INSPECTION PROCEDURE 43002

ROUTINE INSPECTIONS OF NUCLEAR VENDORS

PROGRAM APPLICABILITY: 2507, 2700

43002-01 INSPECTION OBJECTIVES

To verify that vendors supplying basic components are effectively implementing appropriate policies, procedures, instructions and activities in accordance with 10 CFR Part 50 Appendix B and 10 CFR Part 21. To ensure that all technical, quality, and regulatory requirements invoked by the procurement documents are being met. The inspection team will review the processes and observe the related activities being performed by the vendor during the design, fabrication, and testing of basic components. The inspection emphasis will be on observing actual activities whenever possible. The inspection team will verify compliance with applicable industry codes and standards, regulatory requirements, and verify sufficient records are being maintained.

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 inspection team leader will determine what the vendor supplies to the nuclear industry and the relative safety significance of the products. The inspection team leader will determine which aspects of the vendor program should be inspected, and prepare an inspection plan in accordance with the applicable IMC.

02.02 The inspection team will prepare for the inspection, including making travel arrangements, and reviewing the inspection plan, inspection procedures, applicable regulations, and information gathered by the inspection team leader.

02.03 The inspection team will perform the inspection in accordance with the appropriate Inspection Manual Chapter and Inspection Procedures. The inspection team will verify that procurement documentation is correctly converted into vendor instructions to meet technical and quality requirements. The inspection team will observe the activities (and related documentation) being performed by the vendor during the design, fabrication, repair/refurbishment, and testing of basic components. The inspector team should also review the vendor QA program and instructions, procedures, plans, and policies for vendor activities not observed to verify that the

vendor has implemented effective QA controls for safety-related activities. Reviews of vendor processes and procedures shall include reviews of completed documentation and interviews of vendor personnel. The inspectors will verify that vendor quality processes meet applicable industry codes, standards, and regulatory requirements.

02.04 The inspection team leader shall manage the team inspection activities to ensure good communication between the team and the vendor. For each potential finding, the inspection team leader shall ensure the team considers the potential effect on the quality of a safety-related product or service, provided to a purchaser.

43002-03 INSPECTION GUIDANCE

The applicable Inspection Manual Chapter (2507 or 2700) will be used for additional guidance. Inspection Manual Chapter 0617 will be used for guidance on preparing the Inspection report.

Using the procurement documents, determine the basic component that the vendor is supplying, and the applicable technical and quality requirements. The inspection emphasis will be on observing the activities being performed by the vendor during the design, fabrication, repair/refurbishment, and testing of basic components. If there are vendor processes critical to the basic component being supplied, and no activities are being conducted by the vendor during the inspection, then the inspection team should review completed documentation and interview vendor personnel, to inspect the activity.

Inspectors should be familiar with the regulatory requirements (Appendix B and/or Part 21 criteria) and industry standards for the area being inspected. Inspectors should review the vendor QA program, policies, and procedures relative to the area being inspected, and compare the activities observed (or documentation of past activity) to the vendor requirements, and then to the industry standards and regulatory requirements to determine compliance. Interviews of vendor personnel should be conducted to clarify observations, and to verify that vendor personnel understand the vendor QA program, policies, and procedures, industry standards and regulatory requirements. Inspectors will verify that vendor quality processes meet applicable industry codes, standards, and regulatory requirements.

Specific Guidance. The inspection team leader will focus the inspection effort on those activities the vendor is performing during the inspection for safety-related products. If there are vendor processes critical to the basic component being supplied, and no activities are being conducted by the vendor during the inspection, then the inspection team should review completed documentation and interview vendor personnel, to inspect the activity. 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.

03.01 Inspection Plan Preparation

a. The inspection team leader should review applicable enforcement history, outstanding open items, recent (within the last 5 years) inspection results, and recent third-party audit reports (within the last 5 years). The inspection team leader should also review recent applicable (within the last 5 years) 10 CFR Part 21 notifications, 10 CFR Part 50.72 & 73 notifications, Equipment Performance

and Information Exchange (EPIX) reports, and Construction Experience Program information relative to the vendor products being supplied.

b. When applicable, 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.

c. The inspection team leader shall confirm (with the vendor) the actual work activities the vendor will be performing during the inspection.

d. The Inspection plan should include the following sections:

1) INSPECTION BASIS - The inspection plan should document the BASIS for the inspection. The basis includes the regulation(s) (10 CFR) that the inspection will be based on.

