UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 26, 2022

Mr. Joel P. Gebbie
Senior Vice President and Chief
Nuclear Officer
Indiana Michigan Power Company
Nuclear Generation Group
One Cook Place
Bridgman, MI 49106

SUBJECT: DONALD C. COOK NUCLEAR PLANT, UNIT NOS. 1 AND 2 – REVIEW OF QUALITY ASSURANCE PROGRAM CHANGES (EPID L-2022-LLQ-0000)

Dear Mr. Gebbie:

By letter dated February 1, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML22032A315), Indiana Michigan Power Company (I&M or the licensee) requested U.S. Nuclear Regulatory Commission (NRC) approval of changes to the quality assurance program description (QAPD) for the Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2 (CNP). The proposed change was considered a reduction in quality assurance commitment, and in accordance with Title 10 of *the Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," 50.54(a)(4), NRC approval is required prior to implementation.

Specifically, I&M requested NRC approval to increase the internal audit interval from 24 months to 36 months for certain audit topics. The increased period between audits will be supplemented by an interim analysis or evaluation of functional area performance. The requested changes are for CNP and their co-located independent spent fuel storage installation (ISFSI). The change is applicable to audits implemented to meet the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, for nonsafety programs, and programs that do not have a defined audit frequency, as described in the CNP QAPD. The change does not impact audits performed to meet specific regulations (e.g., Physical Security or Emergency Preparedness) or audits of suppliers. These audits will continue to be performed in accordance with the applicable requirements.

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. A 25 percent grace period is also 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

The NRC staff reviewed I&M's requested changes to its QAPD, as documented in the enclosed safety evaluation, and finds that I&M will continue to comply with 10 CFR 50.54(a) and Criterion XVIII, "Audits," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50. Therefore, the NRC staff concluded that the requested changes to the CNP QAPD are acceptable. The requested changes in I&M's application are hereby approved for CNP and its co-located ISFSI.

If you have any questions, please contact Scott Wall at (301) 415-2855 or by e-mail at Scott.Wall@nrc.gov.

Sincerely,

Nancy L. Salgado

Digitally signed by Nancy L. Salgado
Date: 2022.07.26 10:57:12 -04'00'

Nancy L. Salgado, Chief
Plant Licensing Branch III
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Docket Nos. 50-315 and 50-316

Enclosure:
Safety Evaluation

cc: Listserv

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

REQUEST TO REVISE THE QUALITY ASSURANCE PROGRAM DESCRIPTION

INDIANA MICHIGAN POWER COMPANY

DONALD C. COOK NUCLEAR PLANT, UNIT NOS. 1 AND 2

DOCKET NOS. 50-315 AND 50-316

1.0 INTRODUCTION

By letter dated February 1, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML22032A315), Indiana Michigan Power Company (hereafter referred to as I&M or the licensee) requested U.S. Nuclear Regulatory Commission (NRC) approval of changes to its quality assurance program description (QAPD) for the Donald C. Cook Nuclear Plant (CNP), Unit Nos. 1 and 2. The proposed change is a reduction in commitment, and in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities,” 50.54(a)(4), NRC approval is required prior to implementation.

The requested changes are for CNP and the co-located independent spent fuel storage installation (ISFSI). I&M determined that the changes in these audit intervals are a reduction in quality assurance (QA) commitments requiring prior NRC approval to implement pursuant to 10 CFR 50.54(a).

2.0 REGULATORY EVALUATION

2.1 Description of Proposed Changes

The proposed change modifies the internal audit frequency from 24 months to 36 months for certain audit topics. The increased period between audits will be supplemented by an interim analysis or evaluation of functional area performance. The change is applicable to audits implemented to meet the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, for nonsafety programs, and programs that do not have a defined audit frequency, as described in the CNP QAPD. The change does not impact audits performed to meet specific regulations (e.g., Physical Security or Emergency Preparedness) or audits of suppliers. These audits will continue to be performed in accordance with the applicable requirements.

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. A 25 percent grace period is also 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.

The specific areas impacted by this frequency change related to radiation protection are: (1) The radiological environmental monitoring program and radiological effluents monitoring activities and implementing procedures; (2) The Off-site Dose Calculation Manual (ODCM) and implementing procedures; (3) The process control program and implementing procedures for processing and packaging of radioactive wastes.

