

## REACTIVE INSPECTIONS OF NUCLEAR VENDORS

PROGRAM APPLICABILITY: 2507

### 43003-01 INSPECTION OBJECTIVES

01.01 To obtain additional information about reported problems involving vendors supplying basic components. Verify that vendors supplying basic components have taken adequate corrective actions to preclude recurrence of significant conditions adverse to quality. Verify that vendors supplying basic components identified the root **or apparent** cause(s) of a reported deficiency, including evaluation of the adequacy and effectiveness of the vendor's 10 CFR Part 21 program as well as appropriate aspects of the 10 CFR Part 50, Appendix B, quality assurance (QA) program. Verify that vendors supplying basic components have evaluated the deficiency for potential generic implications. Problems may be identified through 10 CFR Part 21 reports, 10 CFR 50.55(e) reports, 10 CFR 50.72 reports (immediate notifications), 10 CFR 50.73 reports (licensee event reports), allegations, and requests from the regional offices or other branches within the NRC.

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 Programs for Reporting Defects and Noncompliance," or 36100.01, "Inspection of 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance During Construction," and IP 43004, "Inspection of Commercial-Grade Dedication Programs."

### 43003-02 INSPECTION REQUIREMENTS

02.01 Review the vendor's nonconformance and corrective action program to verify that the vendor has identified and evaluated conditions adverse to quality that have potentially affected basic components supplied by the vendor.

02.02 Verify that the root **or apparent** causes of significant conditions adverse to quality have been adequately identified, including identification of weaknesses in the QA program that contributed to the condition adverse to quality.

02.03 Verify that actions taken to correct both the specific significant conditions adverse to quality and the causal factors are adequate to preclude recurrence.

02.04 Review the vendor's implementation of corrective actions for outstanding items identified during previous inspections and/or pending issues, as applicable.

02.05 When applicable, in accordance with IP 36100 or 36100.01, verify that the QA program provides adequate controls for evaluating and reporting defects and failures to comply.

02.06 When applicable, in accordance with IP 43004, verify that commercial-grade products or services procured for use in safety-related applications are dedicated through the implementation of a suitable dedication program.

02.07 When directed by the Allegations Review Board, follow-up on potentially safety significant allegations to determine their validity, and, if valid, evaluate the vendor's corrective actions taken to resolve the matter.

02.08 Assess whether the circumstances and/or behavior of the inspected party should be subject to evaluation and possible investigatory measures by the Office of Investigations (OI).

02.09 When applicable, a qualified vendor inspector safety culture assessor should participate when safety culture and/or safety conscious work environment issues (SCWE) need to be evaluated.

#### 43003-03 INSPECTION GUIDANCE

Inspection Manual Chapter 2507 will be followed for additional guidance.

General Guidance. Reactive inspections will be conducted at vendor facilities in response to unexpected situations that could affect the quality of the basic components supplied to assess the vendor's corrective actions related to the reported problem. Problems may be identified through 10 CFR Part 21 reports, 10 CFR 50.55(e) reports, 10 CFR 50.72 reports (immediate notifications), 10 CFR 50.73 reports (licensee event reports), allegations, NRC operating experience community reports, information provided by vendors, applicants, and licensees, and requests from the regional offices or other branches within the NRC.

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. Guidance on inspection plans is contained in IMC 0617, "Vendor and Quality Assurance Implementation Inspection Reports."

The inspector will evaluate the effectiveness of the vendor's QA program and procedures, as it relates to the reported problem, using a graded approach with emphasis in the guidance described below.

03.01 Review the vendor's nonconformance and corrective action process and its implementation to verify if the condition adverse to quality was evaluated and causal factors identified. Examine vendor's records to determine if the condition adverse to quality is repetitive, and, if so, determine why previous corrective actions were ineffective. In the event that other vendor products are affected, verify that corrective actions and notifications have taken place.

03.02 Verify that the vendor has performed ~~a thorough root-cause analysis~~ an adequate root or apparent cause analysis of depth as applicable to the issue or problem significance, including an evaluation of the vendor's QA program to identify potential programmatic deficiencies that may have led or contributed to the significant condition adverse to quality. Verify that the identified root or apparent causes and programmatic deficiencies are being or have been corrected.

