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October 23, 2014

10 CFR 50.54(a)(4)
RA-14-0021

U. S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

Catawba Nuclear Station, Unit Nos. 1 and 2
Docket Nos. 50-413 and 50-414 / Renewed License Nos. NPF-35 and NPF-52

McGuire Nuclear Station, Unit Nos. 1 and 2
Docket Nos. 50-369 and 50-370 / Renewed License Nos. NPF-9 and NPF-17

Oconee Nuclear Station, Unit Nos. 1, 2 and 3
Docket Nos. 50-269, 50-270, 50-287 / Renewed License Nos. DPR-38, DPR-47, and DPR-55

Subject: Change to Quality Assurance Topical Report, Amendment 40

Reference: Letter from NIRMA (Linda Torunski) to USNRC (Eric J. Leeds, et al.), "Regulatory Information Summary 00-18, "Guidance on the Management of Quality Assurance Records on Electronic Media," dated July 7, 2011 (ML11200A122)

Duke Energy Carolinas (DEC) is submitting the following change to their Quality Assurance Topical Report (QATR). These changes are submitted for approval by the Nuclear Regulatory Commission (NRC) in accordance with 10 CFR 50.54(a)(4).

The change:

Change the following portions of Table 17-1, "Conformance of DEC's Program to Quality Assurance Standards, Requirements, and Guides," under the description of Regulatory Guide 1.88 Rev 2 - Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records (pages 17-8 and 17-9):

Delete the following portion:

The DEC program for storage of records on optical disks meets the quality controls contained in NRC Generic Letter 88-18.

DEC fully meets [Nuclear Information and Records Management Association] NIRMA Technical Guide (TG) 11-1998, Authentication of Records and Media, NIRMA TG 15-1998, "Management of Electronic Records," and NIRMA TG 16-1998, "Software Configuration Management and Quality Assurance" for managing quality assurance records in electronic media:

Q0D4
NRR

NIRMA TG 21-1998, "Electronic Records Protection and Restoration" - The data backup provisions in sections 5.4.2 and 5.4.4 are not being fully met. Until the backup requirements are met, dual storage or microfilm will be used for all QA Records

And replace with the following:

The DEC program for storage of records on microfilm, dual storage or in electronic format meets the preservation requirement for the retention of [Quality Assurance] QA Records. For management of electronic records, DEC uses the following:

- NIRMA TG 11-2011 "Authentication of Records and Media"
- NIRMA TG 15-2011, "Management of Electronic Records,"
- NIRMA TG 16-2011, "Software Quality Assurance Documentation and Records"
- NIRMA TG 21-2011, "Required Records Protection, Disaster Recovery and Business Continuation"

Reason for the change:

DEC record media for long term storage has typically been microfilm, with some records being maintained electronically. All DEC Plants have the option in their QATR to maintain electronic records in accordance with Generic Letter 88-18, "Plant Record Storage on Optical Disks," and RIS 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," with 1998 NIRMA TGs. RIS 2000-18 was a significant development for the industry and is the basis for managing electronic records at many of the legacy U.S. nuclear power plants, as well as with new nuclear plant construction. The RIS endorsed the additional guidance needed in the industry to establish adequate programmatic controls in this new environment. As such, the standards it endorsed are currently included in the DEC QATR. However, since RIS 2000-18 refers specifically to the 1998 versions of the NIRMA TGs, DEC interprets that they are limited to the guidance provided in the 1998 versions of the TGs. Therefore, our program is limited to using outdated philosophies, perspectives, and guidance from the early- to mid-1990s rather than fully implementing an integrated approach for records management. This change will allow DEC to use the latest available NIRMA records standards.

Basis for the change:

Criterion XVII of 10 CFR Part 50 Appendix B, Quality Assurance Records, specifies, "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."

Regulatory Guide 1.88, "Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants," Rev. 2 incorporates ANSI N45.2.9-1974. On October 23, 2000, the NRC issued a Regulatory Issue Summary (RIS) 2000-18, "Guidance on Management of Quality Assurance Records in Electronic Media," to address the management of electronic records in support of Quality Assurance requirements for nuclear facilities. 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. RIS 2000-18 refers to the 1998 revisions of the following NIRMA TGs:

- NIRMA TG-11, "Authentication of Records and Media"
- NIRMA TG-15, "Management of Electronic Records"
- NIRMA TG-16, "Software Configuration Management and Quality Assurance"
- NIRMA TG-21, "Required Records Protection and Restoration"

The TGs listed have undergone numerous changes since the publication of RIS 2000-18, with the most current revisions of all four being approved by NIRMA in 2011. The 2011 revisions reflect changes in electronic records best practices and evolved technology.

This issue directly affects not only the legacy reactor sites, but also those firms that are embarking on new plant construction. The new construction projects are striving to embrace new methods and technologies in records and information management (RIM) by attempting complete electronic integration of the entire lifecycle of records to ultimately provide traceability from beginning to end. This includes:

- Early Site Permit/Combined Operating License (ESP/COL) submittals to the USNRC,
- Handover exchange of documents, data, and information between firms during:
 - design and construction,
 - pre-operational startup testing,
 - turnover of baseline as-built information (documents, data, and records) as they enter the operations and maintenance phase.
- Being accessible and useful per state, federal, nuclear insurance and other requirements during the plant's operating life, including decommissioning.

