U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE 1.28, REVISION 6

Issue Date: September 2023
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QUALITY ASSURANCE PROGRAM CRITERIA (DESIGN AND CONSTRUCTION)

A. INTRODUCTION

Purpose

This regulatory guide (RG) describes methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for complying with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities" (Ref. 1), and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. 2), which refer to 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," for establishing and implementing a quality assurance (QA) program for the design and construction of nuclear power plants and fuel reprocessing plants.

Applicability

This RG applies to all applicants for a construction permit and operating license subject to 10 CFR Part 50, Appendix B, and all applicants for a combined operating license, early site permit, design approval, design certificate, and manufacturing license subject to 10 CFR Part 50, Appendix B, through 10 CFR Part 52.

Applicable Regulations

- 10 CFR 21.3, "Definitions," establishes the framework for an acceptance process under the definition for "dedication," and this process is undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function. Specifically, the definition for "dedication" requires that the dedication process be conducted in accordance with the applicable provisions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

- 10 CFR Part 50 establishes QA program requirements for the design and construction of nuclear power plants.

Written suggestions regarding this guide may be submitted through the NRC's public Web site in the NRC Library at https://www.nrc.gov/reading-rm/doc-collections/reg-guides/index.html., under Document Collections, in Regulatory Guides, at https://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html, and will be considered in future updates and enhancements to the "Regulatory Guide" series. During the development process of new guides suggestions should be submitted within the comment period for immediate consideration. Suggestions received outside of the comment period will be considered if practical to do so or may be considered for future updates.

Electronic copies of this RG, previous versions of RGs, and other recently issued guides are also available through the NRC's public web site in the NRC Library at https://www.nrc.gov/reading-rm/doc-collections/reg-guides/index.html/under Document Collections, in Regulatory Guides. This RG is also available through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under ADAMS Accession Number (No.) ML23177A002. The regulatory analysis is associated with a rulemaking and may be found in ADAMS under Accession No. ML22304A055. The associated draft guide DG-1403, may be found in ADAMS under Accession No. ML22304A054, and the staff responses to the public comments on DG-1403 may be found under ADAMS Accession No. ML23177A003.

- General Design Criterion 1 (GDC 1), "Quality Standards and Records," in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50 requires that a QA program be established and implemented.

- 10 CFR 50.34(a)(7) requires a description of the QA program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components (SSCs) of the facility and a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

- 10 CFR Part 52 references 10 CFR Part 50, Appendix B, for QA programs associated with Part 52 licensees.

  - 10 CFR 52.17(a)(1)(xi) requires an early site permit applicant to include a description of the QA program applied to site-related activities for the future design, fabrication, construction, and testing of the SSCs of a facility or facilities that may be constructed on the site, as well as a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

  - 10 CFR 52.47(a)(19) requires a standard design certification applicant to include a description of the QA program applied to the SSCs of the facility that satisfies applicable portions of Appendix B to 10 CFR Part 50, as well as a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 were satisfied.

  - 10 CFR 52.79(a)(25) requires a combined license applicant to include a description of the QA program applied to the design, and to be applied to the fabrication, construction, and testing, of the SSCs of the facility, as well as a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 have been and will be satisfied and how the QA program will be implemented.

  - 10 CFR 52.137(a)(19) requires a standard design approval applicant to include a description of the QA program applied to the design of the SSCs of the facility, as well as a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 were satisfied.

  - 10 CFR 52.157(f)(17) requires a manufacturing license applicant to include a description of the QA program applied to the design, and to be applied to the manufacture of, the SSCs of the reactor, as well as a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 have been and will be satisfied.

Related Guidance

- NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants" (Ref. 3), Section 17.5, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants," provides guidance to the NRC staff on reviewing QA program descriptions submitted by applicants for a design certification, combined license, early site permit, construction permit, and operating license.

- RG 1.33, "Quality Assurance Program Requirements (Operation)" (Ref. 4), addresses additional guidance for the establishment and execution of QA programs for nuclear power plants during the operations phase.

Purpose of Regulatory Guides

The NRC issues RGs to describe methods that are acceptable to the staff for implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses. Regulatory guides are not NRC regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs are acceptable if supported by a basis for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This RG provides voluntary guidance for implementing the mandatory information collections in 10 CFR Parts 21, 50 and 52 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), under control numbers 3150-0035, 3150-0011 and 3150-0151, respectively. Send comments regarding this information collection to the FOIA, Library, and Information Collections Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0035, 3150-0011 and 3150-0151), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW, Washington, DC, 20503; e-mail: oira_submissions@omb.eop.gov.

