

REACTIVE INSPECTIONS OF NUCLEAR VENDORS

PROGRAM APPLICABILITY: 2507

43003-01 INSPECTION OBJECTIVES

01.01 In response to reported problems involving vendor-supplied products or services, verify that vendors supplying basic components have developed and implemented adequate procedures to evaluate and correct conditions adverse to quality.

01.02 In response to reported problems involving vendor-supplied products or services, verify that vendors supplying basic components have taken adequate corrective actions to preclude recurrence of conditions adverse to quality.

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."

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 causes of 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 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, verify that the QA program provides adequate controls for evaluating and reporting defects and noncompliance.

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).

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. 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-0613, "10 CFR Part 52 Licensed Power Reactor Construction and Test 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, including an evaluation of the vendor's QA program to identify potential programmatic deficiencies that may have led or contributed to the condition adverse to quality. Verify that the identified root 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 50.55(e) Programs for Reporting Defects and Nonconformance" 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.

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

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."

NRC Management Directive 8.8, "Management of Allegations."

END

Attachments:

1. Revision History

ATTACHMENT 1

Revision History for IP 43003

| 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 | ML110871939 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 |
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