Improvements in electronic record keeping need to be addressed in current terms. Because the 1998 TGs were developed before currently available technology existed, they do not address the new issues and concerns and/or considerations that must be taken into account in order for the proper advances to be embraced. Without using the information provided by the updated TGs, complete electronic integration becomes stagnant.

Due to the ever-changing technology environment, the lessons learned throughout the industry, and evolution of various technologies including enterprise content management (ECM) since the 1990s, NIRMA has continued to update each of the aforementioned TGs. The latest 2011 TGs represent a "best of class" perspective on the use of electronic information technologies for document control, records management, and data administration, while continuing to comply with the various federal and state regulations, and other legal and business requirements.

The context for the 1998 versions was the nuclear records management approaches and information technologies present in the mid-1990s, consisting primarily of image-capture based systems (scanned documents resulting in single- or multi-page TIF images). These images were typically captured to optical disks, which were managed in multi-platter "jukeboxes," and accessed through client-server, LAN-based networks. The 1998 versions recognized the need to expand beyond optical disk storage systems into magnetic disk storage, and address electronic record formats that can be viewed over time. The 1998 versions also brought to light the need to formally address software configuration management and quality assurance, since it was recognized that licensees would become dependent on the electronic record—only viewable, not as paper, but through the means of information technology (hardware and software). This dependency also dictated the need to address electronic records protection, backups, and disaster recovery, to be compliant with regulatory requirements.

The 2011 TG versions retain the fundamental philosophies of the 1998 versions and maintain the relationship among the four stated TGs, i.e., TG-15 presents the over-arching program for managing electronic records, with TG's 11, 16, and 21 providing more detailed information into specific areas of records authentication, software quality assurance, and disaster recovery, respectively. The key changes are based on development and implementation of enterprise content management systems, web-based technologies, and higher capacity LAN/WAN networks. Leveraging those technologies enabled the development of more efficient and effective best practices for managing electronic records, with authentication and records turnover occurring more frequently in "e-space." The 2011 versions are written in anticipation of wider use of information technologies at the nuclear facilities, and the ever-present need to achieve integration of information to support plant operations and decision-making.

The referenced letter provides a high level comparison of the 1998 version of the TGs versus the recent updates.

The proposed change will remain in compliance with Criterion XVII by continuing to directly impose the requirements of Appendix B. The change will enhance compliance by allowing use of the latest best practices and evolved technology for QA records management.

A markup of the QATR pages affected by this change is included as Attachment 1. Clean typed pages are provided as Attachment 2.

Should you have any questions regarding this request, please contact Julie Olivier at (980) 373-4045.

Sincerely,



Ernest J. Kapopoulos, Jr.
Vice President
Corporate Governance and Operations Support

Attachments:

1. Quality Assurance Topical Report Pages 17-8 and 17-9 with Requested Change
2. Clean Typed Quality Assurance Topical Report Pages 17-8 and 17-9

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xc:

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NCMPA-1
PMPA
NCEMC
ONS Master File - ON02DM (File OS 801.01)
MNS Master File - MG02DM (File MC 801.01)
CNS Master File - CN04DM (File CN 801.01)
RGC Date File- CN01RC
ELL
File: (Corporate)

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Attachment 1

Attachment 1

Quality Assurance Topical Report
Pages 17-8 and 17-9
with Requested Change

3 Pages Follow

Table 17-1 Conformance of DEC's Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
Assurance Requirements for Design of Nuclear Power Plants	Clarification	the originator's immediate supervisor for design verification shall be restricted to special situations where the immediate supervisor is the only individual capable of performing the verification. Advance justification for such use shall be documented and signed by the supervisor's management. And the frequency and effectiveness of the supervisor's use as design verifier are independently verified to guard against abuse. The supervisor will not be the design verifier on work for which he is the actual performer / originator.
Regulatory Guide 1.74 Rev (0) – Quality Assurance Terms and Definitions	Conforms	RG 1.74 Rev (0) Incorporates ANSI N45.2.10-1973. Some definitions used by DEC are worded differently than those in this standard; however, the general meanings are the same.
Regulatory Guide 1.88 Rev (2) - Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records	Alternative	<p>RG 1.88 Rev (2) Incorporates ANSI N45.2.9-1974. The DEC QAP conforms to RG 1.88 except the records storage facilities have a minimum 3-hour rating. A qualified Fire Protection Engineer will evaluate record storage areas (including satellite files) to assure records are adequately protected from damage. The fire protection engineer shall be a graduate of an engineering curriculum of accepted standing and shall have completed not less than 6 years of engineering attainment indicative of growth in engineering competency and achievement, 3 years of which shall have been in responsible charge of fire protection engineering work. The DEC program for storage of records on optical disks meets the quality controls contained in NRC Generic Letter 88-18.</p> <p>DEC fully meets NIRMA Technical Guide (TG) 11-1998, Authentication of Records and Media, NIRMA TG 15-1998, "Management of Electronic Records," and NIRMA TG 16-1998, "Software Configuration Management and Quality Assurance" for managing quality assurance records in electronic media:</p> <p>NIRMA TG 21-1998, "Electronic Records Protection and</p>

