

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

October 5, 2018

**NRC REGULATORY ISSUE SUMMARY 2018-05
SUPPLIER OVERSIGHT ISSUES IDENTIFIED DURING RECENT NRC VENDOR
INSPECTIONS**

ADDRESSEES

All holders of and applicants for a specific source material license under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 40, "Domestic Licensing of Source Material."

All holders of and applicants for a construction permit for a production or utilization facility, including a medical radioisotope facility, under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

All holders and applicants of an operating license or construction permit for a nuclear power reactor issued under 10 CFR Part 50, except those that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

All holders of and applicants for a nuclear power reactor early site permit, combined license, standard design approval, or manufacturing license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." All applicants for a standard design certification, including such applicants after initial issuance of a design certification rule.

All contractors and vendors (C/Vs) that supply basic components to U.S. Nuclear Regulatory Commission (NRC) licensees under 10 CFR Part 50, or 10 CFR Part 52.

All holders of and applicants for a fuel cycle facility license under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

All holders of and applicants for a certificate of compliance (CoC) for radioactive material transportation package designs under 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

All holders of and applicants for a license to receive, transfer, and possess power reactor spent fuel, power reactor-related greater-than-Class-C waste, and other radioactive materials associated with spent fuel storage in an independent spent fuel storage installation, or for a spent fuel storage cask CoC under 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."

INTENT

The NRC is issuing this regulatory issue summary (RIS) to inform addressees of the applicable regulatory requirements for procuring basic components for NRC-licensed facilities and for providing oversight of their suppliers. This includes suppliers implementing quality assurance (QA) programs based on the following standards:

- International Organization for Standardization (ISO) 9001, “Quality Management System—Requirements,” ISO/International Electrotechnical Commission (IEC) 17025:2005, “General Requirements for the Competence of Testing and Calibration Laboratories”
- Subsection NCA-3800, “Metallic Material Organization’s Quality System Program,” in Subsection NCA, “General Requirements for Division 1 and Division 2,” in Section III, “Rules for Construction of Nuclear Facility Components,” of the American Society of Mechanical Engineers (ASME) Boiler & Pressure Vessel (B&PV) Code
- Article NCA-4000, “Quality Assurance Requirements,” in Subsection NCA in Section III of the ASME B&PV Code
- Subsection NCA-4200, “Metallic Quality System Program Requirements,” in Subsection NCA in Section III of the ASME B&PV Code

In addition, this RIS informs the addressees of common violations and nonconformances that the NRC has identified during recent vendor inspections. Specifically, vendors were not adequately imposing the requirements of 10 CFR Part 50, Appendix B, “Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” and 10 CFR Part 21, “Reporting of Defects and Noncompliance,” on their suppliers of basic components in the procurement documents and were not providing adequate oversight of these suppliers.

The NRC expects that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. The NRC acknowledges that certain production or utilization facilities (such as medical radioisotope facilities licensed to construct under 10 CFR Part 50) and many other nonreactor facilities (such as those licensed or certified under 10 CFR Parts 40, 70, 71, or 72) have QA requirements and terminology that may differ from those applicable to nuclear power plants.¹ These licensees or CoC holders should review the content of this RIS for awareness and consider the applicability of the circumstances described in this RIS to ensure the availability and reliability of components that are relied on for the safe operation of certain production or utilization facilities and other non-reactor facilities. This RIS requires no action or written response by addressees.

¹ For non-power production or utilization facilities licensed under 10 CFR Part 50, (1) 10 CFR 50.34 describes the applicable quality assurance requirements, and (2) use of the term “safety-related” is facility-specific and described in an applicant or licensee’s safety analysis report. For facilities licensed or certified under 10 CFR Parts 40, 70, 71, or 72, (1) Appendix B to 10 CFR Part 50 applies only to facilities that engage in plutonium processing and fuel fabrication under 10 CFR Part 70, and (2) terms such as “items relied on for safety” are used in lieu of “safety-related.”