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.

B. DISCUSSION

Reason for Revision

This revision of RG 1.28 endorses, with certain clarifications and regulatory positions, three versions of the ASME NQA-1 standard: NQA-1-2017 (Ref. 5), NQA-1-2019 (Ref. 6), and NQA-1-2022 (Ref. 7). The previous version of RG 1.28 (Revision 5) (Ref. 8) approved the use of NQA-1b-2011 (Ref. 9) Addenda to ASME NQA-1-2008 (Ref. 10), NQA-1-2012 (Ref. 11), and NQA-1-2015 (Ref. 12), with certain clarifications and regulatory positions. The staff determined that the NQA-1-2017, NQA-1-2019, and NQA-1-2022 provide the most current guidance for QA.

Background

The NRC issued RG 1.28, Revision 5, in October 2017. The NRC's approval of NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-2012, and NQA-1-2015 in RG 1.28, Revision 5 includes Part I and Part II. Part I describes the requirements for quality assurance programs for nuclear facilities. Part II contains amplifying QA requirements for certain specific work activities that occur at various stages of a facility's life. These work activities include, but are not limited to, management, planning, site investigation, design, computer software use, commercial-grade dedication, procurement, fabrication, installation, inspection, and testing. Part II of NQA-1-2012 added Subpart 2.22, "Quality Assurance Requirements for Management Assessment and Quality Improvement for Compliance with 10 CFR 830 and Department of Energy (DOE) Order 414.1 for DOE Nuclear Facilities." In addition, Part II of NQA-1-2019 added Subpart 2.25, "Quality Assurance Requirements for High Level Waste Custodians." Subpart 2.25 contains guidance for complying with DOE Order 414.1, "Quality Assurance," and DOE/RW-0333P, "Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description," Revision 20. Facilities subject to 10 CFR 830 and DOE Order 414.1 are not within the regulatory jurisdiction of the NRC. Thus, the NRC's approval for use of NQA-1-2017, NQA-1-2019, and NQA-1-2022, as set forth in this draft RG, excludes Subparts 2.22 and 2.25, as these Subparts are outside the purview of NRC regulated facilities.

In addition, Revision 5 of RG 1.28 introduced the use of accreditation of calibration or testing services in lieu of conducting a survey when performing commercial-grade dedication. Revision 5 of RG 1.28 discussed the use of Nuclear Energy Institute (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, issued August 2014 (Ref. 13), as an acceptable approach for licensees and suppliers subject to the QA requirements of Appendix B to 10 CFR Part 50. This NEI document relates to using laboratory accreditation by Accreditation Bodies that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) in lieu of performing commercial grade surveys as part of the commercial-grade dedication process for procuring calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA. The NEI has updated the guideline, and the staff reviewed the updated guidance in "Final Safety Evaluation by the Office of Nuclear Reactor Regulation for the Nuclear Energy Institute Technical Report 1405A, 'Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,' Revision 1, EPID L-2020-TOP-0011," November 23, 2020. (ML20322A019) (Ref. 16). As such, this RG endorses NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1, issued September 2020 (Ref. 16) as an acceptable approach for licensees and suppliers subject to the QA requirements of Appendix B to 10 CFR Part 50 and the definitions in 10 CFR 21.3

NQA-1-2017 added Subpart 2.19, "Quality Assurance Requirements for the Use of Supplier Accreditation for Calibration and Testing Services." Subpart 2.19 of NQA-1-2017 and NQA-1-2019 does not adequately incorporate the appropriate International Organization for Standardization and International Electrotechnical Commission (ISO/IEC) 17025-2017 version. In addition, Subpart 2.19 does not include the controls to limit consecutive remote accreditation assessments. Thus, the NRC staff does not endorse Subpart 2.19 in NQA-1-2017, NQA-1-2019 and NQA-1-2022.

Consideration of International Standards

The International Atomic Energy Agency (IAEA) works with member states and other partners to promote the safe, secure, and peaceful use of nuclear technologies. The IAEA develops Safety Requirements and Safety Guides for protecting people and the environment from harmful effects of ionizing radiation. This system of safety fundamentals, safety requirements, safety guides, and other relevant reports, reflects an international perspective on what constitutes a high level of safety. To inform its development of this RG, the NRC considered IAEA Safety Requirements and Safety Guides pursuant to the Commission's International Policy Statement (Ref. 14) and Management Directive and Handbook 6.6, "Regulatory Guides" (Ref. 15).