03.03 Verify that the vendor's compensatory measures and corrective actions are adequately documented and sufficient to prevent recurrence. Evaluate the adequacy of the corrective actions to preclude recurrence as well as the timeliness of their implementation.

03.04 Verify that the vendor's corrective actions on previously identified inspection findings have been adequately implemented consistent with its QA program requirements. Identify and document issues of a generic nature.

03.05 Refer to IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," or 36100.01, "Inspection of 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance during Construction," as applicable for additional guidance.

03.06 Refer to IP 43004, "Inspection of Commercial-Grade Dedication Programs for additional guidance.

03.07 If applicable, through interviews and observations, gather the information necessary to either substantiate the alleged's claims or provide reasonable assurance that the claims are unfounded. Some of the information provided by vendor employees, contractors, or other individuals during the inspection may be considered allegations. This information needs to be addressed in conformance with NRC Management Directive (MD) 8.8, "Management of Allegations."

03.08 Evaluate the information obtained during the inspection to determine if potential wrongdoing has occurred. If potential wrongdoing has been identified, it must be considered an allegation and should immediately be reported to the inspector's management and the Office Allegation Coordinator, for possible referral to the Office of Investigations, or other appropriate action.

03.09 If applicable, when dealing with SCWE and/or safety culture issues, utilize the questions from Appendix A of IP71152, "Problem Identification and Resolution," as it applies to vendors.

03.10 Discuss the licensee's oversight activities with the vendor and review licensee audit reports to gauge the adequacy of the licensee's oversight. If inadequacies in the licensee's oversight are identified, discuss the issues with the Vendor Inspection Center of Expertise Branch Chiefs, who may forward the information to regional management or the Nuclear Procurement Issues Committee for additional action, as appropriate.

#### 43003-04 NOTIFICATION TO AFFECTED LICENSEES

The inspector will provide input to the NRC generic communications process to determine the need for wider distribution of information obtained during the inspection.

#### 43003-05 RESOURCE ESTIMATE

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

#### 43003-06 REFERENCES

Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products."

Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs."

Information Notice 86-21 and supplements, "Recognition of ASME Accreditation Program for N Stamp Holders."

Inspection Manual Chapter 2507, "Vendor Inspections."

Inspection Procedure 43002, "Routine Inspections of Nuclear Vendors."

Inspection Procedure 43004, "Inspection of Commercial-Grade Dedication Programs."

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

Inspection Procedure 71152, "Problem Identification and Resolution."

36100.01, "Inspection of 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance During Construction."

NRC Management Directive 8.8, "Management of Allegations."

END

Attachment:  
Revision History for IP 43003

# ATTACHMENT 1

## Revision History for IP 43003

| Commitment Tracking Number | Accession Number<br>Issue Date<br>Change Notice | Description of Change                                                                                                                                                                                                                                                                                   | Description of Training Required and Completion Date | Comment and Feedback Resolution<br>Accession Number<br>(Pre-Decisional, Non-Public) |
|----------------------------|-------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|-------------------------------------------------------------------------------------|
| N/A                        | 10/03/07<br>CN 07-030                           | Researched commitments for 4 years and found none.<br><br>Initial issuance                                                                                                                                                                                                                              | N/A                                                  | N/A                                                                                 |
| N/A                        | ML110871939<br>04/25/11<br>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)).                                                                                                                       | N/A                                                  | N/A                                                                                 |
| N/A                        | ML13248A332<br>10/03/13<br>CN-13-024            | Revised Inspection Procedure to create one reactive vendor inspection procedure. The requirements from IP 43001, "Reactive Inspection of Nuclear Vendors," have been moved to IP 43003, "Reactive Inspections of Nuclear Vendors." Upon issuance of this version of IP 43003, IP 43001 will be deleted. | N/A                                                  | ML13248A333                                                                         |
| N/A                        | ML15323A153<br>12/14/15<br>CN 15-029            | Added a pointer to IP 71152 and added guidance on qualified safety culture assessors.                                                                                                                                                                                                                   | N/A                                                  | ML15323A154                                                                         |