2) INSPECTION SCOPE - The inspection plan should provide the scope for the inspection. The scope starts with a brief description of the activities that the vendor performs and the location(s) where the inspection will be performed. The scope should describe the basic component (in accordance with 10 CFR Part 50 Appendix B and 10 CFR Part 21) to be inspected. The inspection plan should describe the proposed vendor's activities to be observed or reviewed based on the guidance in 03.03, and the applicable regulatory requirements.

a) Optional - The scope may include the procurement document relationship to the inspection and/or the reasoning why the activities to be inspected were chosen.

3) TEAM ASSIGNMENTS - The inspection plan should include the team assignments. The inspection team should be selected and assigned based on their abilities and the activities that are to be observed or reviewed. The inspection plan should identify the work assignments for each inspector. The work assignments should be specific, identifying the specific guidance in 03.03, IP 36100, or IP 43004, to be used. Work assignments can also tie back to a particular issue (such as a 10 CFR Part 21 report, previous inspection finding, or allegation), or to a particular industry code/standard or regulation.

4) PURPOSE AND INSPECTION PROCEDURES USED - The inspection plan should include the purpose of the inspection and the inspection procedures to be used. The purpose should reference the regulatory requirement from the basis to the program/process being inspected.

5) LOGISTICS - The inspection plan should include the team logistics. Logistics should include per-diem rates, inspection schedule, meeting schedule, and time charge information. Logistics may include travel and lodging details, or any other information deemed appropriate by the inspection team leader.

6) DELIVERABLES – The inspection plan should include the deliverables expected by the team leader from the team members during and after the inspection, and the schedule for inspection report issuance.

03.02 Inspection Team Preparation

a. The inspection team leader will obtain the necessary information to adequately prepare the inspection team including those items reviewed for 03.01, the vendor quality assurance program procedures, other applicable vendor procedures, and related procurement documents. This information gathering may require a trip to the vendor. If the information is not obtainable from the vendor prior to the inspection, the length of the inspection at the vendor may need to be increased.

b. The inspection team leader should provide the information gathered to the inspection team, and schedule a team meeting before the inspection, allowing time for the information to be reviewed.

c. The team members should review all the information provided by the team leader, the Inspection Plan, the inspection procedures, industry codes and standards, and regulations applicable to their assignments prior to the team meeting.

d. The inspection team leader should discuss the inspection plan and individual assignments during the team meeting. The members of the inspection team should discuss any insights from the information that has been reviewed, and ensure the inspection team understands the expectations of the team leader.

03.03 Perform the Inspection

The inspectors will evaluate the effectiveness of the vendor's implementation of the purchase documentation, 10 CFR Part 21 and Part 50 Appendix B requirements. For the activities that will be inspected use the guidance below. Ensure the observed activities (or documentation for activities not observed) are in accordance with the vendor instructions, procedures, and drawings and meet the purchase documentation and 10 CFR Part 50 Appendix B requirements. As the inspection proceeds the team should follow up on potential issues discovered, even if this deviates from the Inspection Plan.

a. Translation of Purchase Documentation to Instructions, Procedures, and Drawings. Observe how the purchase documentation is translated into the vendor instructions, procedures and drawings, and control of changes (this includes changes until product or service delivery). When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural/regulatory requirements.

1) Verify that applicable design inputs, from the purchase documentation, 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. Verify that 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. (10 CFR Part 50 App. B Criterion 3)

2) 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. (10 CFR Part 50 App. B Criterion 3)

3) 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 changes are subject to the same degree of control as utilized in the preparation of the original documents. (10 CFR Part 50 App. B Criterion 3)

4) Verify that work and inspection procedures have been established and implemented, including those related to sub-vendor activities. (10 CFR Part 50 App. B Criterion 5)

5) 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. (10 CFR Part 50 App. B Criterion 3)

6) Verify that quality related documents sampled are reviewed for adequacy by qualified personnel. (10 CFR Part 50 App. B Criterion 6)

7) Verify that the final documentation by the vendor for the safety-related product supplied accurately reflects the product and meets the original purchase documentation. (10 CFR Part 50 App. B Criterion 3)

b. Control of Sub-vendors, Material Procurement, and Audits. Observe how the vendor is controlling Safety-related material procurement and sub-vendors who are performing Safety-related work activities (this includes the Vendor Audit process). When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural/regulatory requirements.