2.2 Regulatory Requirements and Guidance

The regulations in 10 CFR 50.54(a)(4) set forth the NRC’s regulatory requirements regarding changes to a QAPD. Changes to the QAPD that reduce the licensee’s quality assurance (QA) commitments must be submitted to the NRC and receive NRC approval prior to implementation. This includes changes made to the QAPD as presented in the safety analysis report or in a topical report that must be submitted as specified in 10 CFR 50.4, “Written communications.” The submittal of a change to the QAPD must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of Appendix B of this part and the QAPD commitments previously accepted by the NRC.

Appendix B to 10 CFR Part 50 sets forth the regulatory requirements for QA program audits. Criterion XVIII, “Audits,” establishes the requirement that a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the QA program and to determine the effectiveness of the program. These audits shall be performed in accordance with written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. The audit results shall be documented and reviewed by management having responsibility in the area audited. Licensee follow-up action, including re-audit of deficient areas, shall be taken where indicated.

The regulations in 10 CFR 71.137 requires licensees to carry out a comprehensive system of planned and periodic audits for the packaging and transportation of radioactive material to verify compliance with all aspects of the QA program and to determine the effectiveness of the program.

Regulatory Guide (RG) 1.28, Revision 5, “Quality Assurance Program Criteria (Design and Construction)” (ML17207A293), describes, in part, methods acceptable to the NRC staff for complying with the provisions of 10 CFR Part 50, Appendix B, for establishing and implementing a QA program for the design and construction of nuclear power plants. RG 1.28, Revision 5, endorses Part I and Part II of multiple revisions of the American Society of Mechanical Engineers (ASME) standard NQA-1, “Quality Assurance Requirements for Nuclear Facility Applications,” including Part I of NQA-1-2015, with clarifications and exceptions.

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.

The regulations in 10 CFR 20.1101(c) require licensees to "periodically (at least annually) review the radiation protection program content and implementation." The answer to question 118 in the Health Physics Questions and Answers[1] provides guidance to nuclear power plants on using a combination of reviews and audits to comply with 10 CFR 20.1101(c). The CNP technical specifications (TSs) implement the requirements of 10 CFR 50.36a, in that, the licensee is required to control radioactive effluents and maintain and use the radioactive waste system. Additionally, the licensee is required to report at intervals no longer than 12 months the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents during the previous 12 months. These reports shall include any other information as may be required by the NRC to estimate maximum potential annual radiation doses to the public resulting from effluent releases. Furthermore, CNP's TS require the reporting of summaries, interpretations, and analyses of trends of the results of the radiological environmental monitoring program for each calendar year. The basis for this reporting requirement is described in 10 CFR 50, Appendix I, sections IV.B.2, IV.B.3 and IV.C.

3.0 TECHNICAL EVALUATION

In evaluating the adequacy of the proposed change, the NRC staff considered the guidance of NUREG-0800 and ASME NQA-1–2015, as endorsed by RG 1.28, Revision 5. The guidance in ASME NQA-1–2015, requirement 18, section 200, requires that audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. The scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage. A grace period of 90 days may be applied to scheduled audits, except where specific regulatory guidance exists or code restrictions apply, organizations shall audit internal activities at the following intervals: all applicable QA program elements for each functional area shall be audited within a period of 2 years. For well-established activities, the period may be extended 1 year at a time beyond the 2-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. However, the internal audit interval shall not exceed a maximum of 4 years.

I&M's requested changes are consistent with the change evaluated in the NRC's safety evaluation (SE) of Exelon Generation Company, LLC regarding, "Review of Quality Assurance Program Changes (EPID L-2019-LLQ-0003)," dated November 5, 2020 (ML20287A130). In that SE, the NRC evaluated the proposed audit frequencies change. The variations between the proposed changes and the NRC endorsed NQA-1-2015 Standard include setting the audit frequency to 36 months with a 25 percent grace period versus the 2-year frequency with a 1-year extension(s) not to exceed 4 years, as described in the NQA-1-2015 Standard. The proposed changes replace the 24-month frequency requirement with a 36-month frequency requirement, and a 25 percent grace period is applied to ensure that the period between audit performance will not exceed 45 months. I&M states in section C.2, "Performance," "An

[1] The answer to question 118 is available on the NRC's public Website at https://www.nrc.gov/about-nrc/radiation/protects-you/hppos/qa118.html. Additional information is available in NUREG-1736, "Consolidated Guidance: 10 CFR 20 – Standards for Protection Against Radiation," October 2001 (Package ML013330179).

