

NRC INSPECTION MANUAL

IQVB

INSPECTION PROCEDURE 35101

QA PROGRAM IMPLEMENTATION INSPECTION FOR OPERATIONAL PROGRAMS

Effective Date: 01/01/2022

PROGRAM APPLICABILITY: **IMC** 2504 and 2514

35101-01 INSPECTION OBJECTIVES

Verify that the licensee has a quality assurance (QA) program that is in conformance with the Quality Assurance Program Description (QAPD) found in the following QA areas: (1) QA organizational structure and functional relationships, (2) QA department independence and training, (3) design change controls for equipment modifications, (4) controls for instructions, procedures and drawings, (5) identification and control of materials, parts and components, (6) inspection and test controls, (7) inspection, test and operating status controls, (8) nonconforming material, parts and components that may contain defects (9) corrective actions, (10) quality records, (11) audits, and (12) process for reporting changes to the QAPD.

Using NRC Inspection Procedure (IP) 35007, "Quality Assurance Program Implementation during Construction and Pre-Construction Activities," the NRC inspection staff should have already completed construction QA inspection activities associated with the design and construction of a nuclear power plant. Therefore, the NRC inspection staff should focus inspection efforts on the need to review operational QAPD activities and its implementation and not inspection efforts on construction QA activities that have already been completed. If the licensee is changing from the construction to the operational QAPD, then those areas that were previously inspected under IP 35007 that the licensee changed should be re-inspected under IP 35101 using the specific guidance in IP 35007.

35101-02 INSPECTION REQUIREMENTS

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 the American Society of Mechanical Engineers (ASME) NQA-1-**2015** "Quality Assurance Requirements for Nuclear Facility Operations," which focuses on design and construction QA activities.

RG 1.33, Revision **3**, and ANSI/ANS-3.2-**2012**, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," provides an adequate basis for complying with the quality assurance program requirements of Appendix B to 10 CFR Part 50 for the operational phase. ANSI/ANS 3.2-**2012** requires the preparation of procedures to carry out an effective quality assurance program. The ANSI/ANS 3.2-**2012**, Appendix A

list of procedures identifies safety related activities that should be covered by written procedures but does not provide a complete listing of needed procedures.

The NRC staff note that it is the responsibility of the licensee to establish and execute a QA program for the operational program phase of plant life. The licensee is required to establish adequate procedures for any activity that is safety-related, important to safety, and/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 and in conformance with the QAPD. While this IP is directed mainly to the plant site aspects of QA, some aspects of QA include corporate procedures and may be included in the inspection scope.

This inspection procedure is concerned with the adequacy and implementation of quality-related procedures that have been established by the licensee. **The team shall inspect at a minimum, the general guidance in sections 03.01 through 03.12 of this procedure. The inspection team should utilize section 03 as a "checklist" of inspection requirements to aid in the inspection, review, and assessment, 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.

35101-03 INSPECTION GUIDANCE

The NRC inspection team should focus inspection resource activities on administrative controls used to implement the operational QAPD, including inspection of the operational QA organization, QA training needed to meet RG 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," design change controls, the adequacy of normally operating, abnormal and emergency operating procedures, tests associated with plant maintenance, modifications or procedure changes, inspection, test and operating status, non-conformances, corrective action, records and audits.

The NRC inspection team should sample safety-related and important to safety systems normally operating, abnormal, and emergency operating procedures used to safely startup, operate and shutdown the nuclear power plant. For passive plant designs, the NRC inspectors should also review normally operating, abnormal, and emergency operating procedures used to verify the adequacy of regulatory treatment for non-safety systems (RTNSS) procedures, such as, the fire protection system or equipment used to meet the station blackout rule (i.e., batteries, non-safety related diesel generators). The NRC inspectors should verify that QA procedures for safety-related, important to safety systems and RTNSS have been independently reviewed and approved to verify procedure adequacy before they are used by plant personnel.

03.01 Operational QA Organizational Structure, Functional Relationships, and Independence from Other Plant Organizations.

