

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555-0001

December 21, 2007

NRC INFORMATION NOTICE 2007-40: INADEQUATE IMPLEMENTATION OF
10 CFR PART 21 REQUIREMENTS BY
VENDORS WHO SUPPLY BASIC COMPONENTS
TO NUCLEAR POWER PLANT LICENSEES

ADDRESSEES

All vendors that supply basic components to facilities licensed by the U.S. Nuclear Regulatory Commission (NRC), and holders of an NRC license, holders of a certificate of compliance, or applicants for a certificate of compliance.

PURPOSE

The NRC is issuing this information notice (IN) to inform addressees about recent NRC findings involving the inadequate implementation of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21 "Reporting of Defects and Noncompliance," by vendors that supply "basic components" (as defined in 10 CFR Part 21) such as materials, equipment, components, or services to be used in NRC-licensed facilities. The NRC expects that recipients will review the information for applicability to their activities and consider appropriate actions to avoid similar problems. However, suggestions contained in this IN are not NRC requirements; therefore, no specific action or written response is required.

DESCRIPTION OF CIRCUMSTANCES

During NRC inspections at vendor facilities that supply basic components to NRC-licensed facilities and during observation of some Nuclear Utility Procurement Issues Committee (NUPIC) joint utility audits, the NRC staff has identified the following examples where vendors failed to adequately implement the requirements of 10 CFR Part 21:

- NRC inspectors identified a situation where a vendor's 10 CFR Part 21 evaluation¹ of a potentially defective basic component was inadequate because the vendor did not know the specific application for the component at the affected licensee facility and, therefore, did not have the capability to determine if this potentially defective component

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1 NRC regulations in 10 CFR 21.3 "Definitions," define *evaluation* as the process of determining whether a particular deviation could create a substantial safety hazard or determining whether a failure to comply is associated with a substantial safety hazard.

represented a substantial safety hazard.² The inadequate evaluation by the vendor and subsequent notification to the licensee that the issue was not a reportable incident was a non-cited violation of 10 CFR 21.21(a). The provisions of 10 CFR 21.21(b) direct the vendor to inform the affected licensee of deviations³ within 5 days when the vendor is not capable of performing the evaluation so that the affected licensees may evaluate the deviation or failure to comply, pursuant to 10 CFR 21.21(a). (NRC Inspection Report 99901338/2006-201, July 25, 2006, Agencywide Documents Access and Management System (ADAMS) Accession No. ML062070385)

- NRC inspectors discovered that a vendor was not meeting the 5-day timeliness requirement in 10 CFR 21.21(b) for informing licensees of deviations when the vendor was not capable of performing the 10 CFR Part 21 evaluation. (NRC Inspection Report 99901358/2006-201, May 25, 2006, ADAMS Accession No. ML061460006)
- NRC inspectors identified that a vendor's 10 CFR Part 21 evaluations, which by definition are required to include a determination of whether a deviation constitutes a substantial safety hazard, only focused on the technical engineering aspects of the deviation performed under its corrective action program. (NRC Inspection Report 99901358/2006-201, May 25, 2006, ADAMS Accession No. ML061460006)
- NRC inspections at two licensees identified examples of purchase orders issued to U.S.-based suppliers that did not meet 10 CFR 21.31 "Procurement Documents," that requires procurement documents to specify that the provisions of 10 CFR Part 21 apply. (NRC Inspection Report 71-0703/04-201, July 28, 2004, ADAMS Accession No. ML042100486; and NRC Inspection Report 71-0121/06-201, November 6, 2006, ADAMS Accession No. ML063100332)
- NRC inspectors found that subcontractors supplying basic components to a vendor were not performing 10 CFR Part 21 evaluations of deviations and/or failures to comply for determining 10 CFR Part 21 reportability of potential defects that could cause a substantial safety hazard. (NRC Inspection Report 99901359/2006-201, August 25, 2006, ADAMS Accession No. ML062400092)
- NRC inspectors discovered that several vendors' 10 CFR Part 21 programs did not have adequate procedural guidance to identify and evaluate deviations associated with a substantial safety hazard. In addition, several vendors did not have guidance to evaluate significant conditions adverse to quality that were identified in their corrective action programs (required by 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," Criterion XVI, "Corrective Action") to determine whether

2 NRC regulations in 10 CFR 21.3 define *substantial safety hazard* as a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to 10 CFR Parts 30, 40, 50, 60, 61, 63, 70, 71, or 72 of this chapter.

