INSPECTION PROCEDURE 43001

REACTIVE INSPECTION OF NUCLEAR VENDORS

PROGRAM APPLICABILITY: IMC 2700

43001-01 INSPECTION OBJECTIVES

01.01 To obtain additional information about reported problems involving vendor supplied products or services. Problems may be identified through Title 10 of the Code of Federal Regulations (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, Nuclear Regulatory Commission (NRC) morning reports, and requests from the regional offices or other branches within the NRC.

01.02 To verify that vendors of safety-related products or services have developed and implemented an adequate procedure to evaluate and correct reported problems or deficiencies, and have taken adequate corrective actions to preclude recurrence.

01.03 To verify whether the root cause of a reported deficiency has been identified, 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, and evaluate the potential for generic implications.

43001-02 INSPECTION REQUIREMENTS

02.01 The assigned inspector or inspection team leader shall develop an inspection plan that summarizes the areas to be inspected and the work assignments for each inspector. The plan should describe the evaluation of the vendor's activities to resolve the identified deficiency including the assessment of generic aspects, contributory deficiencies in the QA program, and status of corrective action measures.

02.02 Verify the accuracy and completeness of information submitted by the reporting party to the purchasers (for deviations, as defined by 10 CFR Part 21) and/or the NRC (for deviations which have been evaluated to be defects).

02.03 Determine whether the vendor has evaluated all potentially affected items or services and has made appropriate notifications to all affected purchasers (for deviations) and the NRC (for defects).

02.04 Ascertain whether the root cause of a reported deficiency has been identified including evaluation of the adequacy and effectiveness of appropriate QA program areas.

02.05 Determine whether the actions taken to correct both the specific deficiencies and the causative contributory factors are adequate to preclude recurrence.

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

02.07 Verify that commercial grade products or services procured for use in safety-related applications are qualified through the implementation of a suitable dedication program.

02.08 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. Determine 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).

43001-03 INSPECTION GUIDANCE

03.01 Prepare the inspection plan in accordance with established guidelines. The scope of the inspection plan addresses the specific item(s) that prompted the inspection and describes the proposed evaluation of the vendor's activities to resolve the identified deficiency. The plan addresses the assessment of generic aspects, contributory deficiencies in the QA program, and status of corrective action measures. The plan also summarizes the aspects to be inspected and identifies the work assignments for each inspector. For inspections involving allegations, Part 21 reports, Part 50.55(e) reports, or licensee event reports, list the internal NRC tracking number in the inspection plan. The completed inspection plan will be signed by a cognizant section chief or branch chief, then copies distributed to all team members and the Branch reading file (or the Branch limited distribution reading file for allegation-related or otherwise sensitive inspection plans).

03.02 Review the vendor's problem resolution program and associated records to determine if the deficiency was evaluated and all contributory causes identified. Verify that problem reports issued to the purchaser and/or NRC characterize the problem and include appropriate recommended corrective actions.

03.03 Evaluate the vendor's problem evaluation process and its implementation to ensure that it includes a determination of the extent of the problem and assurance that identified root causes are evaluated with regard to their possible effect on other vendor-supplied products or services. Examine the vendor's records to determine if the deficiency 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. Check the vendor's system for ensuring that all affected customers are notified of deviations.

03.04 Assure 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 reported deficiency.

03.05 Verify that identified root causes and programmatic deficiencies are being or have been corrected. Evaluate the adequacy of the corrective actions to preclude recurrence as well as the timeliness of their implementation. For those corrective actions not yet complete, determine the proposed date for full implementation.

03.06 Determine if vendor's corrective actions on outstanding items from previous inspections and/or pending issues, when applicable under the scope of the inspection plan, have been implemented. If implemented, evaluate the adequacy of the corrective actions. If not implemented, evaluate the timeliness of the implementation schedule for corrective actions.

03.07 If applicable under the scope of the inspection plan, review several data packages for both safety-related and commercial grade products or services procured for use in safety-related applications. For the safety-related products, verify that Part 21, Appendix B to Part 50, and other applicable quality and technical requirements are passed on to the suppliers through the procurement documents. For commercial grade products, verify that the parts are qualified through the implementation of a suitable dedication program that verifies the part's important design, material, and performance characteristics. Refer to inspection procedure 38703, "Commercial Grade Dedication," for additional guidance on review of dedication practices for commercial grade items.

03.08 If applicable, through interviews and observations, gather the information necessary to either substantiate the alleger's claims or provide reasonable assurance that the claims are unfounded. Evaluate the circumstances and/or the vendor's behavior and determine whether the issue involves potential wrongdoing on the part of the vendor and should be referred to OI for possible investigatory actions.

43001-04 REPORTING SYSTEM AND INFORMATION FEEDBACK

04.01 The results of reactive inspections are documented in an inspection report and transmitted to the vendor organization for development and submittal of necessary corrective actions. The inspection results also are included in the quarterly issue of the White Book ("Licensee Contractor and Vendor Inspection Status Report," NUREG-0040).

04.02 The NRC distribution of inspection reports for reactive inspections will include the requestor(s) of an inspection as well

as the project manager for any specific licensees that are affected.

04.03 Deviations from the requirements of 10 CFR Part 21 are documented in a notice of violation in accordance with established guidelines and format.

04.04 Deviations from applicable requirements of procurement document and specifications, quality assurance programs or regulations are documented in a notice of nonconformance in accordance with established guidelines and format. Other failures to comply with documented QA program requirements identified during inspection of the programmatic subject areas applicable to a specific reactive inspection item are similarly reflected in a notice of nonconformance.

04.05 Evaluate the need for wider dissemination of information obtained during the inspection through NRC generic communications such as information notices, bulletins, and generic letters.

04.06 Identify any issues requiring follow-up in future inspections at other vendors and/or licensees and ensure that they are added to the pending issues tracking file.

04.07 Clearly document the closeout or status of outstanding items from previous inspections, including evaluation of corrective actions contained in the vendor's responses to previous inspection reports.

43001-05 IDENTIFICATION OF AFFECTED LICENSEE/SITES

In situations where the documents/hardware/services reviewed during an inspection clearly impact other specific plant sites, such sites will be entered on the inspection report summary page in the section entitled "Plant Site Applicability," and the associated project manager(s) will be included in the report distribution.

43001-06 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."

Information Notice 89-70 and supplements, "Possible Indications of Misrepresented Vendor Products."

NRC Management Directive 8.8, "Management of Allegations."

NRR Office Letter No. 1003, "Management of Allegations."

NRR Office Letter No. 1300, "Procedures For Handling 10 CFR Part 21 and 10 CFR 50.55(e) Notifications of Defects, Noncompliances, and Construction Deficiencies."

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