Pre-Submittal Meeting

Request for Revision to Quality Assurance Program
Internal Audit Frequency

November 20, 2019

Exelon

Exelon Representatives

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Agenda

- Meeting Objectives
- Background
- Internal Audit Frequency Change Overview
- Evaluation of Change
- Interim Functional Area Evaluations
- Discussion

Meeting Objectives

- Present information to NRC describing a proposed Quality Assurance Program (QAP) change to revise the internal audit frequency

- Engage the NRC in an open and transparent dialog regarding the proposed approach to identify regulatory areas that warrant additional discussion such that they may be satisfactorily addressed in the change request prior to submittal

- Answer questions and obtain feedback from the NRC on the proposed change approach and content

Background

- Exelon QAP complies with administrative controls and quality assurance requirements contained in the specific American National Standards Institute (ANSI) and the American Nuclear Society (ANS) standards. The Exelon QAP requires that internal audits be performed on a 24 month frequency with a 25% grace period.

- Newer versions of industry standards allow audit intervals to be extended up to 4 years but require yearly extensions based on performance evaluation.

- Industry peers have rarely implemented extended frequencies based on the newer standards because the requirements for performance evaluations are not well defined and/or require more resources than performing the audit.

- Proposed changes offer an efficient methodology to extend time between audits allowing Exelon to increase focus of oversight resources based on performance and risk.

Internal Audit Frequency Change Overview

- The proposed change modifies the internal audit frequency to a nominal 36-months with a 25% grace period for scheduling flexibility.
- The increased period between audits will be supplemented by an interim evaluation of functional area performance.
- Interim evaluations are based on indicators, corrective action program review, and completed assessment activity.
- Existing audit tools such as limited scope audit, follow-up evaluation, and observations can be utilized to address any areas that the interim evaluation identifies requiring an "audit activity" prior to the next audit.
- 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."

Internal Audit Frequency Change Overview (Continued)

- The change does not impact audits performed to meet specific regulations that specify audit frequencies (e.g. Physical Security and Emergency Preparedness). Audits required by regulations will continue to be performed in accordance with the applicable requirement.

- This proposed QAP change is considered a reduction in commitment; therefore, NRC approval is required prior to implementation.

Internal Audit Frequency Change Overview (Continued)

- Specific audits proposed for the frequency change

Chemistry	Engineering Design Control
Engineering Programs	Maintenance
Nuclear Fuels	Procurement/Materials Management
Operations	Quality Assurance Functions
Fire Protection	Station Blackout
Radiation Protection	Decommissioned Units
Radioactive Waste Process Control	Off-site Dose Calculation
Technical Specifications and other License Conditions	Non-Radiological Environmental Monitoring
Spent Fuel Storage Installations	Plant Operation Review Committee
Training	Radiological Environmental Monitoring Program

Evaluation of Change

- The purpose of the audit program is to perform planned and scheduled audits at a frequency commensurate with the status and importance of the activity, to verify compliance with all aspects of the QAP and to determine effectiveness.

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

- The proposed methodology differs from standards endorsed by the NRC in that the interim evaluation focuses on identifying areas that require audit activity prior to the next scheduled audit rather than justifying extension.

Evaluation of Change (Continued)

- The change continues to meet the fundamental requirements of an internal audit program as described in quality standards endorsed by the NRC and will continue to provide coverage of QAP activities.

- The proposed audit program continues to meet the fundamental requirements defined in endorsed QA standards including:
  - Audits are performed to verify compliance with all aspects of the quality assurance program.
  - Audits continue to be scheduled at a frequency commensurate with the status and importance of the activity.
  - Regularly scheduled audits are supplemented by additional audit activities when necessary to provide adequate coverage.

- The change will continue to allow audits to be scheduled at a frequency commensurate with the status and importance of the activity.

- Evaluations of performance will be used to more effectively utilize audit resources in areas indicating gaps in QAP implementation.

Evaluation of Change (Continued)

- Because the change represents a methodology different than that previously approved or endorsed by the NRC, the proposed change is a reduction in commitment per 10 CFR 50.54(a)(4) requiring review and approval by the NRC.
- The proposal will be written specifically for the Exelon QAP which is based on ASME NQA-1 1994 standard. However, the details of the proposal were developed with industry input through the Nuclear Quality Leadership (NQML) forum.
- Exelon plans a submittal to revise the QAP before the end of the year (2019).
- If approved for Exelon, the industry will be able to implement this alternate approach through changes in their QAP under 10 CFR 50.54(a), regardless of the specific standard is the basis for the QAP.

Interim Functional Area Evaluations

- Functional area audits and evaluations would be separated into 3 cycles covering a 3 year period. 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 receive an additional performance analysis (evaluation) within 2 years of the last performed audit 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 next scheduled performance.

- These evaluations will be defined and controlled in procedures and 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 audit tools such as observations, follow-up reviews, limited scope audits, and full audits.

Exelon Audit Frequency Change Request

DISCUSSION