

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR REACTOR REGULATION  
WASHINGTON, D.C. 20555-0001

October 23, 2000

**NRC REGULATORY ISSUE SUMMARY 2000-18**  
**GUIDANCE ON MANAGING QUALITY ASSURANCE RECORDS**  
**IN ELECTRONIC MEDIA**

ADDRESSEES

All holders of operating licenses for nuclear power plants, including licensees that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel. In addition, those materials licensees, including certificate holders and vendors, that are required to have an NRC approved quality assurance program.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to provide guidance on managing quality assurance (QA) records in electronic media. This RIS does not supersede or revise existing guidance or abrogate the guidance in Regulatory Guide (RG) 1.88, Revision 2, or RG 1.28, Revision 3. It does not provide guidance on submitting electronic records to the NRC as required by Section 50.4(c) of Title 10 of the *Code of Federal Regulations* (10 CFR 50.4(c)).

The guidance in this RIS is intended to provide, for those licensees with QA programs, a way to satisfy the requirements for the maintenance of QA records. However, the guidance can also be applied to the record keeping and maintenance requirements present in other parts of the regulations that specify that storing records in the form of electronic media is acceptable.

This RIS does not create any new or changed NRC requirements or staff positions, and it requires no specific action or written response. Any action on the part of addressees to use electronic media for managing QA records is strictly voluntary.

BACKGROUND

For nuclear power plants, Criterion VI, "Document Control," and Criterion XVII, "Quality Assurance Records," of 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," establish requirements for issuing, identifying, and retrieving QA records. For other types of licensees, 10 CFR 40.61; 10 CFR 60.150, 60.151, 60.152; 10 CFR 71.1, 71.91, 71.135; 10 CFR 72.48, 72.72, 72.80, 72.150, 72.174, 72.212, and 72.234; and 10 CFR 76.70 and 76.93 establish requirements for QA records.

NRC-accepted practices for the collection, storage, and maintenance of QA records for nuclear power plants, independent storage of spent nuclear fuel and high-level radioactive waste

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facilities, special nuclear materials, packaging and transportation of radioactive materials, and gaseous diffusion plants are described in the following documents:

- American National Standards Institute (ANSI) N45.2.9-1974, "Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants," as endorsed by RG 1.88, "Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records," Revision 2.
- ANSI/American Society of Mechanical Engineers, ANSI/ASME-NQA-1, 1983 edition, "Quality Assurance Program Requirements for Nuclear Facilities," as endorsed by RG 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3.

On October 20, 1988, the NRC staff issued GL 88-18, "Plant Record Storage on Optical Disks," to provide guidance on quality controls for an optical disk document-imaging system. GL 88-18 expanded the guidance of RGs 1.88 and 1.28 to describe an acceptable method for storing QA documents in optical media in accordance with the criteria in Appendix B to 10 CFR Part 50.

## DISCUSSION

Although the guidance in GL 88-18, RG 1.88, and RG 1.28 remains relevant and acceptable, licensees and nuclear steam system suppliers have suggested that additional guidance on the acceptability of new information management technologies is needed. NRC regulations already recognize the acceptability of storing and maintaining licensee records in electronic media. Specifically, 10 CFR 50.71(d)(1), "Maintenance of Records, Making of Reports," states that records that must be maintained pursuant to 10 CFR Part 50 "may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period." In addition, various other parts of the regulations, such as in Part 20, Parts 30-39, and Parts 40 and 70 for example, indicate that electronic media are acceptable for use when the requirements for authentication, reproduction, and storage are met. This RIS provides the additional guidance requested by the nuclear industry on storing and maintaining QA records in electronic media. The guidance applies to QA records that are subject to the requirements of Appendix B to 10 CFR Part 50, Part 60, Part 71, Part 72, or Part 76, and that are noted in a licensee's QA program description. In addition, this guidance may be followed to satisfy the record keeping and maintenance requirements found in other parts of the regulations that specify that electronic media are acceptable for storing documents.

Since addressees are responsible for ensuring the integrity of QA records, Attachment 1 to this RIS provides a list of 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, Part 60, Part 71, Part 72, or Part 76. These guidance documents also describe methods to authenticate electronic records, prevent their alteration or falsification, protect them from or recover them following a disaster, and manage their software configuration. Although the complete set of guidance documents referenced in Attachment 1 constitutes an acceptable method for satisfying the provisions of Appendix B to 10 CFR Part 50, Part 60, Part 71, Part 72, or Part 76 with regard to the storage of QA records in electronic media, this guidance does not supersede current QA record commitments in the addressees' QA program descriptions. These guidelines are intended only for use in meeting recordkeeping requirements and no other requirements.

