



# DRAFT REGULATORY GUIDE

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## DRAFT REGULATORY GUIDE DG-1326

(Proposed Revision 5 of Regulatory Guide 1.28, dated June 2010)

# 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 Rules

- 10 CFR Part 50 establishes QA program requirements for the design and construction of nuclear power plants.
  - Appendix A, General Design Criterion 1 (GDC 1), “Quality Standards and Records,” to 10 CFR Part 50 requires that a QA program be established and implemented.

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This regulatory guide is being issued in draft form to involve the public in the development of regulatory guidance in this area. It has not received final staff review or approval and does not represent an NRC final staff position. Public comments are being solicited on this draft guide and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Comments may be submitted through the Federal-rulemaking Web site, <http://www.regulations.gov>, by searching for Docket ID: NRC-2017-0079. Alternatively, comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments must be submitted by the date indicated in the *Federal Register* notice.

Electronic copies of this draft regulatory guide, previous versions of this guide, and other recently issued guides are available through the NRC’s public Web site under the Regulatory Guides document collection of the NRC Library at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/>. The draft regulatory guide is also available through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML16180A264. The regulatory analysis may be found in ADAMS under Accession No. ML16180A263

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- 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 of the facility, and a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 Appendix B 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 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 Part 50 will be satisfied.
  - 10 CFR 52.47(a)(19) requires a standard design certification applicant to include a description of the QA 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 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 quality assurance program will be implemented.
  - 10 CFR 52.137(a)(19) requires a standard design certification 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 in 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 to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

### **Paperwork Reduction Act**

This RG contains and references information collections covered by 10 CFR Parts 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), control numbers 3150-0011 and 3150-0151.

### **Public Protection Notification**

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

## **B. DISCUSSION**

### **Reason for Revision**

This revision of the guide (Revision 5) updates the guidance to endorse, with clarification or exceptions, multiple revisions of the American Society of Mechanical Engineers (ASME) standard NQA-1, “Quality Assurance Requirements for Nuclear Facility Applications.”

### **Background**

This revision of RG 1.28 endorses, with certain clarifications and regulatory positions, various versions of the ASME NQA-1 standard; the standards included are the NQA-1b-2011 Addenda to ASME NQA-1-2008 (Ref. 5), NQA-1-2012 (Ref. 6), and NQA-1-2015 (Ref. 7). The previous version of RG 1.28 (Revision 4) (Ref. 8), approved the use of NQA-1-2008 (Ref. 9), and the NQA-1a-2009 Addenda (Ref. 10), with certain clarifications and regulatory positions. The staff determined that the NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-1-2012, and NQA-1-2015 provide the most current guidance for QA.

The NRC issued RG 1.28, Revision 4, in June 2010. The guide extended the scope of the NRC’s approval of NQA-1 to include Part II, which contains amplifying QA requirements for certain specific work activities that occur at various stages of a facility’s life. The 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 versions NQA-1-2012 and NQA-1-2015 include 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.” NRC does not intend this RG to approve for use Subsection 2.22 at NRC-regulated facilities because NRC has no authority to set forth requirements applicable to DOE nuclear facilities.

In addition, Revision 4 of RG 1.28 introduced the use of electronic media as a way to satisfy the requirements for the maintenance of QA records. The guide discussed Generic Letter No. 88-18, “Plant Record Storage on Optical Disk,” dated October 20, 1988 (Ref. 11), which was issued to inform licensees of the NRC approval of the use of optical disk document imaging systems for the storage and retrieval of quality assurance records and documented the appropriate quality controls for the use of optical disks. Revision 4 also discussed Regulatory Issue Summary (RIS) 2000-18, “Guidance on Managing Quality Assurance Records in Electronic Media,” dated October 23, 2000 (Ref. 12). Attachment 1 to RIS 2000-18 lists guidance documents on establishing an electronic recordkeeping system to maintain the integrity, authenticity, and acceptability of QA records during their required retention period in accordance with the requirements of Appendix B to 10 CFR Part 50 and other regulations for the storage of QA records in electronic media. The guidance documents listed in RIS 2000-18 also describe methods that the licensee or applicant can use to authenticate electronic records; to prevent their alteration or falsification; to protect them from, or to recover them following a disaster; and to manage their software configuration. The staff determined that more current guidance is available, as discussed in Section C of this RG.

