ROUTINE INSPECTIONS OF NUCLEAR VENDORS

PROGRAM APPLICABILITY: 2507

43002-01 INSPECTION OBJECTIVES

To verify that vendors supplying basic components have implemented effective quality assurance (QA) procedures, policies, instructions, and plans in accordance with a QA program that complies with the requirements of Appendix B to 10 CFR Part 50 (Appendix B).

This procedure is to be used in combination with the following inspection procedures, when applicable: Inspection Procedure (IP) 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance," and IP 43004, "Inspection of Commercial-Grade Dedication Programs."

43002-02 INSPECTION REQUIREMENTS

02.01 The inspector reviews the QA program and instructions, procedures, plans, and policies and verifies, by observing vendor activities, document reviews, and interviewing vendor staff, that the selected vendor has implemented effective QA controls for safety-related activities. The facility's QA program should be based on the appropriate criteria contained in Appendix B.

02.02 The lead inspector will prepare an inspection plan in accordance with established guidelines. The inspection plan should provide the scope and basis for the inspection; describe the proposed evaluation of the vendor's activities, including the QA program procedures and its implementation, and identify the work assignments for each inspector. The inspection plan shall consider inspection of the critical and quality attributes associated with inspections, test, analyses, and acceptance criteria (ITAAC) family groups. The purpose of including these in the plan is to provide input into the ITAAC closure verification process. Guidance on inspection plans is contained in IMC-0613, "10 CFR Part 52 Licensed Power Reactor Construction and Test Inspection Reports."

43002-03 INSPECTION GUIDANCE

The vendor's QA program should contain procedures, policies, and instructions to address the following areas, as appropriate to the vendor's safety-related activities:

a. Organization

b. Quality Assurance Program

c. Design Control

d. Procurement Document Control

e. Instructions, Procedures, and Drawings

f. Document Control

g. Control of Purchased Material, Equipment, and Services

h. Identification and Control of Materials, Parts, and Components

i. Control of Special Processes

j. Inspection

k. Test Control

l. Control of Measuring and Test Equipment (M&TE)

m. Handling, Storage, and Shipping

n. Inspection, Test, and Operating Status

o. Nonconforming Materials, Parts, or Components

p. Corrective Action

q. Records

r. Audits

Specific Guidance. The lead inspector will focus the inspection effort on those Appendix B criteria most relevant to the activities that the vendor performs.

After the inspector becomes familiar with the vendor's QA program and implementing procedures, the inspector will select a sample of QA activities for review. For the selected activities, the inspector will request that the vendor provide (or make available for review) a complete package of the pertinent records. The review should include procurement documents, engineering specifications, analyses, audit reports, calibration reports, and associated documentation pertinent to the area of review. The verification is accomplished by reviewing the vendor's program/procedures, controlling processes and activities, and evaluating the actual implementation of these controls.

The inspector will evaluate the effectiveness of the vendor's implementation of the QA program and procedures using the guidance below.

03.01 Organization. Assess the organizational structure and QA personnel by performing the following:

a. Review the organizational structure and functional relationships. Identify the individuals or the organization responsible for defining the overall effectiveness of

the QA program. Verify that the organizational description addresses the organizational structure, functional responsibilities, levels of authority, and interfaces.

b. Verify qualifications, responsibilities, and duties of personnel performing activities affecting quality. Verify that personnel or organizations performing QA program implementation and verification activities have the authority, independence, and organizational freedom (independent from cost or schedule considerations) to identify quality problems, recommend solutions, and verify implementation of solutions.

c. Verify that an individual has been designated to issue stop work orders.

03.02 QA Program. Verify QA program implementation by performing the following:

a. Verify that the QA program identifies the items and activities to which it applies.

b. Verify that activities affecting quality are accomplished under suitably controlled conditions.

c. Verify that management of those organizations implementing the QA program, or portions thereof, assess the adequacy of that part of the program for which they are responsible and assure its effective implementation in accordance with established procedures.

d. Verify that programs are implemented for the indoctrination and training of personnel performing activities affecting quality. Verify that qualification records and certifications exist for inspection/test personnel, auditors, calibration, repair personnel, and similar specialists performing activities affecting quality. Verify that qualification records of personnel are certified in accordance with industry and/or vendor's program requirements.

e. In order to verify that personnel have been adequately trained, the inspector may conduct interviews with the personnel to ensure they have an understanding of the activities they are performing commensurate with their responsibilities.