- a. Verify an adequate organizational structure is described in the QAPD to ensure it conforms to the QA program commitments in the safety analysis report.

- b. Verify responsibilities and duties of operational QA personnel, including QA personnel freedom and independence from personnel having cost or scheduling responsibilities.
- c. Verify the COL operational organization establishes rules and instructions for personnel conduct and control, including job related factors which influence the effectiveness of operations and maintenance personnel, including such factors as number of hours at duty station, availability of on call personnel, shift turnover, methods of conducting operations, preparing/retaining operator logs and control room access.

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. 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.
- 3. Verify the training and qualification of QA personnel using the guidance in Section 03.02 of this procedure.

03.02 Adequacy of the List of QAPD Plant Procedures and Personnel Training Used to Implement Plant Procedures.

- a. Sample QA training records to verify plant QA personnel have adequate training to implement the operational QAPD including training needed to implement lower tier QA procedures referenced in the QAPD. This includes sampling the QA training records of personnel performing technical specification surveillance inspections and tests on safety-related SSCs.
- b. Evaluate implementation of the licensee's periodic review on the status and adequacy of the QA program. The licensee shall regularly review the status and adequacy of the operational QA program. Management of other organizations participating in the operational QA program shall regularly review the status and adequacy of that part of the QA program that they are executing.
- c. 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.

Independent Review Organizations

- d. In accordance with ANSI/ANS-3.2-2012, Section 3.2.2, "Independent Review Program," verify that an on-site independent review body and an off-site independent review committee are set up to periodically review the following areas:
 - 1. Nuclear Power Plant Operations
 - 2. Nuclear Engineering

3. Chemistry and radiochemistry
 4. Metallurgy
 5. Nondestructive testing
 6. Instrumentation and Control
 7. Radiological safety
 8. Mechanical and electrical engineering
 9. Administrative controls and quality assurance practices
 10. Other appropriate fields associated with the unique characteristics of the nuclear power plant
- e. Verify the independent review program is functional before initial fuel load. Verify that the independent review bodies have standard practices for committee composition, meeting frequency, committee quorum, meeting records and organizational reporting responsibilities to senior site management.
 - f. Verify independent review bodies maintain records of documents reviewed, the results of the review and recommendations made to appropriate site management having responsibility in the areas noted in Section 03.02.d.1 through 03.02.d.10 of this procedure.
 - g. Verify independent review bodies review safety evaluations of changes to (1) the facility, as described in the SAR; (2) the technical specifications; (3) changes, tests and experiments to the plant in accordance with 50.59 requirements; (4) violations, deviations and reportable events to the NRC in writing within 24 hours; (5) review corrective actions for significant conditions adverse to quality; (6) review internal audit reports; (7) review the adequacy of the internal audit program every 24 months; and (8) other matters involving safe operation of the facility which an independent reviewer deems appropriate for consideration.

Specific Guidance.

1. Review a sample of four QA training program procedures to ensure they provide the guidance required to implement the applicable portions of the sampled QA program.
2. Review a sample of five training attendance records to verify QA personnel have received and maintained qualification standards as described in the applicable portion of the sampled QA program.
3. Review applicable section(s) of the QAPD and any associated lower tier procedures for a description of the controls listed above.
4. Review a sample of five procedures and verify the requirements listed above in steps 03.02.a and g.

03.03 Onsite Design Change Controls.

Verify whether controls listed below have been established to ensure that design change activities are carried out in a planned, controlled, and orderly manner, and to ensure that design changes related to technical specifications and/or licensee amendments are subject to design change control measures commensurate with those applied to the original design.

- a. Organization(s) or person(s) responsible for performing design change work are identified. Design change request forms (or equivalent) have provisions for documenting completion of required reviews, evaluations, and approvals prior to change implementation.
- b. Methods exist to ensure that applicable design change inputs are identified, and their selection reviewed and approved.
- c. Design change 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 change analysis, such as physics, stress, thermal, hydraulic, and accident analyses, are performed in a planned, controlled, and correct manner.
- e. Procedures exist that identify the external interfaces between the onsite design organizations, including those responsible for design specifications, changes, technical direction, and approvals.
- f. Procedures exist to ensure that design changes have an adequate design verification performed or are checked by applicable methods.
- g. Administrative controls exist to ensure design change have been incorporated into appropriate plant procedures, the training program and plant drawings.
- h. Administrative controls require design documentation and records that provide evidence the design change review process was performed.

