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

January 21, 2021

MEMORANDUM TO: Chris Miller, Director
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

FROM: Kerri A. Kavanagh, Chief **/RA/**
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

SUBJECT: TRIP REPORT BY THE NUCLEAR REGULATORY COMMISSION STAFF OF THE NUPIC JOINT UTILITY AUDIT AT MIRION TECHNOLOGIES (CONAX-NUCLEAR), INC.

On November 16 - 20, 2020, Yamir Diaz-Castillo, of the Office of Nuclear Reactor Regulation, Division of Reactor Oversight, Quality Assurance and Vendor Inspection Branch, observed the performance of a Nuclear Procurement Issues Corporation (NUPIC) joint utility audit of Mirion Technologies (Conax-Nuclear) (hereafter referred to as MTCN) in Cheektowaga, NY. Southern Nuclear Operating Company led the audit, with participation from Xcel Energy, Talen Energy, Pacific Gas and Electric Company, Entergy Operations Inc., and DTE Energy, using Revision 21 of the NUPIC audit checklist. The MTCN audit number is 24919. The purpose of the NRC staff's observation was to assess the NUPIC quality assurance audit process used for suppliers of components to the nuclear industry. The trip report of the staff's observations includes a list of NUPIC audit team members.

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(301) 415-2228

SUBJECT: TRIP REPORT BY THE NUCLEAR REGULATORY COMMISSION STAFF OF THE NUPIC JOINT UTILITY AUDIT AT MIRION TECHNOLOGIES (CONAX-NUCLEAR) Dated: January 21, 2021

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DATE	1/13/2021	1/21/2021

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NUCLEAR PROCUREMENT ISSUES CORPORATION
JOINT UTILITY AUDIT OBSERVATION TRIP REPORT

Vendor Audited:	Mirion Technologies (Conax-Nuclear) 402 Sonwil Drive Cheektowga, NY 14225
Lead Licensee:	Southern Nuclear Operating Company
Lead Contact:	Mr. Richard Buechler Nuclear Procurement Issues Corporation Lead Auditor Southern Nuclear Operating Company 202-992-5223 rbuechle@southernco.com
Nuclear Industry Activity:	Mirion Technologies (Conax-Nuclear) manufactures American Society of Mechanical Engineers (ASME) valves (explosive); ASME and non-ASME parts for environmentally qualified electrical penetration assemblies, nuclear containment electrical penetrations, service connectors, thermocouples, resistance temperature detector, electrical conductor seal assemblies, lead sealing glands, fiber feed-through kits, grafoil tape, and lubricants for Conax products.
Observation Dates:	November 16 - 20, 2020
Observers:	Yamir Diaz-Castillo, NRR/DRO/IQVB
Approved by:	Kerri A. Kavanagh, Chief Quality Assurance and Vendor Inspection Branch Division of Reactor Oversight Office of Nuclear Reactor Regulation

Enclosure

Subject

This trip report documents observations made by a member of the U.S. Nuclear Regulatory Commission (NRC), Office Nuclear Reactor Regulation, Division of Reactor Oversight, Quality Assurance and Vendor Inspection Branch, during a Nuclear Procurement Issues Corporation (NUPIC) joint utility audit conducted on November 16 - 20, 2020, at the Mirion Technologies' (Conax-Nuclear) (hereafter referred to as MTCN) facility in Cheektowaga, NY.

Background/Purpose

NUPIC was formed in 1989, by a partnership involving all domestic and several international nuclear utilities. The NUPIC program evaluates suppliers furnishing safety-related components, services, and commercial-grade items to nuclear utilities. The NUPIC audit was performed using Revision 21 of the NUPIC audit checklist and the results will be provided to NUPIC members that procure items and services from MTCN.

The purpose of the NUPIC audit was to evaluate the implementation and effectiveness of MTCN's Quality Assurance (QA) program in accordance with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," American Society of Mechanical Engineers (ASME) NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications," and 10 CFR Part 21, "Reporting of Defects and Noncompliance," at the Cheektowaga, NY facility. The NUPIC audit also included assessments of the effectiveness of a corrective action that MTCN took for a previous deficiency identified issued during the last NUPIC audit performed in July 2017. This NUPIC audit team was led by Southern Nuclear Operating Company with participation from Xcel Energy, Talen Energy, Pacific Gas and Electric Company, Entergy Operations, Inc., and DTE Energy. The NUPIC audit team consisted of six audit team members and one technical specialist.

The purpose of the NRC staff's observation of this audit was to ensure that the NUPIC audit process continues to meet the requirements of Appendix B to 10 CFR Part 50. The NRC staff implemented Inspection Procedure 43005, "NRC Oversight of Third-Party Organizations Implementing Quality Assurance Requirements," dated October 2015, during the observation.

Observation Activities

The NRC staff independently assessed and reviewed MTCN's implementation of their QA program to evaluate whether the NUPIC audit team effectively identified and responded to issues. MTCN provided the QA manual and implementing procedures to the NUPIC audit team. The NRC staff observed the NUPIC audit team as they conducted a performance-based review of the specific audit checklist sections which included a review of MTCN's QA manual and other lower tier implementing documents such as procedures, purchase orders, etc. The NRC staff requested additional documents from MTCN in order to draw their own conclusions. The NRC staff also refrained from directing or leading NUPIC, as to not interfere with the conduct of NUPIC's audit.

