and as described in the safety analysis report. Quality requirements are also described in ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Operations."

It is the responsibility of the licensee to establish and execute a QA program for the operational programs. The licensee is required to establish adequate procedures for any activity important to safety, or risk significant, before the start of that activity. These documents may be developed by the Licensee or delegated to others. This aggregate collection of documents is referred to as the "QAPD." This inspection procedure requires the inspector to determine if the licensee has established (written, reviewed, and approved) effective QA instructions, procedures, plans, and schedules in a timely manner which are in conformance with the QAPD.

This inspection procedure is concerned with the adequacy and implementation of quality-related procedures which have been established by the licensee. The intent of items 03.01 through 03.12 in Section 03 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 program manual. This inspection procedure is expected to be initiated as early as practical consistent with realizing valid results for licensee QA programs.

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35100-03 INSPECTION REQUIREMENTS AND GUIDANCE

03.01 Assessment of Organizational Structure, Functional Relationships and Training.

a. Verify the organizational structure described in the QAPD to ensure it conforms to the description of the QA program as stated in the safety analysis report.

Specific Guidance. Review the QA organizational structure described in the QAPD against the criteria established in the safety analysis report.

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

Specific Guidance.

1. 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. Qualifications, responsibilities, and duties of QA personnel are to be defined sufficiently to ensure adequately qualified personnel with appropriate responsibilities.

2. Interview a sample of five QA personnel (as available) to determine whether they have an adequate understanding of the program. The interview should focus on qualifications, duties, and responsibilities.

c. Verify the indoctrination/training and retraining program for QA personnel.

Specific Guidance.

1. Review a sample of the four QA training program documents to ensure they provide the guidance required to implement the program.

2. Review a sample of five training attendance documents to verify QA personnel have received and maintain qualification standards as described in the program.

03.02 Assessment of Onsite Design (or Design Change) Controls.

Verify whether controls listed below have been established 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.

a. Organization(s) or person(s) responsible for performing design work are identified.

b. Design (or design change) request forms (or equivalent) have provisions for documenting completion of required reviews, evaluations, and approvals prior to change implementation.

c. Methods exist to ensure that applicable design inputs are identified and their selection reviewed and approved.

d. 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.

e. Procedures requiring design analysis, such as physics, stress, thermal, hydraulic, and accident analyses, are performed in a planned, controlled, and correct manner.

f. Procedures exist that identify the external interfaces between the onsite design organizations, including those responsible for design specifications, changes, technical direction, and approvals.

g. Procedures exist to ensure that design changes have an adequate design verification performed or are checked by applicable methods.

h. Procedures delineate responsibility for identifying post modification testing requirements.

i. Administrative controls exist to ensure design changes have been incorporated into appropriate plant procedures, operator or technician training programs and plant drawings.

j. Administrative controls require design documentation records to provide evidence that the design (or design change) review process was performed and that the records were stored.

Specific Guidance.

1. Review applicable section(s) of the QAPD and any associated lower tier procedures for a description of the design controls listed above.

2. Review a sample of five design change packages to verify conformance with the controls established above.

03.03 Assessment of Quality Requirements. Verify that the following quality requirements are specified in the program:

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

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

c. 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.

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

e. Procedures provide for the assignment of stop-process and stop-work authority to an onsite individual.

Specific Guidance.

1. Review applicable section(s) of the QAPD and any associated lower tier procedures for a description of the controls listed above.

2. Review a sample of five design and procurement documents and verify the requirements listed above in steps 03.03.a and b.

3. Review a sample of two each for the following and verify that quality requirements have been met as stated in step 03.03.c.

   (a) Material certifications.

   (b) Test reports.

   (c) Receiving inspections.

   (d) Evaluations.

   (e) Auditing results.

4. Review a sample of five procedures and verify the requirements listed above in steps 03.03.d and e.

5. Review established stop-process and stop-work procedures for any activity which does not conform to applicable quality requirements whenever construction activities are in progress at the site. The procedures may specify that this authority may be delegated and/or go through other organizational components, provided that the stop-process or stop-work authority is not abrogated, delayed, or diminished by this delegation or routing.

03.04 Assessment of Document Control. Verify the following for program documents:

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.

f. Provisions exist to ensure that any drawings, procedures, or equipment databases accurately reflect changes to plant configuration.

