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AEP-NRC-2022-01
10 CFR 50.54

Docket Nos.: 50-315
50-316

U. S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555-0001

Donald C. Cook Nuclear Plant, Unit 1 and Unit 2
Quality Assurance Program Change Request for Internal Audit Frequency

In accordance with the requirements of 10 CFR 50.54(a)(4), Indiana Michigan Power Company (I&M), the licensee for Donald C. Cook Nuclear Plant (CNP), requests approval of a proposed change to the Quality Assurance Program Description (QAPD).

The proposed change modifies the internal audit frequency from 24 months to 36 months. The increased period between audits will be supplemented by an interim analysis of functional area performance. The change is applicable to audits implemented to meet the requirements of 10 CFR 50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants; non-safety programs; and programs that do not have a defined audit interval, as described in the QAPD, as shown in the QAPD markups contained in Enclosure 2. The change does not impact audits performed to meet specific regulations, as shown in Section C.2.a.1.k of the QAPD (e.g., Security Program or Emergency Preparedness Program). These audits will continue to be performed in accordance with the applicable requirements.

Since this change is considered a reduction in quality assurance commitment, Nuclear Regulatory Commission (NRC) approval is required prior to implementation of the change. I&M's evaluation of the change concluded that the change does not reduce the effectiveness of the Quality Assurance Program. Enclosure 1 provides a description of the change, the reason for the change, and the basis for concluding that the revised program continues to satisfy the criteria of 10 CFR 50 Appendix B. Enclosure 2 provides a mark-up of the affected QAPD pages.

Approval of the proposed change is requested in accordance with the normal NRC review schedule for such changes. Once approved, the change shall be implemented within 60 days.

There are no new regulatory commitments made in this letter. Should you have any questions, please contact Mr. Michael K. Scarpello, Regulatory Affairs Director, at (269) 466-2649.

Sincerely,

A handwritten signature in cursive script that reads "Q. Shane Lies".

Q. Shane Lies
Site Vice President
Indiana Michigan Power Company

JMT/ml

Enclosures:

1. Description and Basis for Change of Internal Audit Frequency
2. Donald C. Cook Nuclear Plant Quality Assurance Program Description Marked to Show Proposed Changes

c: R. J. Ancona – MPSC
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Enclosure 1 to AEP-NRC-2022-01

Description and Basis for Change of Internal Audit Frequency

Introduction

The Donald C. Cook Nuclear Plant (CNP) Quality Assurance Program Description (QAPD) (Reference 1) ensures conformance to 10 CFR 50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants. In accordance with 10 CFR 50.54(a)(4), Indiana Michigan Power Company (I&M), the licensee for CNP, requests approval of a proposed change to the QAPD. The proposed change modifies the internal audit frequency from 24 months to 36 months. The increased period between audits will be supplemented by an interim analysis of functional area performance. The change is applicable to audits implemented to meet the requirements of 10 CFR 50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants; non-safety programs; and programs that do not have a defined audit interval, as described in the QAPD, as shown in the QAPD markups contained in Enclosure 2. The change does not impact audits performed to meet specific regulations, as shown in Section C.2.a.1.k of the QAPD (e.g., Security Program or Emergency Preparedness Program). These audits will continue to be performed in accordance with the applicable requirements. The proposed change is a reduction in commitment and, therefore, Nuclear Regulatory Commission (NRC) approval is required prior to implementation.

Background

The CNP Quality Assurance Program (QAP) currently complies with administrative controls and quality assurance requirements for performance of internal audits established by ANS 3.2/ANSI N18.7-1976, Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants (Reference 2); and NRC Regulatory Guide 1.33, Quality Assurance Program Requirements (Operation), Revision 2 (Reference 3), which state that audits of selected aspects of plant operational phase activities shall be performed with a frequency commensurate with their safety significance and in such a manner as to assure that an audit of safety-related functions is completed within two years (24 months).

Proposed Change

I&M is requesting NRC approval to change the internal audit frequency from 24 months to 36 months. Currently QAPD Section C, Audit, requires the following:

"... Audits will be conducted as required by the applicable Code of Federal Regulations, safety analysis reports, and commitments by various correspondence to the Nuclear Regulatory Commission. Audits will be conducted at a frequency in accordance with Section C.2.a.1."

Substeps a through i of Section C.2.a.1 identify specific areas to be audited on a 24-month frequency. This proposed change replaces the 24-month frequency requirement with a 36-month frequency requirement. The 25% grace period is applied to ensure that the period between audit performance will not exceed 45 months.