03.03 Design Control. Assess implementation of design controls and design configuration controls by performing the following:

a. Review the vendor's design control process and verify that the procedures delineate design activities in a planned, controlled, and orderly manner. Verify that procedures provide controls for design inputs, outputs, design analyses (e.g., physics, stress, thermal, hydraulic, etc.), records, and organizational interfaces. Verify that design activities are accomplished in accordance with procedures.

b. Verify that provisions in the design process permit the selection and review for suitability of application of materials, parts, equipment and processes that are essential to the safety-related function of the product. When required, assessment of commercial-grade dedication activities is done in accordance with IP 43004, "Inspection of Commercial-Grade Dedication Programs."

c. Verify that applicable design inputs are correctly translated into specifications, drawings, procedures, or instructions. Verify that the design translation is supported by engineering data (i.e., calculations, performance test, etc.), including verification that design inputs are satisfied. The final design (approved design output

documents and approved changes) is relatable to the design input and identifies assemblies and/or components that are part of the item being designed.

d. Verify that procedures identify the interfaces between design organizations, including criteria designs, specifications, changes, technical direction, and approvals.

e. Verify that procedures are implemented to control design changes. Verify that design changes are subject to design control measures commensurate with those applied to the original design. Ensure that design verification is performed by individuals or groups other than those who performed the original design, but who may be from the same organization.

03.04 Procurement Document Control. Select a sample of procurement documents and verify the implementation of procurement document controls by performing the following:

a. Verify that procedures are established and implemented for the control and release of procurement documents and subsequent changes.

b. Verify that quality requirements, including technical, administrative, regulatory, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, witness and hold points, and applicability of 10 CFR Part 21) are specified in procurement documents. Verify that these requirements are extended to lower tier suppliers, where necessary.

c. Verify that, as appropriate to the circumstances of procurement, procurement of basic components require a documented QA program that is implemented and meets the applicable regulatory requirements.

d. Verify that deviations from previously established requirements, including design changes, are adequately controlled and reviewed. These deviations are documented to provide objective evidence of the review. Verify that procurement document changes are subject to the same degree of control as utilized in the preparation of the original documents.

03.05 Instructions, Procedures, and Drawings. Verify the implementation of work and quality instructions, procedures, and drawings by performing the following:

a. Verify that work and inspection procedures have been established and implemented, including those related to sub-vendor activities.

b. Verify that instructions, procedures, and drawings are reviewed, approved, and controlled. Verify that individuals performing activities related to quality have available to them the most recently approved specifications, procedures, and instructions pertinent to activities.

c. Verify that instructions, procedures, and drawings include quantitative and qualitative acceptance criteria for determining that activities have been satisfactorily accomplished.

03.06 Document Control. Select a sample of documents prescribing activities affecting quality for review. Assess the control of documents by performing the following:

a. Verify that a program to control the issuance of documents is implemented. Examples of controlled documents include design drawings, as-built drawings, engineering calculations, design specifications, material analysis records, purchase

orders and related documents, audit and surveillance procedures, technical specifications, nonconformance reports, corrective action reports, work instructions and procedures, calibration procedures, quality verification procedures, and inspection and test reports.

b. Verify that a document control system identifies the documents to be controlled; identifies the individuals responsible for the review, approval, issuance, and distribution of documents, and controls changes or revisions to such documents.

c. Verify that documents attesting to the quality of components used in the manufacturing process, including material certifications, test reports, receiving inspections, evaluations, and audit results are maintained to indicate that quality requirements have been met.

d. Verify that quality-related documents sampled are reviewed for adequacy by qualified personnel.