In the development of RG 1.28, Rev. 6, the NRC staff did not identify any IAEA Safety Requirements or Guides with information related to the topic of this RG.

Documents Discussed in Staff Regulatory Guidance

This RG endorses, in part, the use of one or more codes or standards developed by external organizations and other third-party guidance documents. These codes, standards and third-party guidance documents may contain references to other codes, standards, or third-party guidance documents ("secondary references"). If a secondary reference has itself been incorporated by reference into NRC regulations as a requirement, then licensees and applicants must comply with that standard as set forth in the regulation. If the secondary reference has been endorsed in a RG as an acceptable approach for meeting an NRC requirement, then the standard constitutes a method acceptable to the NRC staff for meeting that regulatory requirement as described in the specific RG. If the secondary reference has neither been incorporated by reference into NRC regulations nor endorsed in a RG, then the secondary reference is neither a legally binding requirement nor a "generic" NRC approved acceptable approach for meeting an NRC requirement. However, licensees and applicants may consider and use the information in the secondary reference, if appropriately justified, consistent with current regulatory practice, and consistent with applicable NRC requirements.

C. STAFF REGULATORY GUIDANCE

The NRC staff endorses the Part I and Part II requirements included in NQA-1-2017, NQA-1-2019, and NQA-1-2022 for the implementation of a QA program during the design and construction phases of nuclear power plants and fuel reprocessing plants. They provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50, subject to the exceptions and clarifications of NQA-1-2017, NQA-1-2019, and NQA-1-2022 identified below. The NRC staff also endorses NEI-14-05A, Revision 1 for the dedication of laboratory calibration and testing services consistent with the definitions in 10 CFR 21.3 and the requirements of Appendix B to 10 CFR Part 50.

1. Quality Assurance Program (NQA-1 Requirement 2)

a. Audit Participation

(1) Prospective lead auditors, with comparable industry experience, may satisfy the lead auditor qualification requirement of participating in a minimum of five QA audits within a period of 3 years prior to the date of qualification by alternatively demonstrating the ability to properly implement the audit process, effectively organize and report results, and participate in at least one nuclear audit within the year preceding the date of qualification, subject to review and acceptance by the responsible QA organization.

2. Control of Purchased Items and Services (NQA-1 Requirement 7 and Subpart 2.19)

a. Laboratory Calibration and Testing Services

(1) The NRC finds that Subpart 2.19 in NQA-1-2017, NQA-1-2019 and NQA-1-2022-does not incorporate the controls and conditions necessary for use. Licensees and suppliers should instead use NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1, issued September 2020, which provides an acceptable approach for licensees and suppliers subject to the QA requirements of Appendix B to 10 CFR Part 50. This NEI document relates to using laboratory accreditation by Accreditation Bodies that are signatories to the ILAC MRA in lieu of performing commercial grade surveys as part of the commercial-grade dedication process for procuring calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

3. Quality Assurance Records (NQA-1 Requirement 17)

a. Lifetime and Nonpermanent Records

(1) Paragraph 400, "Classification," of Requirement 17, "Quality Assurance Records," of NQA-1, provides guidance on the retention of "lifetime" and "nonpermanent" records. Paragraph 401, "Lifetime Records," discusses the scope and responsibilities related to these records. The owner or an authorized agent must maintain lifetime records for the life of the item while it is installed in the plant or stored for future use.

(2) Paragraph 402, "Nonpermanent Records," identifies nonpermanent records as those records that "…show evidence that an activity was performed in accordance with the applicable requirements…." The owner or an authorized agent does not need to retain

these records for the life of the item, because they do not meet the criteria for lifetime records. However, Paragraph 700, "Retention," specifies that document retention periods be documented, and records maintained for their retention period.

NQA-1 Part III, Nonmandatory Subpart 3.1-17.1, "Guidance on Quality Assurance Records," Paragraph 200, "List of Typical Lifetime Records," lists typical lifetime records containing information that meets Requirement 17 of Part I. The list of typical lifetime records in Nonmandatory Subpart 3.1-17.1 should be considered for guidance purposes only. Note that the nomenclature of these records may vary. For records not listed in Subpart 3.1-17.1, the type of record that most nearly describes the record in question should be followed with respect to its retention classification. The applicant or licensee should be aware that the list is not considered to be all--inclusive. The applicant or licensee itself is responsible for ensuring, in accordance with Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50, that it maintains sufficient records to furnish evidence of activities affecting quality.

b. Managing Quality Assurance Records in Electronic Media

(1) For the management of electronic records, appropriate controls on quality include the following:

(a) No deletion or modification of records is allowed unless authorized pursuant to the record retention rule.