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

Specific Guidance. Review a sample 10 program documents to verify that requirements were met in the areas specified in steps 03.04.a through g.

03.05 Assessment of Work and Quality Inspection. Verify the following:

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

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

c. Procedures are complete, reviewed, approved, controlled, and maintained.

d. 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.

Specific Guidance. Review a sample of five procedures to verify that the work and quality inspection requirements listed in steps 03.05.a through d. have been met.

03.06 Assessment of the Control of Material program requirements. Verify Control of Material procedures to assure that they are 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 safety analysis report).

Verify that program procedures for Control of Material policies and guidelines are provided in the following areas :

a. Procurement, Receipt, Storage, and Handling of Equipment and Materials.

NOTE: IP 35746, "Procurement Control and Receipt, Storage and Handling of Equipment and Materials," provides a more extensive review of this area.

1. Documented evidence that quality requirements were met prior to use or installation of material or equipment.

2. Provisions exist for Identification and traceability of material and equipment, including status of inspection or tests performed, as required.

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

4. Procedures provide for identification and control of nonconforming material and components to preclude inadvertent use, including periodic inspections/ surveillances to verify adequate control.

5. Administrative controls for those preparing, reviewing, changing, and approving procurement documents.

6. Administrative controls for procurement of safety and non-safety related items.

7. Administrative controls for bidders/suppliers.

Specific Guidance. Review a sample of five procurement related documents to verify that the requirements listed in steps 03.06.a.1 through 7 have been met.

b. 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 procedural guidelines should be verified:

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

2. 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.

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

4. 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.)

5. 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.

6. 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 they 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

Specific Guidance. Review a sample of five quality certification related documents to verify that the requirements listed in steps 03.06.b.1 through 6 have been met.

03.07 Assessment of Control of Special Processes. Verify the following to assure that adequate measures are in place for Control of Special Processes:

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 special processes such as welding, nondestructive examinations, (NDE), heat treatment, electroplating, etc.

Specific Guidance. Review a sample of five special process related documents to verify that the requirements listed in steps 03.07.a through d. have been met.

03.08 Assessment of Corrective Action Program Requirements. Verify the following for the corrective action process.

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

b. Verify procedures are established to preclude repetition of activities adverse to quality.

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

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

Specific Guidance. Review a sample of five corrective action related documents to verify that the requirements listed in steps 03.08.a through d. have been met.

03.09 Assessment of Test Control and Control of Test Equipment.

NOTE: IP 35750, "QA Program -Test and Measurement Equipment, Tests and Experiments, and Surveillance Tests," provides a more extensive review of this area.

a. Verify 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. Verify procedures are established to ensure adequate control, calibration, and adjustment of measuring and test equipment.

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

Specific Guidance. Review a sample of six documents related to test control and control of test equipment to verify that the requirements listed in steps 03.09.a through c. have been met.

The review 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 Assessment of Quality Records.

a. Verify procedures are established to ensure the following:

1. Evidence of activities affecting quality are documented by qualified personnel.

2. Specified documentation for procured items has been received at the site and has been reviewed.

3. Review of quality records by qualified personnel, including records of appropriate subsequent corrective action if needed.

4. Records are stored in a manner which precludes deterioration.

Specific Guidance. Review applicable section(s) of the QAPD and any associated lower tier procedures for a description of the requirements for quality records stated in step 03.10.a.

b. Verify that requirements and provisions to maintain the following types of records have been established.

1. Pre-operational and startup tests

2. Normal reactor operation including operating logs, recorder charts, and computer printouts.

3. Principal maintenance activities

4. Design changes and modifications including safety evaluations associated with 10 CFR 50.59 type changes.

5. Reportable occurrences

6. Surveillance test results

7. Baseline data and inservice inspections

8. On and offsite safety committee (Group) meeting minutes

9. Procurement documents

10. Receipt inspection and testing

11. QA audit reports

12. Personnel training records

13. Safety related (non Technical Specification) Calibration results

14. Personnel qualification records

15. Special reactor tests

16. Defects and noncompliance (10 CFR 21, 10 CFR 50.55e, as applicable)

17. Fire protection/prevention activities

18. Engineering drawings

Specific Guidance. Review the QAPD and any related lower tier QA procedures to verify requirements and provisions were established to maintain the types of records listed above in step 03.10.b.1 through 18.

c. Verify that record storage controls described in the QA Program provide for the following.