03.07 Control of Purchased Materials, Equipment, and Services. Assess the controls implemented on purchased items and services by performing the following:

a. Verify that procedures have been established and implemented to select and qualify vendors supplying basic components. Examples of procured services include calibration, non-destructive examination (NDE), testing laboratories, software codes/programs, heat treatment, third-party inspections, engineering and consulting services, installation, repair, or maintenance work.

b. Verify that appropriate methods are used to accept a basic component from a supplier, such as certificates of conformance, source verifications, audits, surveillances, receiving inspections, or a combination thereof.

c. Verify that vendors implementing an Appendix B QA program conduct audits and surveys of commercial-grade suppliers. These activities should be based upon the suppliers' capability to supply the commodity desired in accordance with applicable codes/regulations.

d. Verify that the effectiveness of the control of quality is assessed at intervals consistent with the importance, complexity, and quantity of the product or service (i.e., approved suppliers list). See the Audits section of this inspection procedure for additional guidance.

e. Verify that there are provisions in the procedures to verify the validity of certificates and determine the effectiveness of the certification system when desired, such as during the performance of audits. Verify that certificates of conformance/compliance identify the material, equipment, or service supplied; identify specific procurement requirements (codes, standards, certificates, or other specifications) that have been met as well as those that have not been met, together with an explanation and the means for resolving the nonconformance; and identify the supplier's QA individual responsible for authenticating such certificates. If any criteria have not been met, verify if a nonconformance report was initiated and follow up on its resolution.

f. Verify that receiving inspections examine objective evidence of purchased items by verifying attributes specified in procurement documents. Receiving inspections should verify, as a minimum, item configuration, dimensions, physical characteristics, and identification and traceability of material and equipment, including status of inspection or tests performed, as required.

g. Verify that the vendor has a documented method for the identification and control of nonconforming material and components, including fraudulent parts, to preclude inadvertent use.

h. When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural requirements.

03.08 Identification and Control of Materials, Parts, and Components. Assess the identification and control of purchased items by performing the following:

a. Verify that procedures have been established and implemented for the identification and control of items to ensure that only specified and accepted items are used.

b. Verify that identification markings, when used, are applied using materials and methods that provide a clear and legible identification and do not adversely affect the function or service life of the item. Verify that markings are maintained on the item or in documents traceable to the item.

c. Verify that physical identification is used to the maximum extent possible. Ensure that, where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means are employed.

03.09 Control of Special Processes. Assess the control of special processes by performing the following:

a. Verify that procedures have been established and implemented for the control of special processes. Examples of special processes include welding, nondestructive examinations (NDE), heat treatment, soldering, painting, and electroplating.

b. Verify that procedures provide measures for the generation of special process control documents such as travelers, process sheets, instructions, checklists, or other appropriate means.

c. Verify that process control documents include, as a minimum, personnel and equipment qualification requirements; conditions necessary for accomplishing the process; acceptance criteria; results of completion of specific operations at checkpoints of fabrication, manufacture, or installation, and signature, initials, or stamp and date of the authorized representative for the activities witnessed.

d. Verify that special processes are performed by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

e. Verify that qualification records are maintained as appropriate for the currently qualified personnel, processes, and equipment for each special process.

f. When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural requirements.

03.10 Inspection. Assess inspection controls by performing the following:

a. Verify that procedures are established and implemented for the inspection of items and activities affecting quality. Examples of inspections include source, receipt, in-process, in-service, final, operations, modification, maintenance, and third-party oversight.

b. Verify that procedures provide measures for the generation of inspection control documents such as travelers, process sheets, instructions, checklists, or other appropriate means.

c. Verify that inspection control documents include, as a minimum, the item inspected, inspection date, type of observation, results of examination and tests, and the signature, initials, or stamp and date of the authorized representative (e.g., authorized nuclear inspector) for the activities witnessed. Verify that mandatory hold points are indicated in the controlling documents and that work does not proceed without appropriate approval.

d. Verify that inspections are performed by qualified persons other than those who performed or directly supervised the work being inspected.

e. Verify that inspection results are documented by the inspector and reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results.

f. When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural requirements.

03.11 Test Control. Assess test controls by performing the following:

a. Verify that procedures are established and implemented for the test of items. Examples of tests include prototype qualification, production, construction, pre-operational, operational, post-maintenance, post-modification, computer program/software, and proof tests prior to installation.

b. Verify that test procedures include or reference test objectives, test requirements, applicable prerequisites, and acceptance criteria contained in the applicable design or technical documents.

c. Verify that test results are documented and evaluated by a qualified individual to ensure the test requirements have been satisfied. Test records, as a minimum, should identify the item tested, date of test, tester or data recorder, type of observation, instruments used and the validity of their calibration, results and acceptability, action taken in connection with any deviations noted, and the individual evaluating test results.

d. When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural requirements.