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."

I&M has a well-established audit program, and except where other specific regulatory guidance exists, code restrictions apply to functional areas to be audited and may apply changes to their internal audit frequency. In addition, the NRC staff determined that I&M's proposed changes in internal audit frequency for internal audits is in alignment with current NRC staff guidance and, therefore, are acceptable. Internal audits, with changes in audit frequency, shall provide the same oversight, level of consistency and reasonable assurance as before the changes to the audit frequency was implemented. I&M shall ensure follow-up actions, including re-audit of deficient areas, shall be performed where indicated by the additional performance of an analysis or evaluation.

Radiation Protection

In its request, the licensee includes certain radiation protection QA audit topics as being subject to a change in frequency. The licensee also states that this change does not impact audits that are required by specific NRC regulations. More specifically, audits that are required by specific regulations will continue to be conducted in a manner that complies with requirements. The annual program review of 10 CFR 20.1101(c), as clarified by Health Physics Questions and Answer – question 118, does not require that the program review be completed through the licensee's QA program. The review required by 10 CFR 20.1101(c) could be completed by radiation protection supervisory reviews and corporate or 3rd party audits, as well as periodic QA audits. This change only impacts one method a licensee can use to comply with the regulatory requirement to conduct an annual radiation protection program review. Therefore, this change is acceptable because licensees have ready access to other methods for completing reviews required by 10 CFR 20.1101(c), as described in the regulation and its associated clarification, and the licensee intends to continue complying with the regulatory requirement as stated in its application.

Radiological Effluent and Environmental Monitoring Programs

In its request, the licensee subjects "The Off-site Dose Calculation Manual and implementing procedures," and "the radiological environmental monitoring program and radiological effluents monitoring activities and implementing procedures" to a change in QA internal audit frequency. The radiological effluent program is described in the licensee's ODCM. The NRC implements requirements that apply to radiological effluent and environmental monitoring programs through TS as supplemented by guidance. CNP TS 5.4.1.c requires that written procedures be established, implemented and maintained, covering QA for effluent and environmental monitoring. However, this TS does not specify frequencies for QA audits of these programs. The annual reporting requirements for the results of these programs allows the licensee to observe off-normal results every calendar year. In certain situations that are described in 10 CFR Part 50, Appendix I, licensees are required to investigate, correct, and report to the NRC, within 30 days instances when radiological effluent releases approach the as low as is reasonably achievable design objectives. Furthermore, as part of the NRC inspection process these annual reports are reviewed by NRC inspectors as is performance in the areas of radiological effluents and environmental monitoring. Thus, degrading performance in these areas will be readily identifiable by the licensee and the NRC. Therefore, this change is acceptable because there is

no requirement that specifies a frequency for QA audits of radiological effluent, and environmental monitoring programs, existing licensee processes (including the proposed QAPD requirement to conduct an annual (i.e., once per calendar year) evaluation to determine the need for additional audit activities based on performance weaknesses), and NRC regulatory and oversight processes are sufficient to identify degrading performance in these programs in a timely manner.

Radioactive Waste Process Control Program

In its request, the licensee subjects “The Process Control Program and implementing procedures for processing and packaging of radioactive wastes” to a change in QA internal audit frequency. 10 CFR 71.137 specifies the requirements for audits of QA programs for the packaging and transportation of radioactive material, but it does not specify a frequency for such audits. Therefore, this change is acceptable because there is no regulation that specifies a frequency for QA audits of the processing and packaging of radioactive wastes.

4.0 CONCLUSION

As discussed above, the NRC staff reviewed I&M’s requested changes to the internal audit frequency in the CNP QAPD, as described in its application. The NRC staff found that I&M will continue to comply with section 50.54(a), and Criterion XVIII of Appendix B to 10 CFR Part 50. The staff finds that I&M will also continue to comply with the QA requirements for ISFSI in 10 CFR Part 72, subpart G. Therefore, the NRC staff concluded that the requested changes to the CNP QAPD are acceptable.

Principal Contributors: Dong Park, NRR
John Grasso, NRR
David Garmon, NRR

Date of issuance: July 26, 2022

SUBJECT: DONALD C. COOK NUCLEAR PLANT, UNIT NOS. 1 AND 2 – REVIEW OF QUALITY ASSURANCE PROGRAM CHANGES (EPID L-2022-LLQ-0000) DATED JULY 26, 2022

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