1. Description of the record storage facility or facilities for the records identified in (03.10.b) above.

2. Designation of a custodian(s) in charge of storage facilities identified in (03.10.b) above.

3. Description of the filing system(s) to be used to allow for the retrieval of records identified above.

4. A method for verifying that records received are in agreement with the transmittal document or a pre-established records checklist, as applicable.

5. Provisions for governing access to files and for maintaining an accountability of records removed from the storage facility.

6. Establishment of methods for correcting or filing supplemental information and disposing of superseded records. Required review and approval should be specified.

Specific Guidance. Review the QAPD and any related lower tier QA procedures to verify requirements and provisions were established to address the record storage controls listed in step 03.10.c.

d. Verify that responsibilities have been assigned to ensure the following:

1. Record storage controls identified under (03.10.c) above will be implemented.

2. Transfer and retention of construction phase records.

3. Retention periods of records listed under 03.10.b.

4. Authorizing disposal of records no longer required has been specified.

Specific Guidance. Review the QAPD and any related lower tier QA procedures to verify that the responsibilities in step 3.10.d. have been assigned.

e. Verify 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 affecting activities.

Specific Guidance. Review a sample of each of the records listed in step 3.10.b. (as available) and verify the items listed above, as applicable, in step 3.10.e.

03.11 Assessment of Audits. Verify the following:

a. The scope of the audit program has been procedurally defined and that it is consistent with safety analysis report commitments.

b. That an overall plan exists by which management ensures that the audit program addresses all aspects of quality-affecting activities.

c. That responsibilities have been assigned in writing for the overall management of the audit program including:

1. Determining the adequacy of the qualifications of audit personnel, including those of contractors. .

2. Determining the need for special training of audit personnel and/or inclusion of special expertise.

3. Determining the independence of audit personnel.

4. Assuring corrective actions are taken for deficiencies identified during audits.

5. Determining when reaudits are required.

6. Issuance of audit reports to management.

7. Periodic review of the audit program to determine its status and adequacy.

8. Preparation of the long range audit plans or schedules.

d. That methods or administrative channels have been defined for taking corrective actions when deficiencies are identified during audits. Verify that the audited organization is required to respond in writing to audit findings.

e. That distribution requirements for audit reports and corrective action responses have been defined.

f. Verify that checklists or procedures are required to be used in the performance of audits.

Specific Guidance.

1. Review the QAPD to verify the scope of the program is defined as stated in step 03.11.a.

2. Review the current long range audit schedule or plan in effect and verify that areas to be audited and audit frequencies identified are consistent with the QAPD commitments.

3. Review the most recent completed audit report(s) and determine the following:

(a) An audit checklist or procedure was prepared, used and covered the areas designated in the audit schedule.

(b) Auditors were independent of any direct responsibility for the activities which they audited.

(c) Deficiencies identified during the audit have been resolved or they are currently being carried as an "open item."

(d) The audited organization has responded in writing to the audit findings.

(e) Distribution of audit reports and response was consistent with program requirements.

03.12 Assessment of Process for Reporting Changes to the QA Program Description. Verify that a process is in place to notify the NRC of proposed changes to the QA program description.

Specific Guidance. Review the procedural process in place to verify that notification of QA program description change(s), if any, was made in accordance with 10 CFR 50.54(a)(3) and/or 10 CFR 50.54(a)(4).

35100.52-04 RESOURCE ESTIMATE

This procedure supports the QA review of COL operational programs per the guidance contained in Section 17.5 of NUREG 0800. The resource estimate for this inspection procedure is approximately 340 hours of direct inspection effort.

35100.52-05 REFERENCES

NUREG 0800, Standard Review Plan, Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants"

ASME NQA-1 1994, "Quality Assurance Requirements for Nuclear Facility Operations"

END

Attachment 1: Revision History

Attachment 1

Revision History Sheet
IP 35101

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Ascension #
N/A	10/03/07 CN 07-030	1. Initial issue to support inspections of operational programs described in IMC 2504, NON-ITAAC INSPECTIONS 2. Incorporates SRP 17.5 guidance 3. A review for incorporation of generic requirements has been conducted. None identified. 3. Combines information contained in IPs 35001, 35060, 35061, 35740, 35741, 35742, 35744, and 35748.	N	N/A	ML063400034