Specific Guidance:

1. Review applicable section(s) of the QAPD and any associated lower tier procedures for a description of the design change controls listed above.
2. Quality requirements, including appropriate material specifications, test reports, acceptance criteria, and required documentation, are specified in design and procurement documents.
3. Review a sample of five design change packages to verify conformance with the design controls established in 03.03.a through i above.

03.04 Control of Instructions, Procedures and Drawings.

- a. Verify procedures cover safety significant activities such as technical specification process monitoring, surveillance inspections and tests, inspection hold points, the startup test program, and the control of special equipment.
- b. Verify instructions, procedures and drawings are complete, reviewed, approved, controlled, and maintained to address appropriate quantitative and qualitative acceptance criteria used to successfully accomplish important safety activities.
- c. Verify that operations personnel have QA controls in place for safe operation of the reactor, including authorities and responsibilities for shift supervisors and reactor

operators to shut down the reactor when it is determined that reactor safety is in jeopardy or when operating parameters exceed safety set points and automatic shutdown does not occur.

- d. Verify operations personnel are instructed that in the event of an emergency not covered by an approved procedure or an emergency not following the path upon which the approved procedure is based, operations personnel shall **act to** protect public health and safety and to minimize personnel injury and damage to the facility.
- e. Verify the licensee has a process for issuing standing orders, special orders, temporary procedures, equipment controls and controls for maintenance and modifications:
 - 1. Ensure there are provisions for **the** periodic review, update and **cancellation** of standing orders. Standing orders or standard operating procedures typically deal with job turnover and relief, limitations on plant personnel in the control room, duties of operators and transmittal of operating data to management and for periodic review of standing orders.
 - 2. Ensure there are provisions for periodic review, update and **cancellation** of special orders. Special orders are issued by management for short-term applicability. Such special orders encompass special operations, housekeeping, data taking, publications and their distribution, plotting process parameters, personnel actions, or other similar matters.
 - 3. Ensure there are provisions to review, approve and **cancellation** temporary procedures. Temporary procedures may be issued during the operational phase to direct operations during testing, refueling, maintenance and modifications: to provide guidance in unusual situations not within the scope of normal procedures, and to ensure orderly and uniform operations for short periods when the plant, a system or a component of a system is performing in a manner not covered by existing detailed procedures or has been modified in such a manner that portions of existing procedures do not apply.
 - 4. Verify that prior to granting permission, operating personnel determine that equipment or a system can be safely removed from service. Equipment controls grant permissions for the release of equipment and systems for maintenance by designated operating personnel. Prior to granting permission, operating personnel shall verify that the equipment or system can be released and how long it will be out of service. Granting permission shall be documented and attention shall be given to the potentially degraded condition of the plant when one subsystem of a redundant safety system has been removed for maintenance.
 - 5. Ensure proper return of equipment or a system to service following maintenance or modification activities that may affect the function of safety-related SSCs. These activities shall be performed in a manner to ensure quality at least equivalent to that specified in the original design basis, material specifications, and inspection and test requirements. A suitable level of confidence in SSCs where maintenance or modifications have been performed shall be attained by appropriate inspection and performance testing.

Specific Guidance: Review a sample of five procedures to verify that the work and quality inspection requirements listed in steps 03.04.a through 03.04.c have been met.

03.05 Identification and Control of Material, Parts and Components.

- a. Verify that measures are established for the identification and control of material, parts, and components, including partially fabricated assemblies. These measures shall identify the item by heat number, part number, serial number, or other means either on the item or traceable to the item, as required throughout the fabrication, erection, installation and use of the item.
- b. Verify that the licensee identification and controls shall be designed to prevent the use of incorrect or defective material, parts, and components.
- c. Verify that program procedures for control of material, equipment, parts, components and services policies and guidelines for procurement and receipt inspections are provided in the following areas:
 - 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.