1) 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. (10 CFR Part 50 App. B Criterion 7)

2) Verify that appropriate methods are used to accept a basic component from a supplier, such as certificates of conformance, source verifications, audits, surveillances, receipt inspections, or a combination thereof. (10 CFR Part 50 App. B Criterion 7)

3) Verify that vendors implementing an Appendix B QA program conduct audits and surveys of commercial-grade suppliers. These activities should be based on the supplier capability to supply the commodity desired in

accordance with applicable codes/regulations. (10 CFR Part 50 App. B Criterion 7)

4) 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). (10 CFR Part 50 App. B Criterion 18)

5) 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. (10 CFR Part 50 App. B Criterion 7)

6) Verify that receipt inspections examine objective evidence of purchased items by verifying attributes specified in procurement documents. Receipt 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. (10 CFR Part 50 App. B Criterion 7)

7) Verify that there are provisions in the procedures to provide for return of purchased items or rework of services that ensure the requirements of 10 CFR Part 21 are met. (10 CFR Part 50 App. B Criterion 4 & 10 CFR Part 21)

8) Verify that procedures are established and implemented for the control and release of procurement documents and subsequent changes. (10 CFR Part 50 App. B Criterion 4)

9) 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. (10 CFR Part 50 App. B Criterion 4)

10) 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. (10 CFR Part 50 App. B Criterion 18)

11) 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). (10 CFR Part 50 App. B Criterion 18)

12) Verify that audit teams were selected using qualified auditors. Verify that selected auditors are not auditing their own work. (10 CFR Part 50 App. B Criterion 2 and 18)

13) Review a sample of the vendor audits and verify that scheduled audits were performed using checklists and/or procedures that 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. (10 CFR Part 50 App. B Criterion 18)

14) 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. (10 CFR Part 50 App. B Criterion 18)

c. Basic Component Design and Engineering Services Control. Observe implementation of design activities, design control, design configuration control and performance of Engineering Services (such as software development or Engineering Analysis). When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural/regulatory requirements.

1) 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. Review all input information to verify the basic premises. This includes review of sample calculations, analyses performed, review of computer programs and the analytical model for conformance with the design requirements; in addition, where applicable, use NRC software to validate qualified vendor computer software. Ensure 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. (10 CFR Part 50 App. B Criterion 3)

2) 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.” (10 CFR Part 50 App. B Criterion 3)

3) 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 and assure conformance to the design requirements. (10 CFR Part 50 App. B Criterion 3)

4) Select any field design change(s) and verify that the vendor's design change procedure is being effectively and accurately implemented. The inspector should review: the procedure for implementation; the verification

method; the authority for the design change; the documentation to assure that the field change had been evaluated for general implications; and the associated equipment documentation, such as equipment specification purchase orders, IEEE Standards, ASME Codes, and Regulatory Guides. (10 CFR Part 50 App. B Criterion 3)

5) 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. (10 CFR Part 50 App. B Criterion 6)

6) Verify that procedures identify the interfaces between design organizations, including criteria designs, specifications, changes, technical direction, and approvals. (10 CFR Part 50 App. B Criterion 3)

7) 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. (10 CFR Part 50 App. B Criterion 3)

c. Commercial Grade Dedication. Observe the vendors implementation of commercial grade dedication. When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural requirements. Perform assessment of commercial-grade dedication activities in accordance with IP 43004, “Inspection of Commercial-Grade Dedication Programs.”

d. Control of Special Processes, Measuring and Test Equipment (M&TE), and Personnel Qualifications. Observe the vendors implementation of special processes, the M&TE process, and personnel qualification practices (this includes records). When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural/regulatory requirements.