This RIS does not provide guidance pursuant to other regulations, such as 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

In accordance with 10 CFR 50.54(a), 10 CFR 50.71(e), 10 CFR 71.37, 10 CFR 72.11(a), 10 CFR 72.140(c), 10 CFR 76.9(a) or 10 CFR 76.68(b), as appropriate, addressees choosing to use electronic media for managing QA records should include this information in their new or updated QA program descriptions. The new or updated QA program description should describe the addressee's implementation of the guidance in this RIS or otherwise describe how the relevant criteria in Appendix B to 10 CFR Part 50, Part 60, Part 71, Part 72, or Part 76 continue to be satisfied when electronic media are used for managing QA records. The addressee should specify the media in which records will be kept (optical disk, magnetic tape, and so on), and whether GL 88-18 or this RIS is being implemented.

#### RELATED GENERIC COMMUNICATION

GL 88-18, "Plant Record Storage on Optical Disks," issued October 20, 1988.

#### BACKFIT DISCUSSION

Backfitting is defined in 10 CFR 50.109 as "the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position." In addition, 10 CFR 72.62 and 10 CFR 76.76 contain a similar backfitting definition.

This RIS imposes no new requirements and imposes no new regulatory staff positions, nor does it provide a new interpretation of a previously applicable staff position and, as such, does not constitute a backfit as defined in 10 CFR 50.109, 10 CFR 72.62, or 10 CFR 76.76. Furthermore, this RIS requires no action or written response. Any action on the part of addressees to use electronic media for managing QA records is strictly voluntary. Consequently, the staff did not perform a backfit analysis.

#### FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment was published in the *Federal Register* (63 FR 64) on April 3, 1998, seeking comment on a draft supplement to GL 88-18. Comments were received from 11 respondents, including 8 power reactor licensees, 2 industry groups, and 1 consulting firm. The NRC staff's evaluation of the comments is available from the NRC Public Document Room. After considering the comments received, the NRC staff appropriately revised the text of the generic communication. Additionally, the generic letter supplement was reformatted as a regulatory issue summary in keeping with recent actions taken by the staff to improve the agency's generic communications program and its implementation; this is described more fully in RIS 99-01, "Revisions to the Generic Communications Program."

#### PAPERWORK REDUCTION ACT STATEMENT

The information collections contained in this RIS are covered by the requirements of 10 CFR Part 50, 10 CFR Part 60, 10 CFR Part 71, and 10 CFR Part 72, which were approved by the Office of Management and Budget (OMB), approval numbers 3150-0011, 3150-0127, 3150-0008, and 3150-0132, respectively. Pursuant to the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), OMB clearance is not required for 10 CFR Part 76.

**PUBLIC PROTECTION NOTIFICATION**

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

If you have any questions about this matter, please contact the technical contacts listed below, the appropriate Office of Nuclear Reactor Regulation (NRR) or the appropriate Office of Nuclear Material Safety and Safeguards (NMSS) project manager.

**RA/Charles E. Ader FOR**

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**Attachments:**

1. Guidance on Managing Quality Assurance Records in Electronic Media
2. References
3. List of Recently Issued NRC Regulatory Issue Summaries

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## **GUIDANCE ON MANAGING QUALITY ASSURANCE RECORDS IN ELECTRONIC MEDIA**

### Industry Guidelines

The Electronic Recordkeeping Subcommittee of the Regulations Committee of the Nuclear Information and Records Management Association, Inc. (NIRMA) has prepared a set of four guidelines<sup>1</sup> on collecting, storing, and maintaining electronic quality assurance (QA) records for nuclear power plants and other facilities subject to the regulations identified in this generic letter.

1. NIRMA Technical Guide (TG) 11-1998, "Authentication of Records and Media"
2. NIRMA TG 15-1998, "Management of Electronic Records"
3. NIRMA TG 16-1998, "Software Configuration Management and Quality Assurance"
4. NIRMA TG 21-1998, "Electronic Records Protection and Restoration"

When implemented together, these guidelines provide an acceptable basis for complying with the recordkeeping requirements of 10 CFR Part 31, Part 32, Part 34, Part 40, Appendix B to 10 CFR Part 50, Part 60<sup>2</sup>, Part 70, Part 71, Part 72, or Part 76. The scope of the NRC's acceptance of these four NIRMA technical guidelines is only for managing electronic quality assurance records.