Specific Guidance: Review a sample of five delivered SSCs through the licensee's receipt inspection process to verify that the requirements listed in steps 03.05.a through 03.05.c have been met.

03.06 Inspections and Test Controls.

- a. Verify inspection and test procedures important to safety, including procedures for plant workers and suppliers have been established.
- b. Verify inspection and test procedures are established to ensure that acceptance criteria are specified, inspection and test requirements (including prerequisites) have been met, evaluation of inspection and test results are documented, and deficiencies have been detected and reported to the appropriate level of management.
- c. Verify inspection and test procedures cover significant safety-related activities such as process monitoring, surveillance inspection and test hold points.
- d. Verify inspections and tests are performed by individuals other than those who performed the quality activity being inspected and/or tested.
- e. Verify tests are performed following plant modifications or significant changes in operating procedures to confirm that the modifications or changes in operating procedures confirm that the modifications or changes produce the expected test results and that the change does not reduce plant safety.

Specific Guidance: Review a sample of five documents related to the performance of inspection and test activities to verify that the requirements listed in step 03.06.a. through 03.06.d have been met.

03.07 Inspection, Test and Operating Status.

- a. Verify that the licensee established controls for the use of markings such as stamps, tags, labels, routing cards, or other suitable means, to determine the status of inspections and tests of items installed in the plant.
- b. Verify that the licensee established measures to identify items which have satisfactorily passed required inspections and tests.
- c. Verify that the licensee established measures that would prevent inadvertent bypass of required inspection and tests.
- d. Verify that the licensee established measures to indicate the operating status of SSCs in the plant, such as tagging valves and switches, to prevent inadvertent operation.

Specific Guidance:

1. Sample the operating status of five SSCs in the plant to verify that the requirements listed in steps 03.07.a through 03.07.d have been met.
2. Verify that TS requirements for declaring SSCs operable, inoperable and in a limiting condition for operation, and/or in bypass, have been met.

03.08 Nonconforming Material, Parts and Components.

- a. Verify that the procedure provides for identification and control of non-conforming equipment, material, parts, and components to preclude inadvertent use, including periodic inspections/surveillances to verify adequate control.
- b. The procedure should specify the disposition of each non-conforming item (i.e., accept, repair, use-as-is, reject or rework). For non-conforming items dis-positioned for use-as- is or repair, the licensee should provide an engineering justification that the item can still performed its intended safety function.
- c. Verify whether the license QA program requires an evaluation of non-conforming items to determine if a reportable significant condition adverse to quality and a potentially reportable defect exists as defined in 10 CFR Part 21.

Specific Guidance: Sample 5-10 nonconformance reports to verify that the requirements in steps 03.08.a through 03.08.c have been met.

03.09 Corrective Action Program Requirements.

- a. Verify the following for the corrective action program.
 1. Verify procedures are established to identify conditions adverse to quality and significant conditions adverse to quality (SCAQ) under the corrective action program.
 2. Verify procedures are established to identify SCAQ and potential defects and non-compliances that should be evaluated under 10 CFR Part 21, the cause of the condition, the corrective actions taken to preclude repetition and report SCAQ to the appropriate levels of management.

3. Verify provisions are established for the evaluation of deviations, defects or failures to comply associated with substantial safety hazards.
4. Verify the licensee's Part 21 procedure has the following attributes:
 - a) Notification to the responsible officer
 - b) Timeliness requirements for interim and initial written notifications.
 - c) Required information necessary to identify the potential substantial safety hazard.

Specific Guidance: Sample 5-10 corrective action reports identifying potential deviations or defects for evaluation to verify that the requirements listed in steps 03.09.a.1 through 03.09.a.4 have been met.

