



December 9, 2025
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U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555-0001

SUBJECT: REPLY TO A NOTICE OF NONCONFORMANCE – 99901350/2025-201

Dear Sir,

We would like to extend our appreciation to Ms. Kerri Kavanagh, Ms. Deanna Zhang, Ms. Tiffany Lee, Ms. Sheila Ray, and Mr. Yiu Law for their valuable time and expertise during their inspection of ETAP's Quality Assurance Program conducted on August 25–29, 2025. The U.S. Nuclear Regulatory Commission (NRC) performed this inspection at the facilities of Operation Technology, Inc., (OTI) in Irvine, California.

On November 21, 2025, the NRC issued Inspection Report 99901350/2025-201 and Notice of Nonconformance (NON). The report states:

“The NRC inspection team issued Nonconformance 99901350/2025-201-01 in association with OTI's failure to adequately implement the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. This NON cites OTI for failure to establish a documented corrective action program to ensure that (1) conditions adverse to quality are promptly identified and corrected, and (2) causes of significant conditions adverse to quality are identified and corrective actions are taken to preclude recurrence.”

As a result of this inspection, one finding was identified. OTI's response to this finding is provided in **Attachment A**. The NRC inspection team also noted observations, for which OTI's responses are provided in **Attachment B**. The status of corrective action reports opened during the inspection is also included in this attachment.

OTI respectfully submits this response pursuant to the requirements set forth in 10 CFR 2.390 and the instructions contained in the NON. OTI acknowledges the authority of the NRC to conduct inspections and issue findings under applicable federal regulations, and we remain fully committed to compliance with 10 CFR Part 21 and Appendix B to 10 CFR Part 50.

This response is provided in good faith and represents OTI's best knowledge as of the date of submission. OTI will promptly supplement or amend this response if additional relevant information becomes known.

OTI expressly reserves all rights, claims, and defenses available under applicable law. OTI's intent is to provide accurate information in accordance with NRC requirements and to demonstrate our commitment to continuous improvement. Should you have further questions or require additional information, please contact me at (949) 462-0100 or send your e-mail to qa@etap.com.

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NRR

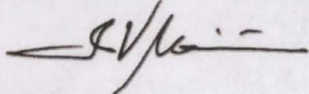
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OTI has reviewed this response for compliance with 10 CFR 2.390 and confirms that it does not contain proprietary, personal privacy, or safeguards information requiring redaction. Should the NRC identify any information requiring withholding, OTI will promptly provide a suitably bracketed and redacted version in accordance with 10 CFR 2.390(b).

OTI appreciates the NRC's detailed evaluation and constructive feedback. We remain committed to full compliance with all NRC regulatory requirements and to maintaining a robust quality assurance program that supports nuclear safety, operational reliability, and transparency. OTI will continue to ensure continuous improvement and sustained alignment with the NRC expectations.

Sincerely,

OPERATION TECHNOLOGY, INC.



Jennifer Marinas
Director of Quality Assurance

Enclosure: Attachment A - REPLY TO A NOTICE OF NONCONFORMANCE
Attachment B - Observations; Status of Corrective Action Reports

CC: Chief, Quality Assurance and Vendor Inspection Branch
Division of Division of Regulatory Oversight
Office of Nuclear Reactor Regulation
Washington, D.C. 20555-0001

ATTACHMENT A

REPLY TO A NOTICE OF NONCONFORMANCE 99901350/2025-201

In response to the Notice of Nonconformance report, please note the following:

ITEM: 99901350/2025-201-01

(1) Reason for Noncompliance

NRC: Criterion XVI, "Corrective Action," 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, "Domestic Licensing of Production and Utilization Facilities," states, that "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined, and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

Contrary to the above, as of August 29, 2025, OTI failed to establish a documented corrective action program to ensure that (1) conditions adverse to quality are promptly identified and corrected, and (2) causes of significant conditions adverse to quality are identified and corrective actions are taken to preclude recurrence. Specifically, OTI's Quality Assurance Manual (QAM), Revision 23 and its referenced implementing procedures did not adequately provide criteria to (1) address all programmatic and product related conditions adverse to quality, (2) classify significant conditions adverse to quality, determine the cause, and implement corrective conditions to preclude recurrence, and (3) report significant conditions adverse to quality to appropriate levels of management."