Section C.2, Performance, is also revised to require an evaluation once per calendar year to determine the need for additional audit activities. Results of the evaluation will be assessed and, when necessary, a review of the identified areas of performance weakness will be planned at the earliest possible opportunity.

Justification for Change

The proposed change is a deviation from CNP QAPD commitments to ANS 3.2/ANSI N18.7-1976 and NRC Regulatory Guide 1.33, Revision 2. The proposed change does not represent a reduction in effectiveness or compliance with 10 CFR 50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants. A comprehensive system of planned and periodic audits will continue to be performed by independent trained personnel using written procedures to verify compliance with all aspects of the QAP and to determine effectiveness of the program. The internal audit program will continue to be conducted on a performance-driven frequency that is commensurate with the status and importance of the activity to be completed. Performance of functional area audits will continue to determine effectiveness of the program.

The proposed frequency change, supplemented by an evaluation each year, is similar to audit requirements outlined in ASME NQA-1-2015, Quality Assurance Requirements for Nuclear Facility Applications (Reference 4), that was endorsed by NRC Regulatory Guide 1.28, Quality Assurance Program Criteria (Design and Construction), Revision 5 (Reference 5). This revision of NQA-1, Requirement 18, Audits, Section 201.2, Nuclear Facilities After Placing the Facility into Operation, references extending the 2-year internal audit interval to 3 years, not to exceed 4 years with performance of an annual evaluation.

Also, the proposed changes are similar to ANSI/ANS 3.2-2012, Managerial, Administrative and Quality Assurance Controls for the Operational Phase of Nuclear Power Plants (Reference 6) that was endorsed by NRC Regulatory Guide 1.33, Quality Assurance Program Requirements (Operation), Revision 3. This quality standard also, provides guidance in Section 3.18.1.1, "Regularly Scheduled Internal Audits," for extending the 2-year frequency not to exceed 4 years with performance of an annual evaluation. In addition, the proposed 36-month audit frequency is consistent with external audit requirements for audit of suppliers and with NRC triennial inspections.

It should be noted that CNP is not adopting NQA-1-2015 or ANSI/ANS 3.2-2012 as part of this proposed change, but is only citing those standards to show that the proposed frequencies are similar to other NRC endorsed standards. The variations between the proposed changes and NRC endorsed quality standards include setting the audit frequency to 36 months with 25% grace versus the 2-year frequency with a 1-year extension(s) not to exceed 4 years described in NQA-1-2015 and ANSI/ANS 3.2-2012 standards. The proposed evaluation will focus on identifying areas that require audit activity prior to the next scheduled audit, rather than justifying extension.

Functional area audits and evaluations would be separated into three cycles covering a period of 36 months. Each cycle includes a set of audits and evaluations. Results of the completed audits will

be reviewed to determine if additional audit activities are necessary prior to their next scheduled performance. Each functional audit area will be evaluated based on internal and external data; functional area changes in responsibility, resources, or management; and consideration of the impacts, as applicable, to determine if additional audit activities are necessary prior to the 36-month scheduled performance. These evaluations will meet the intent of the annual evaluation described in NRC endorsed quality standards by ensuring action by the audit organization upon evaluation of adverse performance trends, should they exist, prior to the next scheduled audit activity. The resulting action will be based on the problem identified and may include one or more of a variety of audit tools, such as simple observations, follow-up reviews, or limited scope audits up to a full audit of the functional area.

This proposed change impacts the frequency of Fire Protection audits. The change in frequency for Fire Protection Program audits does not reduce the effectiveness of the QAP. Audits will be performed on a 36-month frequency and will continue to be comprehensive, risk and performance based reviews to determine effective implementation of the Fire Protection Program. Audits include, but are not limited to, evaluation of organization, personnel, training, program implementation and equipment. Audits of fire protection equipment and program implementation will continue to be conducted using an outside independent fire protection consultant. The audits will be supplemented with an evaluation of the Fire Protection Program implementation activities between scheduled audits.

In aggregate, these changes will continue to meet the fundamental requirements of an internal audit program as described in quality standards endorsed by the NRC and will continue to provide proper coverage of QAP activities. The changes will allow audits to be scheduled at a frequency commensurate with the status and importance of the activity. Evaluations of performance will be used to effectively focus audit resources in areas indicating gaps in QAP implementation.

Precedent

NRC staff reviewed an Exelon request (Reference 7) for similar changes to the internal audit requirements and found it to be acceptable, as documented in a letter from NRC to Exelon Generation Company, LLC regarding, Review of Quality Assurance Program Changes (EPID L-2019-LLQ-0003), dated November 5, 2020 (ADAMS No. ML20287A130) (Reference 8).