03.10 Quality Assurance 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.
- b. For electronic records, verify the licensee (1) used either the 2011 version of **the** four Nuclear Information and Records Management (NIRMA) standards endorsed by an NRC safety evaluation listed in the reference section of this procedure or (2) used NRC RIS-2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," which endorsed the 1998 version of these NIRMA standards. The NRC inspectors should obtain copies of NIRMA standards and verify **by sampling** that the following are in place for the electronic QA records system.
 1. Review and verify electronic QA records are authentic, complete, and accurate with digital signatures and custody controls for electronic records through their entire life-cycle from draft initial to final signature.
 2. Review the types of electronic QA storage media used by the licensee, such as, magnetic, or optical media, computer disks, magnetic tape, optical tape cartridge, CD-ROM, and DVDs with a standard life expectancy equal to the retention period required for electronic QA records.
 3. Verify environmental controls where temperature should be maintained between 60-80 degrees F and humidity between 40-50% for electronic QA storage media.
 4. Verify management controls for electronic QA records, including generation, disposition, distribution, maintenance, retention, security, use, retirement, and media archiving, including storage and inspection requirements.

5. Review the licensee's software quality assurance plan (SQAP), software configuration management plan (SCMP) and software verification and validation plan (SVVP) for the electronic QA record system.
6. Verify the licensee's SQAP, SCMP and SVVP is designed to prevent threats to the electronic QA records system.
7. Verify the licensee ensures the electronic QA records system is reliable, easy to maintain and use with adequate change controls for software errors.
8. Verify the licensee has a reporting process for identifying problems with the QA records system, trends related to adverse conditions and the need for corrective actions which prevent corruption of vital QA records.
9. Verify licensee's on-line storage locations and data backup/disaster recovery storage locations for electronic QA records are in place if the primary QA records storage system is lost.
10. Verify electronic QA records storage locations are sufficiently remote to minimize the risk of exposure to simultaneous types of hazards, such as earthquakes, fires, tornadoes, tsunamis, etc.
11. Verify the licensee has a Disaster Support Team (DST) and an Electronic Records Disaster Recovery Plan (ERDRP).
12. Verify that the licensee's ERDRP has policies and procedures for disaster prevention and disaster recovery, including automatic system backups of vital electronic QA records performed every two weeks.
13. Verify the licensee completes test and maintenance activities on the DST and the ERDRP. A disaster drill should be completed to test various aspects of specific reactions in the ERDRP (i.e., tornadoes, earthquakes, etc.).
14. After the disaster drill, verify if the licensee completes after action observations and updates the ERDRP accordingly with improvements in the plan.

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 steps 03.10.a-1 through 4 above.

- c. Verify that requirements and provisions to maintain the following types of hard copy and/or electronic records in storage facilities 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 in-service 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 steps 03.10.c.1 through 03.10.c.18.

- d. 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.c) above.
 2. Designation of a custodian(s) in charge of storage facilities identified in (03.10.c) above.
 3. Description of the filing system(s) to be used to allow for the retrieval of records identified above.
 4. Methods to verify that records received agree with the transmittal documents 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.d.

- e. Verify that responsibilities have been assigned to ensure the following:
 - 1. Record storage controls identified under (03.10.d) above will be implemented.
 - 2. Transfer and retention of construction phase records.
 - 3. Retention periods of records listed under 03.10.c.
 - 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.e have been assigned.

- f. 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.c. (as available) and verify the items listed above, as applicable, in step 3.10.f.

03.11 Audits. Verify the following:

- a. The scope of the audit program has been procedurally defined and that it is consistent with QA program requirements.
- b. That an overall plan exists by which management ensures that the audit program addresses all aspects of activities affecting quality.
- 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 technical expertise for audits.
 - 3. Determining the independence of audit personnel.
 - 4. Assuring corrective actions are taken for deficiencies identified during audits.
 - 5. Determining when re-audits 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 audit schedules.