03.12 Control of Measuring & Test Equipment (M&TE). Assess M&TE controls by performing the following:

a. Verify that procedures have been established and implemented to ensure adequate control, calibration, and adjustment of measuring and test equipment. Examples of M&TE include instruments, tools, gages, and nondestructive examination equipment.

b. Verify equipment calibration history. Check for dates calibrated, the individual who performed the calibration, results, due date, primary standard, and purchase order number, if a vendor calibrated the instruments.

c. Verify that M&TE is calibrated, adjusted, and maintained at prescribed intervals prior to use. Verify that the method of calibration for each device is defined.

d. Verify that M&TE is labeled, tagged, handled and stored, or otherwise controlled to indicate the calibration status of the instrument and ensure its traceability to calibration test data.

e. Verify that calibration is against certified equipment having known valid relationships to nationally recognized standards. For domestic applications, procurement of commercial-grade calibration services for safety-related applications using laboratory accreditation programs administered by the National Institute of Standards and Technology (NIST) and by the American Association for Laboratory Accreditation (A2LA) are acceptable. If no nationally recognized standards exist, the basis for calibration is documented.

f. When M&TE is found to be out of calibration, provisions in the procedures should require an evaluation to verify if previous inspection or test results are affected. Verify that there are provisions to notify affected customers, where appropriate.

g. Verify that records are maintained to indicate calibration status. Review these records and check calibration logs for As Found/As Left information.

h. Verify that out-of-calibration devices are tagged or segregated.

i. Verify that devices consistently found out of calibration are repaired or replaced.

j. When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural requirements.

03.13 Handling, Storage, and Shipping. Assess handling, storage, and shipping controls by performing the following:

a. Verify that procedures have been established and implemented for the control of shipping activities, which include packaging, marking/labeling, storing, status and shipment of items and components, and control of limited shelf life materials.

b. Verify that special equipment and protective environments are specified, provided, and verified when required. Examples of special equipment include containers, shock absorbers, and accelerometers. Examples of protected environments include humidity and temperature controls, specific moisture content levels, and inert gas atmospheres.

c. Verify that operators of special handling equipment are experienced or trained in the use of the equipment.

d. When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural requirements.

03.14 Inspection, Test, and Operating Status. Assess inspection, test, and operating status controls by performing the following:

a. Verify that the status of inspections and tests performed on individual items are indicated either on the item or on documentation traceable to the item.

b. Verify that procedures specify the authority for application and removal of status indicators.

c. When possible, observe and assess actual techniques being used and their acceptability relative to procedural requirements.

03.15 Nonconforming Materials, Parts, or Components. Assess nonconforming item controls by performing the following:

a. Verify that procedures are established and implemented to control items that do not conform to specified requirements.

b. Verify that written procedures provide for identification, documentation, evaluation, segregation (when practical), disposition (along with technical justifications), reference to instructions or procedures for repair and rework activities (where required), re-inspection of repaired and reworked items (where required), and notification to affected organizations of nonconforming conditions.

c. Verify that procedures identify the responsibility and authority for review and disposition of nonconforming items, and controls further processing, delivery, and installation of nonconforming items until disposition is completed.

d. Review and verify that the vendor has taken adequate actions regarding nonconforming materials or items.

e. Verify that nonconforming items are reviewed and dispositioned in accordance with documented procedures. Nonconforming items are dispositioned as accepted, rejected, repair, rework, or use-as-is.

f. Verify that technical justifications are documented to verify the acceptability of nonconforming items dispositioned as repair or use-as-is.

g. Verify that nonconformance(s) to design requirements dispositioned as use-as-is or repair are subject to design control measures commensurate with those applied to the original design.

h. Verify that the process to control nonconformance(s) provides a connection to the 10 CFR Part 21 procedures. Assessment of the evaluation and reporting of deviations or failures to comply is done in accordance with IP 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance."