BACKGROUND INFORMATION

Appendix B to 10 CFR Part 50 establishes the overall QA requirements for the design, construction, and operation of safety-related structures, systems, and components (SSCs). Consequently, licensees and applicants contractually impose 10 CFR Part 50, Appendix B, on suppliers of basic components. Imposition of these QA requirements provides reasonable assurance that an SSC will perform its intended safety function. Therefore, effective oversight of suppliers of basic components ensures that these suppliers are adequately implementing a QA program in accordance with 10 CFR Part 50, Appendix B.

The regulations in Criterion IV, "Procurement Document Control," of 10 CFR Part 50, Appendix B, require that licensees and applicants shall establish measures to ensure that applicable regulatory requirements, design bases, and other requirements necessary to ensure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. Criterion IV also states that procurement documents shall require, to the extent necessary, contractors or subcontractors to provide a QA program consistent with the pertinent provisions of 10 CFR Part 50, Appendix B.

In addition, Criterion VII, "Control of Purchased Material, Equipment, and Services," of 10 CFR Part 50, Appendix B, requires that licensees and applicants shall establish measures to ensure that purchased material, equipment, and services, whether bought directly or through contractors and subcontractors, conform to the procurement documents. Criterion VII also requires that these measures shall include provisions for obtaining objective evidence of quality furnished by the contractor or subcontractor and inspection at the contractor or subcontractor source, as appropriate. Criterion VII further requires assessment of the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.

Suppliers of basic components to NRC-licensed facilities are required to adhere to these requirements when imposed by their customers through contractual requirements. Furthermore, the provisions of 10 CFR Part 21 for reporting defects and noncompliances apply to suppliers that provide basic components to NRC-licensed facilities, as defined in 10 CFR 21.3, "Definitions." Under 10 CFR 21.31, "Procurement documents," suppliers of basic components shall specify the applicability of 10 CFR Part 21 in the procurement documents for a basic component.

SUMMARY OF ISSUE

The NRC staff performs between 25 and 35 inspections each fiscal year of vendors providing basic components to new and operating reactors. During recent NRC inspections at domestic and international vendor facilities that supply basic components to NRC-licensed facilities, the NRC staff identified several examples of vendor failures to adequately impose the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21 in the procurement documents sent to their suppliers and vendor failures to provide adequate oversight of their suppliers. In these examples, vendors supplying basic components did not implement sufficient controls to ensure that applicable regulatory requirements were being adequately imposed in their procurement documents for basic components, and they did not demonstrate their suppliers had processes and controls in place to meet the applicable requirements of Appendix B to 10 CFR Part 50. Imposing the applicable regulatory requirements in the procurement documents for basic

components and providing adequate oversight of suppliers is not only required, but it is also key in providing reasonable assurance that basic components will perform their intended safety function.²

It is important that vendors impose the applicable regulatory requirements in procurement documents to control the quality of safety-related materials, equipment, and services. When procuring a basic component, the procurement documents shall explicitly specify compliance with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21. Imposition of these two regulatory requirements ensures that adequate QA is applied and that Appendix B to 10 CFR Part 50 and 10 CFR Part 21 are adequately passed down to the sub-suppliers. To provide reasonable assurance that the SSCs will perform their intended safety function, it is important to ensure that basic components are manufactured under a QA program that meets the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21.

ASME B&PV Code Section III, Subsections NCA 3800 and 4000

The NRC staff identified several instances in which vendors did not impose the applicable regulatory requirements when procuring ASME B&PV Code components (ASME B&PV Code pressure-retaining components are basic components) from organizations holding an N-Type Certificate of Authorization Holder (CH) or a Quality System Certificate (QSC) Material Organization (MO). Vendors are reminded that when procuring basic components from organizations holding a QSC with a QA program that meets the requirements of NCA-3800, or CHs with a QA program that meets the requirements of NCA-4000, they must specify in the procurement documents that the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21 apply. Furthermore, CHs and QSC MOs shall also suitably include or reference Appendix B to 10 CFR Part 50 and 10 CFR Part 21 in the procurement documents for basic components to their sub-suppliers.