(b) Redundancy (e.g., system backup, dual storage) is provided.

(c) Legibility is required of each record.

(d) Records media are properly maintained.

(e) Random inspections ensure no degradation of records.

(f) Records are acceptably converted into any new system before the old system is taken out of service.

(2) The Nuclear Information and Records Management Association (NIRMA) technical guides (TGs), as listed below, provide guidance to establish the appropriate quality controls that incorporate the implementation of enterprise content management systems, web-based technologies, and higher capacity local- and wide-area networks. The NRC approves for use the 2011 versions of the NIRMA TGs.

(a) NIRMA TG 11, "Authentication of Records and Media" (Ref. 17)

(b) NIRMA TG 15, "Management of Electronic Records" (Ref. 18)

(c) NIRMA TG 16, "Software Quality Assurance Documentation and Records" (Ref. 19)

(d) NIRMA TG 21, "Required Records Protection, Disaster Recovery and Business Continuation" (Ref. 20)

4. Audits (NQA-1 Requirements 7 and 18)

a. Internal Audits

(1) Applicable elements of an organization's QA program should be audited at least once each year or at least once during the life of the activity, whichever is shorter. In determining the scope of the audit, an evaluation of the activity being audited may be useful. The evaluation may include results of previous QA program audits and the results of audits from other sources, including the nature and frequency of identified deficiencies and any significant changes in personnel, the organization, or the QA program.

b. External Audits

(1) After the award of a contract, the applicant or licensee may determine, based on the evaluation conducted in accordance with Regulatory Position 4.b.(4), that external audits are not necessary for procuring items (a) that are relatively simple and standard in design, manufacturing, and testing and (b) that are adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery. For other procurement actions not covered by the above exceptions, audits should be conducted as described below.

(2) The applicant or licensee should either audit its supplier's QA program on a triennial basis or arrange for such an audit. The triennial period begins when an audit is performed. The licensee or applicant may perform an audit when the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program that has the required scope for purchases placed during the triennial period. If a subsequent contract or a contract modification significantly enlarges the scope or changes the methods or controls for activities performed by the same supplier, the licensee or applicant should conduct an audit of the modified requirements, thus starting a new triennial period. If the supplier is implementing the same QA program for other customers as that proposed for use on the auditing party's contract, the pre-award survey (initially established as a requirement in ASME NQA-1-2008) may serve as the first triennial audit. Therefore, when a pre-award survey is used as the first triennial audit, it should satisfy the same audit elements and criteria as those used on other triennial audits.

(3) If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of this audit should satisfy the needs of all the purchasers, and all the purchasers for whom the audit was conducted should receive the audit report. Nevertheless, each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit.

(4) The applicant or licensee should perform or arrange for annual evaluations of suppliers. It should document these evaluations and take the following considerations into account, where applicable:

(a) the review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions

(b) results of previous source verifications, audits, and receiving inspections

(c) operating experience of identical or similar products furnished by the same supplier and results of audits from other sources (e.g., Nuclear Procurement Issues Corporation audit reports or NRC inspection reports)

Note: The NRC recognizes the ASME Accreditation Program and associated certificates of authorization as evidence that the holder of the certificate of authorization has a documented QA program that meets the requirements of Appendix B to 10 CFR Part 50. However, recognition of the ASME Accreditation Program applies only to the programmatic aspects of the QA programs. Applicants and licensees or their subcontractors should ensure that the suppliers are effectively implementing their approved QA programs. Additional information appears in Information Notice (IN) 86-21, "Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders," dated March 31, 1986 (Ref. 21).

5. QA Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Facilities (NQA-1 Subpart 2.2)

Etching should not be used on nickel alloys, weld areas, or sensitized areas of stainless steel.

6. QA Requirements for Installation, Inspection, Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Facilities (NQA-1 Subpart 2.5)

Codes and standards are referenced or invoked throughout Subpart 2.5. When the referenced or invoked code or standard becomes superseded or canceled, licensees or applicants should submit their proposed alternative for NRC review and approval, as appropriate, for continued use of the code or standard or a proposed alternative.