## **Harmonization with International Standards**

The NRC staff reviewed guidance from the International Atomic Energy Agency (IAEA) and did not identify any standards that provided useful guidance to NRC staff, applicants, or licensees.

## **Documents Discussed in Staff Regulatory Guidance**

This regulatory guide 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 regulatory guide 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 regulatory guide. If the secondary reference has neither been incorporated by reference into NRC regulations nor endorsed in a regulatory guide, 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. REGULATORY POSITION

The Part I and Part II requirements included in the NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-1-2012, and NQA-1-2015, “Quality Assurance Requirements for Nuclear Facility Applications,” for the implementation of a QA program during the design and construction phases of nuclear power plants and fuel reprocessing plants are endorsed by the NRC staff, and 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-1b-2011, NQA-1-2012, and NQA-1-2015 identified below.

1. QA Program
  - 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.
2. Control of Purchased Items and Services
  - a. Laboratory Calibration and Testing Services
    - (1) The NRC finds that 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 (Ref. 13), provides an acceptable approach for licensees and suppliers subject to the QA requirements of Appendix B to 10 CFR Part 50 for 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 procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.
3. QA Records
  - a. Lifetime and Nonpermanent Records
    - (1) Paragraph 400, “Classification,” of Requirement 17, “Quality Assurance Records,” 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 particular 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 cognizant 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 unless authorized pursuant to the record retention rule
  - (b) Redundancy (system backup, dual storage, etc.) is provided
  - (c) Legibility is required of each record
  - (d) Records media are properly maintained
  - (e) Random inspections to ensure no degradation of records
  - (f) Records are acceptably converted into any new system before the old system is taken out of service

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

- (a) NIRMA TG 11, “Authentication of Records and Media” (Ref. 14);
- (b) NIRMA TG 15, “Management of Electronic Records” (Ref. 15);
- (c) NIRMA TG 16, “Software Configuration Management and Quality Assurance” (Ref. 16); and
- (d) NIRMA TG 21, “Electronic Records Protection and Restoration” (Ref. 17).

#### 4. Audits

##### 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) below, 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 preaward survey (initially established as a requirement in ASME NQA-1-2008) may serve as the first triennial audit. Therefore, when a preaward 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; and



- (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 Committee 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. For additional information, see Information Notice (IN) 86-21, "Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders," dated March 31, 1986 (Ref. 18).

5. DOE Elements in NQA-1-2015

Subpart 2.22 of NQA-1-2015 contains guidance for complying with 10 CFR 830 and DOE Order 414.1 for DOE Nuclear Facilities. These facilities are not within the regulatory jurisdiction of the NRC. Thus, the NRC's approval for use of NQA-1-2015, as set forth in this regulatory guide, excludes Subpart 2.22 and this Subpart is not applicable to NRC-regulated facilities.

## D. IMPLEMENTATION

The purpose of this section is to provide information on how nuclear licensees and applicants<sup>1</sup> may use this guide and information regarding the NRC's plans for using this RG. In addition, it describes how the NRC staff complies with 10 CFR 50.109, "Backfitting," and any applicable finality provisions in 10 CFR Part 52.

### Use by Nuclear Licensees and Applicants

Nuclear licensees and applicants may voluntarily<sup>2</sup> use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this RG may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current licensees may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged.

Licensees may use the information in this RG for actions that do not require NRC review and approval, such as changes to a facility design under 10 CFR 50.59, "Changes, Tests and Experiments." Licensees may use the information in this RG or applicable parts to resolve regulatory or inspection issues.

### Use by NRC Staff

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this RG. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this RG, unless the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this RG to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action that would require the use of this RG. Examples of such unplanned NRC regulatory actions include issuance of an order requiring the use of the regulatory guide, requests for information under 10 CFR 50.54(f) as to whether a licensee intends to commit to use of this regulatory guide, generic communication, or issuance of a rule requiring the use of this regulatory guide without further backfit consideration.

During regulatory discussions on plant-specific operational issues, the staff may discuss with licensees various actions consistent with staff positions in this RG, as one acceptable means of meeting the underlying NRC regulatory requirement. Such discussions would not ordinarily be considered backfitting even if prior versions of this RG are part of the licensing basis of the facility. However, unless this RG is part of the licensing basis for a facility, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this RG constitutes a violation.