1) 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. (10 CFR Part 50 App. B Criterion 9)

2) Verify that procedures provide measures for the generation of special process control documents such as travelers, process sheets, instructions, checklists, or other appropriate means. (10 CFR Part 50 App. B Criterion 9)

3) 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. (10 CFR Part 50 App. B Criterion 9)

4) Verify that special processes are performed by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements. (10 CFR Part 50 App. B Criterion 9)

5) Verify that qualification records are maintained as appropriate for the currently qualified personnel, processes, and equipment for each special process. (10 CFR Part 50 App. B Criterion 17)

6) 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. (10 CFR Part 50 App. B Criterion 12)

7) 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 sub-vendor calibrated the instruments. (10 CFR Part 50 App. B Criterion 12)

8) 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. (10 CFR Part 50 App. B Criterion 12)

9) Verify that M&TE is labeled, tagged, handled, segregated and stored, or otherwise controlled to indicate the calibration status of the instrument and ensure its traceability to calibration test data. (10 CFR Part 50 App. B Criterion 12)

10) 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. (10 CFR Part 50 App. B Criterion 12)

11) When M&TE is found to be out of calibration, provisions in the procedures shall require an evaluation to verify if previous inspection or test results are affected. Verify that there are provisions to notify affected customers, where appropriate. (10 CFR Part 50 App. B Criterion 12)

12) Verify that records are maintained to indicate calibration status. Review these records and check calibration logs for As Found/As Left information. (10 CFR Part 50 App. B Criterion 18)

13) Verify that out-of-calibration devices are tagged or segregated. (10 CFR Part 50 App. B Criterion 12)

14) Verify that devices consistently found out of calibration are repaired or replaced. (10 CFR Part 50 App. B Criterion 12)

15) 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. (10 CFR Part 50 App. B Criterion 2)

16) In order to verify that personnel have been adequately trained, the inspector should conduct interviews with personnel to ensure they have an understanding of the activities they are performing commensurate with their responsibilities. (10 CFR Part 50 App. B Criterion 2)

e. Implementation of the Instructions, Procedures and Drawings. Observe the implementation of the vendor instructions, procedures, and drawings to manufacture the product or provide the service (this includes implementation of inspection and test control). When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural/regulatory requirements.

1) Verify that instructions, procedures, and drawings include quantitative and qualitative acceptance criteria for determining that activities have been satisfactorily accomplished. (10 CFR Part 50 App. B Criterion 5)

2) Verify that individuals performing work that could affect the Quality of a Safety-related product or service identify and notify the appropriate authority if a quality issues exists. (10 CFR Part 50 App. B Criterion 1)

3) Verify that an individual has been designated to issue stop work orders. (10 CFR Part 50 App. B Criterion 1)

4) Verify that activities affecting quality during the performance of work are accomplished under suitably controlled conditions. (10 CFR Part 50 App. B Criterion 2)

5) Verify that work and inspection procedures have been established and implemented, including those related to sub-vendor activities. (10 CFR Part 50 App. B Criterion 5)

6) 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. (10 CFR Part 50 App. B Criterion 5)

7) 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. (10 CFR Part 50 App. B Criterion 5)

8) 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. (10 CFR Part 50 App. B Criterion 8)

9) 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. (10 CFR Part 50 App. B Criterion 8)

10) 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. (10 CFR Part 50 App. B Criterion 10)

11) Verify that procedures provide measures for the generation of inspection control documents such as travelers, process sheets, instructions, checklists, or other appropriate means. (10 CFR Part50 App. B Criterion 10)

12) 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. (10 CFR Part 50 App. B Criterion 10)

13) Verify that inspections are performed by qualified persons other than those who performed or directly supervised the work being inspected. (10 CFR Part 50 App. B Criterion 10)

14) Verify that inspection results are documented by the inspector and reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results. (10 CFR Part 50 App. B Criterion 10)

15) Verify that procedures are established and implemented for testing required. Examples of tests include prototype qualification, production, construction, pre-operational, operational, post-maintenance, post-modification, computer program/software functional tests, and proof tests prior to installation. Computer program/software includes system software, firmware, device drivers, middleware, and anything that can perform, effect, or prevent a basic component function. (10 CFR Part 50 App. B Criterion 11)

16) Verify that test procedures include or reference test objectives, test requirements, applicable prerequisites, and acceptance criteria contained in the applicable design or technical documents. (10 CFR Part 50 App. B Criterion 11)

17) 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. (10 CFR Part 50 App. B Criterion 11)

18) 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. (10 CFR Part 50 App. B Criterion 13)

19) 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. (10 CFR Part 50 App. B Criterion 14)

20) Verify that procedures specify the authority for application and removal of status indicators. (10 CFR Part 50 App. B Criterion 14)

f. Implementation of the Corrective Action, Nonconformance, and Part 21 Processes. Observe implementation of the vendor's corrective action, nonconformance, and Part 21 processes. When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural/regulatory requirements.