### Supplemental Industry Guidelines

The NRC does not prohibit a licensee from using additional guidance documents. Licensees may use the following Institute of Electrical and Electronics Engineers (IEEE) standards<sup>3</sup> to supplement the NIRMA guidelines.

- IEEE Std. 610.12-1990, "Standard Glossary of Software Engineering Terminology"
- IEEE Std. 730-1989, "Standard for Software Engineering Quality Assurance Plans"
- IEEE Std. 828-1990, "Standard for Software Configuration Management Plans"
- IEEE Std. 1008-1987 (R1993), "Standard for Software Unit Testing"
- IEEE Std. 1012-1986 (R1992), "Standard for Software Verification and Validation Plans"
- IEEE Std. 1028-1988 (R1993), "Standard for Software Reviews and Audits"
- IEEE Std. 1062-1993, "Recommended Practice for Software Acquisitions"
- IEEE Std. 1219-1992, "Standard for Software Maintenance"
- IEEE Std. 1228-1994, "Standard for Software Safety Plans"

However, implementation of these IEEE standards does not imply or ensure compliance with any NRC requirements.

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<sup>1</sup>NIRMA publications may be obtained from the Nuclear Information and Records Management Association, Inc., 210 Fifth Avenue, New York, NY 10010.

<sup>2</sup>Pages 8640 through 8679 of Federal Register Volume 64, No. 34, dated February 22, 1999, contains proposed rulemaking that would provide requirements for disposal of high-level radioactive wastes in a geologic repository at Yucca Mountain, Nevada (proposed 10 CFR Part 63). The guidance provided in this RIS is acceptable for the QA program requirements proposed in the 10 CFR Part 63 rulemaking.

<sup>3</sup>IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855-1331.

## REFERENCES

1. Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50).
2. Section 50.71, "Maintenance of Records, Making of Reports," of Title 10 of the *Code of Federal Regulations* (10 CFR 50.71).
3. Part 70, "Domestic Licensing of Special Nuclear Material," of Title 10 of the *Code of Federal Regulations* (10 CFR Part 70).
4. Part 71, "Packaging and Transportation of Radioactive Material," of Title 10 of the *Code of Federal Regulations* (10 CFR Part 71).
5. Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste," of Title 10 of the *Code of Federal Regulations* (10 CFR Part 72).
6. Part 76, "Certification of Gaseous Diffusion Plants," of Title 10 of the *Code of Federal Regulations* (10 CFR Part 76).
7. Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3.
8. Regulatory Guide 1.88, "Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records," Revision 2.
9. Generic Letter 88-18, "Plant Record Storage on Optical Disks," October 20, 1988.
10. American National Standards Institute (ANSI) N45.2.9-1974, "Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants."
11. American National Standards Institute/American Society of Mechanical Engineers, (ANSI/ASME) NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities," 1983 edition.
12. Nuclear Information and Records Management Association, Inc. (NIRMA), TG 11-1998, "Authentication of Records and Media."
13. Nuclear Information and Records Management Association, Inc. (NIRMA), TG 15-1998, "Management of Electronic Records."
14. Nuclear Information and Records Management Association, Inc. (NIRMA), TG 16-1998, "Software Configuration Management and Quality Assurance."
15. Nuclear Information and Records Management Association, Inc. (NIRMA), TG 21-1998, "Electronic Records Protection and Restoration."

LIST OF RECENTLY ISSUED  
NRC REGULATORY ISSUE SUMMARIES

Regulatory Issue Summary No.	Subject	Date of Issuance	Issued to
2000-17	Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff	09/21/2000	All holders of OLs for nuclear power reactors
2000-16	Availability of the Reactor Vessel Integrity Database Version 2.0.1	09/07/2000	All holders of OLs for nuclear power reactors, except those licensees who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel
2000-15	Recommendations for Ensuring Continued Safe Plan Operation and Minimizing Requests for Enforcement Discretion During Extreme Weather Conditions	09/07/2000	All holders of OLs for nuclear power reactors, except those licensees who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel
2000-14	Preparation and Scheduling of Operator Licensing Examinations	09/06/2000	All holders of OLs for nuclear power reactors, except those licensees who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel
2000-13	Annual Report on the Effectiveness of Training in the Nuclear Industry for Calendar Year 1999	08/18/2000	All holders of OLs for nuclear power reactors