The QA areas reviewed during the audit included the following: contract review, design, commercial-grade dedication, procurement, fabrication/assembly activities, material control and handling, storage and shipping, special processes, test, inspections and calibration, document control/adequacy, organization/program, internal audit, corrective action,

training/certification, records, nonconforming items, and 10 CFR Part 21. The NRC staff accompanied the NUPIC audit team while they performed walkthroughs and interviews of MTCN's personnel. In addition, although there was no safety-related work performed during the week of the audit, the NUPIC audit team and the NRC staff observed MTCN demonstrate a leak test of an electrical feedthrough assembly and penetrant testing of a header plate of a canister sub-assembly.

Discussion

The NRC staff verified the NUPIC audit team adequately considered MTCN's scope of supply and observed a demonstration of work practices to verify activities were being implemented in accordance with applicable procedures. Due to workplace restrictions associated with the pandemic caused by the Coronavirus Disease 2019 (COVID-19), the NRC staff focused its observation on a limited sample of the NUPIC audit checklist. Specifically, the NRC staff observed the NUPIC audit team members perform the 10 CFR Part 21, commercial-grade dedication, and procurement and supplier oversight portions of the NUPIC audit checklist. The NRC staff observed NUPIC's findings and deficiency determinations during internal NUPIC daily debriefs and briefings with MTCN personnel. The NUPIC audit resulted in six deficiencies in the areas of commercial-grade dedication (4), internal audits (1), and 10 CFR Part 21 (1). During the exit meeting, the NUPIC audit team presented these deficiencies to MTCN's management and technical staff. MTCN initiated several corrective actions to address these deficiencies.

While reviewing a sample of commercial-grade surveys for calibration services, after the NUPIC audit team completed their review, the NRC staff identified that MTCN did not adequately describe the controls the commercial suppliers had for the calibration of their measuring and test equipment (M&TE) by their commercial sub-suppliers. Specifically, the commercial-grade surveys only stated that the commercial supplier was using laboratories accredited to International Standard Organization (ISO)/International Electrotechnical Commission (IEC) standard No. 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." The commercial-grade survey report must document the acceptability of the commercial supplier's control over calibration and not merely state the commercial supplier uses accredited calibration service providers based on accreditation to ISO/IEC 17025. The NRC staff brought this issue to the attention of the NUPIC auditor and the NUPIC team lead. As a result, this issue was included as one of the deficiencies identified in the area of commercial-grade dedication.

The previous NUPIC audit deficiency identified during the July 2017 audit led was reviewed in detail during this audit. As a result of the NUPIC audit team's review of the corrective actions opened in response to the deficiency, NUPIC determined this issue to be closed.

With the exception of the deficiencies identified, the NUPIC audit team determined that MTCN was effectively implementing its QA program for the program elements that were audited. In addition, the NUPIC audit team concluded that the deficiencies had no impact on product quality.

Conclusion

The NRC staff verified a limited sample of the NUPIC audit checklist review areas. The NRC staff found that the NUPIC audit team adequately addressed the specific areas of the checklist on which the NRC staff focused their review.

The NRC staff observed the daily team meetings to verify the NUPIC audit team was adequately addressing issues and effectively verifying the implementation of QA requirements. The NRC staff concluded that the NUPIC audit checklist was effectively implemented by the NUPIC audit team. In addition, all of the NUPIC audit team members were onsite during the audit. The NRC staff noted that the NUPIC audit team engaged the NRC throughout the audit, and when requested, provided clarification on regulatory positions. Specifically, the NRC staff participated in a meeting between MTCN and the NUPIC audit team related to concerns associated with not being able to perform audits or commercial-grade surveys of their suppliers due to the travel restrictions caused by the COVID-19 pandemic. The NUPIC audit team discussed some options available to MTCN and the NRC staff described what actions the NRC has taken to address this issue.

The NRC also had access to all interactions between MTCN and the NUPIC audit team, as well as access to the same records reviewed by the NUPC audit team. The NUPIC audit team was technically capable and effectively engaged the vendor; asking the right questions and challenging the vendor as required. Furthermore, the NUPIC audit team was effective at communicating with each other. The NRC staff concluded the NUPIC audit team met expectations, and NUPIC's oversight of activities were effectively implemented.

List of Participants

Name	Title	Affiliation	Entrance	Exit
Richard Buechler	Audit Team Leader	Southern Nuclear Operating Company (SNC)	X	X
Kenny Edwards	Technical Specialist	SNC	X	X
John Ott	Audit Team Member	Xcel Energy	X	X
Gerard Machalick	Audit Team Member	Talen Energy	X	X
Robert Carvel	Audit Team Member	Pacific Gas and Electric Company	X	X
Tim Czuba	Audit Team Member	Entergy Operations, Inc.	X	X
Diona Russell	Audit Team Member	DTE Energy	X	X