OTI: OTI acknowledges that while the organization had implemented elements of Criterion XVI, the requirements for prompt identification, cause determination, corrective action, documentation, and management reporting for software-related conditions adverse to quality were not clearly or comprehensively defined in the OTI Quality Assurance Program (QAP) Section XVI. Related information was distributed across several sections of the OTI Quality Assurance Manual (QAM), resulting in the absence of a consolidated and fully traceable criterion-specific corrective action process. In addition, OTI did not previously define Conditions Adverse to Quality (CAQs) or classify Significant Conditions Adverse to Quality (SCAQs) verbatim. Consequently, QAP Section XVI, Revision 23, did not by itself satisfy all Criterion XVI requirements and created ambiguity in demonstrating full compliance. Similarly, the procedure for handling programmatic issues in ETAPQA100 Internal Quality

System Audit lacked both a formal definition of CAQs and the required classification of SCAQs as we were using Major Deficiency, Minor Deficiency, and Observations as condition classifications.

Please note that the corrective action processes for software-related and programmatic conditions adverse to quality are separated to avoid confusion between these two distinct processes—QAP Section XVI governs software-related CAQs, while ETAPQA100 governs programmatic CAQs.

(2) Corrective Action

During the NRC inspection conducted on August 25–29, 2025, OTI was informed by the inspectors that the identified issues may constitute potential nonconformances. In accordance with the NON and consistent with industry best practices, OTI implemented corrective actions designed to ensure both immediate remediation of the identified gaps and sustained long-term compliance with Criterion XVI. First, OTI initiated an Audit Finding within its internal corrective action system to address these concerns. **Audit Finding OTI AF-195 was issued on August 29, 2025. This audit finding was closed on November 19, 2025**, with the associated corrective and preventive actions as described below. All corrective actions were executed under controlled quality processes, documented as required quality records, and were subject to verification by qualified reviewers in accordance with our procedures.

Software-Related Conditions Adverse to Quality

The OTI Quality Assurance Manual was updated to Revision 24, effective November 12, 2025. Updates to QAP Section XVI now fully address 10 CFR 50, Appendix B, Criterion XVI by defining and incorporating the following criteria:

- Addressing all CAQs, including identification, reporting, and control
- Classification of SCAQs (based on severity and likelihood)
- Cause determination (root cause analysis)
- Effect assessment
- Corrective action requirements
- Verification of corrective action effectiveness
- Documentation and reporting to management
- Preventive action requirements, including:
 - Post-Release Review of CAQs and SCAQs during nuclear version release and annual Quality Systems Management Review (QSMR)
 - Identification, implementation, and monitoring of preventive actions

Additionally, ETAPQA130, ETAP Deviation Assessment and Reporting, was added to the ETAP QA Plans & Procedures to define deviation assessment requirements and provide detailed classification guidance and examples.

Programmatic Conditions Adverse to Quality

The ETAP Quality Assurance Plans & Procedures were updated to Revision 17, effective November 18, 2025. Updates to ETAPQA100 now fully address 10 CFR 50, Appendix B, Criterion XVI by defining and incorporating the following criteria:

- Addressing all CAQs, including identification, reporting, and control (expanded definition of deficiencies and discrepancies)
- Classification of SCAQs (replacing “Major Deficiency” under the list of ETAP Condition Classifications)
- Management and handling of all deficiencies, CAQs and SCAQs (clarified)
- Preventive action and verification of preventive action

All other Criterion XVI requirements — reporting to management in the case of an audit finding, description of audit findings, root cause determination, corrective action, and corrective action verification — were already established for programmatic issues. Audit Findings for each fiscal year continue to be reviewed during the annual management review, QSMR.