In one example, the NRC staff issued a nonconformance against Criterion IV of 10 CFR Part 50, Appendix B, for a vendor's failure to include the applicable regulatory requirements on procurement documents that are necessary to ensure that adequate quality is suitably included or referenced (see Reference 8). Specifically, the vendor did not impose the requirements of 10 CFR Part 50, Appendix B, in its safety-related purchase orders (POs) for materials and services procured as basic components. Rather than imposing 10 CFR Part 50, Appendix B, the vendor stated in the POs that the work must be performed in accordance with the suppliers' QA manual approved by the vendor. Purchase orders shall specify compliance with the requirements of 10 CFR Part 50, Appendix B, to ensure that adequate QA is applied and that the regulation is adequately passed down to the sub-suppliers. Imposing the applicable regulatory requirements ensures that adequate QA is applied throughout the manufacturing process of the SSCs, which helps to provide reasonable assurance that the SSCs will perform their intended safety function.

The NRC staff also identified an issue with vendors not performing audits to verify the implementation of their suppliers' QA programs. The vendors did not perform these audits because the suppliers have QA programs meeting the requirements of NCA-3800 (QSC) or NCA-4000 (CHs). For example, the NRC staff issued a nonconformance against Criterion VII of 10 CFR Part 50, Appendix B, for a vendor's failure to perform an implementation audit of a supplier's QA program (see Reference 10). Specifically, the vendor procured safety-related

² A basic component could also be a commercial-grade item or service that has successfully completed the dedication process.

weld material based on the supplier's third-party accreditation provided by the ASME B&PV Code certification without verifying the implementation of the supplier's QA program through an audit or other appropriate actions.

The use of third-party ASME certification in lieu of performing implementation audits is not consistent with the requirements of 10 CFR Part 50, Appendix B. As described in Information Notice 1986-21, "Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders," dated March 31, 1986 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML031220635), and its supplements, the NRC recognizes the ASME Accreditation Program for N, NA, NPT, NV stamps, QSC MOs, and associated certificates of authorization as evidence that the holder of the certificate has a documented QA program that meets the requirements of 10 CFR Part 50, Appendix B. However, recognition of the ASME Accreditation Program applies only to the programmatic aspects of the QA programs. An implementation audit is therefore required to demonstrate that the supplier is effectively implementing its approved QA program to ensure that the SSCs will perform their intended safety function.

In addition, the NRC identified an issue with the qualification of suppliers as MOs in accordance with NCA-3820, "Certification or Qualification of Material Organizations," and NCA-3842.2, "Evaluation of the Qualified Material Organization's Program by Certified Material Organizations of Certificate Holders," in Subsection NCA of Section III of the ASME B&PV Code. For example, the NRC staff issued a nonconformance against Criterion VII of 10 CFR Part 50, Appendix B, for a vendor's failure to adequately qualify MOs not certified by ASME in accordance with the requirements of NCA-3842.2 (see Reference 9). Specifically, the vendor inadequately qualified these suppliers as MOs based on the suppliers' ISO 9001:2008 QA programs.

ISO 9001

As explained above, the NRC staff identified an issue with vendors procuring basic components from commercial suppliers with QA programs based on the requirements of ISO 9001. The NRC staff has not approved ISO 9001 for use as an acceptable method for meeting the requirements of 10 CFR Part 50, Appendix B, and has not considered accreditation under ISO 9001 as an acceptable basis for qualifying a supplier of basic components. As described in SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," dated July 9, 2003 (ADAMS Accession No. ML031490421), the NRC staff compared the quality requirements in ISO 9001-2000 and 10 CFR Part 50, Appendix B, to study the feasibility of adopting ISO 9001 for the procurement of basic components into the existing regulatory framework of QA requirements. Based on this review, the NRC staff concluded that supplemental quality requirements would be needed when implementing ISO 9001 within the existing regulatory framework.