- d. 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. 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.
4. The NRC inspectors should verify that the licensee completes audits of selected operational phase activities within a frequency commensurate with their safety significance and to ensure that audits of the following program elements for safety related functions are completed within 2 years.
 - a) The results of actions taken to correct deficiencies that affect nuclear safety and occur in facility SSCs or methods of operation (at least once per 6 months).
 - b) The conformance of facility operations contained within the technical specifications and license conditions (at least once per 12 months)
 - c) The performance, training and qualifications of the facility staff (at least once per 12 months)

03.12 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), including licensee reductions in QA commitments, if any, were made in accordance with 10 CFR 50.54(a)(3) and/or 10 CFR 50.54(a)(4), **as applicable.**

35101-04 RESOURCE ESTIMATE

This procedure supports the QA review of combined license (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.

This procedure is a one-time NRC inspection for new COL QA operational programs under IMC 2504 for 10 CFR Part 52 plants and under IMC 2514 for new 10 CFR Part 50 licensees that may still implement this IP.

35101-05 PROCEDURE COMPLETION

Meeting the inspection objectives defined in Section 35101-01 of this IP will constitute competition.

35101-06 REFERENCES

10 CFR 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Facilities.

10 CFR 50.54, Conditions of Licenses.

American National Standards Institute (ANSI)/American Nuclear Society (ANS) 3.2-2012, "Administrative Controls and Quality Assurance for Operational Phase of Nuclear Power Plants," (ADAMS Accession Number ML13023A051)

American Society of Mechanical Engineers (ASME) NQA-1 and NQA-1a Addenda, "Quality Assurance Requirements for Nuclear Facility Applications."

IP 35007, "Quality Assurance Program Implementation during Construction and Pre-Construction Activities," U.S. Nuclear Regulatory Commission, Washington, DC.

NIRMA TG 15, "Management of Electronic Records,"

NIRMA TG 16, "Software Configuration Management and Quality Assurance," NIRMA TG 21, "Electronic Records Protection and Restoration"

NRC Letter to Duke Power, Subject: Safety Evaluation to Duke Energy Carolinas, LLC, Amendment 40 to the Quality Assurance Topical Report, (TAC Nos, MF5055, MF 5056, MF5057, MF5058, MF 5059, MF5060, MF5061) (ADAMS Accession Number: ML15099A561) which endorsed the 2011 version of NIRMA standards noted above.

NRC Regulatory Issue Summary (RIS) 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," dated October 23, 2000, which endorsed the 1998 version of NIRMA standards noted above.

Nuclear Information and Records Management Association (NIRMA) TG 11, "Authentication of Records and Media," 210 Fifth Avenue, New York, New York 10010

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

Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5," U.S. Nuclear Regulatory Commission, Washington, DC.

Regulatory Guide 1.33, "Quality Assurance Program Criteria (Operation)," Revision 3, U.S. Nuclear Regulatory Commission, Washington, DC.

Regulatory Guide 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," Revision 4, U.S. Nuclear Regulatory Commission, Washington, DC.

END

Attachment 1: Revision History for IP 35101

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Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment and Feedback Resolution Ascension Number (Pre-Decisional, Non-Public)
N/A	10/03/07 CN 07-030	<ol style="list-style-type: none"> 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. 4. Combines information contained in IPs 35001, 35007, 35060, 35061, 35740, 35741, 35742, 35744, and 35748. 	N/A	ML063400034
N/A	ML15293A183 07/08/16 CN- 16-015	Complete rewrite. Revised to focus inspection efforts on operational QAPD activities. Also revised to (1) meet the guidance in RG 1.33, Revision 2; (2) add inspection requirements from IPs 35007, 35746, 35747 and IP 35750; (3) add a reference to a safety evaluation that endorsed storage of electronic QA records from NIRMA 2011 standards and RIS 2000-18 endorsement of NIRMA 1998 standards.	N/A	ML15293A184

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment and Feedback Resolution Ascension Number (Pre-Decisional, Non-Public)
N/A	ML21327A000 12/29/21 CN-21-041	Revised the format to meet IMC 0040 guidance. Updated references to RG and NRC endorsed standards to the most recent revisions. Minor editorial revisions to correct errors in the previous revision.	N/A	N/A