3 NRC regulations in 10 CFR 21.3 define *deviation* as a departure from the technical requirements included in a procurement document.

the requirements of 10 CFR Part 21 applied. (NRC Inspection Report 99901356/2006-201, February 8, 2006, ADAMS Accession No. ML060310185; NRC Inspection Report 99901367/2007-201, October 16, 2007, ADAMS Accession No. ML072770900; NRC Inspection Report 99900067/2007-201, October 9, 2007, ADAMS Accession No. ML072850014; NRC Inspection Report 99900005/2007-201, August 28, 2007, ADAMS Accession No. ML072710236; NRC Inspection Report 99901362/2006-201, January 9, 2007, ADAMS Accession No. ML070100168; NRC Inspection Report 99901360/2006-201, October 5, 2006, ADAMS Accession No. ML062380056; and NRC Inspection Report 99901358/2006-201, October 25, 2006, ADAMS Accession No. ML061460006)

- During inspections and observation of several NUPIC joint utility audits at foreign vendor facilities, the NRC staff identified examples where these vendors were not adequately implementing the requirements of 10 CFR Part 21 in that some of these vendors did not adopt appropriate procedures to perform 10 CFR 21.21(a) evaluations. (NRC Trip Reports, dated October 28, 2005, ADAMS Accession No. ML053010311; June 7, 2006, ADAMS Accession Nos. ML061570442 and ML061510646; and May 24, 2007, ADAMS Accession No. ML071360034)

BACKGROUND

The provisions of 10 CFR Part 21 for reporting defects and noncompliances apply to vendors that provide basic components, as defined in 10 CFR 21.3, to NRC-licensed facilities. These vendors must implement a quality assurance program in accordance with one of the following regulations: Appendix B to 10 CFR Part 50; Subpart H, "Quality Assurance," of 10 CFR Part 71 "Packaging and Transportation of Radioactive Material"; and/or Subpart G, "Quality Assurance," of 10 CFR Part 72 "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste."

Under 10 CFR Part 21, vendors that supply basic components must do the following:

- Post required documents related to 10 CFR Part 21 in a conspicuous location (10 CFR 21.6(a) and (b)).
- Adopt appropriate procedures for evaluating deviations and failures to comply (10 CFR 21.21(a)).
- If not able to perform the evaluation, notify licensees of deviations within 5 days (10 CFR 21.21(b)).
- Report defects or failures to comply within certain timeframes to the NRC (10 CFR 21.21(d)).
- Specify the applicability of 10 CFR Part 21 in procurement documents for a basic component (10 CFR 21.31).

DISCUSSION

The requirements in 10 CFR Part 21 for reporting defects and noncompliances in basic components provided to licensees are important for alerting licensees to a problem that could potentially render safety systems inoperable. The violations of 10 CFR Part 21 requirements identified in this IN are of particular concern because they often involved implementing procedures that were inadequate to reasonably assure the satisfaction of 10 CFR Part 21 requirements. For instance, it is important that implementing procedures include information to (1) identify a 10 CFR Part 21 component deviation by considering potential nonconformances identified through the corrective action process, (2) evaluate the effect of the deviation if the licensee were to use or has used the component, and (3) based on the evaluation, conclude whether the deviation could create a substantial safety hazard. Further information may be obtained by reviewing the examples of violations identified in this IN.

CONTACT

This IN requires no specific action or written response. Please direct any questions about this matter to the technical contacts listed below or to the appropriate Office of Nuclear Reactor Regulation (NRR) project manager.

/RA by EHackett for/

William Brach, Director
Division of Spent Fuel Storage
and Transportation
Office of Nuclear Material Safety
and Safeguards

/RA by TQuay for/

Michael J. Case, Director
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

/RA/

Glenn Tracy, Director
Division of Construction Inspection and
Operational Programs
Office of New Reactors

Technical Contacts: Aida Rivera-Varona, NRO
301-415-4001
email: axr1@nrc.gov

Paul Prescott, NRR
301-415-3026
E-mail: pfp@nrc.gov

Richard McIntyre, NRO
301-415-3215
email: rpm@nrc.gov

James Pearson, NMSS
301-492-3337
E-mail: jjp@nrc.gov

Note: NRC generic communications may be found on the NRC public Web site, <http://www.nrc.gov>, under Electronic Reading Room/Document Collections.

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