D. IMPLEMENTATION

The NRC staff may use this RG as a reference in its regulatory processes, such as licensing, inspection, or enforcement. However, the NRC staff does not intend to use the guidance in this RG to support NRC staff actions in a manner that would constitute backfitting as that term is defined in 10 CFR 50.109, "Backfitting," and as described in NRC Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," (Ref. 22), nor does the NRC staff intend to use the guidance to affect the issue finality of an approval under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." The staff also does not intend to use the guidance to support NRC staff actions in a manner that constitutes forward fitting as that term is defined and described in Management Directive 8.4. If a licensee believes that the NRC is using this RG in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfitting or forward fitting appeal with the NRC in accordance with the process in Management Directive 8.4.

REFERENCES [1]

1. *U.S. Code of Federal Regulations*, 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

2. *U.S. Code of Federal Regulations*, 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants"

3. U.S. Nuclear Regulatory Commission (NRC), NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 17.5, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants," Washington, DC, August 2015. (ADAMS Accession No. ML15037A441)

4. NRC, Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)," Washington, DC.

5. American Society of Mechanical Engineers (ASME), NQA-1-2017, "Quality Assurance Requirements for Nuclear Facility Applications," New York, New York.[2]

6. ASME, NQA-1-2019 "Quality Assurance Requirements for Nuclear Facility Applications," New York, New York.

7. ASME, NQA-1-2022, "Quality Assurance Requirements for Nuclear Facility Applications," New York, New York.

8. NRC, Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5, Washington, DC.

9. ASME, NQA-1b-2011 Addenda to ASME NQA-1-2008, "Quality Assurance Requirements for Nuclear Facility Applications," New York, New York.

10. ASME, NQA-1-2008, "Quality Assurance Requirements for Nuclear Facility Applications," New York, New York.

11. ASME, NQA-1-2012, "Quality Assurance Requirements for Nuclear Facility Applications," New York, New York.

12. ASME, NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," New York, New York.

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1 Publicly available NRC published documents are available electronically through the NRC Library on the NRC's public website at http://www.nrc.gov/reading-rm/doc-collections/ and through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html. For problems with ADAMS, contact the Public Document Room staff at 301-415-4737 or (800) 397-4209, or email pdr.resource@nrc.gov. The NRC Public Document Room (PDR), where you may also examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

2 Copies of American Society of Mechanical Engineers (ASME) standards may be purchased from ASME, Two Park Avenue, New York, NY 10016-5990; telephone 800-843-2763. Purchase information is available through the ASME web-based store at https://www.asme.org/publications-submissions.

13. Nuclear Energy Institute (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, Washington, DC, August 2014. (ML14245A392)

14. NRC, "Nuclear Regulatory Commission International Policy Statement," Federal Register, Vol. 79, No. 132, July 10, 2014, pp. 39415-39418.

15 NRC, Management Directive (MD) 6.6, "Regulatory Guides," Washington, DC, May 2, 2016 (ML18073A170).

16. NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1, Washington, DC, September 2020. (ML20259B731)

17. Nuclear Information and Records Management Association (NIRMA), TG 11-2011, "Authentication of Records and Media," Fairfield, Connecticut.

18. NIRMA, TG 15-2011, "Management of Electronic Records," Fairfield, Connecticut.

19. NIRMA, TG 16-2011, "Software Quality Assurance Documentation and Records," Fairfield, Connecticut.

20. NIRMA, TG 21-2011, "Required Records Protection, Disaster Recovery and Business Continuation," Fairfield, Connecticut.

21. NRC, Information Notice 86-21, "Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders," Washington, DC, March 31, 1986.

22. NRC, Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection," Washington, DC, September 20, 2019. (ML18093B087)

BIBLIOGRAPHY

1. U.S. Nuclear Regulatory Commission (NRC), "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," February 9, 2015. (ML14322A535)

2. NRC, "Final Safety Evaluation by the Office of Nuclear Reactor Regulation for the Nuclear Energy Institute Technical Report 14-05A, 'Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,' Revision 1, EPID L-2020-TOP-0011," November 23, 2020. (ML20322A019)

3. NRC, "Safety Evaluation by the Office of Nuclear Reactor Regulation Quality Assurance Topical Report Change, Duke Energy Carolinas, LLC, Catawba Nuclear Station, Unit Nos. 1 and 2, McGuire Nuclear Station, Unit Nos. 1 and 2; Oconee Nuclear Station, Unit Nos. 1, 2, and 3; Docket Nos. 50-413, 50-414, 50-369, 50-370, 50-269, 20-270 and 50-287;" enclosure to letter dated May 26, 2015. (ML15138A347)