Replace strikethrough with Insert A

Table 17-1 Conformance of DEC's Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
Regulatory Guide 1.94 Rev (1) – Quality for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants	Alternative	<p>Restoration” – The data backup provisions in sections 5.4.2 and 5.4.4 are not being fully met. Until the backup requirements are met, dual storage or microfilm will be used for all QA Records.</p> <p>RG 1.94 Rev (1) Incorporates ANSI program for McGuire and Catawba conforms to ANSI N45.2.5-1974 except the length of bolts shall be flush with the outside face of the nut.</p> <p>Paragraph 5.5 requires inspection of structural steel welding to be performed in accordance with the provisions of Section 6 of the AWS D1.1. Visual Weld Acceptance Criteria (VWAC) for Structural Welding at Nuclear Power Plants, NCIG-01, Revision 2, prepared by the Nuclear Construction Issues Group (NCIG) and accepted by the NRC in their letter to the NCIG dated June 26, 1985 may be used as an alternative to AWS D1.1 for non ASME Code structural weld inspections. (July 31, 2000 J M Farley SER)</p>
Regulatory Guide 1.116 Rev (0-R) – Quality Assurance Requirements for Installation, Inspections, and Testing of Mechanical Equipment and Systems	Conforms	RG 1.116 Rev (0-R) Incorporates ANSI N45.2.8-1975
Regulatory Guide 1.123 Rev (1) – Quality Assurance Requirements for control of Procurement of Items and Services for Nuclear Plants	Alternative	<p>RG 1.123 Rev (1) Incorporates ANSI N45.2.13-1976. With respect to ANSI N45.2.13, Section 3.2, “Content of the Procurement Documents,” Subsection 3.2.3, “QAP Requirement,” DEC takes the following exception: When purchasing commercial-grade calibration services from calibration laboratories accredited by a nationally recognized accrediting body, the procurement documents are not required to impose a QAP consistent with ANSI N45.2-1977. Nationally-recognized accrediting bodies include the National Voluntary Laboratory Accreditation Program (NVLAP) administered by the National Institute of Standards and Technology (NIST) and other accrediting bodies recognized by NVLAP via a Mutual Recognition Arrangement (MRA). In such cases, accreditation</p>

QATR Insert A:

The DEC program for storage of records on microfilm, dual storage or in electronic format meets the preservation requirement for the retention of QA Records.

For management of electronic records, DEC uses the following standards:

- NIRMA TG 11-2011 "Authentication of Records and Media"
- NIRMA TG 15-2011, "Management of Electronic Records,"
- NIRMA TG 16-2011, "Software Quality Assurance Documentation and Records"
- NIRMA TG 21-2011, "Required Records Protection, Disaster Recovery and Business Continuation"

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Attachment 2

Attachment 2

Clean Typed
Quality Assurance Topical Report
Pages 17-8 and 17-9

2 Pages Follow

Table 17-1 Conformance of DEC's Program to Quality Assurance Standards, Requirements and Guides

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Assurance Requirements for Design of Nuclear Power Plants	Clarification	<p>the originator's immediate supervisor for design verification shall be restricted to special situations where the immediate supervisor is the only individual capable of performing the verification. Advance justification for such use shall be documented and signed by the supervisor's management. And the frequency and effectiveness of the supervisor's use as design verifier are independently verified to guard against abuse. The supervisor will not be the design verifier on work for which he is the actual performer / originator.</p>
Regulatory Guide 1.74 Rev (0) – Quality Assurance Terms and Definitions	Conforms	<p>RG 1.74 Rev (0) Incorporates ANSI N45.2.10-1973. Some definitions used by DEC are worded differently than those in this standard; however, the general meanings are the same.</p>
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Standard, Requirement or Guide	Conformance Status	Remarks
Regulatory Guide 1.94 Rev (1) – Quality for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants	Alternative	<p>Documentation and Records”</p> <ul style="list-style-type: none"> – NIRMA TG 21-2011, “Required Records Protection, Disaster Recovery and Business Continuation” <p>RG 1.94 Rev (1) Incorporates ANSI program for McGuire and Catawba conforms to ANSI N45.2.5-1974 except the length of bolts shall be flush with the outside face of the nut.</p> <p>Paragraph 5.5 requires inspection of structural steel welding to be performed in accordance with the provisions of Section 6 of the AWS D1.1. Visual Weld Acceptance Criteria (VWAC) for Structural Welding at Nuclear Power Plants, NCIG-01, Revision 2, prepared by the Nuclear Construction Issues Group (NCIG) and accepted by the NRC in their letter to the NCIG dated June 26, 1985 may be used as an alternative to AWS D1.1 for non ASME Code structural weld inspections. (July 31, 2000 J M Farley SER)</p>
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