

May 11, 2015

MEMORANDUM TO: Robert Pascarelli, Chief
Plant Licensing Branch LPL 2-1
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

FROM: Kerri A. Kavanagh, Chief **/RA/**
Quality Assurance Vendor Inspection Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

SUBJECT: SAFETY EVALUATION OF DUKE ENERGY CAROLINAS, LLC
AMENDMENT 40 TO THE QUALITY ASSURANCE TOPICAL
REPORT, (TAC NOs. MF5055, MF5056, MF5057, MF5058, MF5059,
MF5060 and MF5061)

By letter dated October 23, 2014, Duke Energy Carolinas, LLC submitted a change to their Quality Assurance Topical Report (QATR), Amendment 40, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14300A011) to the U. S. Nuclear Regulatory Commission (NRC) for approval per 10 CFR 50.54(a)(4). The proposed change would revise the QATR to reference the 2011 Nuclear Information and Records Management Association (NIRMA) technical guides. An older version (1998) of the NIRMA technical guides were referenced in Regulatory Issue Summary 2000-018, "Guidance on the Management of Quality Assurance Records on Electronic Media," dated October 23, 2000 (ADAMS Accession No. ML 003739359.)

By letter dated February 12, 2015 (ADAMS Accession No. ML15041A544), the NRC transmitted a request for additional information. By letter dated March 12, 2015 (ADAMS Accession No. ML15092A098), Duke Energy Carolinas, LLC responded to the NRC's request for additional information.

The Quality Assurance Vendor Inspection Branch (QVIB) staff has reviewed the Duke Carolinas, LLC submittal in accordance with the provisions of NUREG-0800, Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition, Section 17.5 Revision 0, "Quality Assurance Program Description – Design Certification, Early Site

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Permit and New License Applicants.” Based on its review, the staff finds that the proposed change to the QATR meets the quality assurance record requirements of Appendix B to 10 CFR Part 50, and is acceptable.

Enclosure:
Safety Evaluation

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Enclosure:
Safety Evaluation

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ADAMS Accession No.: ML15099A561

NRO-002

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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

1.0 INTRODUCTION

By letter dated October 23, 2014, as supplemented by letter dated March 12, 2015, (References 1 and 2), Duke Energy Carolinas (DEC) submitted a change, Amendment 40 to the Quality Assurance Topical Report (QATR), pertaining to the Catawba Nuclear Station Unit Nos. 1 and 2, McGuire Nuclear Station, Unit Nos. 1 and 2, and Oconee Nuclear Station, Unit Nos. 1, 2 and 3. The purpose of this proposed change is to use the latest guides for electronic records, storage and management. Specifically, the following Nuclear Information and Records Management Association (NIRMA) Technical Guides (TG) are being requested for use:

TG 11-2011, "Authentication of Records and Media,"

TG 15-2011, "Management of Electronic Records,"

TG 16-2011, "Software Quality Assurance Documentation and Records,"

TG 21-2011, "Required Records Protection, Disaster Recovery and Business Continuation"

This proposed change allows use of the 2011 NIRMA technical guides instead of the older 1998 version, which are listed in Attachment 1 of Regulatory Issue Summary 2000-018, "Guidance on Managing Quality Assurance Records in Electronic Media."

2.0 REGULATORY EVALUATION

The proposed change is for the electronic records, storage, and management program. The current regulatory bases for the quality assurance record program are listed below.

The Commission's regulatory requirements related to QA programs are set forth in Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 and 10 CFR 50.54(a).

Appendix B of 10 CFR Part 50 establishes QA requirements for the design, construction, and operation of structures, systems, and components (SSCs) of the facility. The pertinent requirements for quality assurance records are contained in Criterion XVII which states that "Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data

recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.”

Section 50.54(a)(4) of 10 CFR Part 50, states that “changes made to the quality assurance program description that do reduce the commitments must be submitted to the NRC and receive NRC approval prior to implementation.”

NRC accepted practices for the collection, storage, and maintenance of QA records for nuclear power 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 Regulatory Guide 1.88, “Collection, Storage and Maintenance of Nuclear Power Plant Quality Assurance Records,” Revision 2 and
- ANSI/American Society of Mechanical Engineers, (ANSI/ASME) NQA-1-2008 and the NQA-1a-2009 addenda, “Quality Assurance Program Requirements For Nuclear Facilities,” as endorsed by Regulatory Guide 1.28, “Quality Assurance Program Requirements (Design and Construction),” Revision 4.