03.16 Corrective Action. Select a sample of corrective action reports and related documents for review. Assess corrective action controls by performing the following:

a. Verify that procedures have been established and implemented for correcting conditions adverse to quality.

b. Verify that corrective action reports provide for documentation and description of the condition adverse to quality, the cause and corrective action taken to prevent recurrence, review and approval by the responsible authority, status of corrective actions reviewed, and follow-up action taken to verify timely and effective implementation of corrective action.

c. Verify that the corrective action process provides a connection to the 10 CFR Part 21 procedures. Assessment of the evaluation and reporting of deviations or failures to comply is done in accordance with IP 36100.

d. Verify if subcontractors are required to submit nonconforming reports and proposed corrective action for approval before implementing corrective action.

e. Verify that deficiencies identified or reported by customers (e.g., receipt inspection rejections, nonconformances, etc.) are adequately assessed and entered into either the nonconformance or corrective action program.

f. Verify that a management system is established for overview of trends for conditions adverse to quality.

03.17 QA Records. Select a sample of QA records for review. Assess QA records controls by performing the following:

a. Verify that the vendor implements a documented record system that provides measures for, as a minimum, the identification of records to be maintained; classification of records; validation of records; control of distribution, handling, maintenance, and storage, and procedures implementing configuration management requirements.

b. Examples of QA records include inspection and test records; audit reports; quality-related procedures/instructions/drawings; qualifications and certifications; material analysis records; vendor-supplied documents; certifications of compliance/conformance; laboratory/engineering/manufacturing operating logs; calibration records; and nonconformance documents.

c. Verify that procedures identify the designated person or organization responsible for records access, including receipt control, processing, corrections, and safekeeping.

d. Verify that the records sampled are legible, adequate, retrievable, adequately protected, and traceable to markings, identification tags, or other means of identifying materials, components, and activities important to safety.

e. Verify that records are stored in a manner that precludes deterioration, environmental effects, damage, and loss.

f. Verify that QA records stored in electronic media are subject to the same controls described above. Electronic recordkeeping systems shall maintain the integrity, authenticity, and acceptability of QA records during their required retention period in accordance with NRC requirements. This includes management of software configuration, record migration/regeneration programs, and electronic media control.

g. Verify that design records are stored and maintained in accordance with established procedures. Design records include, but are not limited to, the final design output, subsequent revisions, the important design steps (e.g., calculations, analyses, and computer programs), and the sources of input that support the final output.

03.18 Audits. Select a sample of audit records for review. Assess audit controls by performing the following:

a. Verify that procedures have been established and implemented to provide a comprehensive independent audit of activities and procedures, including the status and adequacy of the QA program.

b. Verify that procedures describe the scope and purpose of audits to be performed, frequency or schedule of audits (including supplemental audits to provide adequate coverage), audit criteria, basis for re-audit, documentation of audit results,

management review and assessment, corrective action, and follow-up (where required).

c. Verify that audit teams were selected using qualified auditors. Verify that selected auditors are not auditing their own work.

d. Review a sample of audits and verify that scheduled audits were performed using checklists and/or procedures. These checklists/procedures include an audit plan, documented objective evidence, audit results, and a review of audit results by responsible management. Verify that audits were performed at the minimum frequency specified in the QA manual. Verify that follow-up action was taken where indicated.

e. During inspections at ASME certificate holders, verify that the authorized nuclear inspector (ANI) is performing its third-party oversight as required. Verify that the ANI has reviewed and signed the ASME Section III code data report.

43002-04 RESOURCE ESTIMATE

This inspection procedure is used for routine inspections of vendors providing basic components to licensees. The resource estimate for this inspection procedure is approximately 200 hours of direct inspection effort.

43002-05 REFERENCES

Inspection Procedure 36100, “Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance.”

Inspection Procedure 43003, “Reactive Inspections of Nuclear Vendors.”

Inspection Procedure 43004, “Inspection of Commercial-Grade Dedication Programs.”

END

Attachments:

1. Revision History

ATTACHMENT 1

Revision History for IP 43002

Commitment Tracking Number	Issue Date	Description of Change	Training Required	Training Completion Date	Comment Resolution Accession Number
N/A	10/03/07 CN 07-030	Researched commitments for 4 years and found none. Initial issuance	None	N/A	N/A