ISO/IEC 17025:2005

The NRC staff has not approved ISO/IEC 17025:2005 by itself for use as an acceptable method for meeting the requirements of 10 CFR Part 50, Appendix B, and does not consider solely having ISO/IEC 17025:2005 accreditation an acceptable basis for qualifying laboratory calibration or testing services. The NRC staff's position is described in RIS 2016-01, "Nuclear Energy Institute Guidance for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," dated March 16, 2016 (ADAMS Accession No. ML15323A346). The NRC staff identified an issue with vendors procuring basic

laboratory calibration and testing services from commercial suppliers based solely on the supplier's QA programs meeting the requirements of ISO/IEC 17025:2005. When purchasing commercial-grade calibration and testing services from domestic and international laboratories accredited by the International Laboratory Accreditation Cooperation (ILAC), licensees and suppliers of basic components may use the ILAC accreditation process in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process provided that specific conditions are met as specified in the RIS. For example, the NRC staff issued a nonconformance against Criterion VII of 10 CFR Part 50, Appendix B, for a vendor's failure to establish adequate measures for selection of contractors and subcontractors (see Reference 9). Specifically, the vendor qualified these commercial laboratories as suppliers of safety-related services even though these laboratories provided services with QA programs based solely on ISO/IEC 17025:2005 that do not meet the applicable requirements of 10 CFR Part 50, Appendix B.

10 CFR Part 21

Part 21 of 10 CFR is directly applicable to suppliers of basic components or commercial grade items which have successfully completed the dedication process. The NRC staff identified several situations where vendors did not impose the requirements of 10 CFR Part 21 in procurement documents. For example, the NRC staff issued a violation against 10 CFR 21.31 for a vendor's failure to specify in procurement documents that the provisions of 10 CFR Part 21 apply to suppliers of safety-related materials and services (see Reference 8). Specifically, the vendor imposed in POs that suppliers shall meet a procedure developed by the vendor rather than imposing the requirements of 10 CFR Part 21. The vendor developed this procedure because its international suppliers do not accept POs that impose 10 CFR Part 21. This procedure improperly relieves the vendor's suppliers from responsibilities under 10 CFR Part 21 and requires the suppliers to notify the vendor of any deviations identified in the materials or services supplied. Any materials, equipment, and services procured from a supplier who refuses to accept a PO with 10 CR Part 21 imposed within it, would not meet the definition of a basic component. The requirements in 10 CFR Part 21 for reporting defects and noncompliances in basic components supplied to licensees are important for alerting licensees to a defect that could create a substantial safety hazard.³

In response to the above identified deficiencies, the suppliers entered the deficiencies into their corrective action programs⁴ and took appropriate corrective measures.

Conclusion

The issues described above reflect a current trend identified during recent NRC vendor inspections. Imposing 10 CFR Part 50, Appendix B, in procurement documents, in conjunction with effective oversight of the supply chain, is important to ensure that SSCs procured as basic components are manufactured under a QA program that provides reasonable assurance that the SSCs will perform their intended safety function. In addition, imposing the requirements of 10 CFR Part 21 in procurement documents provides a method for notifying licensees and the NRC of any defects identified during the manufacturing process that could cause a substantial

³ 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.

⁴ The NRC's public Web site at <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/insp-reports.html> gives details of the identified deficiencies and the associated vendor responses.

safety hazard. Furthermore, when evaluating the implementation of a supplier's QA program during an audit, vendors must adequately document the objective evidence examined to the depth necessary to confirm effective implementation of the applicable quality criteria.

Available NRC Resources

The NRC has published several communications, including publicly available inspection reports, which provide additional information on the agency's regulatory positions when procuring basic components from suppliers with QA programs based on ISO 9001, ISO/IEC 17025, and Subsections NCA-3800 and Article NCA-4000 of the ASME B&PV Code.