1) Verify that procedures have been established and implemented for correcting conditions adverse to quality. (10 CFR Part 50 App. B Criterion 16)

2) Verify that procedures are established and implemented to control items that do not conform to specified requirements. (10 CFR Part 50 App. B Criterion 15)

3) Verify that corrective action reports provide for documentation and description of the condition adverse to quality, the corrective action taken, review and approval by the responsible authority, and status of corrective actions reviewed. (10 CFR Part 50 App. B Criterion 16)

4) Verify that corrective action reports provide for documentation and description of the significant 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. (10 CFR Part 50 App. B Criterion 16)

5) 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. (10 CFR Part 50 App. B Criterion 15)

6) 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. (10 CFR Part 50 App. B Criterion 15)

7) Verify that technical justifications are documented to verify the acceptability of nonconforming items dispositioned as repair or use-as-is. Review and verify that the vendor has taken adequate actions regarding nonconforming materials or items. (10 CFR Part 50 App. B Criterion 15)

8) 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. (10 CFR Part 50 App. B Criterion 15)

9) Verify that the corrective action process and the process to control nonconforming items provide 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. (10 CFR Part 21)

10) Verify if subcontractors are required to submit nonconforming reports and proposed corrective action for approval before implementing corrective action. (10 CFR Part 50 App. B Criterion 16)

11) Verify that deficiencies identified or reported by customers (e.g., receipt inspection rejection, nonconformance, etc.) are adequately assessed and entered into either the nonconformance or corrective action program. (10 CFR Part 50 App. B Criterion 15 or 16)

12) Verify that a management system is established for overview of trends for conditions adverse to quality. (10 CFR Part 50 App. B Criterion 16)

13) 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. (10 CFR Part 50 App. B Criterion 15)

03.04 Managing the Inspection

a. The inspection team leader must be kept informed of inspection activities and deviations from planned activities to ensure proper application of team resources. The inspection team leader should be promptly notified if there is a significant issue.

b. During the inspection, the team should debrief daily with a vendor representative to discuss team activities completed, activities planned for the next day, potential findings, and any specific information requests. The inspection team should hold a meeting, prior to the daily debrief, to discuss these items, and ensure group input and knowledge is shared.

c. When a potential finding is identified, the team needs to consider the effect of that issue on the quality of the safety-related product or service supplied to the industry. The team should request that the vendor determine if the issue could have an effect on quality of a safety-related product or service during the inspection. If there is no effect on the quality of a safety-related product or service supplied to the industry (either determined by the vendor or obvious to the team), then the item may still be a potential finding. If the vendor determines that there is an adverse effect on the quality of a safety-related product or

service supplied to the industry then 10 CFR Part 21 should be applied by the vendor. If the vendor does not make a determination during the inspection, the inspection team should consider if the vendor is following their procedural requirements, and if the vendor is meeting NRC regulations 10 CFR Part 21and 10 CFR Part 50 Appendix B (Criterion 16).

d. The inspection team leader is responsible to ensure that potential findings are understood by the vendor representatives (include QA management and management over the area of the finding), before the exit meeting. The inspection team leader is responsible for explaining to the vendor representatives, whether the potential finding would be a Notice of Violation or a Notice of Nonconformance, and possible enforcement consequences.

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

Manual Chapter 0617, “Vendor and Quality Assurance Implementation Inspection Reports.”

Manual Chapter 2507, “Vendor Inspections.”

Manual Chapter 2700, “Vendor Inspection Program.”

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
N/A	ML1108719 33 04/25/11 CN 11-007	Revised Inspection Procedure to refer to Manual Chapter 2507. Added Manual Chapter 2507 to the references. This revision is in response to OIG audit (OIG-10-A-02 (ML103020267)).	None	N/A	N/A
		Complete rewrite. Rewritten to provide additional guidance on how to perform inspection, reorganized the inspection guidance to align with the process being inspected, and made the inspection procedure applicable to both Manual Chapter 2507 and 2700.			