Regulatory Issue Summary (RIS) 2000-018, “Guides on Managing Quality Assurance Records,” and Generic Letter 88-18, “Plant Record Storage on Optical Discs,” provide guidance for the maintenance of QA records in electronic media. RIS 2000-018 states that four NIRMA guides (TG 11-1998, TG 15-1998, TG 16-1998, and TG 21-1998) 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, Part 70, Part 71, Part 72, or Part 76.

3.0 TECHNICAL EVALUATION

The NRC staff reviewed the DEC request by comparing the difference between the newer 2011 NIRMA technical guides to the 1998 NIRMA technical guides. The staff reviewed Attachment 1 of the submittal which discussed the differences between the newer 2011 NIRMA guides and the 1998 version.

In RIS 2000-018, the NRC staff determined that NIRMA technical guides TG 11-1998, “Authentication of Records and Media,” TG 15-1998, “Management of Electronic Records,” TG 16-1998, “Software Configuration Management and Quality Assurance,” and TG 21-1998, “Electronic Records Protection and Restoration,” provided acceptable methods for managing QA records in electronic media. NIRMA updated these four technical guides in 2011 to reflect the best practices for managing electronic records.

The newer 2011 NIRMA technical guides provide supplemental guidance for electronic records to ensure the records are identifiable and retrievable for their required retention period. The updated NIRMA technical guides provide detailed guidance in the areas of records authentication, software quality assurance, and disaster recovery. These changes are based on the development and implementation of enterprise content management systems, web-based technologies, and higher capacity LAN/WAN networks. The key difference between the 1998 and 2011 NIRMA technical guides is that the newer technical guides provide better

understanding and controls for an integrated approach to the creation, capture, and maintenance of records using electronic tools.

The QATR change affects Table 17-1, "Conformance of DEC's Program to Quality Assurance Standards, Requirements, and Guides," as an alternative to Regulatory Guide 1.88, Revision 2. For the management of electronic records, the 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 met
- (c) Legibility is required of each record
- (d) Records media is 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 NRC staff has reviewed the licensee analysis provided in Attachment 1 of the submittal, dated March 12, 2015, and find that the four 2011 NIRMA technical guides referenced above in Section 1.0 provide adequate guidance for electronic records, storage, and management. Based on these findings, the NRC staff concludes that there is reasonable assurance that the requirements of Criterion XVII of Appendix B continue to be met. Therefore, the staff finds the proposal acceptable.

4.0 CONCLUSION

The NRC staff evaluated the licensees' QATR (Reference 1) submittal and the supplement (Reference 2) and concludes that the licensees' QA program continues to satisfy the QA requirements of Appendix B to 10 CFR Part 50. Specifically, the newer 2011 version of the NIRMA technical guides provide additional implementing details that continue to meet the quality assurance record requirements contained in Appendix B, Criterion XVII. The proposed change is acceptable.

5.0 REFERENCES

1. Duke Energy Carolinas to the NRC, Catawba Nuclear Station, Units Nos. 1 and 2, McGuire Nuclear Station Unit, Nos. 1 and 2, and Oconee Nuclear Station, Unit Nos. 1, 2, and 3, Submission of "Change to Quality Assurance Topical Report, Amendment 40," Dated October 23, 2014, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14300A011).
2. Duke Energy Carolinas to the NRC, Response to Request for Additional Information Regarding Change to Quality Assurance Topical Report, Dated March 12, 2015, (ADAMS Accession No. ML15092A098).
3. NRC Regulatory Issue Summary 2000-018, "Guidance on Managing Quality Assurance Records In Electronic Media," dated October 23, 2000.
4. NIRMA TG 11-2011, "Authentication of Records and Media"

5. NIRMA TG 15-2011, "Management of Electronic Records"
6. NIRMA TG 16-2011, "Software Quality Assurance Documentation and Records"
7. NIRMA TG 21-2011, "Required Records Protection, Disaster Recovery and Business Continuation"

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