

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR REACTOR REGULATION  
WASHINGTON, DC 20555-0001

September 27, 2023

**NRC DRAFT REGULATORY ISSUE SUMMARY 20XX-XX  
REQUIRED ASSESSMENT OF U.S. DEPARTMENT OF ENERGY LABORATORIES BY  
LICENSEES, APPLICANTS, AND SUPPLIERS TO VERIFY THE EFFECTIVE  
IMPLEMENTATION OF THEIR QUALITY ASSURANCE PROGRAMS**

**ADDRESSEES**

All holders of and applicants for a construction permit for a production or utilization facility, including a medical radioisotope facility, under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

All holders of and applicants for an operating license 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 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 licensees, certificate holders, and applicants for a Certificate of Compliance (CoC) for an NRC-approved quality assurance (QA) program that must conform to the requirements of Subpart H to 10 CFR Part 71, "Packaging and Transportation of Radioactive Material." This includes those licensed under another part of Title 10 that have been issued an NRC 10 CFR Part 71 QA program approval that limits the scope of their activities solely to the use of NRC-approved packaging.

All holders of and applicants for a license or CoC with an NRC-approved QA program that must conform to the requirements of Subpart G to 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 draft regulatory issue summary (RIS) to clarify the agency's regulatory position about the required assessment of U.S. Department of Energy (DOE) national laboratories by licensees, applicants, and vendors to verify the effective implementation of the laboratories' QA programs. This draft RIS requires no action or written response on the part of an addressee.

## BACKGROUND INFORMATION

Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 establishes the overall QA requirements<sup>1</sup> for the design, construction, and operation of safety-related structures, systems, and components. Licensees, applicants, and vendors contractually impose Appendix B to 10 CFR Part 50 on suppliers of basic components.<sup>2</sup> Imposition of these QA requirements provides reasonable assurance that a structure, system, or component will perform its intended safety function. Effective assessment of suppliers of basic components ensures that these suppliers are adequately implementing a QA program in accordance with the applicable requirements of Appendix B to 10 CFR Part 50.

Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50 states:

Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure 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. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix.

Similar quality assurance program requirements are included in Subpart H to 10 CFR Part 71 (§ 71.109) and Subpart G to 10 CFR Part 72 (§ 72.148).

In addition, Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 states, in part:

Measures shall be established to assure that purchased material, equipment,

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<sup>1</sup> As stated in Appendix B to 10 CFR Part 50, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

<sup>2</sup> Section 21.3 of 10 CFR states, in part, that a basic component, when applied to nuclear power plants licensed under 10 CFR Part 50 or Part 52, is a structure, system, or component, or part thereof that affects its safety function. In all cases, a basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under 10 CFR Part 52, whether these services are performed by the component supplier or others.

and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for . . . [obtaining] objective evidence of quality furnished by the contractor or subcontractor [and] inspection at the contractor or subcontractor source . . . . The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

Similar quality assurance program requirements are included in Subpart H to 10 CFR Part 71 (§ 71.115) and Subpart G to 10 CFR Part 72 (§ 72.154).

All holders of and applicants for a fuel cycle facility license under 10 CFR Part 70 must apply the QA criteria discussed above to items relied upon for safety in a manner consistent with the management measures program contained within their license application.

NRC safety evaluation report (SER), “Final Safety Evaluation for Technical Report NEI 11-04, Quality Assurance Program Description, Revision 0,” dated May 9, 2013 (Agencywide Documents Access Management System (ADAMS) Accession No. ML13023A051), and issued to the Nuclear Energy Institute (NEI), discusses the NRC staff’s acceptance of 10 CFR Part 52 permit or license applicants’ use of the QA program description template in NEI 11-04, Revision 0, for establishing a QA program that complies with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Parts 50 and 52.

## **SUMMARY OF ISSUE**

In section 3.2.7, “Control of Purchased Material, Equipment, and Services,” of its May 2013 SER, the NRC staff documented its regulatory position that an applicant is not required to evaluate or audit 10 CFR Part 50 and 10 CFR Part 52 licensees, Authorized Nuclear Inspection agencies, the National Institute of Standards and Technology, and other State and Federal agencies, which may provide items or services to NRC licensees, as these are organizations are known to the NRC to have acceptable QA programs. The applicant or holder is still responsible for ensuring that the items or services conform to its Appendix B 10 CFR Part 50 QA program, applicable American Society of Mechanical Engineers Boiler and Pressure Vessel Code requirements, and other applicable regulatory requirements and licensing commitments.

The NRC staff has received several inquiries from nuclear industry stakeholders on whether an evaluation or audit is required for DOE national laboratories that provide basic components to the U.S. nuclear power industry.

The DOE national laboratories are contractor-operated facilities owned or leased by the U.S. Federal Government and managed by third party contractors. As such, the national laboratories are not considered Federal agencies, and the NRC staff’s regulatory position outlined in the May 2013 SER, as discussed above, does not apply to the DOE national laboratories.

When licensees, applicants, and vendors procure items or services from a DOE national laboratory that will be used in a safety-related application, they are responsible for verifying the effective implementation of the laboratory’s programmatic quality controls and other technical and regulatory requirements imposed through contractual documents, consistent with Appendix

B to 10 CFR Part 50, Subpart H to 10 CFR Part 71, or Subpart G to 10 CFR Part 72, as applicable.

### **BACKFITTING AND ISSUE FINALITY DISCUSSION**

This draft 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. This draft RIS is a clarification of the May 2013 SER because that SER did not, and reasonably could not, address every potential entity that is not “10 CFR Part 50 and Part 52 licensees, Authorized Nuclear Inspection Agencies, the National Institute of Standards and Technology, and other State and Federal Agencies.” Further, this draft RIS requires no action or written response, and it 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, 71 or 72. For these reasons, this draft RIS does not meet the definition of “backfitting” and, therefore, is not a backfit, under 10 CFR 50.109, 10 CFR 70.76, or 10 CFR 72.62, all titled “Backfitting,” and does not affect the issue finality of an approval under 10 CFR Part 52.

### **FEDERAL REGISTER NOTIFICATION**

The NRC will publish a notice of opportunity for public comment on this draft RIS in the *Federal Register*.

### **CONGRESSIONAL REVIEW ACT**

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

### **PAPERWORK REDUCTION ACT STATEMENT**

This draft 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 3150-0008, 3150-0009, 3150-0011, 3150-0132, and 3150-0151.

### **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.

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

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