References

1. Donald C. Cook Nuclear Plant Quality Assurance Program Description, Revision 27
2. ANS 3.2/ANSI N18.7-1976, Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants
3. NRC Regulatory Guide 1.33, Quality Assurance Program Requirements (Operation), Revisions 2 and 3
4. ASME NQA-1-2015, Quality Assurance Requirements for Nuclear Facility Applications
5. NRC Regulatory Guide 1.28, Quality Assurance Program Criteria (Design and Construction), Revision 5

6. ANSI/ANS 3.2-2012, Managerial, Administrative and Quality Assurance Controls for the Operational Phase of Nuclear Power Plants
7. Letter from Exelon Generation Company, LLC to the NRC regarding "Request for Approval of Change to Exelon Generation Company, LLC, Quality Assurance Topical Report," dated December 5, 2019 (ADAMS No. ML19339E544)
8. Letter from NRC to Exelon Generation Company, LLC regarding, "Review of Quality Assurance Program Changes (EPID L-2019-LLQ-0003)," dated November 5, 2020 (ADAMS No. ML20287A130)

Enclosure 2 to AEP-NRC-2022-01

**Donald C. Cook Nuclear Plant Quality Assurance Program Description
Marked to Show Proposed Changes**

Quality Assurance Program Description

An evaluation is performed once per calendar year to determine the need for additional audit activities. When determined to be necessary, an additional audit activity will be performed within a timeframe established by the evaluation.

2. Performance

- a. A program of planned and periodic audits is established and implemented to confirm that activities affecting quality comply with the QAPD and that the QAPD has been implemented effectively. Audits will be conducted as required by the applicable Code of Federal Regulations, safety analysis reports, and commitments by various correspondence to the Nuclear Regulatory Commission. Audits will be conducted at a frequency in accordance with Section C.2.a.1.
 1. Audit schedules assure that the following areas are audited at the indicated frequencies, or more frequently as performance dictates.
 - a. The conformance of unit operation to provisions contained within the Technical Specifications and applicable license conditions at least once per 24 months. 36
 - b. The performance, training, and qualification of the entire station staff at least once per 24 months. 36
 - c. The results of actions taken to correct deficiencies occurring in unit equipment, structures, systems, or method of operation that affect nuclear safety at least once per 24 months. 36
 - d. The performance of activities required by the QAPD to meet the requirements of 10 CFR 50, Appendix B, at least once per 24 months. 36
 - e. The fire protection programmatic controls including implementing procedures at least once per 24 months by qualified licensee personnel. 36
 - f. The fire protection equipment and program implementation at least once per 24 months using either a qualified licensee fire protection engineer or an outside independent fire protection consultant. An outside independent fire protection consultant shall be used at least once every 36 months. 36 an
 - g. The Radiological Environmental Monitoring Program and radiological effluents monitoring activities and implementing procedures at least once per 24 months. 36
 - h. The Off-site Dose Calculation Manual and implementing procedures at least once per 24 months. 36

Quality Assurance Program Description

i. The Process Control Program and implementing procedures for processing and packaging of radioactive wastes at least once per 24 months.

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j. The performance of activities implementing NRC Order EA-12-051, Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation, requirements to provide reliable Spent Fuel Pool water level instrumentation on a periodic basis.

k. Audits of the following programs are performed at the frequencies specified in the governing regulation:

Program	Governing Regulation
Safeguards Contingency Plan	10 CFR 50.54(p)(3)(i-ii) Appendix C to 10 CFR 73
Security Program	10 CFR 73.55(m)(1-4)
Cyber Security Program	10 CFR 73.55(m)
Site Access Authorization Program	10 CFR 73.56(n)
Site Fitness for Duty Program	10 CFR 26.41(b)
FFD Laboratory	10 CFR 26.41(c)
Emergency Preparedness Program	10 CFR 50.54(t)
Packaging and Transportation of Radioactive Waste	10 CFR 71.137
Independent Spent Fuel Storage Installation	10 CFR 72.176

l. Any other area of facility operation considered appropriate by the off-site review committee or the executives responsible for overall plant nuclear safety and engineering.

25%

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2. A grace period of 90 days may be applied to the 24-month frequency for internal audits. For activities deferred in accordance with the 90-day grace period, the next performance due date will be based on their originally scheduled date.

25%

3. Audits shall provide an objective evaluation of quality-related practices, procedures, instructions, activities, and items, and a review of documents and records, as applicable.

4. Audits shall be performed in accordance with approved written procedures or checklists. Items from previous audits shall be reviewed and re-audited, as appropriate. The checklists are used as guides to the auditor.

5. Scheduling and resource allocations are based on the status and safety importance of the activity or process being assessed.