(3) Preventive Action

Software-Related Preventive Actions

- A new ERCA/INFR Management Review Form was created for use by the Sr. VP of Engineering (or designee) following report distribution. Future functional audits conducted prior to each nuclear version release will include independent verification of these reviews.
- The Post-Mortem Report Template was revised to require documentation of all ERCA/INFR discussions, ensuring consistent evidence that CAQs and SCAQs are identified, analyzed, corrected, and evaluated for effectiveness following each nuclear release. In addition, the QSMR report format has been enhanced to include a presentation of the classification, severity, and likelihood of all CAQs associated with the Error and Informative Reports.
- Corrective Action training was provided to employees on November 19, 2025.

Programmatic Preventive Actions

- A new section titled “Reporting Conditions Adverse to Quality (CAQs) and Quality Program Issues” was added to the ETAP QA Plans & Procedures. It defines CAQs, provides instructions and points of contact for reporting quality program concerns.
- The Audit Finding Form OTI-606/AF was updated to Revision 1 to require entries for Preventive Action and Verification of Preventive Action.
- As part of OTI’s annual Internal Audits, an Audit of Audits continues to be performed and now incorporates the updated processes.

(4) Implementation

The OTI QAM Revision 24 (dated November 12, 2025) and ETAP QA Plans & Procedures Revision 17 (dated November 18, 2025) have been approved, signed, controlled, and distributed. All changes identified in the corrective and preventive actions associated with these documents have been completed. Notifications of the revisions have been issued to all ETAP employees, and updated controlled copies of the OTI QAM have been provided to ETAP Management and nuclear customers.

The Quality Systems Management Review held on November 20, 2025, included an enhanced report presenting classification, severity, and likelihood of all CAQs associated with the Error and Informative Reports for ETAP 24.0.3N. Based on the Sr. VP of Engineering's evaluation, no SCAQs were identified. This report format will continue to be presented and reviewed during each QSMR.

OTI attests that all completed corrective and preventive actions described herein have been validated and incorporated into the controlled quality system. OTI will continue to monitor the effectiveness of these measures through ongoing internal audits, QSMRs, and ETAP nuclear version functional audits, as applicable, to ensure sustained compliance with Criterion XVI and all other applicable NRC requirements.

ATTACHMENT B

OBSERVATIONS

- 1) The NRC inspection team reviewed OTI's 10 CFR Part 21 procedure and observed that it did not fully document all applicable requirements of 10 CFR Part 21. The inspectors determined this issue to be no more than minor based on substantial objective evidence demonstrating that OTI is implementing the requirements of 10 CFR Part 21 within its processes. **Audit Finding OTI AF-193 was initiated on August 25, 2025, to address this observation and was closed on November 19, 2025.**

OTI updated the OTI QA Manual to Revision 24 to align with OTI's established practice of notifying all safety-related ETAP clients of deviations determined by OTI to be reportable—regardless of classification (Substantial, Informative, or Minor/Cosmetic)—within five working days of OTI's assessment. Employee training on this update was conducted on November 19, 2025.

2. The NRC inspection team reviewed OTI's records retention practices. While OTI QA currently backs up completed nuclear orders provided by Sales and issues a Submittal Log thereafter, the inspectors noted that this process was not independently verified through the existing annual internal audits. **Audit Finding OTI AF-194 was initiated on August 29, 2025, to address this observation and was closed on September 22, 2025.**

During the most recent OTI Internal Audits conducted on September 19, 2025, OTI expanded the audit scope to include verification that nuclear purchase orders (POs) and associated purchase documentation are retained permanently. The Records Retention Audit Checklist was revised to include sampling of nuclear POs and confirmation of their permanent retention within the designated OTI QA repository. This revised audit checklist will be used for all future internal audits to ensure ongoing verification of permanent retention of nuclear purchase orders and related documentation.

These measures reflect OTI's commitment to operational excellence, risk-informed decision-making, and a culture of continuous quality enhancement consistent with leading enterprise governance standards. The integration of these processes into OTI's enterprise quality governance model ensures that compliance is not only achieved, but continuously measured, monitored, and improved.

STATUS OF CORRECTIVE ACTION REPORTS OPENED DURING THE INSPECTION

- OTI AF-193 opened on August 25, 2025; closed on November 19, 2025
- OTI AF-194 opened on August 29, 2025; closed on September 22, 2025
- OTI AF-195 opened on August 29, 2025; closed on November 19, 2025