1. Information Notice 1986-21, "Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders," dated March 31, 1986 (ADAMS Accession No. ML031220635), and Supplement 1, dated December 4, 1986 (ADAMS Accession No. ML082970427), and Supplement 2, dated April 16, 1991 (ADAMS Accession No. ML031220630)
2. Information Notice 1988-95, "Inadequate Procurement Requirements Imposed by Licensees on Vendors," dated December 8, 1988 (ADAMS Accession No. ML031150017)
3. SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," dated July 9, 2003 (ADAMS Accession No. ML031490421)
4. Memorandum from Sabrina Cleavenger to John A. Nakoski, "Revision 1 to NRC Responses to 10 CFR Part 21 and Fuel Cycle Facility Questions Received During the Vendor Workshop on New Reactor Construction in December 2008," dated October 5, 2009 (ADAMS Accession No. ML092660129)
5. Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)," Revision 3, issued June 2013 (ADAMS Accession No. ML13109A458)
6. Nuclear Regulatory Commission Safety Evaluation Report, "Final Safety Evaluation for Technical Report NEI 14-05, 'Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,' Revision 1," dated February 9, 2015 (ADAMS Accession No. ML14322A535)
7. Regulatory Issue Summary 2016-01, "Nuclear Energy Institute Guidance for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," dated March 16, 2016 (ADAMS Accession No. ML15323A346)
8. Nuclear Regulatory Commission Inspection Report No. 99900061/2017-201, dated June 5, 2017 (ADAMS Accession No. ML17142A142)
9. Nuclear Regulatory Commission Inspection Report No. 99901356/2017-201, dated August 22, 2017 (ADAMS Accession No. ML17214A819)
10. Nuclear Regulatory Commission Inspection Report No. 99901451/2017-201, dated September 13, 2017 (ADAMS Accession No. ML17235B230)

11. Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5, issued October 2017 (ADAMS Accession No. ML17207A293)

BACKFITTING AND ISSUE FINALITY DISCUSSION

This RIS does not set forth any new or changed NRC requirements. It does not set forth any new or changed guidance or positions on compliance with any existing NRC regulatory requirements. It requires no action or written response, and does not impose any requirements on NRC licensees or any other applicants, licensees, or holders of NRC regulatory approvals under 10 CFR Parts 50, 52, 70, or 72. For these reasons, this RIS is not a backfit under 10 CFR 50.109, 10 CFR 70.76, or 10 CFR 72.62 and is not otherwise inconsistent with any issue finality provision in 10 CFR Part 52. Consequently, the NRC staff did not prepare a backfit analysis for this RIS or further address the issue finality criteria in 10 CFR Part 52.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because this RIS is informational and does not represent a departure from current regulatory requirements.

CONGRESSIONAL REVIEW ACT

This RIS is not a rule as defined by the Congressional Review Act (5 U.S.C. §§ 801–808).

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget (OMB) under approval numbers 3150-0011 and 3150-0035.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

CONTACTS

Please direct any questions about this matter to the technical contacts listed below.

RA (William Jones for)

Timothy J. McGinty, Director
Division of Construction Inspection
and Operational Programs
Office of New Reactors

RA (Jeremy R. Groom for)

Christopher G. Miller, Director
Division of Inspection and Regional Support
Office of Nuclear Reactor Regulation

RA (Sabrina D. Atack for)

Daniel S. Collins, Director
Division of Materials Safety, Security,
State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards

Technical Contacts: Yamir Diaz-Castillo
NRO/DCIP/QVIB-1
301-415-2228
E-mail: Yamir.Diaz-Castillo@nrc.gov

Raju Patel
NRO/DCIP/QVIB-2
301-415-3511
E-mail: Raju.Patel@nrc.gov

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

NRC REGULATORY ISSUE SUMMARY 2018-05, "SUPPLIER OVERSIGHT ISSUES IDENTIFIED DURING RECENT NRC VENDOR INSPECTIONS," Date: October 5, 2018

ADAMS Accession No.: ML18151A739

***concurred via e-mail**

EPID: L-2018-CRS-0004

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