If an existing licensee voluntarily seeks a license amendment or change and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this new or revised regulatory guide and (2) the specific subject matter of this regulatory guide is an essential consideration in the staff's

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<sup>1</sup> In this section, "licensees" refers to licensees of nuclear power plants under 10 CFR Parts 50 and 52; and the term "applicants" refers to applicants for licenses and permits for (or relating to) nuclear power plants under 10 CFR Parts 50 and 52, and applicants for standard design approvals and standard design certifications under 10 CFR Part 52.

<sup>2</sup> In this section, "voluntary" and "voluntarily" mean that the nuclear licensee or applicant is seeking the action of its own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action.

determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this regulatory guide or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR 50.109(a)(1) or a violation of any of the issue finality provisions in 10 CFR Part 52.

If a licensee believes that the NRC is either using this regulatory guide or requesting or requiring the licensee to implement the methods or processes in this regulatory guide in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfit appeal with the NRC in accordance with the guidance in NUREG-1409, "Backfitting Guidelines" (Ref. 19), and NRC Management Directive (MD) 8.4, "Management of Facility-specific Backfitting and Information Collection" (Ref. 20).

## REFERENCES <sup>3</sup>

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, “Quality Assurance Program Requirements (Operation),” Regulatory Guide 1.33, Washington, DC.
5. American Society of Mechanical Engineers (ASME), “Quality Assurance Requirements for Nuclear Facility Applications,” ASME NQA-1b-2011 Addenda to ASME NQA-1-2008, New York, NY.
6. ASME “Quality Assurance Requirements for Nuclear Facility Applications,” ASME NQA-1-2012, New York, NY.
7. ASME, “Quality Assurance Requirements for Nuclear Facility Applications,” ASME NQA-1-2015, New York, NY.
8. NRC, “Quality Assurance Program Criteria (Design and Construction),” Regulatory Guide 1.28, Revision 4, Washington, DC.
9. ASME, “Quality Assurance Requirements for Nuclear Facility Applications,” ASME NQA-1-2008, New York, NY.<sup>4</sup>
10. ASME, “Quality Assurance Requirements for Nuclear Facility Applications,” ASME NQA-1a-2009 Addenda to ASME NQA-1-2008, New York, NY.
11. NRC, “Plant Record Storage on Optical Disks,” GL 88-18, Washington, DC, October 20, 1988.
12. NRC, “Guidance on Managing Quality Assurance Records in Electronic Media,” RIS 2000-18, Washington, DC, October 23, 2000.

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<sup>3</sup> Publicly available NRC-published documents are available electronically through the NRC Library on the NRC’s public Web site at: <http://www.nrc.gov/reading-rm/doc-collections/>. The documents can also be viewed online or printed for a fee in the NRC’s Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone 301-415-4737 or 800-397-4209; fax 301-415-3548; and e-mail [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov)

<sup>4</sup> Copies of American Society of Mechanical Engineers (ASME) standards may be purchased from ASME, Three Park Avenue, New York, NY 10016-5990; telephone 800-843-2763. Purchase information is available through the ASME Web-based store at <http://www.asme.org/Codes/Publications/>.

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 (ADAMS Accession No. ML14245A392)
14. Nuclear Information and Records Management Association (NIRMA), "Authentication of Records and Media," TG 11-2011, New York, NY.<sup>5</sup>
15. NIRMA, "Management of Electronic Records," TG 15-2011, Windham, NH.
16. NIRMA, "Software Configuration Management and Quality Assurance," TG 16-2011, Windham, NH.
17. NIRMA, "Electronic Records Protection and Restoration," TG 21-2011, Windham, NH.
18. NRC, "Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders," IN 86-21, Washington, DC, March 31, 1986.
19. NRC NUREG-1409, "Backfitting Guidelines," Washington, DC, July 1990.
20. NRC, "Management of Facility-Specific Backfitting and Information Collection," MD 8.4, October 9, 2013. (ADAMS Accession No. ML12059A460)

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<sup>5</sup> Copies of Nuclear Information & Records Management (NIRMA) technical guides may be purchased from NIRMA, 245 Sunnyridge Avenue #34 Fairfield, CT 06824; telephone 203 388 8795. Purchase information is available through the NIRMA Web based store at <https://www.nirma.org/shop>.

## **BIBLIOGRAPHY**

1. 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, ADAMS Accession No. ML14322A535.
2. Safety Evaluation of the Quality Assurance Topical Report, Amendment 40 for 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 50-269, 50-270, and 50-287; Renewed License Numbers DPR-38, DPR-47, and DPR-55, ADAMS Accession No. ML15099A561.